1997 SUNSET REVIEW

Regulation of Medication Administration by Unlicensed Persons

Submitted by the
Colorado Department of
Regulatory Agencies
Office of Policy & Research

STATE OF COLORADO

DEPARTMENT OF REGULATORY AGENCIES
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Roy Romer
Governor

October 15, 1997

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 Colorado Department of Regulatory Agencies has completed the evaluation of the regulation of Medication Administration by Unlicensed Persons. I am pleased to submit this written report, which will be the basis for my office's oral testimony before the 1998 Legislative Committees of Reference. The report is submitted pursuant to Section 24-34-104 (8)(a), of the Colorado Revised Statutes, 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 article 1 of title 25, C.R.S. The report also discusses the effectiveness of the division and staff in carrying out the intention of the statutes and makes recommendations for statutory and administrative changes in the event this regulatory program is continued by the General Assembly.

Sincerely,

Joseph A. Garcia
Executive Director

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EXECUTIVE SUMMARY

The Department of Regulatory Agencies (DORA) has concluded its 1997 Sunset Review of the administration of medication by unlicensed persons in facilities identified in §25-1-107 (1)(ee), C.R.S., and administered by the Colorado Department of Public Health and Environment (CDPHE). DORA found there is little benefit derived or protection afforded to the public by this program. However, it is a necessary function to maintain reasonably cost effective health care alternatives for certain individuals. DORA recommends exploring improvements to the enforcement options available to health care regulators to facilitate the privatization of the training program. In evaluating the operation of the program against the Sunset Evaluation Criteria in §24-34-104 (9)(b), C.R.S., DORA found areas where statutory changes would remove impediments, or enhance the ability to operate the program in the public interest. The report contains a total of 3 statutory recommendations.

Each recommendation is followed by a brief summary and an expanded discussion of the analysis and issues surrounding the recommendation. A single discussion section is used for several recommendations concerning a single topic area. The recommendation section begins on page 20 of the report.

The first recommendation is to continue the authorization for unlicensed persons completing a training program approved by the Colorado Department of Health and Environment to administer medications under specifically identified circumstances. The review explores the possibility of eliminating the state administered training program and holding employers responsible for the actions of employees. However, there are obstacles to enforcing training requirements on licensed facilities. Addressing these obstacles is beyond the scope of the current review. The report requests the General Assembly to authorize an expanded review during the next Sunset.

The report recommends expanding the use of qualified individuals to administer medications for all services funded by the Department of Human Services. Some programs under the direction of the Department of Human Services do not always fit into the categories defined in the current statute. Limiting this program to the specific programs listed in the statute may unnecessarily stifle innovative health care alternatives.

The filling of medication reminder boxes is currently limited to licensed health care professionals. This places an unnecessary burden on individuals in some alternative health care settings. Once a licensed practitioner has prescribed a medication and a pharmacist has dispensed it, the storage of the medication should be up to the patient. The report recommends allowing qualified people to fill medication reminder boxes.

BACKGROUND

Sunset Process/Methodology

The administration of medication by unlicensed persons in facilities identified in §25-1-107 (1)(ee), C.R.S., shall be terminated effective July 1, 1998 unless continued by the General Assembly. Pursuant to §24-34-104(9)(b), C.R.S., the Department of Regulatory Agencies is required to conduct a review of the Colorado Department of Public Health and Environment's (CDPHE) performance in the operation of this program. During the review, the CDPHE must demonstrate there is a need for the program to continue, and that the regulation is the least restrictive form of regulation consistent with the public interest, in accordance with the Sunset Evaluation Criteria, found in Appendix A.

The sunset review process includes an analysis of the statute and regulations promulgated under its authority, interviews with CDPHE staff, other departments, and interested parties affected by the provision of the law. Research of current literature, related statutes, and the procedures in other states was also conducted.

History

The authority for the administration of medication by unlicensed persons was created as a result of a 1987 sunrise application for the licensure of a new class of health care professionals to be known as Community Living Specialists. The licensure application was one of the few received by the General Assembly that was not initiated by the profession. The Colorado Board of Nursing requested the Sunrise review. The application was denied, and there is no current licensed occupation performing the duties described as a Community Living Specialist.

The application indicated a potential danger to the public by the administration of medication, and the performance of other nursing functions, by untrained individuals in alternative health care settings. The subsequent report was heard by the Joint Legislative Sunrise/Sunset Committee in the fall of 1987.

The Sunrise report made the following findings:

- There is no documentable harm to the public by the absence of licensure of community living specialists.

- Some persons in personal care boarding homes and similar facilities have difficulty, or inability, to self-administer medication due to mental or physical limitations.

- Unlicensed persons in community living situations perform certain medical functions, such as administering medications.

- The administration of medications are part of the practice of medicine which, in general, may be performed in limited legally prescribed ways by regulated individuals or persons receiving no compensation, such as family members or friends.

- Repackaging of prescription drugs into smaller quantities to be taken at prescribed times is in violation of state and federal statutes, unless the person doing so is registered with the federal Food and Drug Administration.

- The Department of Health licenses and inspects personal care boarding homes and other health facilities.

- Clients of facilities using the services of community living specialists, who cannot self-administer medications could be forced into more expensive settings, such as nursing homes, if the facilities comply with existing laws.

The report recommended against the creation of a regulatory program for community living specialists. The review indicated that enhancing the licensing requirements for facilities would protect the public in a cost effective manner. During the Sunrise hearing, a compromise was reached which resulted in the introduction of HB 88-1065. As originally introduced, HB 88-1065 exempted persons administering medications in residential care facilities from licensure if they were deemed competent to do so by a person licensed to practice medicine. Subsequent hearings in the House HEWI Committee resulted in the creation of the current training and testing program and an exemption for "Qualified" individuals.

SUMMARY OF STATUTE

The authority to regulate a program for the administration of medications by unlicensed persons in facilities is contained in §25-1-107 (1)(ee), C.R.S. The statute requires the Colorado Department of Public Health and Environment (CDPHE) to oversee a program to train individuals in the administration of medications. The program provides standardized training and testing for persons administering medications in facilities. Other agencies may use individuals trained by CDPHE approved instructors or develop their own programs, subject to the approval of CDPHE. Several agencies within the Departments of Human Services and Corrections use their own programs in place of the CDPHE training.

Facilities are defined as any correctional facility under the supervision of the Executive Director of the Department of Corrections, or specific facilities regulated by the Department of Human Services. Specifically identified facilities include:

- Institutions for juveniles provided for in part 11 of article 2 of title 19, C.R.S.;

  A facility for the care, education, training, treatment and rehabilitation of juveniles legally committed to custody under the juvenile code. These facilities include, group care homes, halfway houses, training schools, conservation camps, diagnostic centers, and evaluation centers.

- Personal care boarding homes (PCBH) as defined in §25-27-102 (8), C.R.S.;

  A residential facility providing room and board to three or more adults who are not related to the owner and who, because of impaired capacity for independent living, elect protective oversight, personal services, and social care but do not require regular 24 hour nursing or medical care.

- Adult foster care facilities provided for in §26-2-122.3, C.R.S.;

  A facility providing room, board, care and service that includes but is not limited to personal services, recreational opportunities, transportation, utilization of volunteer services and special diets for those persons who need to reside in a supervised non-medical setting on a 24 hour basis.

- Alternate care facilities provided for in §26-4-603 (3), C.R.S.;

  A facility primarily engaged in directly arranging and providing 24 hour residential care and support services; adequate sleeping areas, adequate recreational areas and opportunities; the availability of three adequate, nourishing meals per day and provision for special diets when those diets are prescribed as part of a medical plan.

- Residential child care facilities for children as defined in §26-6-102 (8), C.R.S.;

  A facility providing 24 hour group care and treatment for five or more children, operated under private or nonprofit sponsorship.

- Secure residential treatment centers as defined in §26-6-102 (9), C.R.S.;

  A facility operated under private ownership that is licensed by the state to provide 24 hour group care and treatment in a secure setting for five or more children or persons up to the age of 21 years over whom the juvenile court retains jurisdiction pursuant to §19-2-104 (6), C.R.S., who are committed by a court pursuant to an adjudication of delinquency or pursuant to a determination of guilt of a delinquent act or having been convicted as an adult and sentenced for an act that would be a crime if committed in Colorado, or in the committing jurisdiction, to be placed in a secure facility.

- Facilities that provide treatment for mentally ill persons as defined in §27-10-102 (4.5), C.R.S., except for those facilities which are publicly or privately licensed hospitals;

  A clinic, community mental health center or clinic, institution, sanitarium, or residential child care facility that provides treatment for mentally ill persons.

- Residential and day care programs providing services in support of persons with developmental disabilities pursuant to article 10.5 of title 27, C.R.S.;

  "Developmental disability" means a disability that is manifested before the person reaches 22 years of age, which constitutes a substantial disability to the affected individual, and is attributable to mental retardation or related conditions which include cerebral palsy, epilepsy, autism, or other neurological conditions when such conditions result in impairment of general intellectual functioning or adaptive behavior similar to that of a person with mental retardation.

- Adult day care facilities providing services in support of persons as defined in §26-4-603 (1), C.R.S.;

  A facility which meets all applicable state and federal requirements and is certified by the state to provide adult day care services to eligible persons.

The statute defines several terms:

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

"Administration" also means ingestion through gastrostomy tubes or naso-gastric tubes, if administered by an individual authorized pursuant to §27-10.5-103 (2) (k), C.R.S., as part of residential or day program services provided through service agencies approved by the Department of Human Services and supervised by a licensed physician or nurse.

"Self-administration" means: The ability of a person to take medication independently without any assistance from another person. Such a person is personally responsible for medication administration. No facility shall be responsible for observing or documenting the self-administration of medication. Compliance with the requirements for the training of unlicensed persons in medication administration pursuant to §25-1-107(1)(ee)(a), C.R.S., is not required when persons being cared for are self-administering.

"Monitoring" means: Reminding the resident to take medication or medications at the time ordered by the physician or other authorized licensed practitioner; handing a resident a container or package of medication lawfully labeled previously for the individual resident by a licensed physician or other authorized licensed practitioner; visual observation of the resident to ensure compliance; making a written record of the resident's compliance with regard to each medication, including the time taken; notification to the physician or other authorized practitioner if the resident refuses to or is not able to comply with the physician's or other practitioner's instructions with regard to the medication.

Monitoring of self-administered medications is not a regulated activity and is exempt from the provisions of this statute. Most of the medication administered in facilities under the supervision of the Department of Corrections involve the self-administration of medication. The emphasis of these facilities is on proper monitoring, storage, and security of medications, not the administration of medications by qualified individuals.

The statute exempts qualified individuals administering medications in facilities from the licensing requirements of the Colorado Medical Practice Act, Nurse Practice Act and some of the restrictions of the Uniform Controlled Substances Act. This allows trained personnel to administer medications without the direct supervision of a licensed health care professional.

Training may be conducted by CDPHE staff or contracted with a private provider or instructor. Private providers may only use approved training programs and must provide the CDPHE with a list of persons who have taken the training or passed a competency evaluation. The CDPHE must ensure that training is available throughout the state. The statute allows the CDPHE to order retraining for individuals who do not properly administer medications in any regulated facility.

Regulations

The Colorado Board of Health has promulgated regulations to implement the administration of medications by unlicensed individuals. The regulations require that any facility administering medications have qualified individuals on staff. Personnel records of the facilities must contain documentation of the training of qualified individuals.

The regulations specify requirements for the storage and handling of medications by both the facility and the qualified individual. The regulations define the qualifications of individuals contracting as instructors for the administration of medications training program. To qualify to teach the program, the individual must be licensed as a physician, nurse, pharmacist, or be certified as a physician assistant.

PROGRAM DESCRIPTION & ADMINISTRATION

Medication Administration Training Program

The training of qualified persons for the administration of medication began in 1991. The initial sunset report expressed a concern about the lack of training opportunities for individuals entering the field and the number of qualified persons. In 1991, five training classes were held, qualifying 24 people. In fiscal year 1995-96 (the last year complete figures are available), 330 classes were held, qualifying 1,989 people.

The CDPHE currently contracts with 32 instructors to conduct classes and examinations. The number of instructors and classes varies from year to year based on the demand for qualified individuals. The classes are regularly available in both the Denver Metro and rural areas. The authorizing statute requires participants in classes to pay fees sufficient to cover the cost of administering the program. Currently the fee is set at $55 for the class and examination. Participation in the class is not mandatory and individuals may take the examination for a $30 fee. However, if a satisfactory score is not achieved on the examination, attendance in a class is mandatory for certification.

Generally the training program is divided into two portions conducted on separate days. The first portion is the training program. This is a combination classroom-style lecture and demonstration lab. Students practice identifying various medications and routes of administration. Recognizing different types of medications, reading chart orders, prescription instructions and documenting medication administration are also included.

The second portion of the training program is a two part examination. The written examination consists of a 100 question written examination. This examination is a combination of true/false, short answer and multiple choice questions. Students must achieve 85% correct for a passing score.

The second part of the examination is a practical demonstration of the administration skills learned in the training program. During this portion of the exam, the candidates must demonstrate the ability to correctly identify the patient, read a chart or prescription order, measure liquid medications, and determine quantities of pill or capsule medications to be taken orally. The candidates must also describe and demonstrate, using a doll, steps to be taken to administer suppositories, creams and ointments, eye and ear drops, and the use of an inhaler. Candidates must document on the patient's chart after administering each medication.

According to instructors interviewed for this review, approximately 95% of the candidates successfully pass the examination. Anecdotal information indicates a higher success rate for those individuals successfully completing the training program. Verifiable statistics are not compiled to separate those that pass the examination with or without the benefit of the training program.

The CDPHE devotes less than one FTE to the administration of the program. The program operates with a budget of approximately $113,000, (Table 1 contains program budget information). In addition to maintaining a data base of approved instructors, classes and students trained, the administrator also:

- Reviews medication courses,
- Approves instructors,
- Monitors training classes,
- Provides technical assistance to regulated facilities and instructors,
- Participates in policy development, curriculum and training development,
- Conducts enforcement as necessary, and
- Authorizes billing and reimbursement payments.

TABLE 1

FISCAL YEAR	BUDGET	REVENUES	EXPENSES	FTE
1996	$113,580	*$111,002	*$111,002	.81
1995	$77,000	$101,174	$101,174	.54
1994	$55,000	$69,078	$69,078	.45
1993	$69,600	$50,523	$50,523	.18

* Partial year data

What is the program used for?

Personal care boarding homes range in size from small three to five bed residential homes to large apartment type dwellings, commonly referred to as assisted living homes. These facilities provide 24 hour supervision and assistance with activities of daily living, such as dressing, bathing, and grooming. The assistance can be stand-by supervision or actual hands-on care. Some residents may be unable to walk and need staff assistance with transfers from bed to wheel chair. Some residents may need assistance propelling their wheel chair or need someone to walk with them. The resident population is quite diverse in age and care needs.

Many facilities choose to specialize. For example some homes choose to care for persons with chronic mental illnesses, such as schizophrenia or bi-polar disorder. These residents may exhibit challenging behaviors that can be managed by medications, staff interventions, and other therapies. These homes typically serve a younger population who do not need the degree of hands on care that the elderly need. However, they do need supervision and assistance

Some homes specialize in caring for persons with dementia. Many of these homes provide a secured setting to prevent residents from wandering off. Due to their cognitive impairment, these residents need close supervision and direction. It is not unusual for persons with dementia to become agitated. This is managed by staff intervention and medications. Residents with dementia may need hands-on care because they forget how to perform daily living tasks. Other facilities specialize in younger persons with physical disabilities such as multiple sclerosis or persons with brain injuries. Care needs in these homes vary greatly.

Alternative care facilities are licensed as personal care boarding homes (PCBHs). However, they are certified for Medicaid reimbursement for personal care services. In order to be eligible, residents must meet income eligibility and medical necessity criteria.

Adult foster care facilities are also licensed as PCBHs. In order to be eligible, residents must also meet income eligibility and level of care criteria. Many of the adult foster care homes serve persons with chronic mental illness.

Various medical practices acts define the administration of medications. These acts have been broadly interpreted to include such activities as: opening a bottle of aspirin for a disabled individual in a group home, placing the appropriate medications in the individual compartments in a medication reminder box for a blind adult living in an assisted living situation, and removing a pill from a properly labeled prescription bottle and handing it to a developmentally disabled adult living in a group home.

All of these scenarios have at least two factors in common: the individuals requiring the medication lack the physical or mental capacity to administer the medication without some type of assistance, and licensed medical personal are not typically employed or available in the setting in which the medication is being administered. In all of these scenarios, a licensed health care professional has examined the individual, and prescribed or authorized the medication to be administered.

Individuals and organizations contacted for this report echoed a common theme: economic considerations continue to drive the need for this program. Persons utilizing the services of programs using qualified persons to administer medications do not require 24 hour medical care in a nursing home or similar long term care facility. They are not, however, capable of living completely independent lives.

Treatment in a long term care facility is expensive. Requiring individuals to seek admittance to these facilities based on an inability to self-administer medications would be a tremendous financial burden to their families. Individuals contacted for this review expressed a concern regarding the probability that excessive costs would force some individuals into Medicaid-supported health care settings as the only alternative for families unable to afford placement in long term care facilities.

Quality of care

Can persons receiving a minimal amount of training administer medications safely in these settings?

Any medications administered in either a long-term care facility (LTC) or a PCBH are ordered by a health care professional licensed to diagnose and prescribe medications. All medications are dispensed under the direction of licensed pharmacists. Clients in these facilities require the administration of medications, in proper dosages, at the proper times, and by the correct route. Failure to administer medications according to the appropriate directions could have severe consequences.

Under-medicating someone requiring heart or high blood pressure medication places the client at risk for a heart attack or stroke. Over-medicating a client with behavior disorders or mental heath problems could negatively impact cognitive functions, or send them into a coma. In severe situations, missing medications, or receiving the wrong medication could prove fatal to a client.

A concern expressed by nurses and nursing home administrators centers around the quality of care afforded individuals in facilities without licensed medical staff. The CDPHE has approved several training programs of various length and content. Before any individual is considered qualified to administer medications, they must successfully pass a standardized examination. However, these qualified individuals do not have the training and experience nurses and others have in patient assessment and drug interaction recognition.

Another issue is the general erosion of doctor patient relationships brought about by the pressures of health care reform. An increasing number of services traditionally held to be in the realm of physicians are being performed by other licensed health care professionals. Nurses and physician's assistants are assuming diagnostic and prescription responsibilities. As nurses and other medical professionals assume a more active role in primary patient care, traditional nursing duties are being assumed by non licensed, and unregulated personnel.

If traditional nursing functions can be performed by non licensed personnel in a cost effective manner, without compromising patient care, it is sound public policy. However, patient care decisions based solely on economic considerations and not on what is in the best interest of the individual requiring care is unreasonable.

One measure of the effectiveness of the medication administration program is the number of medication related errors in facilities using qualified persons. A clear measure of the effectiveness would be obtained by comparing the number of medication related errors in these facilities prior to the implementation of the training program to the number of errors in facilities after the program had been fully implemented. Unfortunately, because CDPHE was not required to collect this information, data is not available for medication errors by non licensed personnel prior to the implementation of the program.

What is available is a comparison of medication related deficiencies in PCBHs to long term care facilities (LTC). In 1993, there were 342 licensed PCBHs in Colorado with the capacity to serve 6476 clients. By 1996, the number of PCBHs had increased to 409 with a capacity of approximately 8200. In 1996, 109 facilities were cited by the CDPHE for 239 deficiencies related to medication administration. Deficiencies included improper documentation of training for qualified personnel, failure to administer correct dosages of medications, administering medications without the written order of a licensed practitioner, and failure to keep current records of residents' medications.

In 1996, there were 219 licensed LTCs in Colorado with a capacity to serve 20,000 clients. Medications in LTCs are administered by licensed medical professionals. In 1996, 55 of these facilities were cited by the CDPHE for 98 deficiencies related to medication administration. Deficiencies ranged from failure to administer correct dosages of medications, failure to follow correct procedures in administering medications, and failure to administer medications according to physicians' instructions.

These statistics indicate that approximately 26% of the PCBHs account for medication errors impacting 3% of the clients served. In LTC facilities, where medication is administered by licensed nurses, 25% of the facilities account for errors impacting just under 1% of the clients served. According to the Health Facilities Division in the CDPHE, persons in PCBHs are just as likely as those in LTC facilities to require medications.

While it may appear that the incidence of medication related deficiencies is higher in PCBHs, it must be remembered that the standard for deficiencies is different in the two types of facilities. LTC deficiencies are directly related to the administration of medication, while the PCBH deficiencies include administrative errors. The data reviewed does not indicate a significant difference in the number of medication errors between facilities using the services of nurses and those using trained, unlicensed personnel for medication administration. It can be concluded from this analysis that limiting the administration of medications to licensed health care professionals is not necessary to protect the public health and safety.

Quality of life

Many of the individuals in facilities covered by §25-1-107(1)(ee), C.R.S., are elderly or disabled persons who are mentally sound but require some physical assistance to take medications. One alternative to the medication administration program is to institutionalize these individuals. The information available on LTCs would not suggest a substantial increase in the quality of care afforded these individuals.

LTCs serve a very different need in the health care industry. Many of the clients of facilities using unlicensed personnel for medication administration do not require 24 hour nursing care. Placing these individuals in other types of care facilities may negatively impact quality of life by limiting social and recreational opportunities. Affordable LTCs may not be located conveniently to established friends and family. In addition, the increased financial burden may limit discretionary expenditures for other forms of entertainment.

Another alternative suggested would require facilities to contract with a licensed medical professional, such as a nurse, with expanded authority to delegate nursing functions. The nurse would then review each client's medical treatment plan and delegate the administration of medication function to a responsible individual. The nurse would be required to periodically visit the facility to oversee the implementation of the medication administration.

This scenario creates a stronger link between licensed health professionals and clients in these facilities. There would be an increase in expenses to the facilities and clients. However, the increase would not be as significant as under the institutionalization scenario. The link between supervision by a licensed nurse and reduced errors in medication administration is tenuous, as demonstrated by the data on errors in LTCs.

SUNSET ANALYSIS

Continue The Program With Minor Modifications

The program is very popular with both the clients served, the owner/operators of the facilities, and regulators. Very few complaints regarding the cost, economic impact, or effectiveness of the program were identified by the affected parties.

Parties generally believe the program allows clients to obtain service at an affordable price and maintain a quality of life that could not be achieved in other settings. Some modifications to the statute were identified as desirable to reflect the changing environment of alternative health care.

The Department of Human Services offers a wide range of programs to assist the developmentally disabled. Section 25-1-10 (1)(ee)(II.5), C.R.S., limits the administration of medication program to "[r]esidential and day care programs providing service in support of persons with developmental disabilities pursuant to article 10.5 of title 27, C.R.S." Amending the statute to read "[a]ll services funded through the Department of Human Services in support of persons with developmental disabilities pursuant to article 10.5 of title 27, C.R.S." would allow greater flexibility for innovative programs.

Home health care agencies are another growing alternative to residential placements. A home health care agency provides personnel to visit clients in their homes to provide services that the client is not able to accomplish on their own. Unless the individual employed by the home health care agency is a licensed nurse, he or she would not legally be able to assist a client with opening a bottle of aspirin.

Discontinue The Program Completely

The first test in the sunset evaluation criteria is whether regulation is necessary to protect the public health, whether conditions which led to regulation have changed and whether more, less, or the same degree of regulation is warranted. The condition which led to this program was a concern in the medical community that common practice in certain regulated facilities constitute an unauthorized practice of medicine. This concern has not changed.

Personnel in the facilities identified in the statute do not prescribe medication. Administering medication consists of assisting incapacitated individuals in taking medications as instructed by a licensed health care professional. It should be noted that if a family member or friend performed the same service, there would be no legal concern, although some would question whether family members should be permitted to administer medications in some situations.

As previously discussed, discontinuing the program without implementing an alternative would have severe economic consequences.

Require Facilities To Contract With A RN To Delegate

An ongoing argument in the health care policy debate, concerns the erosion of patient care by medical professionals. Requiring facilities to have medical professionals review medication plans and administration for individual clients on a regular basis would reverse this trend.

Nurses are authorized, under the provisions of §12-38-132(6), C.R.S., to delegate certain nursing functions to non licensed persons. The administration of medication would fall under the guidelines for delegation promulgated by the State Board of Nursing.

Under this scenario, a nurse would evaluate each client in a facility and specifically train, instruct and delegate the administration of medication procedure to a specific individual at the facility. The nurse would be required to periodically visit the facility to evaluate the client and the performance of the individual delegated to administer medication.

The advantage of this system would be a closer link to a licensed health care professional. Presumably, this would result in higher quality care for the client. However, in terms of medication errors, this argument has questionable merit.

There are two major drawbacks to this option. The first, and most obvious, is the economic impact. The use of a nurse, even on a contract basis, to supervise medication administration would increase costs to the facilities. These costs are passed on to the families of the client requiring care. In many cases, taxpayers will assume the increased costs though increased Medicaid reimbursements.

The second drawback would be inflexibility for the facility operator. There is high turnover in personnel in this industry. Anytime there is employee turnover, the nurse would have to visit the facility to re-delegate. Anytime a new resident or client joined the facility, the nurse would have to visit. If a client visited his or her physician and had a medication change, the nurse would have to re-delegate.

Some of these situations could be remedied by changes in the delegation criteria for nurses. However, this option may result in a more complex system than is necessary to protect the public.

Require Facilities To Develop Individual Training And Procedures, Hold Them Accountable

There is no question that improper administration of medication has the potential for harm to the public. Improper dosage, frequency, improper medication or taking medication contrary to instructions can have severe consequences. The program administered by the CDPHE attempts to address this by providing training and testing of individuals administering medications.

The program under review is a pseudo regulatory program. Individuals completing the training and testing process are not licensed by the state. The state does not evaluate qualifications other than the completion of a standardized examination. No annual registration or renewal is required. Qualified individuals do not have to update their address or phone number with a regulatory agency. Individuals who fail to follow proper procedures in administering medications can not have their qualified status revoked. However, they may be ordered to undergo retraining.

The primary liability for errors in medication administration is with the facility employing the qualified individual. If a medication error occurs, action can be taken against the facility's license. Facilities licensed by the state are subject to periodic inspections or reviews by the regulatory authority issuing the license. Part of the review evaluates the administration of medications in each facility.

All facilities contacted for this review indicated support for the continuance of the program. Several indicated that they conduct their own training to supplement the approved program. Some indicated a desire to use in-house training programs in place of the approved program.

Requiring facilities to conduct in-house training programs would likely increase expenses for some of the smaller facilities. The consistency of training would definitely be lacking without a standardized program and examination process. However, individualized training would allow the facilities greater flexibility to address specific client needs. Such training would also cause facilities to be more aware of the liability involved with medication administration errors.

RECOMMENDATIONS

Recommendation 1: Continue the authorization of the medication administration program with minor modifications. Broaden the scope of the next Sunset Review.

Training of non licensed individuals in the administration of medication is an important safeguard for public protection. However, the current training program falls far short of providing the protection of a regulatory program. There is no license or certification to take action against, and no oversight board to administer discipline or establish educational alternatives. Disciplinary actions are limited to the license of the facility. Indeed, the facility itself is what is truly being regulated.

Interviews with CDPHE staff indicate difficulty in taking disciplinary action against licensed facilities. A review of complaint activity and enforcement options is beyond the scope of this review. It is recommended that the scope of the next sunset review be expanded to explore alternatives to the certification program based on holding facility operators accountable for the actions of employees.

Since facilities are inspected on a regular basis and have licenses renewed periodically, it would be efficient to require the facilities to train individuals administering medications. The training programs could be tailored to the individual clients served by the facility. Verification of training would be made part of the bi-annual facility inspection as is the current practice. Self-verification could be incorporated into the license renewal process.

When this alternative was proposed to the stakeholders and regulatory agencies involved, it was met with a less than enthusiastic response. The CDPHE indicated that additional FTE would be required to approve training programs and verify training. Since this option is a self-regulatory program, approving programs is not a necessity. Therefore training verification should be part of the regular inspection program.

It was also asserted that the various agencies involved in regulating programs and facilities using qualified people for medication administration, lack the enforcement tools to discipline licensees who fail to implement a training program. Concerns were raised over the consistency in training and the ability of qualified individuals to move among various employment settings without a centralized agency to verify qualifications.

It is believed that solutions to these concerns could be resolved if a thorough review of options was conducted. However, such a review would have to be authorized by the General Assembly, since it is beyond the scope of this Sunset Review.

Recommendation 2: Amend §25-1-107(1)(ee)(II.5)(I), C.R.S., to "All services funded through the Department of Human Services in support of persons with developmental disabilities pursuant to article 10.5 of title 27, C.R.S."

Alternative care is an evolving area of health care. The definition of "facility" in the current statute does not reflect the terminology used in the developmental disabilities field. Changing the language to properly reflect the terminology used by practitioners, regulators and advocates will reduce confusion as to which settings the medication administration program is limited. This language change will not expand the population or settings in which unlicensed medication administration is permitted.

Recommendation 3: Amend §25-1-107(1)(EE)(I.5), C.R.S., to "An unlicensed person may fill and label a medication reminder box or system, provided the unlicensed person has undergone training in this procedure by the facility providing service to the client."

Medication reminder boxes or systems are designed to assist individuals in self administering medications. They can also be used by qualified persons to administer medications to clients. These boxes are used by thousands of people everyday to efficiently track the intake of medication and self-regulate dosages.

A typical system involves placing vitamins, prescription drugs, diet supplements and other pills in a container divided into compartments labeled for each day of the week. Placing all the medication required to be ingested during the course of a day in a single compartment reduces the chance that a client will take multiple doses of a medication, or skip a dose altogether. It also facilitates monitoring medication intake by family members or other concerned parties.

The filling of medication reminder boxes has been considered dispensing medications, which is the function of a pharmacist. However, it can be argued that once a prescription has been filled and removed from the pharmacy, it is beyond the authority of the pharmacy laws to further regulate how a patient chooses to store his or her medications.

APPENDICES

Sunset Statutory Evaluation Criteria

(I) 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;

(II) 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;

(III) 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;

(IV) Whether an analysis of agency operations indicates that the agency performs its statutory duties efficiently and effectively;

(V) 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;

(VI) The economic impact of regulation and, if national economic information is available, whether the agency stimulates or restricts competition;

(VII) 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;

(VIII) Whether the scope of practice of the regulated occupation contributes to the optimum utilization of personnel and whether entry requirements encourage affirmative action;

(IX) Whether administrative and statutory changes are necessary to improve agency operations to enhance public interest.

Statute

§ 25-1-107(1)(ee)(I) To establish and maintain by rule and regulation a program for the administration of medications in facilities, which program shall be developed and conducted by the department of human services and the department of corrections within the following guidelines:

(A) As a condition to authorizing or renewing the authorization to operate any facility that administers medications to persons under its care, the authorizing agency shall require that the facility have a staff member qualified pursuant to sub-subparagraph (B) of this subparagraph (I) on duty at any time that the facility administers such medications and that the facility maintain a written record of each medication administered to each resident, including the time and the amount of the medication. Such record will be subject to review by the authorizing agency as a part of its procedure in authorizing the continued operation of the facility. Notwithstanding any exemption enumerated in sub-subparagraph (B) of this subparagraph (I), any facility may establish a policy which requires a person authorized to administer medication to report to, be supervised by, or to be otherwise accountable for the performance of such administration to a registered nurse as defined in section 12-38-103, C.R.S.

(B) Any individual who is not otherwise authorized by law to administer medication in a facility shall be allowed to perform such duties only after passing a competency evaluation. An individual who administers medications in facilities in compliance with the provisions of this paragraph (ee) shall be exempt from the licensing requirements of the "Colorado Medical Practice Act", the "Nurse Practice Act", and the laws of this state pertaining to possession of controlled substances as contained in part 1 of article 22 of title 12, C.R.S., or the "Uniform Controlled Substances Act of 1992", article 18 of title 18, C.R.S.

(B.5) The department, in cooperation with appropriate agencies or advisory bodies, shall develop or approve training curricula and competency evaluation procedures for those who administer medications in facilities.

(C) If either the department of human services or the department of corrections wishes to use a different training curriculum and competency evaluation procedure for those who administer medications in the facilities whose operation is authorized by those departments, such department shall ensure that such training curriculum and competency evaluation procedure are first submitted to the department of public health and environment for its review. If, after such review, the department of public health and environment has no objection, the submitting department shall assume responsibility for the cost and implementation of such curriculum and evaluation in keeping with the other provisions of this medications administration program for those facilities whose operation is authorized by such department. Any department that administers competency evaluations shall maintain a list of those who have successfully completed such competency evaluation and shall forward a copy of such list to the department of public health and environment within forty-five days of administration of such evaluation.

(D) The department shall assure that training sessions, each followed by a competency evaluation set to measure basic competency only, are offered at various geographic locations in the state. An individual who does not pass the competency evaluation may apply to retake it. An appropriate fee must be paid each time the competency evaluation is taken. An individual may apply for and take the competency evaluation only once without having first attended a training session approved by the department. If such individual fails to meet a minimum competency level on such first evaluation, the applicant must attend an approved training session before again taking the competency evaluation.

(E) The department shall set and collect a uniform fee for any training session given and a uniform fee for any competency evaluation administered under the provisions of this paragraph (ee) whether the department administers such training or testing or contracts with a private provider pursuant to subparagraph (I.3) of this paragraph (ee), so that the revenue generated from such fees approximates the direct and indirect costs incurred by the department in the performance of its duties under this paragraph (ee). No person shall enroll in a training session or take the competency evaluation test until such person applies and makes payment of the appropriate fees to the department.

(F) If the individual authorized to administer medication pursuant to sub-subparagraph (D) of this subparagraph (I) is found, during the course of any review by the authorizing agency as part of its procedure in authorizing the continued operation of the facility, to be unable or unwilling to comply with the training regimen established for medication administration, the department may order retraining as a remedial measure.

(I.3) (A) If the department determines that it is not able to provide the training and administer competency evaluations pursuant to subparagraph (I) of this paragraph (ee), the department may contract with a private provider or instructor to provide such training and administer such competency evaluations.

(B) Before any private contractor may offer training pursuant to sub-subparagraph (A) of this subparagraph (I.3), such private contractor shall be reviewed by the department. Only those private contractors approved by the department may offer training. Any such approved private contractor shall offer only a medication administration training program which has been approved by the department. The department shall maintain a list of approved medication administration contractors. The department shall compensate contractors from the fees collected from each trainee in attendance at any such privately contracted training session or competency evaluation.

(C) All private contractors shall provide the department with a list of all persons who have taken such contractor's approved training sessions or have passed the competency evaluation or both. Such contractors shall also provide the department with any other pertinent information reasonably requested by the department pursuant to its obligations and authority under this paragraph (ee).

(I.5) Medication reminder boxes or systems may be used if such containers have been filled and properly labeled by a pharmacist licensed pursuant to article 22 of title 12, C.R.S., a nurse licensed pursuant to article 38 of title 12, C.R.S., or filled and properly labeled through the gratuitous care by members of one's family or friends. Unlicensed persons may physically assist a person who is physically impaired if such impairment affects the ability of the person to use the medication reminder, if such unlicensed person is trained pursuant to the provisions of this paragraph (ee).

(II) For the purposes of this paragraph (ee), "administration" means assisting a person in the ingestion, application, inhalation, or, using universal precautions, rectal or vaginal insertion of medication, including prescription drugs, according to the legibly written or printed directions of the attending physician or other authorized practitioner or as written on the prescription label and making a written record thereof with regard to each medication administered, including the time and the amount taken, but "administration" does not include judgment, evaluation, or assessments or the injections of medication, the monitoring of medication, or the self-administration of medication, including prescription drugs and including the self-injection of medication by the resident. "Administration" also means ingestion through gastrostomy tubes or naso-gastric tubes, if administered by an individual authorized pursuant to section 27-10.5-103 (2) (k), C.R.S., as part of residential or day program services provided through service agencies approved by the department of human services and supervised by a licensed physician or nurse.

(II.5) For purposes of this paragraph (ee), "facility" means:

(A) The correctional facilities under the supervision of the executive director of the department of corrections including, but not limited to: Those facilities provided for in article 20 of title 17, C.R.S.; minimum security facilities provided for in article 25 of title 17, C.R.S.; jails provided for in article 26 of title 17, C.R.S.; community correctional facilities and programs provided for in article 27 of title 17, C.R.S.; the regimented inmate discipline and treatment program provided for in article 27.7 of title 17, C.R.S.; the Denver regional diagnostic center provided for in article 40 of title 17, C.R.S.; and the Limon correctional facility provided for in section 24-35-210 (4) (f) (I) (B), C.R.S.;

(B) Institutions for juveniles provided for in part 11 of article 2 of title 19, C.R.S.;

Editor's note: This version of sub-subparagraph (B) is effective until January 1, 1997.

(B) Institutions for juveniles provided for in part 4 of article 2 of title 19, C.R.S.;

Editor's note: This version of sub-subparagraph (B) is effective January 1, 1997.

(C) Personal care boarding homes as defined in section 25-27-102 (8);

(D) Adult foster care facilities provided for in section 26-2-122.3, C.R.S.;

(E) Alternate care facilities provided for in section 26-4-603 (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 mentally ill persons as defined in section 27-10-102 (4.5), C.R.S., except for those facilities which are publicly or privately licensed hospitals;

(I) Residential and day care programs providing services in support of persons with developmental disabilities pursuant to article 10.5 of title 27, C.R.S.; and

(J) Adult day care facilities providing services in support of persons as defined in section 26-4-603 (1), C.R.S.

(III) (A) For the purposes of this paragraph (ee), "monitoring" means: Reminding the resident to take medication or medications at the time ordered by the physician or other authorized licensed practitioner; handing a resident a container or package of medication lawfully labeled previously for the individual resident by a licensed physician or other authorized licensed practitioner; visual observation of the resident to ensure compliance; making a written record of the resident's compliance with regard to each medication, including the time taken; notification to the physician or other authorized practitioner if the resident refuses to or is not able to comply with the physician's or other practitioner's instructions with regard to the medication.

(B) The executive directors of the departments which control the "facilities" defined in sub-subparagraphs (A) and (B) of subparagraph (II.5) of this paragraph (ee) may direct the unlicensed staff of any such facility to monitor medications in any part of any such facility. Administration of medications in any such facility shall be allowed only in those areas of any such facility which have a licensed physician or other licensed practitioner on duty.

(IV) (Deleted by amendment, L. 92, p. 1151, 8, effective July 1, 1992.)

(IV.5) For purposes of this paragraph (ee), "self-administration" means the ability of a person to take medication independently without any assistance from another person. Such a person is personally responsible for medication administration. No facility shall be responsible for observing or documenting the self-administration of medication. Compliance with the requirements for the training of unlicensed persons in medication administration pursuant to this paragraph (ee) is not required when persons being cared for are self-administering.

(V) (A) All fees collected pursuant to this article shall be transmitted to the state treasurer, who shall credit the same to the medication administration cash fund, which fund is hereby created.

(B) The general assembly shall make annual appropriations from the medication administration cash fund for expenditures of the department incurred in the performance of its duties under this paragraph (ee).

(C) Any moneys collected by the department from persons taking a training program or a competency examination from a private contractor approved pursuant to subparagraph (I.3) of this paragraph (ee) shall be transmitted to the state treasurer, who shall credit the same to the medication administration cash fund created in sub-subparagraph (A) of this subparagraph (V). Such moneys collected from the fees charged for any such training program or competency examination shall be annually appropriated by the general assembly to the department for the purpose of paying private contractors for services rendered and for paying the department's direct and indirect costs incurred pursuant to subparagraph (I.3) of this paragraph (ee).

(D) In accordance with section 24-36-114, C.R.S., all interest derived from the deposit and investment of the medication administration cash fund created in sub-subparagraph (A) of this subparagraph (V) shall be credited to the general fund.

(VI) (A) This paragraph (ee) is repealed, effective July 1, 1998.

(B) Prior to such repeal, the program established by this paragraph (ee) shall be subject to review by a legislative committee of reference designated pursuant to section 2-3-1201, C.R.S., to conduct the review pursuant to section 24-34-104, C.R.S., and the provisions of section 24-34-104 (5) to (12), C.R.S., concerning a wind-up period, an analysis and evaluation, public hearings, and claims by or against an agency shall apply to the operation of the program specified in this paragraph (ee).

(VII) Repealed.