

COLORADO DEPARTMENT OF REGULATORY AGENCIES
OFFICE OF POLICY AND RESEARCH

RESPIRATORY THERAPISTS

1999 SUNRISE REVIEW



STATE OF COLORADO

DEPARTMENT OF REGULATORY AGENCIES

Office of the Executive Director
Office of Policy and Research
H. Rene Ramirez, Director

1560 Broadway, Suite 1550
Denver, CO 80202
Phone (303) 894-7855
FAX (303) 894-7885
V/TDD (303) 894-7880



Bill Owens
Governor

M. Michael Cooke
Executive Director

October 15, 1999

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 its evaluation of the sunrise application for regulation of respiratory therapists and is pleased to submit this written report. The report is submitted pursuant to §24-34-104.1, Colorado Revised Statutes, 1988 Repl. Vol., (the "Sunrise Act") which provides that the Department of Regulatory Agencies shall conduct an analysis and evaluation of proposed regulation to determine whether the public needs, and would benefit from, the regulation.

The report discusses the question of whether there is a need for the regulation in order to protect the public from potential harm, whether regulation would serve to mitigate the potential harm, and whether the public can be adequately protected by other means in a more cost-effective manner.

Sincerely,

M. Michael Cooke
Executive Director

Table of Contents

EXECUTIVE SUMMARY.....	1
BACKGROUND	2
THE SUNRISE PROCESS	2
PROPOSAL FOR REGULATION.....	3
PROFILE OF THE PROFESSION	4
PRACTICE SETTING.....	5
REGULATION.....	8
EDUCATION AND TRAINING.....	8
BENEFITS OF RESPIRATORY THERAPY	11
PUBLIC HARM.....	13
REGULATION IN OTHER STATES	13
PRACTICE OF MEDICINE.....	16
OTHER INSTANCES OF POTENTIAL HARM.....	18
RECOMMENDATION – ESTABLISH A REGULATORY PROGRAM FOR RESPIRATORY THERAPISTS THAT IS THE LEAST RESTRICTIVE POSSIBLE TO PROTECT THE PUBLIC.	20
APPENDIX A - RESPIRATORY CARE SERVICES IN MEDICARE	23

Executive Summary

The Department of Regulatory Agencies (DORA) has completed its evaluation of the application by the Colorado Society for Respiratory Care (CSRC) for regulation of respiratory therapists. The applicants seek state certification of respiratory care practitioners (RCP). Pursuant to the Colorado Sunrise Act, §24-34-104.1, Colorado Revised Statutes (C.R.S.), the applicant must establish the need for regulation according to the following criteria:

- 1) 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 harm is easily recognizable and not remote or dependent on tenuous argument;
- 2) Whether the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional or occupational competence; and,
- 3) Whether the public can be adequately protected by other means in a more cost-effective manner.

The applicant is the Colorado chapter of a professional association made up of respiratory care practitioners (RCP) certified by a private credentialing organization, the National Board for Respiratory Care (NBRC). There are approximately 550 members of the CSRC representing an estimated 50 percent of the individuals practicing respiratory care in the state.

The applicant made a very strong case for the benefits of quality respiratory care. When performed properly, respiratory therapy is credited with reducing hospital stays, reducing emergency room visits and improving the quality of life for persons with chronic respiratory diseases such as asthma and emphysema. Certification by the NBRC requires intensive education, clinical practice and successful completion of an examination. Negligent or unprofessional conduct can result in the certification being suspended or revoked.

There was also a finding of potential harm to the public by the unregulated practice of respiratory therapy. On this basis, DORA recommends the creation of a regulatory program for respiratory therapists. The proposed program should recognize the availability of a private credential and present the least restrictive form of regulation necessary to protect the public.

Background

THE SUNRISE PROCESS

The Colorado Sunrise Act, §24-34-104.1 Colorado Revised Statutes (C.R.S.) requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review. The intent of the Act is to impose regulation on occupational and professional only when it is necessary to protect the public health, safety or welfare. DORA must evaluate the information submitted in to prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:

(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.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must be accompanied by supporting signatures and must include a description of the proposed regulation and justification for such regulation. Applications received by June 30 must have a review completed by DORA by October 15 of the year following the year of submission.

Background

PROPOSAL FOR REGULATION

The Colorado Society for Respiratory Care (CSRC) has submitted a sunrise application to the Department of Regulatory Agencies (DORA) for review in accordance with the provisions of §24-34-104.1, Colorado Revised Statutes (C.R.S.). The application identifies state certification of respiratory therapists as the appropriate level of regulation to protect the public. DORA investigates the need for regulation of a previously unregulated occupation or profession based on the three criteria contained in §24-34-104.1(3), C.R.S.

CSRC previously submitted sunrise applications in 1986, 1987, 1993, 1995, and 1996. The applications in 1987 and 1996 were withdrawn before the completion of the DORA reports. DORA completed reports in 1986, 1993, and 1995. In each of those reports, DORA recommended against regulation of respiratory therapists by the state. However, following the issuance of the reports in 1993 and 1995, legislation was introduced to implement new regulation for this profession. Neither of those bills was successful in passage through the General Assembly.

The sunrise application asks the question "If the occupational group is a former applicant re-submitting a sunrise application, please include updated information that will substantiate the request for regulation." The applicant submitted no new information regarding actual harm to the public by the unregulated practice of respiratory therapy. The applicant again raises concerns regarding the practice of respiratory therapy by unqualified individuals. The application also contains additional information concerning licensing programs in other states, other states' disciplinary actions, and changes to the practice setting for therapists.

Background

PROFILE OF THE PROFESSION

In the 1995 sunrise application, the Colorado Society for Respiratory Care (CSRC) submitted the following justification for licensure:

Respiratory care practitioners are members of the critical care team, treating individuals who are seriously ill. This includes using equipment that will mechanically breathe for the patient. With the assistance of sophisticated monitory devices and techniques, they give round the clock care to individuals who otherwise would not be able to survive life threatening conditions ranging from severe head injuries to chest wounds. Respiratory care practitioners perform invasive procedures such as drawing arterial blood gases for diagnostic tests and assist physicians in performing other invasive procedures such as therapeutic and diagnostic bronchoscopy, thoracentesis and histamine and methacholine challenge stress testing.

“Respiratory Care” as a practice means providing therapy, management, rehabilitation, support services for diagnostic evaluation and care of patients with deficiencies and abnormalities which affect the pulmonary system and other system functions. The practice 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, 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 symptom, reactions, general behavior, and general physical response to respiratory care treatment and diagnostic testing for:

Background

- (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 or 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 biomedical therapy; pharmacologic agents related to respiratory care procedures; mechanical or physiological ventilator support; bronchopulmonary hygiene; respiratory protocol and/or evaluation, cardiopulmonary resuscitation; maintenance of the natural airways; insertion 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;

- (f) The transcription and implementation of the written and verbal orders of a physician pertaining to the practice of respiratory care.

PRACTICE SETTING

Because of the changes in health care delivery, particularly managed care, the practice of respiratory therapy is changing. Although respiratory therapists primarily work in a hospital setting, more therapists are working in other types of environments. Respiratory therapists are employed in nursing homes, acute care clinics, out-patient clinics and by home health care agencies.

Background

In a home health care setting, the respiratory therapist will likely be the only health care professional on site during a treatment session. In other settings, although there are other health care professionals available, the respiratory therapist does not usually work under the direct supervision and control of a physician or other licensed health care practitioner.

Respiratory care services can be divided into several categories. RCP may provide all of the service categories in some practice settings. Other practice settings services may be limited to a particular category. The service categories are generally outlined as:

General Therapeutic Services

- Therapeutic gas administration
- Aerosols and humidity therapy
- Inspiratory positive pressure breathing (IPPB)
- Hyperinflation therapy (incentive spirometry)
- Pulmonary physical therapy
- Airway care

Critical Care Services

- Mechanical ventilation
- Continuous positive airway pressure (CPAP)
- Physiologic and hemodynamic monitoring

Pulmonary Rehabilitation And Home Care

- Home care discharge planning and follow-up
- Outpatient pulmonary rehabilitation:
- Patient instruction
- Follow-up supervision

Background

Diagnostic Services

- Pulmonary function testing
- Arterial blood gas analysis
- Pulmonary exercise testing
- Sleep studies
- Metabolic studies
- Diagnostic bronchoscopy
- Sputum induction

Emergency Services

- Cardiopulmonary resuscitation
- Endotracheal intubation
- Patient transport

Educational Services

- Patient and family education
- In-service education (hospital, clinic staff)
- Student clinical education
- Community education

Support Services

- Equipment cleaning, disinfecting, and sterilization
- Biomedical equipment quality control and preventative maintenance

Regulation

There is no federal regulation of the practice of respiratory therapy. Forty states currently have state level regulatory programs for the profession. In some states, licensed respiratory therapists are eligible for third party insurance reimbursement and Medicaid and Medicare reimbursement. Therapists in Colorado are not eligible for Medicaid, Medicare, or third party insurance reimbursement.

EDUCATION AND TRAINING

The National Board for Respiratory Care (NBRC) is a private professional organization that provides education, testing, and support to the profession and regulatory agencies. NBRC credentials are used by regulatory agencies in many states as the minimum standard for licensure to practice. NBRC offers continuing education programs and maintains a database of disciplinary actions against certified RCPs in states with regulatory programs.

Technicians have one year of formal education at an accredited program combined with a clinical training program. There are several approved programs offered through Colorado community colleges and private higher education institutes in the state. Graduates of these programs are eligible to take the NBRC entry-level examination. Successful examination candidates receive designation as a Certified Respiratory Therapist Technician (CRTT).

Therapists must have two years of formal education in an accredited program, followed by a clinical training period. There are several approved programs offered through Colorado community colleges and one private institution. Graduates of these programs are eligible to take the NBRC examination for the Registered Respiratory Therapist (RRT) certification.

Regulation

The American Association of Respiratory Care (AARC), maintains that certified RCP receive more training in respiratory care than other health care professionals. The AARC commissioned a comparison of educational contact hours in respiratory care topics between accredited nursing schools and respiratory care programs. The survey was conducted by the Indiana University Center for Survey Research (CSR) in Bloomington, Indiana in the spring of 1994. The survey was sent to 1,471 institutions offering an associate, three-year, or baccalaureate degree in nursing. The response rate was over 73 percent, or 1,077 institutions. Three hundred nineteen RCP programs were surveyed, with a response rate of 70 percent or 223 institutions. Summaries of the average total contact hours as reported by the institutions for the major practice areas of respiratory therapy are included in Table 1.

Table 1

Average Total Contact Hours

PROCEDURE	ASSOCIATE DEGREE	THREE-YEAR PROGRAM	BACHELOR DEGREE	RRT PROGRAM
Oxygen Therapy	23.8	72.5	27.2	99.3
Mechanical Ventilators	9.7	45	16.3	305.7
Chest Physiotherapy	8	71.7	10.9	54.3
Intermittent Positive Pressure Breathing (IPPB)	4	3.7	3.9	43.7
Continuous Positive Airway Pressure (CPAP)	8.6	19.9	7.6	51.6
Incentive Spirometry	13	80.9	13.9	45.4
Aerosolized Drug Administration	7.4	49.1	4.4	98.6
Pulmonary Function Testing	2.2	56.8	2.1	73.9
Respiratory Home Care	1.3	23.1	3.9	38.7
Arterial Puncture	2.3	18.9	2.1	59.9
Arterial Blood Gas Analysis	11.3	94.2	12.4	69.1
Intubation and Extubation	4.5	18.2	8.1	55.9

Regulation

The sunrise application included letters of support from the American Society of Anesthesiologists, the National Association for Medical Direction of Respiratory Care, and the American College of Chest Physicians, as well as letters from individual practitioners. These letters all praised the training, education and skill of certified RCP. The applicant expressed concern regarding cost saving measures in some hospital settings which result in respiratory care services being performed by unregulated persons with minimal on the job training from hospital staff.

Benefits of Respiratory Therapy

Expenses associated with respiratory diseases are approximately 8 percent of the total cost of illness in the United States.¹ Changes in health care delivery, particularly managed care has changed the way RCP practice. Patients are being shifted from expensive settings such as hospitals, to lower cost settings such as skilled nursing facilities (SNF) or even home care. In some situations, preventative care administered by RCP result in substantial cost savings.

There are numerous studies that demonstrate the benefits of respiratory care in different health care settings. These studies have found that when respiratory therapy is properly administered, hospital stays are reduced, overall health care costs are reduced, and hospital admissions decrease. One study found average monthly savings of \$14,500 for ventilator dependent adults receiving home care from a respiratory therapist compared to patients with similar injuries admitted to a hospital.²

The applicant supplied information from a program developed by large insurance company, which compares hospital costs with home care expenses for specific illnesses requiring respiratory therapy. A summary of the findings is included in Table 2.

Table 2
Cost Per Month of Hospital Care Compared to Home Care, Selected Conditions

Condition	Hospital Care	Home Care	Cost Savings	Percent Difference
Infant born w/breathing & feeding problems	\$60,970	\$20,209	\$40,761	66.8
Respiratory distress/oxygen dependency	36,000	11,500	24,500	68.0
Ventilator-dependent children	15,742	9,153	6,589	41.9
Patient requiring respiratory support	24,715	9,267	15,448	62.5
Oxygen-dependent children with a tracheostomy	12,236	5,304	6,932	56.7

Source: Aetna Life & Casualty Individual Care Management Program

¹ American Journal of Managed Care, June, 1999, Vol. 5, No. 6 p 749.

² Bach, J.R., Intinola, P., Alba, A.S., & Holland, I.E. "The Ventilator-Assisted Individual: Cost Analysis of Institutionalization vs. Rehabilitation and in-home Management" Chest, 1992 Vol. 101 (2), p 26-30.

Benefits of Respiratory Therapy

In 1997, the AARC commissioned a study of Medicaid and Medicare patients requiring respiratory care. The impetus behind the study was a concern regarding changes to payments by the federal Health Care Financing Administration (HCFA) related to skilled nursing facilities (SNF) payments. The study was prepared by Muse & Associates of Washington D.C. and released in June of 1998. The report found Medicaid and Medicare cost savings associated with the use of respiratory therapy services in SNF. The executive summary of the report is included in this report as Appendix A.

Public Harm

The sunrise statute requires an analysis of whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public. This is a difficult standard for an applicant to demonstrate. Previous applications by this applicant have included anecdotal information related to potential harm by unqualified RCP. Application materials have also included information and documentation regarding actions that would constitute a violation of the proposed practice act.

The most recent application stressed potential harm to the public. For example: forty jurisdictions currently regulate RCP. Potentially, a RCP who is prohibited from practicing in another state could relocate to Colorado to practice since Colorado does not regulate the profession. The applicant documented one situation where a hospital in Colorado Springs employed an individual as a RCP with the understanding that the individual had been licensed in another state. A RCP working at the hospital alerted the administration that the newly hired RCP was not a certified RRT and had been disciplined in the other state for forging RRT certification papers. The hospital terminated the employment of the RCP.

In this situation, a state regulatory program should have prevented this individual from practicing in Colorado. If the unqualified RCP had harmed a patient at the hospital, the hospital may have been held liable. However, findings of liability, even when they result in financial compensation to the victim, or dependents, does not always make the damaged party whole.

REGULATION IN OTHER STATES

The NBRC maintains a database of disciplinary actions taken by various state agencies. As part of this sunrise review, disciplinary actions by regulatory agencies in surrounding states were reviewed. Of the states surrounding Colorado, Wyoming is the only other state without a regulatory program for RCP. Arizona had the most disciplinary actions of any state listed in the NBRC database. Because of the proximity of Arizona and the size of the program in that state (Arizona has over 4,000 licensed RCP), a more detailed review of the Arizona program is highlighted in this report for illustrative purposes.

Public Harm

The Arizona legislature initiated a licensing program for RCP during the 1990 legislative session. At that time it was estimated the Arizona Board of Respiratory Care Examiners would regulate 1,400 RCP. Within five years of the implementation of the program Arizona had over 4,000 licensees. The NBRC database includes over 100 disciplinary actions for Arizona licensees from January 1992 through January 1998. The database identifies 21 separate offenses, which resulted in disciplinary action by the Arizona board. The NBRC evaluates disciplinary action taken in a member state and imposes additional discipline against the national credentials of the disciplined party. The NBRC identifies 19 separate disciplinary actions. A breakout of the offenses identified by the Arizona Board of Respiratory Care Examiners and the NBRC discipline is included as Table 3.

Table 3

Arizona RCP Disciplinary Actions January 1992 through January 1998

Offense	#
Misrepresentation of Credentials	1
Cheating (on examination)	0
Candidate Substitution	0
False NBRC Certificate	2
False NBRC Score Report	0
False NBRC Wallet Card	0
False Certificate of Completion/Graduation	0
Unauthorized Material Reproduction	0
Trademark Violation	0
Practice Related Offense	0
State Licensure Denied/Revoked	3
Alcohol/Substance Abuse	19
Incompetent/Negligent Practice	2
Felony	4
Fraud	8
Unprofessional Conduct	52
Physically/Mentally Unfit to Practice	1
Practice with an Unauthorized Person	0
Disciplinary Action in Another State	1
Violation of Probation or Other Condition	5
Violation of Statute or Regulations	10
Other	2
TOTAL	110

Public Harm

The Arizona board reports that 26 percent of complaints received result in disciplinary action and that 34 percent of the complaints received result in a letter of concern. The two most common complaints that result in disciplinary action are unprofessional conduct and alcohol/substance abuse. Examples of unprofessional conduct provided by the Arizona board included: sleeping on duty, failure to answer a page, abusive language to patients or coworkers, and incomplete or inaccurate patient charting.

Of these possible offenses, improper charting presents the largest potential for harm. Although knowledge of proper charting is required for licensure, the fact that there are violations found is evidence a regulatory program will not prevent negligent acts. However, a regulatory program could discipline a practitioner who fails to exercise proper care and possibly prevent additional violations. There is no formal process in Colorado to address negligent practices by respiratory therapists.

When a state reports disciplinary action against a licensed RCP to the NBRC the NBRC imposes disciplinary action against the credentials issued by this organization. NBRC can and does discipline members in states without regulatory programs as well. However, because of the lack of a formal reporting mechanism, actions in those states are infrequent. A summary of the disciplinary actions taken by NBRC against Arizona licensees from January 1992 through January 1998 is included in Table 4.

Public Harm

Table 4

NBRC Disciplinary Actions Against Arizona Licensees, 1992-1998

Action	#
Admonishment	0
Formal Censure	1
Suspension from Examinations	6
Removal from Directory/Active Status	0
Disqualification from Recredentialing	0
Credential Suspended	0
Publication of Offense	0
Mandatory Re-Examination	0
Revocation	32
Probation	37
Suspension	4
Reprimand/Censure	12
Surrender	2
Denied for Initial Licensure	6
Denied for Renewal	2
Fine	0
Other Disciplinary Action	3
License Restored or Reinstated	3
Reinstatement Denied	2
TOTAL	110

PRACTICE OF MEDICINE

The Colorado Medical Practice Act defines the practice of medicine and provides exemptions from licensing requirements in §12-36-106, C.R.S. The definition, in part, defines the practice of medicine as:

“Suggesting, recommending, prescribing, or administering any form of treatment, operation, or healing for the intended palliation, relief, or cure of any physical or mental disease, ailment, injury, condition, or defect of any person with the intention of receiving therefor, either directly or indirectly, any fee, gift, or compensation whatsoever;” (§12-36-106 (1)(b), C.R.S.)

Public Harm

This definition includes the activities of respiratory therapists in the practice of medicine. However, §12-36-106 (3)(l), C.R.S., exempts from the definition “The rendering of services, other than the prescribing of drugs, by persons qualified by experience, education, or training, under the personal and responsible direction and supervision of a person licensed under the laws of this state to practice medicine, but nothing in this exemption shall be deemed to extend or limit the scope of any license, and this exemption shall not apply to persons otherwise qualified to practice medicine but not licensed to so practice in this state.” This exemption would appear to exempt respiratory therapists from the definition of the practice of medicine. However, there are some key elements to the exemption, which are not present in the standard practice of respiratory therapy.

Individuals providing respiratory therapy services have the qualifications (“experience, education or training”) required by the exemption. The level of direction and supervision by a person licensed to practice medicine is questionable. RCP receiving certification from the NBRC have demonstrated experience, education and training to perform procedures associated with respiratory therapy. Individuals receiving on the job training in a medical facility will not meet the criteria to perform many procedures in the RT scope of practice without direct supervision or delegation by a licensed medical professional.

As part of the research for this review, observations of RCP were made in a hospital setting. Hospitals generally have several RCP on staff, covering various shifts. Therapists routinely performed procedures for patients without directly communicating with the physician. In some situations, it was obvious the attending physician could not possibly have known which therapists would be performing the procedure. This shows that the physicians have confidence that any therapist would have the knowledge and expertise to competently carry out written instructions, even instructions calling for the use of medical judgement.

However, by using this confidence in the expertise of the RCP both the physician and the respiratory therapist may be violating the medical practices act. Even though the therapist has the education and training to perform the procedures, in most situations observed during the hospital visit there was a lack of supervision by a licensee. It appears that licensees in the hospital setting take for granted that RCP are qualified for the limited practice of medicine related to respiratory therapy.

Public Harm

Administering prescription medication and therapy for "...the intended palliation, relief, or cure of any physical or mental disease, ailment, injury, condition, or defect of any person..." without the supervision of a licensed health care practitioner is a violation of the Medical Practices Act (ACT). It can be presumed the ACT was written with this specific language to provide public protection against unqualified persons attempting to treat sick or injured persons.

It can be concluded from the analysis of the practice of respiratory therapy that RTs are in violation of the ACT. There is a potential for harm to the public when unregulated individuals perform medical procedures. However, when procedures within the scope of practice of a RCP are performed by qualified RCP certified by the NBRC the risk to the public is reduced.

OTHER INSTANCES OF POTENTIAL HARM

Like most health care workers, RCP have access to controlled substances. A RCP under the influence of alcohol or a controlled substance can potentially expose a patient to harm. While regulatory programs will not prevent substance abuse, they can react to discipline abusers and possibly prevent future harm once a problem has been identified.

Reparatory therapists provide services which have a demonstrable benefit to the public in the form of lower medical expenses, shorter hospital stays, and presumably a higher quality of life. There is also evidence of potential for harm to the public. Therapists routinely perform invasive procedures, such as arterial punctures and intubation. If the procedures are not performed properly, the patient could be exposed to harm in the form of infection, permanent damage to vocal cords, oxygen starvation resulting in brain damage, and in extreme situations, death.

Previous applications have provided examples of actual harm to patients in hospital settings. These cases have involved:

- A week old baby burned by excessive temperature of an aerosol device;

Public Harm

- An 84 year old patient dying when a therapist did not respond to low blood oxygen levels;
- Death of a patient resulting from improper maintenance of a mechanical ventilator by a therapists; and

The applications indicate that these cases resulted in civil actions against the hospital employing the therapist. A state regulatory program would address concerns regarding additional harm to the public caused by negligent or incompetent RCP.

The second question to be answered is whether the public can reasonably be expected to benefit from an assurance of initial and continuing professional competence. There are numerous studies that document the benefits of respiratory therapy. The applicant and many supporters in the health care field believe that RCP meeting the private credentialing standards of the NRCB provide the highest level of care.

The cases cited by the applicant that involved public harm by RCPs did not differentiate between RCPs that were trained on the job and those certified by the NRCB. In most situations where severe harm to a patient was caused, both the practitioner and the employing facility may be held liable in a civil action. However, civil action by survivors of injured parties is a reactive measure. It requires knowledge of the legal process, resources to access the judicial system, and does not prevent reoccurrences of the harmful act by the same individual.

The question becomes, who is responsible for ensuring that the practitioners are competent, the state, through a regulatory program, or the employing facility through its hiring and training practices? In the current environment, facilities may rely on the existing private credentialing process to screen job applicants. However, there is no state requirement for RCP to demonstrate any qualifications.

The absence of a state regulatory program presents facilities with the option of employing unqualified individuals to perform procedures within the scope of practice of respiratory therapists. This presents a significant potential harm to the public.

The final question to be addressed is whether the public can be adequately protected by other means in a more cost-effective manner. The current lack of regulation in Colorado effectively places the burden of public protection on the institution employing the RCP. There is a widely recognized private certification process available for RCP. Any

Public Harm

SNF, hospital or home health care agency that employs a NRCB certified therapist has a reasonable assurance that the RCP has the education and training necessary to perform the standard job functions. However, there is no legal recognition of this certification or obligation for institutions to utilize it.

RECOMMENDATION – Establish a regulatory program for respiratory therapists that is the least restrictive possible to protect the public.

The applicant made a showing of potential harm to the public by improper respiratory care. There is also clear evidence of the economic and health benefits associated with proper respiratory therapy.

Some advocates for regulation interviewed for this review maintained that some hospitals employ unqualified persons as RCP to lower costs, thus endangering the public. Representatives of one hospital system openly discussed their on-the-job training program which requires significantly less education and no formal testing before an unlicensed person is permitted to perform many of the functions previously performed by certified RCPs.

It may be argued that using lower paid, less trained persons to perform therapy places the public at risk. However, the hospitals in question report that they limit the procedures that non-certified personnel are permitted to perform and supervise their activities. No documentation is available to demonstrate that this practice has caused public harm.

An estimated 15 percent of certified RCP work in home health care settings. Other certified RCP are employed in SNF and other health care settings. Thus, the majority of individuals performing respiratory therapy are employed by hospitals. The state, through the Colorado Department of Public Health and Environment regulates hospitals, including monitoring patient care. The federal government does not directly regulate hospitals, although, a significant percentage of hospital revenue comes from Medicaid and Medicare reimbursements. These federal programs are not designed to reimburse unless adequate care is administered.

Although state law does not formally recognize it, certification by the NRCB is a cost-effective form of regulation. Respiratory therapists that have obtained this designation are highly qualified professionals. The

Public Harm

designation is recognized by the institutions employing RCP. If an institution chooses to use non-certified individuals as a RCP, it is potentially increasing its liability and placing the public at risk.

Therefore, it is the recommendation of DORA that the practice of respiratory therapy be limited to those individuals who have demonstrated competency by obtaining the NBRC certification or an equivalent nationally recognized certification. The General Assembly should define the scope of practice for respiratory therapists and establish a registration program in the Department of Regulatory Agencies, Division of Registrations to document the qualifications of individuals registered to perform those defined functions. The scope of practice should recognize that other regulated health care professionals are qualified to perform those procedures, and should not preclude other licensed health care professionals from performing procedures within their own scope of practice. The entry requirements for certification should also include grounds for denial and discipline that are consistent with other regulated health care professionals in Colorado.

Appendices

Muse &
Associates

**Respiratory Care Services
in Medicare**

June, 1998



Muse & Associates
919 Eighteenth Street, NW
Suite 1001
Washington, DC 20006
(202) 496-0200
(202) 496-0201 (fax)

EXECUTIVE SUMMARY

Respiratory therapy is an important and growing component of Medicare Inpatient Hospital and Skilled Nursing Facility (SNF) care. Congress has directed the Health Care Financing Administration (HCFA) to develop and implement a Prospective Payment System (PPS) for Medicare SNFs effective July 1, 1998. The SNF PPS design has been based on data collected in the Nursing Home Case-Mix and Quality (NHCMQ) Demonstration.

The American Association for Respiratory Care (AARC) and others have met with HCFA staff over the last year concerning the design of the SNF PPS system. Based on those briefings, AARC has become concerned regarding the position of respiratory therapy in the SNF PPS system. Muse & Associates was commissioned by AARC to:

1. Examine and outline the HCFA methodology regarding respiratory therapy;
2. Determine the scope and extent of respiratory care services in Medicare inpatient settings using the most recently data;
3. Determine if there are significant numbers of Medicare beneficiaries who are intense users of respiratory services; and
4. Speculate on how these intense users might be dealt with in the SNF PPS system.

The results of the analysis are summarized as follows.

How many Medicare beneficiaries who are admitted to a SNF or Inpatient Hospital setting receive respiratory therapy services and at what cost?

HCFA data show that approximately 4.2 million (33 percent) of the 13 million Medicare beneficiaries who were in a SNF or Inpatient Hospital setting in 1996 received respiratory therapy services at a cost to Medicare of \$3.2 billion.

How many Medicare beneficiaries who are admitted to a SNF received respiratory therapy services and at what cost?

HCFA data show that approximately 363 thousand (24 percent) of the 1.6 million Medicare beneficiaries who were in a SNF setting in 1996 received respiratory services at a cost to Medicare of \$386 million.

How much and in what way have Medicare respiratory therapy services grown in recent years?

Medicare received 300,320 claims and \$493 million in charges for respiratory therapy services from Medicare SNFs in 1994. By 1996, Medicare was receiving 580,940 claims and \$1.1 billion in charges from Medicare SNFs for respiratory therapy services, a growth of 280,620 claims and \$658 million in charges. In the same period, claims from Inpatient Hospitals for respiratory therapy services decreased by 531,860 and charges decreased by \$417 million. These data clearly show that hospitals were shifting beneficiaries with respiratory care needs to the SNF setting during the 1994 to 1996 period. Industry data suggest that this trend has continued.

Do certain diagnoses account for the majority of respiratory therapy payments?

The top 100 diagnoses account for 98.6 percent of all respiratory care services. The top 10 account for approximately half of all respiratory payments and the top five diagnoses account for one-third of all payments.

Did the top diagnoses differ between SNF and Inpatient Hospital settings?

No significant differences were found between SNF and Inpatient Hospital diagnoses patterns.

Were there intense users of respiratory care services?

Yes. Intense users of respiratory therapy services, defined as those with paid claims of more than \$1,000, comprised only 18 percent of all Medicare beneficiaries who received respiratory therapy services but accounted for 74 percent of all Medicare expenditures for respiratory care services.

Did the top diagnoses for intense utilizers differ between SNF and Inpatient Hospital settings?

No significant differences were found between SNF and Inpatient Hospital diagnoses patterns for the intense utilizers.

What were the differences in gender and age between Medicare beneficiaries with the top 5 diagnosis who did and did not receive respiratory therapy treatment in the SNF setting?

The data show that slightly more than half of those who used respiratory therapy services in SNFs were female. However, females consist of approximately two-thirds of all SNF patients. Conversely, 44.5 percent of respiratory therapy users are males, even though males comprise only 33 percent of the SNF population. Therefore, a higher proportion of males relative to their presence in the overall SNF population appear to use respiratory therapy services.

Users of respiratory services in SNFs also tend to be significantly younger. Only 19 percent of those who used respiratory services were over 85 years of age, whereas 33 percent of all SNF patients are over 85 years of age.

How do the length of stays and costs for the top diagnoses compare to national averages?

The average length of stay for SNF patients who receive respiratory therapy services was 22.6 days. This is significantly less than the 1996 average length of stay for all 1.6 million Medicare SNF patients of 26.2 days. Costs per day just for respiratory care services for the top ten diagnosis ranged from \$39 to \$85, with the average of all diagnosis being \$47. More importantly, the top 5 diagnoses, which ranged in cost from \$58 to \$85 per day for respiratory care only, were all diseases of the lung.