

**SUNRISE ANALYSIS
OF A PROPOSAL TO REGULATE
THE PRACTICE OF RESPIRATORY CARE**

A Report to the Legislature of the State of Hawaii

**Submitted by the
Legislative Auditor of the State of Hawaii**

**Report No. 86-10
January 1986**

TABLE OF CONTENTS

	<i>Page</i>
Introduction	1
Occupational Characteristics	2
Legislative Proposal to Regulate Respiratory Care.	9
Analysis of the Proposed Regulation.	12
Conclusion	31
Recommendation	32

SUNRISE ANALYSIS
OF A PROPOSAL TO REGULATE
THE PRACTICE OF RESPIRATORY CARE

Introduction

In 1984, the Legislature amended the Hawaii Regulatory Reform Act, or the "Sunset Law," by incorporating a "sunrise" provision requiring the Legislative Auditor to analyze proposed legislation that seeks to impose licensing or other regulatory controls on unregulated occupations.

The Legislative Auditor is required to assess the probable effects of the proposed measure and to determine whether its enactment would be consistent with state regulatory policies in the Sunset Law. These policies establish criteria for regulation such as the following:

- . Regulation is warranted only where reasonably necessary to protect the health, safety, and welfare of consumers.
- . Evidence of abuse shall be awarded great weight in determining whether regulation is desirable.
- . Regulation shall not be imposed except to protect relatively large numbers of consumers who may be at a disadvantage in choosing the provider of the service.
- . Regulation should not unreasonably restrict entry into the occupation by qualified persons.
- . The purpose of regulation is to protect the consumer and not the regulated occupation.

During the 1985 legislative session, Senate Bill No. 364 relating to respiratory care services was introduced. The bill would establish licensing requirements for

the practice of respiratory therapy.¹ Pursuant to Section 26H-6, Hawaii Revised Statutes, it was referred to the Legislative Auditor for sunrise analysis of whether its enactment would be consistent with sunset law policies.

This analysis contains some background information on the respiratory therapy occupation, an examination of the need to regulate the practice of respiratory therapy, and an assessment of the proposed legislation.

Occupational Characteristics

Respiratory therapy is one of more than 100 allied health occupations and specialties that exist in the United States today.² The purpose of respiratory therapy is to maintain, improve, and restore lung function. Respiratory therapists work under direct medical supervision to deliver health services to patients with cardiopulmonary problems. They provide oxygen therapy,³ aerosol therapy,⁴ physical therapy, and mechanical aids to lung inflation.⁵ They also conduct diagnostic tests, maintain respiratory equipment, assist in the administration of cardiopulmonary resuscitation (CPR), and educate patients about respiratory care techniques.

1. The generic term "respiratory therapy" is commonly used to describe the activities of allied health personnel who are involved in providing respiratory care services.

2. Allied health personnel complement and supplement services provided by such independent practitioners as physicians and dentists.

3. Oxygen therapy is the delivery of oxygen to restore blood oxygen to normal levels.

4. Aerosol therapy is the delivery of water droplets or fine particles of medication for deposition on the surface of the lungs.

5. Mechanical aids to lung inflation pump air into the lungs to support the ventilatory function of the respiratory system.

In 1982, approximately 46,000 persons were employed in the respiratory therapy field in the United States.⁶ In 1984, there were approximately 200 respiratory therapy personnel in Hawaii.⁷

Other allied health workers who provide some respiratory therapy services include pulmonary function technologists, medical technologists, and medical technicians. Physicians, nurses, physical therapists, and emergency ambulance technicians also deliver some respiratory therapy services.

Development of the occupation. Respiratory therapy has its origins in the therapeutic use of oxygen to treat heart disease, asthma, and opium poisoning. The occupation is relatively new and is still evolving. The need for specially trained nonmedical personnel to manage patients with respiratory problems was first recognized after World War II. In 1947, a group of physicians and oxygen technicians established the Inhalational Therapy Association [now the American Association for Respiratory Therapy (AART)] to promote higher standards and professional advancement in the field.

During the 1950s, hospital orderlies were often trained to provide oxygen therapy to respiratory patients. These services were placed under the direction of hospital nursing departments or organized as separate hospital departments. Advances in medical knowledge resulting from the treatment of polio victims, technological advances, and the establishment of the first hospital intensive care units in the late 1950s spurred the development of the field and increased the need for specially trained personnel.

6. U.S., Department of Labor, *Occupational Projections and Training Data, 1984 Edition*, Washington, D.C., May 1984, p. 31.

7. Ronald R. Sanderson, "Respiratory Therapy Personnel Survey," Honolulu, Respiratory Therapy Program, Kapiolani Community College, March 1984.

In the 1960s training standards and a certification program were developed for inhalation *therapists*. Later, concern about a shortage of therapists led to the establishment of hospital training programs and a certification program for inhalation therapy *technicians*.

It was not until the 1970s that respiratory therapy emerged as a clearly identifiable allied health occupation. In 1972, the federal government awarded a research contract to AART to delineate the roles and functions of respiratory therapy personnel, develop competency examinations, and establish a uniform mechanism for administering the examinations. In 1973, the Joint Commission on Accreditation of Hospitals (JCAH) issued the first standards requiring medical supervision of respiratory therapy services. In 1974, the National Board for Respiratory Therapy was established to administer national certification examinations for respiratory therapists and respiratory therapy technicians.

In 1977, AART issued a report delineating the roles and functions of respiratory therapy personnel which concluded that there was a need to establish a credential for respiratory therapy personnel at the entry level of practice. In 1983, the National Board for Respiratory Therapy changed its name to the National Board for Respiratory Care (NBRC), and it administered the first national certification examination for *entry-level* respiratory therapy technicians.

In 1983, NBRC also developed a national certification examination for pulmonary function technologists. Pulmonary function technologists are allied health workers who perform various tests relating to lung function. In 1985, some 30,000 workers were employed in this field.⁸ The scope of practice for pulmonary

8. National Board for Respiratory Care, *NBRC Newsletter*, Shawnee Mission, Kans., November 1985, p. 1.

function technology overlaps with respiratory therapy as both occupations perform diagnostic tests relating to lung function. However, pulmonary function technologists do not provide therapy. In 1984, the first certification examination for pulmonary function technologists was administered by NBRC.

Today, respiratory therapists provide a wide range of services to patients who are acutely or chronically ill. These services include the administration of medical gases and pulmonary medications, maintenance of airways, mechanical aids to lung inflation, chest physiotherapy, and diagnostic testing. Respiratory therapists also counsel patients and families and inspect and maintain respiratory care equipment. They must work under direct medical supervision, and they may only deliver services that have been prescribed or ordered by a physician. Respiratory therapists do not engage in independent medical practice.

AART is the major professional organization for respiratory therapists. The association serves the needs of health professionals working in the field of respiratory care. It provides members with continuing education opportunities, information about advances in the field, and a forum to discuss important issues and ideas. It also sponsors community programs to help reduce the incidence of lung disease. In 1983, AART had more than 25,000 members and 48 chartered affiliates in the United States.⁹

AART lobbies for the interests of the profession. It is the primary force behind the current drive to regulate respiratory therapists. It advocates state legal credentialing of these health workers through modification of state medical practice

9. Ray Masferrer, "History of the Inhalation Therapy-Respiratory Care Profession," in George Burton, M.D., and John Hodgkin, M.D., (eds.), *Respiratory Care: A Guide to Clinical Practice*, 2nd ed., Philadelphia, J.B. Lippincott Co., 1984, p. 9.

acts, registration or certification under a state regulatory agency or board, or licensure.

The Hawaii Society for Respiratory Care (HSRC) is a chartered affiliate of AART. It provides continuing education to members, sponsors community education programs, and promotes the interests of the occupation. In cooperation with the national association, HSRC is spearheading the drive to license respiratory therapists in Hawaii. In 1985, the organization had 75 members.¹⁰

Education and certification. Respiratory therapy technicians and respiratory therapists are trained on the job and in formal training programs approved by the Committee on Allied Health Education and Accreditation (CAHEA) of the American Medical Association. In 1977, a national survey conducted by AART found that approximately one-third of the respiratory therapy work force lacked any formal training.¹¹ In recent years, formal training has been stressed for entry into the field due to the increasing complexity of respiratory equipment.

Technician training programs last about one year and graduates are awarded certificates. Therapist training programs are between 21 months and four years. Graduates are awarded associate degrees for the shorter programs, and bachelor's degrees for the longer programs.

Both the technician and the therapist training programs include instruction in the basic sciences, clinical sciences, and respiratory care procedures. Students learn to assess patients' cardiopulmonary status, perform diagnostic tests, deliver

10. Interview with Wilfred Kouke, President, Hawaii Society for Respiratory Care, January 21, 1986.

11. Thomas DeKornfeld and Craig Scanlan, "Education of Respiratory Care Personnel," in George Burton, M.D., and John Hodgkin, M.D., (eds.), *Respiratory Care: A Guide to Clinical Practice*, p. 33.

various forms of therapy, maintain airways, and administer CPR. They are also instructed on the ethics of respiratory therapy and medical care.

Graduates of any CAHEA-approved training program who are at least 18 years old are eligible to take the "Certification Examination for Entry Level Respiratory Therapy Practitioners" which is administered by NBRC. Individuals who pass this examination are awarded the "Certified Respiratory Therapy Technician (CRTT)" credential. In 1985, there were approximately 52,000 CRTTs in the United States.¹²

NBRC also administers the "Advanced Practitioner Registry Examination" which tests knowledge and skills acquired *after* entry into practice. Applicants must be CRTTs with at least 12 months of clinical experience following graduation from a CAHEA-approved training program. CRTTs with equivalent training and experience may also take the examination. Individuals who pass this examination are awarded the "Registered Respiratory Therapist (RRT)" credential. In 1985, there were approximately 23,500 RRTs in the United States.¹³

CRTT and RRT credentials are lifelong certificates. However, NBRC has a voluntary recertification program for both groups. It strongly encourages CRTTs and RRTs to retake their respective examinations every three to five years to keep informed about technological advances. Individuals who retake and pass an NBRC examination are awarded certificates recognizing them as "recertified" practitioners.

12. National Board for Respiratory Care, *NBRC Newsletter*, Shawnee Mission, Kans., September 1985, p. 5.

13. National Board for Respiratory Care, *NBRC Newsletter*, Shawnee Mission, Kans., August 1985, p. 5.

State regulation of respiratory therapists. Only ten states have passed legislation to regulate the practice of respiratory therapy. Eight states have established licensing programs and two states have established certification programs. (We use the term "licensure" to describe programs which *prohibit* practice by uncredentialed respiratory therapists and "certification" to describe programs which grant title protection to individuals who meet certain standards but permit anyone to practice respiratory therapy.) Nine of the ten programs were established between 1983 and 1985 in response to lobbying efforts by respiratory therapists. These programs take various forms.

In 1969, Arkansas became the first state to regulate the practice of inhalation therapy. This program is currently inactive, and the state medical board merely issues temporary permits to respiratory therapy personnel who practice outside hospitals.

Currently California, New Mexico, and Texas license only entry-level technicians while Florida, Louisiana, Maine, and North Dakota license both entry-level technicians and advanced therapists. Virginia certifies entry-level technicians but allows others to practice if they do not use the title. Iowa certifies both entry-level technicians and advanced therapists.

The states use different regulatory structures to administer their programs. The Florida, Louisiana, and Virginia programs are administered by the state medical boards in consultation with advisory committees. California has an examining committee placed under the state medical board. The Iowa, New Mexico, and Texas programs are administered by the state health departments in consultation with advisory committees. Maine and North Dakota have established independent boards.

All states require respiratory therapists to practice under medical supervision. Most states require applicants to graduate from a CAHEA-approved

training program and pass written examinations that are equivalent to the NBRC examinations. Three states have adopted rules implementing their regulatory programs. The remaining states are in the process of developing their rules.

Legislative Proposal to Regulate Respiratory Care

Senate Bill No. 364 would establish an independent board to regulate the practice of respiratory care. The board would be composed of five respiratory care practitioners, one licensed physician with at least three years of experience in pulmonary medicine, and one public member. The members would be appointed by the Governor and confirmed by the Senate. They would serve without pay but be reimbursed for their expenses. The board would be placed in the Department of Commerce and Consumer Affairs (DCCA) for administrative purposes only. The intent of the bill is to prohibit the delivery of respiratory care services by incompetent persons and thereby protect the public.

The board would be authorized to issue, suspend, revoke, and renew licenses for "respiratory care practitioners." It would also be authorized to set licensing standards, contract for a national examination and set the passing score, cooperate with educational institutions in setting standards for respiratory care education programs, establish guidelines for the delivery of respiratory care services, accept and act on consumer complaints, and adopt rules. It would be required to ensure the availability of continuing education programs conducted by HSRC, hospitals, or other institutions; maintain records; and report annually to the Governor. The board would also be required to protect the confidentiality of board meetings, hearings, and investigations unless disclosure of information is necessary to protect the public.

Scope of practice. The scope of practice for respiratory care would include but not be limited to the following activities:

- . Therapeutic and diagnostic use of medical gases and administration apparatus, environmental control systems, humidification, and aerosols;
- . Administration of drugs and medications to the cardiopulmonary system;
- . Ventilatory support, including the maintenance and management of life support systems;
- . Bronchopulmonary drainage and breathing exercises;
- . Respiratory rehabilitation;
- . Assistance with cardiopulmonary resuscitation;
- . Maintenance of natural airways, including the insertion of, and maintenance of artificial airways; and
- . Specific testing techniques to assist in diagnosis, monitoring, treatment, and research including:
 - Measurement of ventilatory volumes, pressures, and flows;
 - Specimen collection and analysis of blood for gas transport and acid/base determinations;
 - Pulmonary function testing; and
 - Other related physiologic monitorings of the cardiopulmonary system.

Unless otherwise authorized by law, it would be unlawful for anyone to practice respiratory care without a license except for the following persons:

- . Nurses who practice in the absence of a respiratory care practitioner when care is ordered and supervised by a physician;
- . Students who practice under the supervision of a respiratory care practitioner in an education program approved by the board;
- . Family members and friends who deliver respiratory care services in the home after instruction by a physician or respiratory care practitioner; and
- . Persons who deliver respiratory care in an emergency.

Medical supervision and control. Respiratory care practitioners would be required to practice under the supervision and control of licensed physicians who assume legal liability for services rendered under their orders. They would also be required to render services in accordance with protocols established by hospitals, other licensed health care providers, or the board. It would be unlawful for anyone to offer or sell respiratory care services not rendered under the direction and control of a physician. Persons who assist respiratory care practitioners would be required to do so under the direct supervision of the respiratory care practitioner.

Licensing standards. In order to qualify for a respiratory care practitioner license, applicants would be required to complete a CAHEA-approved training program or its equivalent. They would also be required to pass a national examination and meet other education, experience, and employment standards set by the board.

The board would be authorized to license applicants who had passed the national certification examination provided they were not absent from practice for more than one year. Licensed applicants from other states that meet Hawaii's requirements would be licensed provided that they were not absent from practice for more than one year.

In order to renew their licenses, respiratory care practitioners would be required to complete continuing education programs approved by the board.

Temporary licenses. Applicants who are eligible to take the board examination would be permitted to practice under the supervision of a respiratory care practitioner on a temporary basis while waiting to take their first examination. If they fail the examination, they could continue to practice if they are recommended by their supervisor and retake the next available examination.

Failure to obtain a favorable recommendation would result in withdrawal of permission to practice.

Failure to pass the examination after three attempts would disqualify applicants from taking any further examinations for 18 months. In order to become eligible to take another examination, applicants would have to complete additional education and obtain recommendations from their supervisor and medical director.

Grandfather provisions. Anyone who had practiced respiratory care in Hawaii after July 1, 1980, would be eligible for licensing provided that the following requirements were met:

- . Complete an application meeting qualifications determined by the board;
- . Demonstrate practice that is consistent with professional behavior and standards determined by the board; and
- . Furnish three recommendations from health care professionals including at least one physician.

Disciplinary program. The board would be authorized to revoke or suspend licenses for the following causes: rendering services without direct medical supervision; rendering services without appropriate training; incompetency; unprofessional behavior; misrepresentation or fraud in filling out license applications; and violating the provisions of the licensing law.

The board would also be authorized to impose fines for unlicensed activity or for violations of the licensing law.

Analysis of the Proposed Legislation

Summary of findings. Our analysis of Senate Bill No. 364 is based on criteria in the Sunset Law. We find that regulation of respiratory therapists is not

warranted because it does not comply with state regulatory policies in the Sunset Law. In summary, our findings are:

1. Regulation of respiratory therapists is not reasonably necessary to protect the health, safety, and welfare of consumers.

2. Licensing of respiratory therapists would increase the cost of health care, reduce the flexibility of health care providers to utilize qualified personnel in delivering health care services, and have other adverse consequences including the restriction of entry into the occupation.

3. There are numerous problems with Senate Bill No. 364 including its broad powers, the lack of clarity on the level of practice to be regulated, restrictive or unnecessary provisions, and an inadequate disciplinary program.

Potential for harm to consumers. There is a potential for harm to consumers in the practice of respiratory therapy. Improper use of respiratory equipment can endanger a patient's health and safety, and certain respiratory care procedures can lead to cardiac arrest. However, this potential for harm is *remote* because respiratory therapists work under direct medical supervision and are employed by knowledgeable health care providers.

Respiratory therapists work under direct medical supervision. Respiratory therapists are not independent health care practitioners, and insurance companies generally do not reimburse directly for their professional services. Section 453-5.3(a) of the medical practice act requires respiratory therapists to work under the direction of a physician. The bylaws of AART, and standards published by JCAH, also state that respiratory therapists must work under competent medical supervision. Senate Bill No. 364 recognizes the dependent status of these health workers by providing that they would work under the supervision and control of licensed physicians.

Under the current system of health care delivery, the physician is the primary contractor and most other health care practitioners function as assistants or "legal servants" of the physician (or as employees of hospitals or other health care providers). When a physician accepts a patient, a professional relationship is created in which the physician accepts the responsibility for rendering due care. This professional relationship is governed by the law of tort, and a physician must use "reasonable skill and care" in providing services to patients.¹⁴

If there is an employer–employee relationship between the physician and a respiratory therapist, the physician is generally liable for the actions of the therapist under the legal doctrine of *respondeat superior*. This doctrine holds that the employer is responsible for all damages caused by the employee if it can be demonstrated that the employee acted within the scope of employment, that the employee was negligent, and that this negligence was the proximate cause of injury.¹⁵

If a respiratory therapist is employed by a hospital, the physician may still be liable for damages under the doctrine of the "borrowed servant." This doctrine holds that a physician who fully controls the activities of hospital employees is responsible for their actions. For example, the courts have found that a surgeon in the operating room has the right to control hospital employees in the performance of their duties and is thus liable for any injury caused by these employees.¹⁶

14. Thomas DeKornfeld, "Legal Implications of Respiratory Care," in George Burton, M.D., and John Hodgkin, M.D., (eds.), *Respiratory Care: A Guide to Clinical Practice*, p. 93.

15. *Ibid.*, p. 99.

16. *Ibid.*, p. 100.

Respiratory therapists who knowingly provide services that are outside the scope of usual and customary practice, even though these services are ordered by a physician, may be held liable for any injury to a patient. Respiratory therapists have a duty to contact physicians and seek clarification or correction of unusual orders.

Respiratory therapists are employed by knowledgeable health care providers. Respiratory therapists are employed by sophisticated and knowledgeable consumers including hospitals, home health agencies, and durable medical equipment companies. These employers are responsible for establishing and maintaining personnel standards for the protection of patients. Under the doctrine of *respondeat superior*, they may be held liable for the negligent actions of their employees. Most of these employers are regulated by federal and state law or private accreditation programs.

Most respiratory therapists work for hospitals. Ninety-one percent of all respiratory therapists are employed by hospitals that must conform with JCAH standards for respiratory care services in order to qualify for federal reimbursement. These standards apply to inpatient, outpatient, and home care services provided by hospitals. All services provided outside the hospital must be approved by the medical staff and conform with JCAH standards designed to ensure patient safety.

Respiratory care services must be under the medical direction of a physician member of the active medical staff who has special interest and knowledge in the diagnosis, treatment, and assessment of respiratory problems. Respiratory care personnel may only provide services that are commensurate with their documented training, experience, and competence. New personnel must receive an orientation of sufficient duration and content to prepare them for their role in respiratory

care. The standards do *not* require respiratory therapists to be nationally certified or licensed in order to practice.

Respiratory care services may only be delivered in accordance with a written prescription from the responsible physician, and these services must be documented in the patient's medical record. The standards include detailed guidelines on how prescriptions should be written and documentation maintained.

Nonphysician respiratory care personnel who perform patient care procedures associated with a potential hazard, including arterial puncture for obtaining blood samples, must be authorized to do so in writing by the medical director in accordance with medical staff policy. JCAH has also issued standards for intensive care units which cover all hospital personnel working in these units.

Respiratory therapists testified in support of Senate Bill No. 364 citing the potential for harm to patients receiving hospital respiratory care services. The example given was of a nurse who had incorrectly adjusted the controls on a hospital ventilator. The patient's condition worsened until a respiratory therapist recognized the error and changed the settings. The patient recovered with no lasting damage. However, the nurse's error would not have been prevented by the proposed licensing bill since nurses would continue to be authorized to practice.

Respiratory therapists also testified that a licensing program is needed so that hospitals could verify credentials in a timely manner, save money, and promote patient safety. They cited several incidents where respiratory therapists were hired by hospitals on the basis of false or fraudulent information on job applications. The activities of these personnel could have endangered patient health and safety.

Hospitals are responsible for verifying the credentials of applicants *before* they are hired or put to work in patient care. This is relatively easy to do. For example, NBRC will answer inquiries from employers and verify credentials over the

phone. If there are any questions about the credentials, the employers are asked to send copies of the applicant's documentation to the national office.¹⁷ NBRC also publishes an annual directory that lists the names of all CRTTs and RRTs. Information on college credentials can be verified by contacting the colleges directly. In one of the cases cited, the employer admitted that an applicant was hired even though the college could not verify the applicant's degree.

We conclude that JCAH standards for hospital respiratory care services and intensive care units adequately protect patients receiving care delivered by hospitals. The problem of falsified credentials is one that can and should be dealt with by hospitals, and it does not justify the imposition of state regulation on the occupation.

Respiratory therapists employed by home health agencies. A small but increasing number of respiratory therapists are employed by home health agencies that provide part-time or intermittent skilled nursing services and other therapeutic services to patients. Patients who receive home health services do not require acute or intensive care. They are generally recovering from an illness or they suffer from chronic conditions that require some medical supervision.

The Medicare program does not reimburse directly for the professional services of respiratory therapists. However, some home health agencies employ respiratory therapists and build this cost into their administrative overhead. It is expected that the number of home health agency patients requiring respiratory care services will grow in the future due to the early discharge of patients under the new Medicare hospital prospective payment system.

17. Interview with Jody Burns, National Board for Respiratory Care, Shawnee Mission, Kans., January 7, 1986.

Home health agencies must comply with numerous federal regulations in order to participate in the Medicare program. They must have a governing board that assumes full legal authority and responsibility for agency operations. All services must be provided under the supervision and direction of a physician or registered nurse. Drugs and treatment may only be administered by agency staff upon a physician's order.

All care provided by a home health agency must be governed by written policies established by a group of professionals that includes at least one physician and one registered nurse. The care must follow a written plan of treatment that is established and periodically reviewed by a physician. All care must continue under the supervision of a physician.

Agencies must have written policies covering their organization, services, administrative controls, and lines of authority for the delegation of responsibility down to the patient care level. Proprietary (for-profit) home health agencies must be licensed under state law. In addition, all home health agencies must meet state licensing standards, whether or not they are covered by a particular state licensing law.

In Hawaii, home health agencies are licensed by the Department of Health (DOH). DOH rules define a home health agency as one that provides "direct or indirect skilled nursing services and other therapeutic services under a physician's direction to homebound patients on a part-time or intermittent basis."¹⁸ It is unlawful for any person to conduct, maintain, or operate a home health agency without a license. It is also unlawful for anyone to participate in the activities of an

18. Section 11-97-1, Hawaii Administrative Rules.

unlicensed home health agency. Violators may be fined \$500 or imprisoned for not more than one year or both.

DOH rules state that treatment plans must be established and regularly reviewed by a physician. The total treatment plan must be reviewed at least every two months, and the plan can only be altered or terminated upon a written order from a physician.

The rules require home health agencies to establish an advisory committee to set policies for nursing and other therapeutic services. The advisory committee must also establish the qualifications of all staff, including therapists. The rules set minimum standards for the following home health agency personnel: home health aide, licensed practical nurse, medical social worker, occupational therapist and occupational therapy assistant, physical therapist and physical therapy assistant, physician, public health nurse, registered nurse, and speech therapist. They do *not* set any minimum standards for respiratory therapists.

Respiratory therapists testified that patients could be harmed by the activities of unqualified respiratory therapists hired by home health agencies. They also expressed concern that home health agencies are not required to verify the credentials of respiratory therapists.

They cited one case where an exercise instructor changed the setting on a mechanical ventilator and created a life-threatening situation in the home. The patient was transferred to a backup machine and recovered. The incident would not have been prevented by licensing as the exercise instructor was not acting as a respiratory therapist hired by a home health agency.

It is the responsibility of DOH to set standards for home health agency personnel where needed, and concerns about home health agency services should be directed to DOH.

Respiratory therapists employed by durable medical equipment companies.

A very small number of respiratory therapists are employed by durable medical equipment companies that rent or sell respiratory equipment to patients upon a physician's prescription. The major activity of these companies is the rental and sale of oxygen and related equipment. All medical devices, including respiratory equipment, are regulated by the federal government.

Patients who use respiratory equipment in the home are generally recovering from an illness or they suffer from chronic conditions. They are under the care of a physician, and they may also be receiving services from a home health agency.

Respiratory therapists employed by durable medical equipment companies are generally responsible to install the equipment, instruct patients on its use, and monitor the equipment's use by patients. They do not provide the actual treatment, and they do not deliver any therapeutic services to patients at home. Although respiratory therapists do not provide professional services to patients in the home, some may take an active role in promoting patient welfare by counseling them on the use of equipment and contacting their physicians when problems arise.

Patients using respiratory equipment in the home may qualify for benefits under the Medicare program. However, these benefits do not include payment for the professional services of a respiratory therapist. Durable medical equipment companies that employ respiratory therapists must build this cost into equipment rental charges or administrative overhead. Although there is no financial incentive for the companies to hire respiratory therapists, most health care providers will not refer patients to companies that do not have qualified respiratory therapists on staff.

Respiratory therapists have expressed concern that durable medical equipment companies may hire unqualified personnel to handle respiratory equipment in the home. These personnel may give patients the impression that they are

knowledgeable practitioners. Patient health and safety could be endangered by the activities of unqualified staff.

Testimony supporting Senate Bill No. 364 cited two incidents in which patients' health and safety were endangered by personnel employed by durable medical equipment companies. In the first case, a patient was sent home from the hospital with a prescription for oxygen to be delivered by a "nasal cannula." The oxygen vendor changed the equipment to an oxygen mask after the patient complained about discomfort with the cannula system. This was done without consulting the patient's physician. The patient began to experience headaches and went in for laboratory tests where the problem was discovered and corrected. Since there was no medical supervision of the vendor's actions, there may have been a violation of the State's medical practice act which requires respiratory therapy services to be delivered under direct medical supervision.

In the second case, a mechanical ventilator patient was being prepared for hospital discharge and transport to Guam. The hospital nursing staff was working with a durable medical equipment company to plan the discharge and transport. A respiratory therapist was not called in for consultation until one hour before departure time. At this point, it was noted that some major changes had to be made in the life-support equipment for use on the aircraft. In this case, the hospital's discharge planning process was at fault for not calling in the respiratory therapist earlier. However, the patient suffered no actual harm.

Durable medical equipment companies are not currently regulated by the State. However, the companies are responsible for the actions of their employees under the doctrine of *respondeat superior*. The problem of unscrupulous companies hiring unqualified staff will not be solved by requiring respiratory

therapists to be licensed, since these companies still would not be required to hire respiratory therapists.

If the Legislature is concerned about this sector of the health care marketplace, a more relevant solution would be to require DOH to set standards for the operation of durable medical equipment companies. In addition, it might consider asking DOH or the state medical board to clarify the conditions under which personnel employed by durable medical equipment companies can provide respiratory care services in the home.

Care of mechanical ventilator patients. In recent years, the development of new medical technology has permitted hospitals to discharge patients on mechanical ventilators. There is widespread controversy about whether mechanical ventilator patients should be allowed to go home at all, and there are currently no national standards for the care of such patients in the home. Medicare handles these cases on an individual basis, and in 1984 only 160 patients *nationally* had been granted a waiver to go home.¹⁹

Respiratory therapists have expressed concern about the health and safety of these mechanical ventilator patients. They state that the absence of a licensing program for respiratory therapists may mean that unqualified personnel will provide professional services to these patients. However, no incidents of harm to homebound mechanical ventilator patients receiving professional services were reported.

Hospitals routinely orient these patients and their families to the equipment that will be used in the home *before* they are discharged. Discharge planning

19. "Respirator Patient Wants to go Home Where Costs are Lower," *Honolulu Star-Bulletin*, August 24, 1984.

involves hospital personnel, including respiratory therapists, as well as personnel from home health agencies and representatives of durable medical equipment companies supplying the equipment. These patients are under medical supervision at home, and they usually receive care from home health agencies after they are discharged.

The new and evolving field of home care for mechanical ventilator patients does not justify the establishment of a licensing program governing all respiratory therapy services. It would be more appropriate at this time for hospitals to develop standards for discharge and follow-up on these patients.

Increased cost of health care and other adverse consequences. Licensing increases the cost of health care by restricting the supply of health workers. It has also been found that health workers in states with restrictive licensing standards have higher earnings than those practicing in states with liberal licensing standards. For example, one study found that medical technologists in states with restrictive licensing standards earned 13 percent more than workers in states with more liberal licensing standards.²⁰

A loss of geographic mobility also results when health occupations are licensed. States may use different entrance requirements which inhibit movement from state to state despite the fact that most health occupations have national standards of practice. Restrictions on geographic mobility could create or aggravate shortages of health care personnel in the licensed occupations despite the availability of qualified personnel. This is of concern in the field of respiratory therapy which has experienced shortages in recent years.

20. Gary Gaumer, "Regulating Health Professionals: A Review of the Empirical Literature," *Milbank Memorial Fund Quarterly/Health and Science*, v. 62, no. 3, 1984, p. 387.

Licensing programs may also restrict health workers from moving into related occupations, thereby preventing the most efficient utilization of health personnel. Qualified technicians who are trained to perform specific tasks may be prevented from working because they cannot meet entry-level standards for a broader occupational field. For example, a technician who is trained to provide oxygen therapy using a new technology would not be permitted to practice if the technician did not meet all of the entrance requirements for licensure as a respiratory therapy technician.

Scope of practice definitions in licensing laws are difficult to change once they have been enacted. If they are too narrowly worded, they can restrict innovation and have a negative impact on occupations that are involved with rapidly changing medical technology. If they are too broadly worded, they may overlap with the activities of other health occupations.

The federal government's concern about health care costs and skepticism about the value of state regulation in protecting the public have led it to loosen requirements that health care personnel be licensed in order to receive reimbursement for their services. In 1982, the U.S. Office of Management and Budget issued a policy stating that the federal government will rely on *voluntary* standards for credentialing health manpower whenever feasible and consistent with the law.²¹

In March 1983, Congress established a new Medicare hospital prospective payment system which will be fully implemented in 1987. Under this system, Medicare will no longer reimburse hospitals for any reasonable cost of care.

21. Sybil Goldman and W. David Helms, *The Regulation of the Health Professions*, Bethesda, Md., Alpha Center, October 1983, p. 18.

Instead, Medicare will pay hospitals a fixed price for treating each admission in 470 separate diagnostic related groups of patients. This new approach to reimbursement is fundamentally changing the way hospitals are run. For example, ancillary service departments, such as respiratory therapy, are no longer valued as hospital revenue-producing centers.

In 1983, a spokesman for the American Hospital Association stated that as hospital resources are increasingly restricted, the effective deployment of personnel must be of major concern. He also stated that credentialism is perhaps the most restrictive limitation on hospital flexibility since 60 percent of hospital expenses consist of salaries and wages.²²

Enactment of the hospital prospective payment system has caused hospitals to reassess their support for state regulation of health workers. State regulation, especially licensing, is seen as increasing the cost of health care, reducing the flexibility of hospitals to employ the most qualified personnel at the least cost, and restricting innovation in health care delivery.

In 1984, a senior staff specialist for the American Hospital Association urged the establishment of viable *alternatives* to state legal credentialing which would permit hospitals to use multicompetent technicians in the delivery of health care services.²³ In addition, hospitals have begun to experiment with collapsing two or more jobs under one job title in an effort to "broadband" jobs and achieve more

22. "Will Credentialing Survive in New Competitive Environment?," *Reports: The Newsletter of the National Commission for Health Certifying Agencies*, v. 4, no. 2, Fall 1983, p. 11.

23. "Pay for Performance, Multicompetent Personnel Seen as Hospital Trends," *Reports: The Newsletter of the National Commission for Health Certifying Agencies*, v. 5, no. 1, Spring 1984, p. 5.

employee productivity. Licensing would impede hospital efforts to control costs by restricting their ability to utilize the most qualified personnel in a cost-effective manner.

JCAH is also in the process of revising its standards to remove requirements for state legal credentialing of hospital employees in favor of in-hospital credentialing programs. These in-house programs are viewed as an effective alternative to state legal credentialing. They also provide hospitals with more flexibility to achieve their goals of quality care at a reasonable cost.

In 1984, the Associate Executive Director of the National Association for Health Certifying Agencies summarized the current trend away from support for state regulation of health occupations as follows:

"Along with both conservative and liberal commentators in the United States, the Commission is inclined to be skeptical about the value of state regulation of health professions. State, or federal, regulation is seen as generally serving the interests of the regulated profession more than the interests of the public. It is also regarded as expensive, inhibitive of mobility, and subjective as a result of political influence."²⁴

Licensing respiratory therapists may establish a precedent for state regulation of other allied health occupations. There are more than 100 allied health occupations (and 250 secondary or alternate job titles) in the United States today.²⁵ In 1978, it was estimated that two-thirds of the total health care work force, or 3.5 million workers, were allied health personnel.²⁶ At that time,

24. Neil Weisfeld, "The National Commission for Health Certifying Agencies: An Introduction," *Health Policy*, v. 4, 1984, p. 70.

25. U.S., Bureau of Health Manpower, *A Report on Allied Health Personnel; Prepared for the Committee on Interstate and Foreign Commerce, House of Representatives*, DHEW Publication No. (HRA) 80-28, Washington, D.C., 1980, p. II-3.

26. *Ibid.*, p. I-1.

14 health occupations were regulated by at least one state.²⁷ In 1983, 44 different health occupations were regulated by at least one state.²⁸ In Hawaii, approximately 26 health occupations are currently regulated.

Many allied health occupations, such as kidney dialysis technicians and pulmonary function technologists, are currently unregulated in Hawaii. These health workers may practice under the provisions of Section 453-5.3 of the medical practice act. This law permits health personnel who are trained to perform a limited number of health care procedures to practice under the direction of a physician.

Members of unregulated health occupations are experiencing intense competition as the Medicare hospital prospective payment system is put into place. Hospital experimentation with the use of health care personnel may lead to an erosion of the boundaries between allied health occupations, and some allied health workers view licensing as a means to prevent encroachment upon their domain.

Another reason unregulated health workers seek licensing protection is their belief that licensure will pave the way for direct reimbursement of their services by health care insurers. However, licensure does not assure direct payment of benefits by health care insurers. For example, the Hawaii Medical Service Association states that coverage decisions should be based on need and market demand, and licensing has no bearing on whether a practitioner's services will be covered in its health plans.²⁹

27. Goldman and Helms, *The Regulation of the Health Professions*, p. 10.

28. *Ibid.*

29. Letter from Eugene Fujii, Contracts and Legal Liaison Administrator, Hawaii Medical Service Association, to Office of the Legislative Auditor, January 13, 1986.

If respiratory therapists were to achieve licensing, other health occupations that are currently unregulated in the State might seek similar recognition. This would reduce the flexibility of health care providers to utilize the most qualified personnel in a cost-effective manner. It would also increase the cost of health care.

Licensing costs may be restrictive. Given the small number of respiratory therapists in Hawaii, licensing fees may be prohibitive and restrict entry into the occupation. Act 92, SLH 1980, requires the Director of DCCA to maintain a reasonable relationship between licensing fees and the cost or value of services rendered. These costs include the operational costs of a board and apportioned costs for DCCA staff services, including its Regulated Industries Complaints Office, hearings office, administrative services, and the director's office, central services, and apportioned costs of the Department of the Attorney General.

Licensing fees are generally higher for regulatory programs with fewer licensees as the costs are spread among only a few members. Applicants in some of the smaller regulatory programs pay as much as \$100 for the application fee, \$100 for the examination fee, another \$100 for the original license fee, and \$150 for the biennial license renewal. These expenses may be prohibitive for certain applicants and may also discriminate against minorities and lower income individuals.

Deficiencies in Senate Bill No. 364. The proposed legislation is deficient in a number of respects. The regulatory structure would be unwieldy, the scope of practice encroaches on and restricts the activities of other health personnel, licensing standards are vague, and other provisions are restrictive or unnecessary.

Should the Legislature determine that regulation is needed, the bill should be revised to correct the aforementioned problems and to conform the bill with other occupational licensing statutes. Some of the more important considerations include the following:

- . Instead of an independent board which would entail additional costs and fragment the State's approach to regulating health care personnel, the regulatory program should be placed under the medical board with assistance from a respiratory therapy advisory committee.
- . Under the bill, the board would be authorized to establish standards for approving training programs and protocols (guidelines) for the delivery of care. These powers are unnecessary as both training and care are subject to national standards.
- . The board would be authorized to accept and act on consumer complaints and to investigate and hold hearings on these complaints. These powers would conflict with Act 204, SLH 1982, which requires all boards and commissions to delegate to DCCA their powers to receive and investigate complaints.
- . The board's authorization to set licensing fees would also conflict with Act 92, SLH 1980, which requires the Director of DCCA to maintain a reasonable relationship between licensing fees and the cost of services rendered.
- . The scope of practice for respiratory care practitioners would need to be clarified and more sharply defined, because under the bill, the proposed scope encroaches on services provided by other allied health personnel. For example, one of the activities enumerated in the scope of practice is pulmonary function testing. This activity is currently performed by unregulated personnel known as pulmonary function technologists. These health workers could be prevented from practicing unless they qualify for a respiratory care practitioner's license.

- . The bill would require respiratory care practitioners to directly supervise those who assist them in their work. This could place other licensed health workers, such as nurses, under respiratory care practitioners even though they are qualified and authorized to perform respiratory care procedures. It could also interfere with the physician's responsibility to direct and supervise respiratory care services. And, it could reduce the flexibility of health care providers to utilize personnel in the most cost-effective manner. This provision should be removed.
- . Friends and family members would be allowed to provide respiratory care services only *after* they have received instruction from physicians or respiratory care practitioners. Given the broad scope of practice for respiratory therapists, this provision could prevent family members from administering domestic remedies such as the use of humidifiers. This provision should be removed as it also conflicts with Section 453-2, HRS, which specifically exempts the domestic administration of home remedies from the practice of medicine.
- . Currently, there are two nationally recognized levels of practice: entry level "respiratory therapy technicians" or advanced "respiratory therapists." It is not clear from the scope of practice or the standards what level of care the bill proposes to license. The standards should clearly designate that the NBRC entry-level examination will be used to license entry-level technicians.
- . The requirement for applicants to take an unspecified number of hours of continuing education in order to renew their license should be deleted as NBRC does not impose any continuing education requirements on CRTTs and RRTs.

- . The requirement for applicants who are nationally-certified or licensed in another state to have been in active practice in order to qualify for a Hawaii license is overly restrictive and should be removed since national certification and licenses are lifelong credentials.
- . Standards for the board to issue licenses to persons who have practiced respiratory therapy in Hawaii since July 1, 1980, are vague and would be difficult to implement. They require applicants to meet qualifications determined by the board, have practiced in accordance with professional behavior standards determined by the board, and submit recommendations from three health professionals including at least one physician. These licensing standards should be clarified.
- . Disciplinary provisions would not provide adequate grounds for disciplining respiratory therapists or a sufficient range of sanctions that may be taken against licensees. It should be made to conform with disciplinary provisions in the medical practice act.

Conclusion

Licensing is an exclusionary measure that places restraints on the freedom of individuals to pursue their professions. Unless there is clear evidence that it is needed to protect public health, safety, and welfare, licensure should not be imposed.

The potential for harm to patients from the practice of respiratory therapists is remote because they do not practice independently. They may only provide care upon a physician's order and they must work under the direct supervision of physicians. In addition, they are employed by knowledgeable health care providers.

Ninety-one percent of all respiratory therapists work for hospitals which are closely regulated by the Joint Commission on Accreditation of Hospitals. A small

but increasing number of respiratory therapists work for home health agencies which must comply with federal Medicare regulations and Department of Health licensing standards. A few respiratory therapists work for durable medical equipment companies which are unregulated. However, these respiratory therapists do not provide any actual therapy in the home. They are merely responsible to install and maintain equipment and monitor the use of equipment.

It is commonly acknowledged that licensing of health occupations increases the cost of health care, reduces the flexibility of health care providers to utilize the most qualified personnel in a cost-effective manner, and reduces the mobility of health care workers. These adverse consequences dictate against the imposition of licensing requirements on new health occupations. Private national credentialing programs, such as the certification program for respiratory therapy technicians operated by the National Board for Respiratory Care, provide adequate indicators of the competency of health care practitioners.

We conclude from our analysis that regulation of respiratory therapists does not meet the criteria set forth in the Sunset Law.

Recommendation

We recommend that Senate Bill No. 364 not be enacted.