Department of Regulatory Agencies

Office of Policy, Research and Regulatory Reform

2008 Sunset Review: Administration of Medications by Unlicensed Persons

October 15, 2008

Consumer Protection

Department of Regulatory Agencies

Executive Director's Office
D. Rico Munn
Executive Director

Bill Ritter, Jr.
Governor

October 15, 2008

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The mission of the Department of Regulatory Agencies (DORA) is consumer protection. As a part of the Executive Director's Office within DORA, the Office of Policy, Research and Regulatory Reform seeks to fulfill its statutorily mandated responsibility to conduct sunset reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA has completed the evaluation of Administration of Medications by Unlicensed Persons I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 2009 legislative committee of reference. The report is submitted pursuant to section 24-34-104(8)(a), of the Colorado Revised Statutes (C.R.S.), which states in part:

> The department of regulatory agencies shall conduct an analysis of the performance of each division, board or agency or each function scheduled for termination under this section...
>
> The department of regulatory agencies shall submit a report and supporting materials to the office of legislative legal services no later than October 15 of the year preceding the date established for termination….

The report discusses the question of whether there is a need for the regulation provided under Part 3 of Article 1.5 of Title 25, C.R.S. The report also discusses the effectiveness of the Colorado Department of Public Health and Environment, the Department of Corrections, and the Department of Human Services staff in carrying out the intent of the statutes and makes recommendations for statutory changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

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Executive Director

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Department of Regulatory Agencies

2008 Sunset Review:
Medication Administration by Unlicensed Persons

Summary

What is Regulated?
Qualified medication administration persons (QMAPs) are individuals who do not have a medical license, that help people take medication. Because of legal, physical, or cognitive reasons, some people are unable to administer medication to themselves without the help of QMAPs.

Why is it Regulated?
Because QMAPs are unlicensed they undergo a training and evaluation so they are allowed exemptions to the Medical Practice Act, the Nurse Practice Act, and the Uniform Controlled Substances Act of 1992.

Who is Regulated?
During the review period, fiscal year 02-03 through 06-07, an average of approximately 5,500 people became QMAPs each year. There is no record concerning the total number of QMAPs currently working in Colorado.

How is it Regulated?
This is not a regulatory program. The Colorado Department of Public Health and Environment (CDPHE) does not regulate QMAPs performing their duties of administering medications. This is a legal exemption and education function. CDPHE develops a curriculum to train and qualify individuals who work in CDPHE-regulated facilities and approves curriculum used to educate QMAPs who work in Colorado's Department of Human Services (DHS) and Department of Corrections (DOC) facilities.

What Does it Cost?
CDPHE's average expenditure to administer this function was $159,653 from fiscal year 02-03 through 06-07 and there were roughly 0.6 full-time equivalent employees devoted to its administration. The majority of the dollars expended, approximately 72 percent, went to contract instructor reimbursement.

What Disciplinary Activity is There?
There is no disciplinary activity associated with this function. Once a student is qualified he or she is under the control of his or her employer. An oversight agency will inspect a facility and the medication administration records in that facility, but there is no inspection specific to the QMAP function or individual QMAPs.

Where Do I Get the Full Report?
The full sunset review can be found on the internet at: www.dora.state.co.us/opr/oprpublications.htm.

Key Recommendations

Continue the QMAP program.
The marketplace has become dependant on QMAP services. If the program was to sunset, the cost to both facilities and consumers would increase substantially. The education and evaluation program qualifies QMAPs for legal exemptions necessary to perform medication administrations. The exemptions remove the necessity of facilities hiring otherwise unneeded healthcare professionals simply to perform basic medication administrations.

Remove the QMAP education and evaluation program from the sunset review calendar.
The QMAP program educates and creates exemptions from other statutes without rising to any level of licensure, i.e., QMAPs are not a regulated occupation typical of those that undergo sunset review. QMAPs perform medication administration as an adjunct to, rather than a primary occupation. There has been no risk to the health, safety, or welfare of the public discovered by past or current sunset reviews and it is unlikely additional sunset reviews will uncover problems.

Require employers to document that all unlicensed medication administration persons currently in their employ, pass the QMAP competency evaluation at least every five years, as a condition of employment in that facility.
An employer should know if employees are qualified to do their jobs. If an employer wants to use an employee's legal exemptions, the employer should see to it that the employee is trained, competent, and has all official prerequisites to carry out job functions.

Major Contacts Made During This Review

American Association of Retired People
Colorado Board of Nursing
Colorado Cross-Disability Coalition
Colorado Department of Corrections
Colorado Department of Human Services (DHS)
Colorado Department of Public Health and Environment
Colorado Health Care Association
Colorado Nurses Association
DHS Division of Developmental Disabilities
DHS Division of Youth and Family Services
DHS Division of Youth Corrections

What is a Sunset Review?

A sunset review is a periodic assessment of state boards, programs, and functions to determine whether or not they should be continued by the legislature. Sunset reviews focus on creating the least restrictive form of regulation consistent with protecting the public. In formulating recommendations, sunset reviews consider the public's right to consistent, high quality professional or occupational services and the ability of businesses to exist and thrive in a competitive market, free from unnecessary regulation.

Sunset Reviews are Prepared by:
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Background

Introduction

Enacted in 1976, Colorado's sunset law was the first of its kind in the United States. A sunset provision repeals all or part of a law after a specific date, unless the legislature affirmatively acts to extend it. During the sunset review process, the Department of Regulatory Agencies (DORA) conducts a thorough evaluation of such programs based upon specific statutory criteria[1] and solicits diverse input from a broad spectrum of stakeholders including consumers, government agencies, public advocacy groups, and professional associations.

Sunset reviews are based on the following statutory criteria:

- Whether regulation by the agency is necessary to protect the public health, safety and welfare; whether the conditions which led to the initial regulation have changed; and whether other conditions have arisen which would warrant more, less or the same degree of regulation;
- If regulation is necessary, whether the existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms and whether agency rules enhance the public interest and are within the scope of legislative intent;
- Whether the agency operates in the public interest and whether its operation is impeded or enhanced by existing statutes, rules, procedures and practices and any other circumstances, including budgetary, resource and personnel matters;
- Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;
- Whether the composition of the agency's board or commission adequately represents the public interest and whether the agency encourages public participation in its decisions rather than participation only by the people it regulates;
- The economic impact of regulation and, if national economic information is not available, whether the agency stimulates or restricts competition;
- Whether complaint, investigation and disciplinary procedures adequately protect the public and whether final dispositions of complaints are in the public interest or self-serving to the profession;
- Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;
- Whether administrative and statutory changes are necessary to improve agency operations to enhance the public interest.

[1] Criteria may be found at § 24-34-104, C.R.S.

Types of Regulation

Regulation, when appropriate, can serve as a bulwark of consumer protection. Regulatory programs can be designed to impact individual professionals, businesses or both.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

Regulation, then, has many positive and potentially negative consequences.

There are also several levels of regulation.

Licensure

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection – only those individuals who are properly licensed may use a particular title(s) – and practice exclusivity – only those individuals who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

As regulatory programs relate to businesses, they can enhance public protection, promote stability and preserve profitability. But they can also reduce competition and place administrative burdens on the regulated businesses.

Regulatory programs that address businesses can involve certain capital, bookkeeping and other recordkeeping requirements that are meant to ensure financial solvency and responsibility, as well as accountability. Initially, these requirements may serve as barriers to entry, thereby limiting competition. On an ongoing basis, the cost of complying with these requirements may lead to greater administrative costs for the regulated entity, which costs are ultimately passed on to consumers.

Many programs that regulate businesses involve examinations and audits of finances and other records, which are intended to ensure that the relevant businesses continue to comply with these initial requirements. Although intended to enhance public protection, these measures, too, involve costs of compliance.

Similarly, many regulated businesses may be subject to physical inspections to ensure compliance with health and safety standards.

Sunset Process

Regulatory programs scheduled for sunset review receive a comprehensive analysis. The review includes a thorough dialogue with agency officials, representatives of the regulated profession and other stakeholders. To facilitate input from interested parties, anyone can submit input on any upcoming sunrise or sunset review via DORA's website at: www.dora.state.co.us/pls/real/OPR_Review_Comments.Main.

The functions of the Department of Public Health and Environment (CDPHE) relating to Part 3 of Article 1.5 of Title 25, Colorado Revised Statutes (C.R.S.), shall terminate on July 1, 2009, unless continued by the General Assembly. During the year prior to this date, it is the duty of DORA to conduct an analysis and evaluation of administration of medications pursuant to section 24-34-104, C.R.S.

The purpose of this review is to determine whether the currently prescribed education, evaluation, and exemption from regulation for administration of medication by unlicensed persons should be continued for the protection of the public and to evaluate the performance of the program and staff of the CDPHE. During this review, the program must demonstrate that the program serves to protect the public health, safety or welfare, and that the program is the least restrictive policy consistent with protecting the public. DORA's findings and recommendations are submitted via this report to the legislative committee of reference of the Colorado General Assembly.

Methodology

As part of this review, DORA staff conducted a literature review; interviewed CDPHE staff, Department of Human Services (DHS) staff, and Department of Corrections (DOC) staff; audited Qualified Medication Administration Person (QMAP) training; reviewed CDPHE and DHS records; interviewed officials with state and national professional associations, health care providers, QMAP class instructors, and QMAPs; reviewed Colorado statutes and program rules; and reviewed the laws of other states.

Profile of the Profession

QMAPs do not meet the traditional definition of a profession. Rather they perform a set of tasks that are taught in CDPHE directed or approved classes. These tasks, involving administration and recording of medication intake, are performed by people employed at facilities where the residents, because of various medical, physical, or legal reasons, do not have the ability to take medication without some degree of assistance. A QMAP administers medication in addition to his or her chief occupation, performing tasks that ordinarily require a medical license of some sort. Because a QMAP's chief occupation does not demand a license, he or she is required to pass an examination to acquire legal exemptions to the Nurse Practice Act, the Medical Practice Act, and the Uniform Controlled Substances Act of 1992.

CDPHE is directed, by the Colorado General Assembly, to develop a training course and a set of protocols for QMAPs to follow. There is no license issued to a QMAP. Once a person passes the QMAP two-part examination process, including a written portion and a practicum portion, he or she becomes *qualified* to administer medication under section 25-1.5-301, *et seq.,* CRS.

QMAPs are only utilized in particular classifications of facilities listed in law, including: correctional facilities, assisted living facilities, foster care facilities, daycare facilities, and other facilities in which a resident lives or is monitored. Typically, residents in these types of facilities do not have access to the medications they need or desire, neither over the counter nor prescription medications. Consequently, they require assistance with medication administration.

Colorado also has a different, more stringent, level of regulation regarding medication administration. The Colorado Nurse Aide Practice Act defines what a Certified Nurse Aide (CNA) must do to acquire additional authority to administer medication in a nursing home facility. [2] The key difference between the QMAP and CNA is setting. QMAPS are not allowed to perform medication administration in nursing homes.

The notion behind the increased level of training for CNAs is the difference in the level of infirmity of the residents. The residents at a facility where QMAPs work are, in many cases, fit, lucid, and merely need medication administration help over the short term. The level of care is far more intense at a nursing home facility where CNAs perform this function.

[2] § 12-38.1-110.5, C.R.S.

QMAPs may give a person his or her medication and monitor the intake or, if the resident has a physical or cognitive impairment, he or she can personally administer the medication. Post administration, the QMAP is required to record the event on the recipient's medication administration record (MAR). Notwithstanding, there are specific prohibitions in statute:

> …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…[3]

QMAPs also may not fill medication reminder boxes (MRB) without direct supervision. As they are defined in Colorado law, QMAP duties are extremely limited with regard to what, where, how and to whom they may administer medication.

History of Regulation

The discussion of the administration of medication by unlicensed persons began in Colorado as early as 1986. At that time, the Colorado Attorney General's office set out the opinion that the "common and widespread practice" constituted the unauthorized practice of medicine according to the definition in the Colorado Medical Practice Act.[4]

During 1987, the Colorado Board of Nursing submitted a sunrise application seeking to regulate "Community Living Specialists." The application indicated danger to the public from unlicensed persons administering medication. Though the subsequent report recommended against establishing an entirely new regulated profession, its findings did recognize potential public harm and the legal dilemma associated with the unregulated administration of medication by unlicensed individuals. The legislature's solution amounted to the creation of an education program and medication administration function, which carves out an exemption to medical licensing, and trains QMAPs to perform limited medical tasks. The statute ordered the Colorado Department of Health (DOH) to develop the training program and have it in place by January 1989. The program was based on a Department of Institutions (DOI) program and allowed DOI and the Department of Social Services (DSS) to choose to manage their own programs as long as the programs were approved by DOH.

Since adoption, the authorizing statute has undergone several changes of varying substantive degree. The original definition of "administration" included: "…ingestion, application, inhalation, or, using universal precautions, rectal or vaginal insertion of medication…"[5] During the 1991 legislative session, the General Assembly added to the definition, the administration of nutrition and fluids via gastronomy tube to residents of a recognized residential or day program for the developmentally disabled.[6]

[3] § 25-1.5-301(1), C.R.S.
[4] Communication between David Burlage, First Assistant Attorney General and Linda Fleming, State Board of Nursing, February 18, 1986.
[5] § 25-1-107(1)(ee)(II), C.R.S.
[6] House Bill 91-1275, Session Laws of Colorado, First Regular Session 1991, vol.2, p.1162-1165.

Following a 1992 sunset review, the General Assembly changed and added several items that gave more authority to the DOH.[7] Among the changes was one which stipulated that DOH was to establish and maintain the program by rule and regulation. DOH was also authorized to approve all contract instructors that administered the class and examination regardless of what agency has jurisdiction. Added too, was a remedial reeducation provision for QMAPs unable or unwilling to follow the administration regimen taught by DOH. The Department of Corrections (DOC) was added to DOI and DSS as an agency that could execute its own program with DOH approval.

That same year, the legislature expanded the medication administration prohibitions section of the law. The General Assembly explicitly stated that administration of medication under this exemption excluded "judgment, evaluation, or assessment."[8] This change further defined the role of a QMAP solely as a delivery person and record keeper.

The General Assembly statutorily reorganized state departments dealing with social services policy issues in 1993. Among other changes, DSS and DOI were merged into the Department of Human Services (DHS), which inherited its predecessors' ability to operate an approved QMAP program, and DOH became the Department of Public Health and Environment (CDPHE). CDPHE retained oversight authority of the program because its new directive was the licensing of health and human services providers. [9] Currently, CDPHE has placed that oversight in its Health Facilities and Emergency Medical Services Division.

Another substantial change was made in 1998. Qualified Managers were created and authorized to oversee the filling of medication reminder systems. To become a Qualified Manager a person must successfully complete the QMAP training once every four years, and either be an owner of, or have a supervisory position in a facility.[10]

[7] Senate Bill 92-84, Session Laws of Colorado, Second Regular Session 1992, vol.1, p.1151-1158.
[8] Ibid.
[9] House Bill 93-1317, Session Laws of Colorado, First Regular Session 1993, vol.2, p.1079-1081.
[10] House Bill 98-1015, Session Laws of Colorado, Second Regular Session 1998, vol.1, p.543.

Legal Framework

Statute Summary

The authority for unlicensed persons to administer medication can be found in by Part 3 of Article 1.5, Title 25, Colorado Revised Statutes (C.R.S.). The law has three sections: Definitions; Administration of Medications, Powers and Duties of the Department; and Medication Reminder Boxes, Medication Cash Fund.

Definitions

This section defines administration, facility, monitoring, qualified manager, and self-administration as the terms relate to statutory context:

- *Administration* of medication is assisting a person according to the written directions of a physician, or other authorized medical practitioner, or following the directions on a prescription label. It also includes making a detailed written record for each instance he or she assists.[11]
- *Facilities* are adult and juvenile correctional facilities, assisted living residences, adult foster care, statutorily defined alternate care, mental health, developmentally disabled, and both adult and child day care facilities, as well as licensed, privately-operated, secure residential treatment facilities.[12]
- *Monitoring* means reminding a resident to take medication, handing a resident authorized medication, observing to validate compliance to directions, recording the event, and notifying proper authorities when a resident refuses or is not able to follow instructions.[13]
- *Qualified Manager* is someone in a supervisory position who is either a licensed pharmacist or nurse or passes the Qualified Medication Administration Person (QMAP) training examination every four years.[14]
- *Self-Administration* pertains to a person's ability to take medication without help from another person.[15]

[11] § 25-1.5-301(1), C.R.S.
[12] § 25-1.5-302(2), C.R.S.
[13] § 25-1.5-302(3), C.R.S.
[14] § 25-1.5-302(4), C.R.S.
[15] § 25-1.5-302(5), C.R.S.

Administration of Medications, Powers and Duties of the Colorado Department of Public Health and Environment

This section of the statute establishes oversight authority in the Colorado Department of Public Health and Environment (CDPHE). It also mandates that the CDPHE create, manage by rule and regulation, and enforce a training program for medication administration.[16]

As a requirement of licensing, every CDPHE-licensed facility which administers medication as a component of the service it provides, must have a qualified staff member on duty when the medication administration takes place. It must also maintain records of each administration.[17]

CDPHE must see that training sessions and competency evaluations are provided around the state for those individuals who want to become QMAPs.[18] The sessions may be run by either CDPHE or an instructor from a CDPHE-approved instructor list, who teaches a CDPHE-approved curriculum.[19] CDPHE must also keep a list of all those who take the training and who pass the competency evaluation. A person may take the evaluation portion without taking the training session. However, if he or she does not pass, the training is required before a retest is allowed.[20]

There are two sets of exemptions provided in this section: legal exemptions for QMAPs and program exemptions for other state agencies.

The first carves out exemptions to the Colorado Medical Practice Act and the Nurse Practice Act. It states that all QMAPs are exempt from the licensing requirements otherwise required by the acts. It also exempts QMAPs from the Uniform Controlled Substance Act of 1992 so that they may administer those types of medications, when necessary, only while they are working in a suitable facility.[21]

The second set of exemptions allows the Colorado Departments of Human Services (DHS) and Corrections (DOC) to develop and implement their own qualification programs. These departments are responsible for both the cost and implementation of the function. Training and evaluation programs must be reviewed and approved by CDPHE before being put into practice. They must keep records of persons successfully completing the competency evaluation, and they must also forward the list of those QMAPs to CDPHE within 45 days of the evaluation.[22] The statute demands that in DOC or the DHS-Division of Youth Corrections (DYC) facilities, medication administrations shall be administered in a section of the facility where a licensed medical practitioner is present.

[16] § 25-1.5-302(1), C.R.S.
[17] § 25-1.5-302(1)(a), C.R.S.
[18] § 25-1.5-302(4), C.R.S.
[19] § 25-1.5-302(7), C.R.S.
[20] § 25-1.5-302(4), C.R.S.
[21] § 25-1.5-302(1)(b), C.R.S.
[22] § 25-1.5-302(3), C.R.S

Medication Reminder Boxes or Systems, Medication Cash Fund

This third section specifies the proper protocols for using Medication Reminder Boxes (MRBs) and establishes a fee-based cash fund for the implementation of the program. [23]

MRBs are to be filled and labeled by a Colorado-licensed pharmacist, a Colorado-licensed nurse, a QMAP who is supervised by a Qualified Manager, or gratis, by a patient's friend or a family member. All QMAPs working in facilities are required to have documented, supervised, on-the-job training and must comply with the other statutory requirements.[24] If a person self-administers medication, then neither a QMAP nor a facility is responsible for observing or documenting the administration.[25]

All persons qualified by CDPHE, under Part 3 of Article 1.5, Title 25, C.R.S., must pay a fee before beginning the qualification process.[26] The money collected from those fees is used to establish a cash-fund used by CDPHE for program administration and contracted services.[27]

Rules and Regulations

CDPHE has established rules that direct QMAP actions in facilities. However, according to program administrators, they have no provision or power to enforce the rules other than making note of deficiencies during facility inspections. Neither DHS nor DOC has established rules.

The initial provision laid out in the regulations developed by CDPHE is that licensed facilities, and the QMAPs employed in them, must follow the regimen taught for medication administration in the QMAP training.[28]

[23] § 25-1.5-303(1), C.R.S
[24] § 25-1.5-303(3), C.R.S.
[25] § 25-1.5-303(4), C.R.S.
[26] § 25-1.5-302(5), C.R.S.
[27] § 25-1.5-303(5), C.R.S.
[28] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, I.A, B.

Qualified Staff

A QMAP staff member is defined as a person trained in medication administration and employed by a licensed facility, who administers medication, a contract employee who is trained and administers medication only to residents of the facility, or a person employed by a home health agency who is trained and administers medication only to facility residents.[29] A temporary employee who is qualified to administer medication is not considered a staff member for compliance purposes. This is an important distinction because only staff members, not temporary employees, may administer prescription and non-prescription medications to facility residents, regardless of his or her qualification status.[30] In performing medication administrations, the following rules apply:

- "Lawfully labeled" medications are labeled in accordance with pharmacy practice law.[31]
- Non-prescription medications must be labeled with the resident's full name.[32]
- No resident shall take another resident's medication nor shall staff give one resident's medication to another resident.[33]
- The contents of a medication container without a label or an illegible label shall be destroyed immediately.[34]
- No medication shall be administered after its expiration date.[35]
- Facilities shall document the disposal of discontinued, out-dated, or expired medication.[36]
- All medications shall be stored in a safe manner away from disinfectants, insecticides, bleaches, cleaning solutions, and poisons.[37]

[29]Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV II.A(1)(2)(3)
[30] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV II.B, IV.A.
[31] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV III.A
[32] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, IV.B
[33] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, IV.C.
[34] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, IV.D.
[35] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, IV.E.
[36] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, IV.F.
[37] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV VI.A-B.

MRBs

As is the case with the statute, the rules specifically speak to MRBs[38] and their use by QMAPs.[39] Again, unless a resident is self-administering, only a QMAP staff member may assist a resident with his or her medication, and record the administration event on the proper forms.[40] The following rules focus on MRB usage and address the filling, labeling, and appropriate usage of the devices.

- Licensed pharmacists shall prepare the medication for MRBs according to physician orders. [41]
- If the MRB is prepared by a licensed nurse or gratuitously by a resident's friend or family member then it must have a detailed label attached.[42]
- If a change in the medication is made, the facility will discontinue use of the MRB until a pharmacist has refilled the MRB according to any change.[43]
- If there is any inconsistency with regard to the MRB medications or label, administration shall not proceed until the person who filled the MRB or the prescribing authority has been contacted and all problems have been resolved.[44]
- MRBs may not be filled for longer than two weeks at a time.[45]

In addition to these rules, MRBs may only be used for orally ingested medication and there are to be no special instructions such as: "as needed" or "30 minutes before meals." Rules allow only medication administered routinely to be placed in an MRB.[46]

[38] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV V.A. Compartmentalized containers meant to house medications according to some time element
[39] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV V.A-K.
[40] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, V.B, C, D.
[41] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, V.E.
[42] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, V.F.
[43] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, V.E.
[44] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, V.G.
[45] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, V.J.
[46] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV, V.I.

Contract Instructors

To teach a QMAP training course, one must be a Colorado-licensed physician, nurse, pharmacist, or a licensed physician assistant in good standing. If a person meets these qualifications, he or she may contract with CDPHE to teach an approved curriculum.[47]

[47] Department of Health and Environment; Health Facilities and Emergency Medical Services Division; *State Board of Health Medication Administration Regulations, 6 CCR 1011-1,* Chapter XXIV VII.A.

Program Description and Administration

The Colorado Department of Public Health and Environment (CDPHE) is responsible for the development of the Qualified Medication Administration Person (QMAP) curriculum for facilities that it regulates.[48] However, under statute, it must also approve the educational content and the instructors of the QMAP function for non-CDPHE regulated facilities that are allowed to use QMAPs. The statute allows the Department of Human Services (DHS) and the Department of Corrections (DOC) to use QMAPs in their facilities and to develop their own programs, if they choose.[49]

Though the regulatory oversight of facilities is split among agencies and departments, the educational content is such that once a person is a qualified QMAP it does not matter which agency sponsored the training. The qualification means that the person is qualified to administer medication regardless of the type of facility that employs him or her. Once trained and qualified in a DOC or DHS program, a record of the training and qualification is passed to CDPHE.[50]

The table below shows only the fiscal information attributable to CDPHE program administration. Total expenditures, during the sunset review period, range from approximately $146,000 during fiscal year 03-04 to approximately $169,000, which was spent the previous fiscal year. Overall, average expenditures by CDPHE were $159,652 and it used 0.62 full-time equivalent (FTE) employees. The slight variation in dollars, is due to a difference in the number of students since the program is cash-funded by course and evaluation fees. Approximately 72 percent of program expenditures went to contract instructor reimbursement and the rest on program administration.

Table 1
CDPHE QMAP Program Expenditures

Fiscal Year	Expenditures	FTE
06-07	$167,938	0.6
05-06	$153,527	0.8
04-05	$162,028	0.7
03-04	$145,845	0.4
02-03	$168,925	0.6
Average	**$159,653**	**0.62**

DHS uses QMAP services in multiple divisions. The DHS-Division of Developmentally Disabled (DDD) delegated an estimated 0.075 FTE (7.5 percent) to QMAP related activities, or approximately three hours per week. The Division of Youth Corrections (DYC) in DHS does not keep track of expenses related to QMAP training. DYC has licensed medical staff who teach the CDPHE curriculum as part of their duties and have

[48] § 25-1.5-302(1), C.R.S.
[49] § 25-1.5-302(3), C.R.S.
[50] Ibid.

approximately 250 QMAPs on staff in 14 facilities at any given time. Combined, these QMAPs perform more than 500,000 administrations per year in DYC facilities.

At this time, DOC does not utilize the services of QMAPs in its facilities. Because of the current availability of licensed medical staff in facilities, medication administrations are either performed or monitored by licensed medical staff. This has been DOC policy since approximately 2006. However, there is the possibility that those staffing levels could change. When DOC judges that QMAP services are needed, all correctional officers are trained as QMAPs during their department basic training. Currently there are 900-1,000 new correctional officers who go through basic training per year.

Facilities

Approved QMAP education programs are presented and the functions of the QMAP are overseen by the department that has jurisdiction over the specific facility. The following lists the facility type and the regulating agency(s) where QMAPs are allowed administer medication. In the case of DOC facilities, the list is comprised of facilities where QMAPs may to be utilized if there is a need, rather than facilities where QMAPs are currently administering medication.

CDPHE regulates:

- Assisted living residences (ALR) – licensed by CDPHE;
- Adult foster care facilities – licensed by CDPHE as an ALR;
- Alternative care facilities - licensed by CDPHE as an ALR;
- Adult day care facilities – Adult day care facilities are not licensed;
- Community residential homes for persons with developmental disabilities – licensed by CDPHE. DDD reviews the programmatic services to the residents and issues program approval to CDPHE, a requirement for licensure; and
- Facilities that provide treatment for mentally ill persons – this includes residential treatment facilities for the mentally ill which are licensed by CDPHE as ALRs, Acute Treatment Units and Community Mental Health Centers, also licensed by CDPHE. DHS-Mental Health Services reviews the programmatic/treatment services provided and issues program approval to CDPHE, a requirement for licensure.

DHS regulates:

- Residential child-care facilities – licensed by the Office of Child Care Licensing;
- Secure residential treatment centers – licensed by the Office of Child Care Licensing;
- Community residential homes for persons with developmental disabilities – licensed by DDD;
- Youth correctional facilities – operated by the DYC; and
- Facilities that provide treatment for mentally ill persons – see CDPHE facilities above.

DOC operates:

- Correctional facilities;
- Minimum security facilities;
- Jails;
- Community correctional facilities;
- Regimented inmate discipline and treatment programs; and
- Denver diagnostic center.

QMAP Instruction

The QMAP course is meant to provide the minimum amount of training necessary to execute medication administration safely. Typically, the instruction is completed in one day followed by a two-part examination the next day. The CDPHE curriculum is broken into eight units, all of which are interactive. The interaction involves verbal communication and practicing procedures. The content consists of: [51]

1. Legal Implications
    a. Defines the difference between monitoring and administering medication.
    b. Lists the routes by which QMAPs may and may not administer medication once qualified.
    c. Defines a QMAP's legal responsibility in filling Medication Reminder Boxes (MRB).

[51] Health Facilities and Emergency Medical Services Division, CDPHE, *Medication Administration Student Syllabus,* July 2007.

2. Uses and Forms of Drugs
    a. Describes what medications are used for throughout society.
    b. Identifies the different forms drugs are presented in: liquids, solids, and semi-solids; defines the difference between local and systemic drug actions; and prescription and over-the-counter drugs.
    c. Defines and discusses controlled substances.
    d. Instructs students what to do in suspected drug diversion cases.
    e. Contrasts desired and therapeutic effects of drugs as well as side effects and adverse reactions.

3. Dosages of Medications
    a. Explains the role of size, frequency, and duration of a dose.
    b. Explains the different measurement methods used to determine strength of dosage.
    c. Instructs how to read, translate, and interpret a medication order.
    d. Defines QMAP's role in restocking, changing, and/or stopping medication.

4. Medication Administration Records (MAR)
    a. Explains industry-wide norms for recording medication administration and when a patient refuses administration.
    b. Instructs student as to the correct protocols to correct mistakes on the MAR.
    c. Clarifies the difference between per requested need (PRN) medication administrations and other types of administrations, and how to record them.

5. Administering Medications
    a. Explains a tool named the "five rights" of medication administration – making sure the QMAP knows it is the right client, right time, right medicine, right dose, and right route when he or she administers medication.
    b. Educates the students about medication storage, universal precautions, how to use resources at their disposal to look up drugs, and the protocols to follow if he or she makes an administration error.
    c. Delineates responsibilities, requirements, procedures, and guidelines surrounding the use of MRBs.

6. Medication Administration Procedure and Guidelines

    a. Provides step-by-step instruction of standard medication administration practices.

7. Administration Guidelines

    a. Provides a step-by-step instruction on how to administer different forms of medication, i.e., lotion, tablet, patches, etcetera.

8. Procedures for Filling Medication Reminder Boxes

    a. Provides specific step by step instructions concerning the rules and actions to be used when filling MRBs.

Once a student has passed the examination, he or she must execute a disclosure form stating he or she understands the regulatory parameters that QMAPs are allowed to perform within. When the paperwork is complete, CDPHE is informed and a QMAP's name is added to a list noting he or she is indeed a QMAP. Thereafter, when an employer makes an inquiry to find out if a person is qualified, the CDPHE administrator looks up the name and replies in either the affirmative or the negative. Beyond the record of completion, there is no data recorded concerning job status, complaints, violations, or any enforcement actions as they apply to individual QMAPs.

QMAP Instructors

The statute states that CDPHE needs to make the training and evaluation available around the state and that it may contract with private providers if there is a need.[52] Currently, CDPHE contracts out all of its classes to 47 approved instructors located in various geographical regions of Colorado. Of those 47 on the CDPHE-approved instructor list, 13 are willing to travel to do the training and two will travel statewide if necessary.

Instructors must be licensed nurses, physicians, or pharmacists. They contract for one year with the CDPHE to implement the training curriculum and evaluate the candidates. Anyone who meets the initial minimum qualifications may submit an application to CDPHE. CDPHE evaluates the applicants and fills positions based on projected need concerning geographical area and number of projected students.

[52] §§ 25-1.5-302(4), and 25-1.5-302(7), C.R.S.

Evaluated Students

The statute directs that QMAP instruction be available throughout the state. It also directs that all DHS- and DOC-evaluated QMAP's names be forwarded to CDPHE. The following information was compiled from CDPHE records to provide an overview of how many QMAPs are qualified each year in Colorado.

Table 2
QMAPs Qualified During Review Period
(Fiscal year, CDPHE and DHS-DYC)

Fiscal Year	CDPHE Classes Offered	QMAPs	DYC Classes Offered	QMAPs
06-07	390	2,479	N/A	87
05-06	310	2,318	N/A	63
04-05	320	2,877	N/A	50
03-04	314	2,791	N/A	108
02-03	341	2,970	N/A	92

Table 3
QMAPs Qualified During Review Period
(Calendar Year, DHS-DDD)

Calendar Year	DDD Classes Offered	QMAPs
2006	93	1,099
2005	177	4,699
2004	63	1,821
2003	206	4,925
2002	71	1,082

The variation in numbers reported for DDD facilities can be explained by the listing of reevaluated QMAPs. During 2003, the training manual used during QMAP training was reworked and DDD required all QMAPs to be reevaluated using the new material as the standard. The 2005 increase is similar in that many facilities require competency evaluations periodically and it appears that they are on a two year cycle beginning with the 2003 reevaluation. DDD estimates that it trains and evaluates 1,000 to 1,500 new QMAPs per year.

In addition to these CDPHE and DHS programs, when DOC utilizes QMAPs in its facilities, all correctional officers complete QMAP training during basic training. At current completion levels, that means another 900 to 1,000 QMAPs each year could be trained and evaluated.

Examinations

Becoming a QMAP requires passage of a two-part examination. Though there is a pre-examination training program, it is not mandatory unless the applicant fails the examination and wishes to take it again.

To pass the examination, an applicant must get 85 percent of the written portion correct and 100 percent of the practicum portion correct. The table below shows that more than 9 of every 10 students (92.5 percent average) who take the QMAP training become qualified.

Table 4
CDPHE QMAP Students and Results

Fiscal Year	Students	QMAPs	Percent Qualified
06-07	2,869	2,479	86.4
05-06	2,536	2,318	91.4
04-05	3,043	2,877	94.5
03-04	2,944	2,791	94.8
02-03	3,139	2,970	94.6

The written examination consists of true or false, multiple-choice, fill-in-the-blank, and short answer questions. To pass, a student must know where a QMAP is allowed to administer medication, the different methods by which a QMAP is allowed to administer medication, how to read a doctor's order, how to measure and calculate different dosages of medication, and how to record all actions taken connected to medication administration. This section of the examination is designed to determine if a student understands all of the duties and procedures expected of a QMAP.

The practicum section of the examination is where students demonstrate that they are able to practice what they learned in the classroom by performing the duties of a QMAP under the scrutiny of the course instructor. Each student must fill an MRB and record all of the applicable information from a doctor's order as if he or she were working in a facility. The student must also demonstrate that he or she is proficient at administering liquid suspensions and solutions, inhalant, and suppository type medications during a one-on-one interaction with the instructor. During this individual interaction, the medication administration includes a dialogue with the resident/instructor describing what the resident can expect during the administration and what actions are expected by both the administrator and the resident, i.e., "You need to sit straight up in your chair, bend your head back, and I will…".

The role playing function is an important part of the administration and examination process for several reasons. In the case of suppository medications, the discussion is meant to ease any embarrassment or discomfort. In other cases, the administration may not be mechanically easy for the resident, so the conversation prepares the resident for the process. It is also the responsibility of the QMAP to be sure that medication is administered. By following the specific regimens, determined by both best medical practices and individual facility policy, a QMAP can usually be sure that a medication administration is completed successfully.

Inspections

No inspections are made specific to individual QMAP performance. CDPHE inspects all the facilities that it licenses. During those facility inspections, the records for medication administration are examined; the same is true for DHS. In fact, the QMAP program is conducted under the authority of the Health Facilities and Emergency Medical Services Division of CDPHE. In so doing, CDPHE reinforces the notion that medication administration is a basic system of operation rather than a regulated occupation.

When inspectors enter facilities, an examination of medical records is performed to look for patterns. The table below shows the major types of violations cited that are attributable to QMAPs in Colorado's Assisted Living Residences, only one category of facility that utilizes QMAP services, from fiscal year 02-03 through 06-07.

Table 5
QMAP Violations at Assisted Living Residences

Fiscal Year	Percent Not Following Curriculum Regimen	Percent Incorrectly Labeled	Percent of Total QMAP Violations
06-07	47.9	51.2	99.1
05-06	55.8	26.3	82.1
04-05	51.6	29.0	80.6
03-04	30.0	29.0	59.0
02-03	37.7	27.7	65.4

Two types of issues represent the overwhelming majority of violations cited. Close to half of all violations (44.6 percent), during the review period, were because the administration regimen taught in the QMAP training was not followed. Approximately one-third (32.6 percent) were the result of incorrect MRB labeling. The non-specific nature of these violation categories, combined with the forensic nature of the inspections, may lead to the large numbers of violations being cataloged in them. The bump in the numbers after fiscal year 03-04 is attributable to both a change in evaluation system and the subjective nature of the categories.

Complaints/Disciplinary Actions

There are no records kept concerning individual QMAPs. Therefore, there are no records of complaints or disciplinary actions. When a violation is noted during a facility inspection, it is recorded in one of several categories inspectors examine and is attributed to the facility, not to an individual QMAP.

Since this is a legal exemption from other Colorado statutes and not a certification or licensure program, there is no state-issued credential against which to file a complaint or take any disciplinary or punitive action. The only action allowable is that a QMAP may be ordered to retake the training as a condition of employment. Furthermore, there is no way to determine if, or how many individuals are required to undergo retraining because the only records kept on QMAPs are whether they are initially qualified.

Analysis and Recommendations

Recommendation 1 – Continue the Qualified Medication Administration Person program.

Originally, the justification to give unlicensed persons the ability to administer medication in certain circumstances was based on a two part premise. First, medication was being administered illegally because licensed medical personnel were not available in all facilities and the cost of hiring licensed people to perform every medication administration was prohibitive. Second, if the first part could not change, then the better alternative was to ensure that people who administer medication have the training necessary to perform the medication administration function safely and legally.

The solution was the genesis of the Qualified Medication Administration Person (QMAP) program, qualifying non-medical professionals to perform medication administration and allowing exemptions to the medical licensing statutes for the qualified individuals. The program is meant to provide the minimum training necessary to execute medication administration safely. Once qualified, the QMAPs are only utilized in particular classifications of facilities listed in law, including: correctional facilities, assisted living facilities, foster care facilities, daycare facilities, and other facilities in which a resident lives or is monitored. The environment that produced the problem and the solution has not changed.

The need to have trained unlicensed staff members perform certain basic medical tasks is necessitated by cost. Many facilities have limited, or no, medical staff or medical consulting services on site. An example of such a facility is a daycare program for people with cognitive disabilities. The costs associated with having a licensed medical practitioner present whenever an individual resident needs medication at a specific time, is more than many facilities can afford.

Both the legislature and previous sunset reviews recognized that the potential harm from closing a facility would be greater than the benefit realized by training QMAPs. The alternative, in the case of many physically or cognitively impaired people, who currently live independently but attend daycare facilities or are residents of assisted living residences, would be institutionalization. Many elderly or physically disabled people are mentally sound but need physical assistance taking medication. Conversely, others may not be able to understand schedule or dosage requirements necessary for self-administration, but may be able to live in society somewhat autonomously. To demand that these people be institutionalized would increase individual costs, program costs, overburden facilities, and inhibit the individual freedom that these people enjoy.

Keep in mind that QMAPs do not solely administer prescribed pharmaceuticals. Medication administration can refer to giving a person over-the-counter cough syrup or even an aspirin. Prior to this program, it was illegal to perform even these tasks without a license, and still is in most settings.

The program allows only certain types of facilities, listed in law, to utilize trained employees to give that aspirin or other medication. The employees' other job functions may, or may not, have anything to do with healthcare. Because medication administration is merely one function of an employee's job, there is no added expense to be passed on to the consumer.

CDPHE commissioned a study concerning the QMAP program in 2008. That study recommended that regulation of QMAPS should be increased. [53] However, DORA's analysis, based on the criteria dictated in statute, found increasing regulation unwarranted.

Because this is a quasi-registration program, the next higher level of regulation is certification. Several other states require unlicensed medical persons to be certified to perform medication administrations. Generally, unlike in Colorado, these people must be employed in the healthcare industry as some type of a caregiver, and complete a rigorous education/training program. These certified medication assistant-type programs are equivalent to Colorado's Certified Nurse Aide with Medication Aide Authority program, which a person must complete prior to performing medication administrations in long-term care facilities.

The qualification given for QMAP training is not meant to be a substitute for the certification program. QMAPs are prohibited from performing medication administrations in any clinical or institutional setting not specifically delineated in law. Moreover, it is the prohibitions in Colorado's statute against, "…judgment, evaluation, or assessments…"[54] that draw the distinction between QMAPs and any other program or certification. QMAPs follow orders, record administrations, and report any issues that are out of the norm to someone in a supervisory position for judgment, evaluation, or assessment.

The extreme limits on what – the statutory definition of medication administrations specific to QMAPS, where – the statutory list of places QMAP services may be used, when – the rule that QMAPs are only allowed to follow a physician's written orders, even in the case of over the counter medications, and how – the prohibitions on administering injections or monitoring self-administration, QMAPs perform medication administrations preclude the need for a higher level of regulation.

Both the training and evaluation program and the prohibitions in the law, interact to protect Colorado citizens from both poor medical practices and financial hardship. The statutory criteria that determine what is examined during a sunset review ask, first and foremost, if a program is necessary to protect the health, safety and welfare of the public. The statutory exemption which demands a QMAP acquire basic skills, to complete basic medication administration functions, does protect the public.

[53] Francile Beights, Final Report, June 13, 2008, Colorado Department of Public Health and Environment Medication Administration Program.
[54] § 25-1.5-301(1), C.R.S.

The sunset criteria also inquire as to how a program is affected by marketplace conditions. In this case, the marketplace has grown dependant on the existence of the legal exemptions. While accurate data regarding the number of QMAPs currently employed in Colorado is unavailable, records indicate several thousand have been trained and thousands more complete the training every year. Eliminating the program would likely cause cost increases for consumers and lead to lax enforcement of the statutes that QMAPs are currently exempt from. The former because some facilities would bring in licensed staff they currently do not employ, and the latter because some facilities would revert to using unlicensed, untrained staff as was the case prior to adoption.

Therefore, the General Assembly should continue the QMAP program.

Recommendation 2 – Remove the QMAP education and evaluation program from the sunset review calendar.

This recommendation, to remove medication administration by unlicensed persons from the sunset review cycle, is based in the makeup of the program established under statute. The non-regulated status of the QMAP function, the resolution of conditions that the QMAP function is meant to address, the dearth of data suggesting that there have been problems associated with QMAPs and/or the program, the nature of the employer/employee relationship in facilities that employ QMAPs, and a precedent that medical exemption qualifications need not be reviewed, make further sunset reviews unnecessary.

The QMAP education and evaluation program, established under section 25-1.5-301, *et seq.,* Colorado Revised Statutes (C.R.S.), is not a regulatory program. It does not track professional practitioners who are registered, certified, or licensed. It is an education program that ***qualifies*** employees who are employed in certain classifications of facilities to perform medication administrations within specific parameters. It also exempts the people who complete the program from three Colorado laws:

- Article 18 of Title 18, C.R.S., Uniform Controlled Substances Act of 1992;
- Article 38 of Title 12, C.R.S., the Nurse Practice Act; and
- Article 36 of Title 12, C.R.S., the Medical Practice Act.

It makes sense to continue the program to carve out exemptions to these acts. It is doubly important since the exempted people are needed and valued in State-run or licensed facilities. However, because it is not a regulated profession, disciplinary actions against QMAPs are virtually nonexistent. Typically, sunset reviews examine regulatory programs and the processes programs implement while regulating an industry or a profession.

The QMAP authorizing statute merely directs that CDPHE establish and direct an education and evaluation program, and it has accomplished that. The Department of Regulatory Agencies (DORA) was able to find little programmatic substance to comment on during this sunset review. The same is true for a previous sunset review conducted more than a decade ago, during 1997.

While conducting this review, attempts were made to compare this program to other education, training, regulatory, and health-related programs. None compare well. The QMAP program is basic education, instructing students how to read a licensed medical practitioner's directions, follow those directions, and record the occurrence. QMAPs do nothing more than any parent does for a sick child. In many cases, because of the nature of their training and employment, they may be more qualified than a parent to administer medication. It is only after completing the training that QMAPs are allowed the statutory exemptions and only while working in the facilities specifically delineated in statute.

The origin of the QMAP program is founded on certain industry conditions and those conditions have not changed. A 1986 Colorado Attorney General opinion stated that unlicensed persons who were administering medication in licensed facilities were running afoul of Colorado law.[55] If the QMAP program were to disappear, it is reasonable to conclude that medication administration by unlicensed, unqualified, and non-exempt persons would once again happen. The thought at the time was, giving basic education, concerning measurement, application, and recording procedures, was better than insisting that only licensed persons perform medication administrations and driving up costs, or allowing untrained persons to carry out administrations. The solution is the QMAP program. By most qualitative and quantitative measures, qualifying lay persons to carry out medication administration has successfully rectified the condition without verifiable problems.

In the main, it is incumbent on an employer to make sure that those in his or her employ are qualified and competent, regardless of the tasks in the job description. This is true whether the employee is a lifeguard or an automobile mechanic. In reality while these professions demand training, and performance can have life affecting consequences, they still do not adequately compare to QMAPs. They do not compare because they are career occupations not a function of those occupations.

If a facility utilizes QMAP services, under law, it is responsible for providing on-the-job QMAP training beyond the initial education and evaluation. The on-the-job training ensures that an employee knows the nuances of medication administration specific to that facility. Moreover, there is nothing in the statute that prohibits an employer from asking a QMAP to take training as a condition of employment regardless of how many times the employee has taken it in the past. If there is an in-house change in medication administration procedure, again, it is the facility that is responsible for instructing the employee(s) on the subject of any policy change.

[55] Communication between David Burlage, First Assistant Attorney General and Linda Fleming, State Board of Nursing, February 18, 1986.

As part of the sunset review process, DORA staff conducted a survey of facility administrators that utilize QMAP services. Of those who responded, more than 44 percent said that they review medication administration procedures monthly and the total jumps to 79 percent for those who review at least quarterly. Also, 79 percent of these administrators think the QMAP training is effective.[56]

These results indicate that, generally, employers actively monitor the QMAP function to ensure that the facilities under their supervision operate safely.

Medication administration is viewed as a facility function not as a regulated occupation. In other words, medication administration is a function in a facility that helps it operate, similar to the gasoline in an automobile rather than the person licensed to drive an automobile. The violations attributable to QMAPs, when they do occur, are generally for not following the correct administration protocols or not keeping records correctly. In discussions with organizations which represent medical professionals, they acknowledged that those types of violations can occur even when a person is a licensed medical professional. Level of education and training does not appear to have a significant effect on those types of administration errors. Both the literature on the subject and a survey of Colorado facilities that utilize QMAPs, corroborates those statements. These are mistakes made at all types of facilities by employees regardless of the title associated with their position.

This recommendation is not unprecedented; at least one instance does exist when the General Assembly chose not to review an exemption qualification to the Medical Practice Act. “Qualified Athletic Trainers,” who have fewer limitations on how they function, are able to make health-related judgments, and in some cases make a diagnosis, are granted an exemption to the Medical Practice Act by section 12-36-106(3)(s) C.R.S.

Therefore, the General Assembly should remove the QMAP program from the sunset review calendar explicitly for the following reasons:

- QMAPs are not a regulated occupation. The program educates and creates exemptions to other statutes without rising to any level of regulation.
- Conditions that initially prompted the education program and legal exemptions are ongoing but rectified by the program without any verifiable problems.
- Medication administration is regarded as a facility function. Employers are responsible for keeping facilities functioning properly.
- Data suggesting that QMAPs perform any differently on the job than a more highly trained medication administration person is not available.
- Precedent exists that excludes a medical exemption qualification from sunset review.
- There has been no risk to the health, safety, and welfare of the public discovered by past or current sunset reviews. Because of the nature and structure of the program, it is unlikely that additional sunset reviews will uncover problems.

[56] Appendix A

Recommendation 3 – Require employers to document that all unlicensed medication administration persons, currently in their employ, pass the QMAP competency evaluation at least every five years, as a condition of employment in that facility.

According to statute, CDPHE must keep a record of all people who pass the QMAP evaluation, whether it is administered in a class instructed by a contractor or in a CDPHE-approved, Department of Human Services (DHS), or Department of Corrections (DOC) program. To what end? This is not a regulatory program. There is no provision in the authorizing statute which allows any regulatory unit to take a qualification away for misconduct, negligence, or malpractice. Currently, the qualification is an exemption, bestowed in perpetuity, which can only be used at specific times in specific places. The sole existing disciplinary action is that CDPHE can order a QMAP to be retrained if it feels it is necessary. However, retraining is not noted on a QMAP's record, because a personal information record does not exist. Only the name of each person who has passed the training and evaluation process is required to be listed.

Here the reality is different from the conceptual. There is no true master list of QMAPs at CDPHE even though the qualification is supposed to be life-long. CDPHE has never required contractors, DHS, or DOC to use a specific central database to record the names of QMAPs. The result is bureaucratic confusion. Some names are listed in hard copy and others in an electronic database. It can take weeks to get information and the form and function of the information is of questionable utility when it is received. During this sunset review, DORA asked to receive the total number of people who became QMAPs during the five-year study period. An aggregate number is unavailable. The inability to acquire aggregate numbers is problematic only for the few researchers who examine programs. However, it raises legitimate questions about the efficacy of an employer inquiring of CDPHE if a person is a QMAP. The preferable way to deal with this disorder is to eliminate it.

There is provision, in section 25-1.5-303(3), C.R.S., that every employer provide and document on-the-job training for each employee who uses the exemptions. This recommendation merely extends that training mandate to include the QMAP competency evaluation and requires that the evaluation be passed at least every five years. As stated in Recommendation 2 above, it is the responsibility of an employer to see that all employees are qualified to do their jobs. If an employer wants to use an employee's exemption, the employer should see that the employee is trained and competent. The exemption should be good only as long as a QMAP is employed in the facility where he or she is employed when becoming qualified and exempt, rather than indefinitely. Every time a QMAP changes his or her work-place, then he or she must be re-qualified to use the legal exemptions; the exemption should not be transferable. In effect, the exemption is awarded to both the individual and the facility simultaneously. Any separation of the two would nullify the exemption. Both the DHS-Division of Developmental Disabilities (DDD) and DOC already employ similar policies. DDD demands that all employees demonstrate core competencies, including those of a QMAP when applicable, as a condition of employment. DOC, when it utilizes QMAP

services, mandates that all correctional officers are trained to be QMAPs during basic training. By requiring all employers to document that each QMAP is trained and competent, the need for a central list is eliminated and the system becomes streamlined and more efficient.

An immediate knee-jerk response to a recommendation of this nature might be, “It is unfair to make a person continually retake the eight hour training.” However, there is provision in section 25-1.5-302(4), C.R.S., that allows a person to take the evaluation portion of the program without taking the training portion. If that person fails the evaluation, then he or she must take the training before he or she can retest.

One criticism of the QMAP program is, currently nothing stops a QMAP who has been fired for not using correct administration protocols, from getting another job with QMAP responsibilities. Because, a person’s name is on a list of qualified individuals an employer could erroneously assume that there have been no problems. However, eliminating the list and making an employer directly responsible for the qualifications of its QMAPs makes this criticism irrelevant and the system more efficient.

More than 97 percent of the facility administrator respondents surveyed for this review, believe that QMAPs are important to their respective facility. More than 90 percent of those same administrators feel the QMAP qualification adds value to a staff member’s employment status. Given those widespread opinions, it makes sense to have each facility responsible for the qualifications of its employees.[57]

There are two goals connected to this recommendation. First, each employer has specific knowledge that facility employees are qualified. The second is that it eliminates the need for CDPHE to keep a centralized list of QMAPs.

Sunset evaluation criterion IV instructs DORA to evaluate agency operations for effectiveness and efficiency. What can be confidently stated is that the system in use is not efficient. Requiring employers to qualify their employees and provide documentation to inspectors, when necessary, eliminates any need for CDPHE to keep lists, decreases confusion, and lessens the bureaucratic burden created by the statute.

Because there is no cogent reason for CDPHE to keep an available, easily negotiated list of QMAPs and because it is an employers responsibility to ensure the proficiency of its employees; the General Assembly should require employers to document that all unlicensed medication administration persons, currently in their employ, pass the QMAP competency evaluation, as a condition of employment in that facility.

[57] Appendix A

Recommendation 4 – Require employers who utilize QMAP services to conduct a drug-related criminal history background check on each QMAP.

The General Assembly has decided that the QMAP exemptions are necessary to keep people and facilities from operating outside the law. The laws that a QMAP are exempt from, the Medical Practice Act, the Nurse Practice Act, and the Uniform Controlled Substances Act of 1992 provide important protections for all Colorado citizens.

Given that QMAPs are awarded legal exemptions and are placed in a position of trust handling narcotics, psychotropics, and other controlled substances, they should undergo a drug-related criminal background check prior to issuance of the exemption. Drug diversions have wide ranging, problematic affects, and no person with a drug-related conviction within the previous five years should be allowed to be exempt from these statutes.

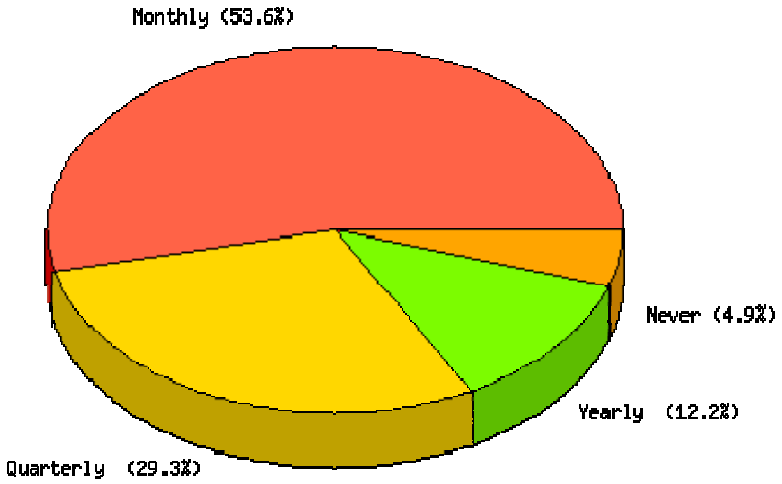
When there is trust there is potential for abuse of that trust. If the General Assembly is the entity that bestows that trust on individuals it has a responsibility to attempt to prevent abuse from occurring. Demanding that an individual have a clean drug-related, criminal history before being allowed to handle medications is a reasonable step in that direction.

Appendix A – Survey Results

The following results are from a survey conducted by DORA of facility administrators during June 2008. This appendix A includes only those questions and answers referenced in the Analysis and Recommendations section of this review.

Question: How often do you review medication administration procedures?

Results

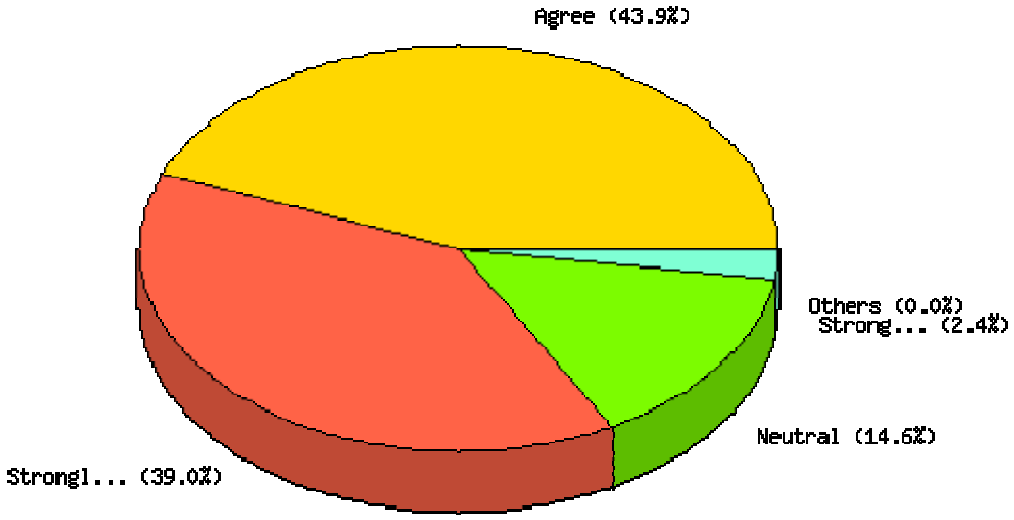


	Count	% Sample Answered	% Sample Asked	% Sample Total
Monthly	22	53.7%	48.9%	48.9%
Quarterly	12	29.3%	26.7%	26.7%
Yearly	5	12.2%	11.1%	11.1%
Never	2	4.9%	4.4%	4.4%
Not Answered	4	N/A	8.9%	8.9%
Not Asked	0	N/A	N/A	0.0%
Total	45	100%	100%	100%

Statistics	
Minimum Value	1.00
Maximum Value	4.00
Average	1.68
Sum	69
Standard Deviation	0.88
Median	1
Mode	1

Question: The QMAP training is effective.

Results

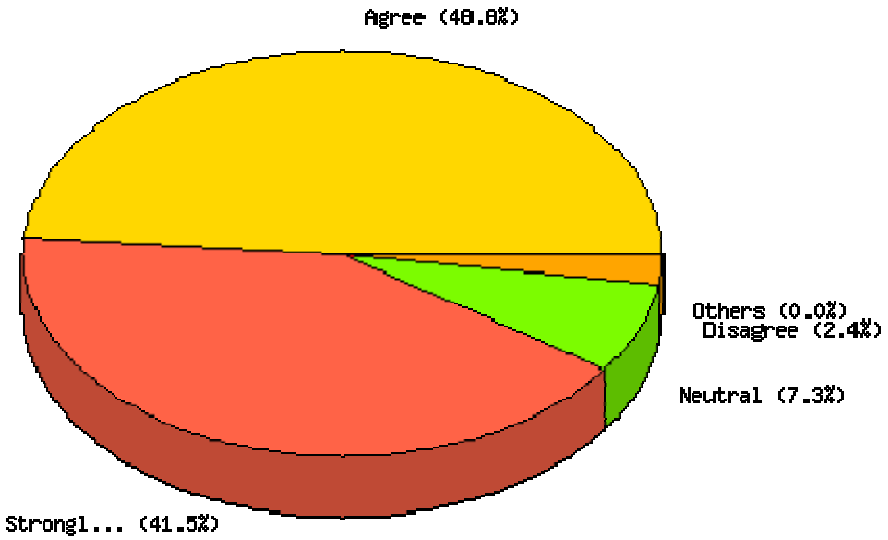


	Count	% Sample Answered	% Sample Asked	% Sample Total
Strongly Agree	16	39.0%	35.6%	35.6%
Agree	18	43.9%	40.0%	40.0%
Neutral	6	14.6%	13.3%	13.3%
Disagree	0	0.0%	0.0%	0.0%
Strongly Disagree	1	2.4%	2.2%	2.2%
Not Answered	4	N/A	8.9%	8.9%
Not Asked	0	N/A	N/A	0.0%
Total	45	100%	100%	100%

Statistics	
Minimum Value	1.00
Maximum Value	5.00
Average	1.83
Sum	75
Standard Deviation	0.86
Median	2
Mode	2

Question: The QMAP qualification adds value to a staff member's employment status.

Results

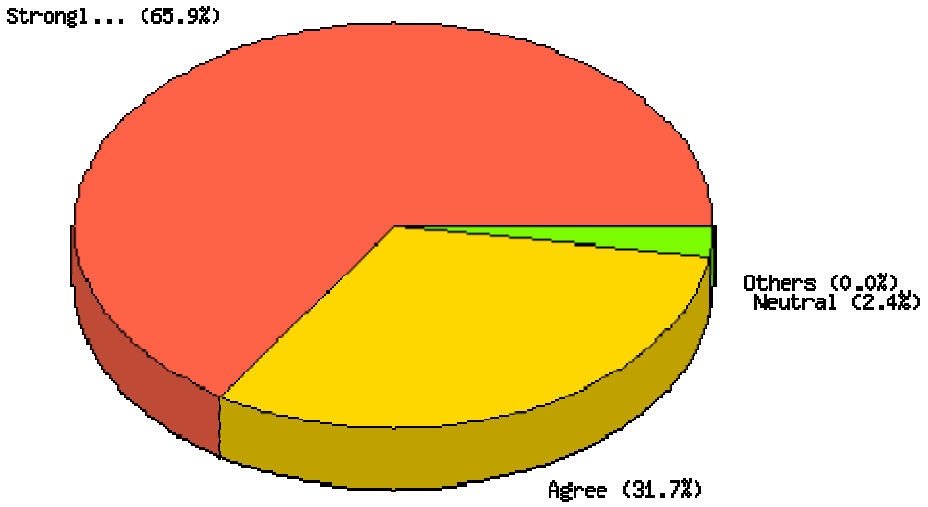


	Count	% Sample Answered	% Sample Asked	% Sample Total
Strongly Agree	17	41.5%	37.8%	37.8%
Agree	20	48.8%	44.4%	44.4%
Neutral	3	7.3%	6.7%	6.7%
Disagree	1	2.4%	2.2%	2.2%
Strongly Disagree	0	0.0%	0.0%	0.0%
Not Answered	4	N/A	8.9%	8.9%
Not Asked	0	N/A	N/A	0.0%
Total	45	100%	100%	100%

Statistics	
Minimum Value	1.00
Maximum Value	4.00
Average	1.71
Sum	70
Standard Deviation	0.72
Median	2
Mode	2

Question: QMAPs are important to the operation of the facility.

Results

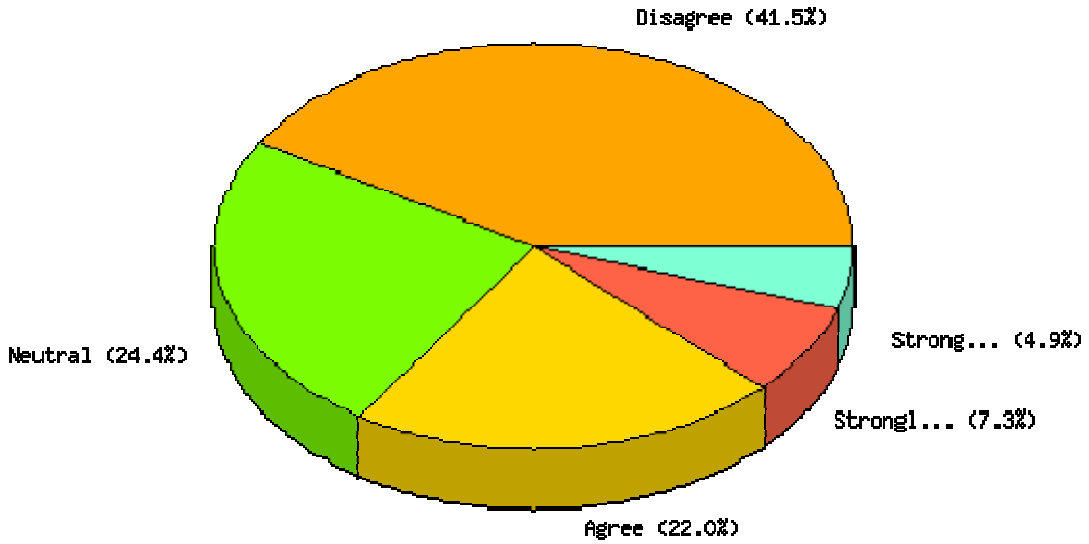


	Count	% Sample Answered	% Sample Asked	% Sample Total
Strongly Agree	27	65.9%	60.0%	60.0%
Agree	13	31.7%	28.9%	28.9%
Neutral	1	2.4%	2.2%	2.2%
Disagree	0	0.0%	0.0%	0.0%
Strongly Disagree	0	0.0%	0.0%	0.0%
Not Answered	4	N/A	8.9%	8.9%
Not Asked	0	N/A	N/A	0.0%
Total	45	100%	100%	100%

Statistics	
Minimum Value	1.00
Maximum Value	3.00
Average	1.37
Sum	56
Standard Deviation	0.54
Median	1
Mode	1

Question: Licensed medical staff makes fewer medication administration errors than QMAPs.

Results



	Count	% Sample Answered	% Sample Asked	% Sample Total
Strongly Agree	3	7.3%	6.7%	6.7%
Agree	9	22.0%	20.0%	20.0%
Neutral	10	24.4%	22.2%	22.2%
Disagree	17	41.5%	37.8%	37.8%
Strongly Disagree	2	4.9%	4.4%	4.4%
Not Answered	4	N/A	8.9%	8.9%
Not Asked	0	N/A	N/A	0.0%
Total	45	100%	100%	100%

Statistics	
Minimum Value	1.00
Maximum Value	5.00
Average	3.15
Sum	129
Standard Deviation	1.06
Median	3
Mode	4