STATE OF COLORADO

DEPARTMENT OF REGULATORY AGENCIES
Office of the Executive Director
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1987 SUNRISE REVIEW OF RESPIRATORY THERAPY

The Department of Regulatory Agencies has the statutory responsibility to analyze and evaluate all requests for new occupational regulation under section 24-34-104.1. According to the statute, it is the responsibility of the applicant to prove that the regulation proposed is necessary for public protection. The applicant must give reasons for the proposed regulatory alternative, show the benefits to the public from the proposed regulation and estimate the cost of such proposed regulation.

In 1986, the Colorado Society for Respiratory Therapy submitted an application proposing licensure for the practice of respiratory therapy. The department undertook extensive research in evaluating this proposal, including interviews with respiratory therapists, physicians, pulmonary function technologists, respiratory therapy educators and home care and medical equipment company representatives; field visits to hospitals, home care companies and home sites where care was being provided; and other research.

The department recommended against regulation based on findings that the more complex and potentially hazardous functions of the respiratory therapists were performed in institutional settings subject to a variety of regulatory requirements and staffed with other licensed health care providers, such as physicians. Medical protocols provided adequate regulation and safeguards. (See attached report.)

Outside of institutions, therapists' functions were more oriented to monitoring patients and educating families to provide respiratory care in the home. Most diagnostic procedures could not be performed in the home and most home care companies used only registered respiratory therapists on their staffs. The Sunrise and Sunset Review Committee unanimously voted against the need for further regulation of respiratory therapists.

In 1987, the Colorado Society for Respiratory Therapy re-applied and provided the same information in the application that was submitted the previous year. Given that no new information was submitted for review and that the statutory burden of proof is on the applicant, the department again recommends against the regulation of respiratory therapy.

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1986 SUNRISE REVIEW OF RESPIRATORY THERAPISTS

SUMMARY OF FINDINGS AND RECOMMENDATIONS

The Department of Regulatory Agencies has evaluated the proposal submitted by the Colorado Society for Respiratory Therapy for licensure of respiratory therapists and assistants. (The organization has since changed its name to the Colorado Society for Respiratory Care.) The evaluation criteria, according to 24-34-104.1(4)(b),are the following:

(I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;

(II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence; and

(III) Whether the public can be adequately protected by other means in a more cost-effective manner.

The department has made the following findings regarding the practice of respiratory therapy and the delivery of respiratory therapy services. The department recommends that the practice not be regulated at this time. The current health care system has provided sufficient quality control over these practitioners and there is little evidence that consumers are being harmed by those respiratory care practitioners.

1. Certain functions performed by respiratory therapists are a part of the practice of medicine.

2. There is no documented public harm being caused by respiratory therapists in Colorado resulting from the current regulatory system.

3. The responsibility for respiratory care is generally delegated to the therapist under the general prescriptive direction of "oxygen protocol." The specific protocol followed is determined by hospital or institutional policy.

4. The growing home health care industry, along with the increasing costs of hospitalization, has increasingly moved respiratory care to the home, eroding the connection between the prescribing physician and the respiratory therapist.

5. Home health care personnel regulations currently exist through federal regulation of home health care agencies and state regulation of hospitals and other institutions.

6. Some medical equipment supply companies have a medical director or consulting physician as part of their corporate structure.

7. In the urban areas and contiguous rural areas, hospitals, and medical equipment supply companies generally hire only credentialled respiratory therapists. It is in the remote rural areas that respiratory care is sometimes rendered without the assistance of respiratory therapists.

8. Urban medical equipment supply companies often provide services in rural areas also.

9. Most of the patients receiving home oxygen care services are covered by Medicare or Medicaid.

10. Small businesses in the medical equipment supply industry might be burdened by additional regulation.

11. Drivers employed by medical equipment supply companies place equipment such as the cannula or oxygen mask on patients, turn on oxygen, and give some instruction on the use and the care of the equipment.

12. The scope of practice of a respiratory therapist overlaps with other occupations such as registered nursing and physical therapy.

BACKGROUND

The Colorado Society for Respiratory Therapy has submitted a proposal for licensure (both practice and title protection). There are approximately 530 members in the society. The society estimates that there are approximately 1,000 respiratory therapists practicing in Colorado.

Work Settings

Generally, respiratory care services are provided by respiratory therapists in two work settings -- the hospital or clinical setting, and the home care setting (both the home health care agency and the medical equipment supply company). As the costs of hospital care have risen, more respiratory care is being provided in the home. The Colorado Society for Respiratory Care estimates that less than 20 percent of respiratory therapists work in home care. Surveys in other states indicate as many as 91 percent work in hospitals.

Hospital/clinical. Respiratory care in hospitals is determined by protocol. Equipment and procedures reflect the latest advances in medical technology. The personnel who use this equipment have to be trained in the use of such sophisticated equipment. Physician orders or prescriptions may be as general as "oxygen protocol." Treatment includes both invasive and diagnostic procedures and the administration of medication. The respiratory therapist in a hospital may make patient evaluations and be responsible for maintaining the patient's chart. There is variation in the frequency in which the physician will check the chart of the person hospitalized. Under certain conditions determined by hospital protocol the respiratory therapist may begin oxygen before the physician gives an order.

Home care. Home health care began as the administration of oxygen to a patient to ease discomfort in the last phase of a terminal respiratory illness.

In 1970, Drs. Thomas Petty and Thomas Neff (currently, both are Colorado practitioners) conducted a series of studies and concluded that oxygen could be used to improve the quality of life for patients with long-term respiratory problems. Oxygen could be transported to the home in industrial cylinders and the patient could be treated at home. Later, liquid oxygen and oxygen concentrators were developed and increased the mobility of the patient, so oxygen could be carried wherever the patient went.

Many home health care agencies provide 24-hour nursing services and other services such as respiratory therapy, physical therapy, occupational therapy, speech therapy, and social services. The patient contracts with a medical equipment supplier for oxygen and nurses provide respiratory care. Respiratory therapists may be used occasionally but the lack of reimbursement for their services, according to federal rules, prevent their frequent use.

Home health care agencies are certified by the U.S. Department of Health and Human Services under Medicare regulations (42 CFR 405). Medicare certification is required for Medicaid reimbursement (42 CFR 442). Home health care agencies provide a wide variety of services for the patient who has been discharged under diagnosis related group (DRG) requirements established by Medicare and Medicaid. Most of these patients are being sent home earlier under this system than they would have been in the past. Many still have comprehensive care needs when they go home.

Home health care agencies may be for profit or non-profit. To be certified by Medicare, a home health agency must offer at least part-time skilled nursing services and one other therapeutic service. The home health care agency must have a supervising physician or registered nurse who must be available at all times during operating hours and participates in all activities that are relevant to the professional services provided (42 CFR 405.1221). In addition to Medicare certification, the state, through its medical assistance programs, imposes other requirements for home health services providers but does not require the use of respiratory therapists (10 CCR 2505-10).

Another option available for a patient who has a prescription for oxygen is to obtain the equipment from a medical supply company (also called home care companies). Some are small businesses which may have only one respiratory therapist in their employ. Others may be part of national corporations and employ several respiratory therapists. A driver is usually sent out first to deliver the equipment and set it up in the home. Drivers often enter the home before the respiratory therapist and perform functions such as placing the cannula and the oxygen mask over the patient's face and setting the oxygen at the prescribed flow. They may give some instruction on equipment use and care. The respiratory therapist then visits the patient and instructs the patient and family members on medical procedures that the family needs to know in order to care for the patient and use the equipment effectively, including emergency procedures such as CPR.

Respiratory therapists can monitor some ventilator-dependent patients in their homes. They are able to run tests to determine things such as arterial oxygen saturation and make assessments on numerous observable symptoms in the home. The physician can then give instructions without having to visit or hospitalize the patient. They can administer medication such as aerosol bronchodilators in the home.

Some medical equipment supply companies have a medical director or physician consultant. The medical director or consulting physician may do in-house training for the agency's personnel. Delivery people and drivers may receive training in emergency procedures (first aid and CPR) as well as instruction on equipment use. Customer service representatives are trained to answer questions about the equipment dispensed. Medical directors and consulting physicians teach respiratory therapists new medical techniques and technological developments in respiratory care.

If the patient has an emergency, the family will call emergency assistance (911). For routine care the respiratory therapist visits the patient at least once a month and in certain cases once a week. Some medical equipment supply companies have a therapist on call who will respond after business hours. The physician is consulted if there is any change in the person's condition.

The medical equipment supply company cannot dispense oxygen to anyone without a prescription. Oxygen prescriptions must be renewed at least once a year or must be reissued whenever the need to change the treatment flow occurs. The only exceptions to these restrictions on the use of oxygen would be in the case of emergencies or in cases where travelers may not have a prescription with them, but it is apparent that they use and need oxygen.

Generally in remote rural areas, if the treatment requires more than just oxygen use, the patient has to be hospitalized. For those receiving care at home the services of a respiratory therapist may not be available.

Urban medical supply companies may also service many of the rural areas that are contiguous (50 or 60 mile radius) as well as other rural areas of the state. Some companies have branches in small towns across the state.

Third Party Payments

Insurance. Insurance plans may cover respiratory care. State insurance regulatory requirements do not address this area specifically, so the determination rests with contracts negotiated between employers and insurance companies or with the individual who is purchasing a policy. Some plans cover respiratory care, including the services of a respiratory therapist. Most often, it is a private insurance plan that will support keeping a ventilator-dependent person at home as long as possible.

Medicare. Currently, Medicare allows any approved home health care agency or medical equipment supplier to be reimbursed from $250 for an oxygen concentrator for patients using oxygen for eight or more hours a day to $105 a day for stationary or portable liquid oxygen. Medicare updates allowable charges every 18 months based on costs documented through claims submitted, unless Congress determines otherwise. The practitioner is not reimbursed.

Medicaid. Medicaid reimbursement works similarly. Low-income families, persons who qualify for Supplemental Security Income, the mentally retarded, and other handicapped persons are some of the clientele that could receive respiratory care services under the state's medical assistance programs. Medicaid allowable charges are determined by the state's medical assistance program in the Department of Social Services. Agencies or companies do not know in advance what the allowable charges will be for a particular patient as they are made on a case-by-case basis. To update allowable charges organizations such as the Colorado Association of Medical Equipment Suppliers (CAMES) must gather documentation on costs and present this to the Department of Social Services. Again, the respiratory therapist or other personnel is not reimbursed.

Hospitals, home health care agencies, and medical equipment supply companies consistently report that approximately 90 percent of the patients needing oxygen are Medicare and Medicaid patients. (This does not include ventilator dependent patients, who are generally not reimbursed for home care.)

Scope of Practice

The scope of practice for the respiratory therapist as outlined in the application of the CSRT includes the following:

(a) Direct and indirect pulmonary care services that are safe, aseptic, preventative, and restorative to the patient;

(b) The teaching or instruction of the techniques and skill of respiratory care whether or not in a formal educational setting;

(c) Direct and indirect respiratory care services including but not limited to the administration of pharmacological and diagnostic and therapeutic agents related to respiratory care procedures necessary to implement a treatment, disease prevention, and pulmonary rehabilitative or diagnostic regimen prescribed by a physician;

(d) Observation and monitoring of signs and symptoms, reactions, general behavior, and general physical response to respiratory care treatment and diagnostic testing for:

(1) The determination of whether such signs, symptoms, reactions, behavior, or general response exhibit abnormal characteristics; or

(2) The implementation based on observed abnormalities of appropriate reporting or referral or respiratory care protocols, or changes in treatment regimen pursuant to a prescription by a physician or the initiation of emergency procedures;

(e) The diagnostic and therapeutic use of the following, in accordance with the prescription of a physician: Administration of medical gases, exclusive of general anesthesia, aerosols, humidification, environmental control systems and baromedical therapy, pharmacologic agents related to respiratory care procedures, mechanical or physiological ventilatory support, bronchopulmonary hygiene, respiratory protocol and/or evaluation, cardiopulmonary resuscitation, maintenance of the natural airways, insertion without cutting tissues and maintenance of artificial airways, diagnostic and testing techniques required for implementation of respiratory care protocols, collection of specimens from the respiratory tract, or analysis of blood gases and respiratory secretions and participation in cardiopulmonary research.

Pulmonary function technologists (PFT). Pulmonary function technology is a specialty of respiratory therapy. A PFT can perform all the other functions of a respiratory therapist or technician if he or she has the training, or the person can be trained to practice only pulmonary function technology. These specialists participate in diagnostic evaluation to determine the presence and extent of pulmonary disease. Any diagnostic tests would be ordered and supervised by the physician. The PFT can administer a wide variety of prescribed medications and is also skilled in basic life support techniques. The PFT is also responsible for infection control during pulmonary testing. The PFT works in the same settings as a respiratory therapist.

Nursing and physical therapy. The respiratory therapist's scope of practice overlaps with the RN's functions in respiratory care and the physical therapist's use of chest physiotherapy. In many hospitals and home health care settings, both RNs and respiratory therapists practice respiratory care. However, many of the more technical aspects of respiratory care are being delegated to the respiratory therapists.

Current Legal Status

Certain functions performed by respiratory therapists, such as administering drugs and invasive procedures, are part of the practice of medicine. While these are performed under the auspices of a physician prescription, the legal relationship between the physician and the respiratory

therapist is not always clear. When a physician uses a physician extender (PE), as authorized under the Colorado Medical Practice Act, he or she is personally responsible for the actions of the PE. PEs are registered with the medical board and regulations allow the physician to supervise no more than two persons unless more than two are specifically authorized by the board on a case-by-case basis.

The respiratory therapist, on the other hand, has a much more vague relationship with the physician. Most physicians do not do respiratory therapy and only write the prescription, so the therapist is required to make certain medical judgments.

The therapist also goes out into the community to perform these tasks without personal oversight from the physician. The therapist will usually consult with the physician, but the physician has no specific control over the therapist. The physician may not even know the therapist.

Respiratory therapy is one of many unlicensed allied health occupations that is technically in violation of Colorado law. The practice of medicine in Colorado includes, in part," [s]uggesting, recommending, prescribing, or administering any form of treatment, operation, or healing for the extended palliation, relief, or cure of any physical or mental disease, ailment, injury, condition, or defect..." (12-36-106(1)(b), C.R.S.).

Colorado is not the only state with an all-inclusive act and its accompanying problems. A 1985 report of the California Board of Medical Quality Assurance on who is practicing illegally outlined what is and is not legal, as follows:

> Basically, if you are not licensed to do it, then it probably is illegal. Now obviously, there are some things that can be done by unlicensed health occupations. In general, they are permitted to do most anything that does not involve direct patient contact. For example, setting up examination or treatment equipment, assisting licensed personnel by handling equipment, taking notes, and so on. There also are certain patient-contact activities that are not illegal. Examples including taking vital signs, assisting a patient in ambulating or transfers, collecting biological specimens (as long as no penetration of the tissues is involved) and performing simple non-invasive testing. Thus, performing and electrocardiogram or electroencephalogram is permitted if there is no tissue penetration.
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> Problems occur if the unlicensed person is providing treatment, analyzing results of tests, advising patients about their conditions or treatment regimen, making assessments, or performing any kind of decision-making activities. There is no prohibition on a doctor consulting with an unlicensed person who has expertise in some technical area. However, the physician may not direct that person to provide the treatment the physician chooses, even if it is done under the physician's supervision.

Private Credentialling

Education. Currently, a person may receive training from three educational institutions in Colorado that are accredited by the Joint Review Committee for Respiratory Therapy Education. Programs accredited by this committee would also be approved by the American Medical Association. Pueblo

Community College and Front Range Community College offer a two-year associate's degree program in respiratory therapy. Part of this training occurs at clinical sites. Many of the hospitals in the Denver metro area and some in Pueblo and Colorado Springs are used as training sites. Students go to these sites with the instructor.

T. H. Pickens Technical Center (Aurora Public Schools) is the only school in Colorado running a one-year technician program. This training also includes clinical site training.

Credentialling bodies. The National Board for Respiratory Care (NBRC) is the credentialling body for these practitioners. Respiratory therapists are credentialled at the therapist level and the technician level. The credentials awarded are the Registered Respiratory Therapist and the Certified Respiratory Therapy Technician. NBRC also allows equivalency determinations to be made on the basis of clinical experience if the educational qualifications of the applicant are not those specified above. It also certifies pulmonary function technologists.

To become a certified respiratory therapy technician, a person must have attended a one-year accredited technician program or a two-year therapist program. Experience is not necessary. The person must take and pass the entry level certification exam.

To become a registered respiratory therapist, a person must have attended a two-year accredited program and have at least one year of clinical experience. The clinical experience must be obtained in a work setting that employs a medical director who is responsible for the quality of care received by patients and verifies the quality of the applicant's clinical experience.

The NBRC has now developed a pulmonary function certification examination. A person who is a graduate of an AMA-accredited school or a National Society for Cardio-Pulmonary Technology-approved school may take the certification examination. The credentials awarded are a Certified Pulmonary Function Technologist for the technician level and as of 1987 a Registered Pulmonary Function Therapist credential will be available for those who also qualify at the therapist level. Currently, registration is available through the National Society for Cardio-Pulmonary Technology and the National Board for Cardio-Pulmonary Care.

All credentialling examinations given by the NBRC are based on job analyses from which test specifications have been developed. A committee of content experts produce and review test items.

Other States

According to the American Association for Respiratory Care, seventeen states now regulate respiratory therapy. (This figure includes bills passed during the 1986 legislative sessions.) Some regulate under medical boards, and others have separate regulatory boards. Most mandate licensure, exempting only other licensed health care practitioners. Some of the laws require that each medical equipment supplier have a medical director or consulting physician as well as licensed respiratory therapists on staff.

PUBLIC HARM

The Colorado Society for Respiratory Therapy has produced no documentation on harm that has occurred to patients in Colorado as a result of incompetent respiratory care rendered. Comments received by the department indicate that a substantial number of persons in the medical and business community feel that the current system has worked well so far.

The American Association for Respiratory Care cites a few cases nationally that have produced lawsuits in the area of respiratory care involving death or permanent injury. In most cases, the physician and the health care facility were named defendant and held legally responsible, and respiratory care practitioners were only indirectly involved.

COSTS OF REGULATION

As with any regulatory scheme, the cost of implementing it varies greatly depending upon the specific requirements. The specific provisions supported by the applicant group would be licensure through an advisory committee on respiratory care to the medical board. Any health care organization would have to have a medical director knowledgeable in respiratory care or medical sponsorship approved by the advisory committee. A medical director would be a member of the organization's active medical staff. Medical sponsorship would be provided by a consulting physician. Other licensed practitioners, students of respiratory therapy, and others who perform cardio-pulmonary diagnosis and testing under general medical direction would be exempt. There is no consensus on what the actual costs of regulation would be.

Some in the medical community feel that increased costs in hiring these practitioners would be negligible. According to persons in the medical and business community, there is an ample labor supply, and many beginning practitioners have difficulty in finding work.

Others in the medical community see licensure as eventually restricting the labor supply and putting upward pressure on prices. These persons feel that there are adequate controls in hospitals and other work settings for employing qualified personnel. The state would be placing restrictions on respiratory care practices that have worked well in the past.

In the medical equipment supply industry there is also a lack of consensus. Some larger companies feel that they can absorb costs, and many currently have a medical director or consulting physician as part of their operation or corporate structure.

Some small companies, on the other hand, see increased costs with regulation that could threaten their existence. The department received comments from these businesses and from CAMES expressing the greatest concern over medical directorship or the consulting physician requirement. Small businesses have been burdened by these requirements in other states. Having a medical director in a business often necessitates malpractice insurance and administrative liability coverage. Small businesses in other states are finding that they cannot meet these costs. (Some of these costs could be attributed to conditions in the insurance industry.)

Another cost to business would be created by restricting the practice of respiratory therapy to a licensed practitioner. If drivers could no longer be trained by the business to perform the tasks they now do, a respiratory therapist would have to be used to perform these functions. A therapist would have to go out with each driver on every delivery. This would be a substantial cost increase for the business. Similarly, businesses would face increased costs if only a respiratory therapist could answer patient questions rather than allowing a service representative to do this. Such a law would have the effect of mandating a respiratory therapist's time in ways that are inefficient and medically unnecessary.

BENEFITS OF REGULATION

One of the benefits of regulation would be the standardization of training and the assurance to the public that a practitioner had at least a minimum amount of training before practicing respiratory therapy. Another benefit of regulation would be to provide regulatory oversight over a group of practitioners who perform some arts which are part of the practice of medicine.

According to the application submitted by the Colorado Society for Respiratory Therapy, the current lack of regulation makes respiratory therapists ineligible for third party insurance payments and Medicare/Medicaid payments outside the hospital, where patients could receive more cost-effective care. In fact, licensure in other states has not guaranteed reimbursement. Medicare regulations still specify providers. Reimbursement under Medicaid is still determined by individual states through the administration of medical assistance programs. Federal regulations require only that providers be licensed according to state law. Private insurance plans will continue to vary.

RECOMMENDATION

The potential for harm is recognizable but actual documented harm to patients in Colorado has not been produced by the society. Quality control measures taken by hospitals minimize the opportunity for harm to occur. Hospitals generally hire only credentialled therapists (Joint Commission on the Accreditation of Hospitals requirements) and some have additional in-house training programs before employed therapists actually practice on patients. Supervision may be general in nature and even after-the-fact in some cases, but respiratory therapists are nevertheless supervised.

The national credentialling process is a rigorous screening process which identifies for any employer those who have met these requirements. Since credentialling is available to the therapists, title protection would be of little benefit.

There are legal questions surrounding the practice of respiratory therapy. However, many other groups of allied health professionals are also technically in violation of the Colorado Medical Practice Act.

Respiratory therapists receive the least supervision in home care situations. However, much of home care involves teaching patients and families to use equipment and monitoring the patient who uses the equipment. Most invasive and diagnostic procedures cannot be performed in the home.

The medical directorship or the consulting physician requirement would also have limited benefit. The consulting physician would not know the patient for whom care is being provided and would have no direct knowledge of why a particular treatment approach was chosen for a patient over another. There could be differing medical opinions between the prescribing and consulting physician.

In spite of the rapid growth of the home care industry, most respiratory therapists are still employed by hospitals (estimates range from 80 to over 90 percent). Internal controls and administrative oversight provide supervision and establish legal liability. On-site supervision and accountability does exist.

In the home care industry, requiring credentialling for the performance of any respiratory care and physician consultative services in order to do business would be very expensive for small businesses, especially rural businesses. Even if all of these requirements were met, there would still not be on-site supervision for respiratory therapists in home care settings.

The department concludes that, in spite of the legal uncertainties faced by respiratory therapists, there is not sufficient evidence to indicate that the public is at risk under the current regulatory system, and recommends against new regulation.