REPORT OF THE
BOARDS OF HEALTH PROFESSIONS
AND HEALTH ON

NEED TO REGULATE OUTPATIENT CARDIOVASCULAR AND PULMONARY REHABILITATION FACILITIES IN THE COMMONWEALTH OF VIRGINIA

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 25

COMMONWEALTH OF VIRGINIA
RICHMOND
1995

COMMONWEALTH of VIRGINIA

Office of the Governor

George Allen
Governor

Kay Coles James
Secretary of Health and Human Resources

January 6, 1995

TO: The Honorable George Allen

and

The General Assembly of Virginia

This report contained herein is pursuant to House Joint Resolution 223, agreed to by the 1994 General Assembly.

This report constitutes the response of the Boards of Health Professions and Health that they be requested to study the need for regulation of cardiovascular and pulmonary rehabilitation programs.

Respectfully Submitted,

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1994 SESSION

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HOUSE JOINT RESOLUTION NO. 223

Offered January 25, 1994

Requesting the Boards of Health and Health Professions to study the need for regulation of cardiovascular and pulmonary rehabilitation programs.

Patron—Davies

Referred to Committee on Health, Welfare and Institutions

WHEREAS, heart and lung diseases and disorders are among the most prevalent causes of disability and death in the United States; and

WHEREAS, as health care costs have soared, the health care community has sought ways to contain costs; and

WHEREAS, one popular and efficient means of containing costs is to provide, on an outpatient basis, care which has traditionally been delivered only on an inpatient basis; and

WHEREAS, outpatient care for individuals with cardiopulmonary illnesses has become a feasible alternative for many patients; and

WHEREAS, one disadvantage of these outpatient facilities is the lack of accountability, because such facilities are not required to be licensed or accredited as are hospitals and other health care facilities; and

WHEREAS, the lack of standards can lead to a reduction in the quality of the health care; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Boards of Health and Health Professions be requested to study the need for regulation of cardiovascular and pulmonary rehabilitation programs. The Boards are requested to avail themselves of the expertise of other state agencies and to consult private physicians and other health care providers as necessary.

All agencies of the Commonwealth shall provide assistance to the Boards, upon request.

The Boards shall complete their work in time to submit their findings and recommendations to the Governor and the 1995 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for processing legislative documents

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November 1994

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Executive Summary

House Joint Resolution 223 of the 1994 General Assembly called for the Board of Health Professions and the Board of Health to study the need to regulate outpatient programs for cardiovascular and pulmonary rehabilitation.

The Boards reviewed the professional literature, current regulations in other states, consumer complaint informational sources, and public comment. The fundamental criterion employed by the Boards was the risk for harm to the consumer resulting from the unregulated practices of these programs. In assessing public risk, the Boards considered the characteristics of the clients served, the setting and supervisory arrangements for the delivery of the health service, as well as combinations of these factors. Further, the study revealed that:

- National voluntary accreditation standards for the facilities will become available soon -- the American Association of Cardiovascular and Pulmonary Rehabilitation is devising guidelines which are to be published in October 1994 and the Commission of Rehabilitation Accreditation is revising its outpatient standards to encompass some pulmonary rehabilitation facilities as of July 1, 1995;

- Voluntary standards and third-party payors also currently require licensure of the health care providers of these rehabilitation programs, thus, the public has regulatory recourse against unprofessional conduct of the licensees through the respective licensing boards;

- Nationally recognized specialization certification for health care providers in the facilities currently exists as a further safeguard for the public; and

- The sole rationale for other states which regulate these programs is their failure to receive third-party payor reimbursement without state regulation. This problem does not exist in Virginia.

The results of the study revealed no evidence of risk to the public which could not be remedied more readily through currently existing means. There is no justification for state regulation of outpatient cardiovascular and pulmonary rehabilitation facilities.

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Background

HJR 223 requested that the Board of Health Professions and the Board of Health review the need to regulate outpatient cardiovascular and pulmonary rehabilitation programs.

The workplan devised for the study included: (1) a review of the literature on freestanding treatment centers and outpatient services; (2) a review of regulations in other states; (3) a review of accreditation standards for inpatient services; (4) a review of relevant complaints received by state agencies and of malpractice claims and settlements, as well as (5) a public hearing and solicitation of written comments.

Results

I. Literature Review: No literature focusing solely on the *regulation* of cardiovascular and pulmonary freestanding or hospital based rehabilitation programs was discovered. The bulk of the literature that was relevant to cardiovascular and pulmonary rehabilitation primarily centered around the risks and benefits of cardiovascular rehabilitation rather than pulmonary rehabilitation. Further, the public debate centers predominantly around the cardiovascular issue, therefore, this report will primarily concentrate on information pertinent to cardiovascular rehabilitation facilities. However, a review of the available literature revealed a number of discussion themes centering around the general mental and physical components of cardiovascular and pulmonary rehabilitation and the safety and effectiveness of each.

Cardiovascular rehabilitation (CR) programs have gradually evolved since the late 1940's when the benefits of mobilization after a heart attack (as opposed to strict bed rest) were first proposed. A plethora of research has emerged since that time which documents the relative safety and benefits of CR (see Consolvo, 1990; Leon, Certo, Comoss, Franklin, Froelicher, Haskell, Hellerstein, Marley, Pollock, Ries, Sivarajan, & Smith, 1990; Van Camp, 1991). CR has emerged as an entire field of specialization across professions (e.g. physicians, nurses, physical therapists, occupational therapists).

Coinciding with the movement to mobilize the cardiac patients was a move to contain health care costs by reducing the length of hospital stay. In the 1960's, it was not uncommon for the typical cardiac patient to be hospitalized for 3 weeks or longer. That time has been reduced to an average stay of one week inpatient with follow-up outpatient rehabilitation extending typically from 6 months to a year. Outpatient CR programs began to appear as early as the mid-1960s (Pashkow, 1993; Smith, 1990). Currently 60 cardiac or cardiopulmonary rehabilitation programs exist in Virginia (Virginia Association of Cardiovascular and Pulmonary Rehabilitation). With the exception of one, all of the outpatient programs are housed within a hospital or physician's office.

The net result of these scientific and social factors has been the development of a system

of cardiac (also termed "cardiovascular") rehabilitation today that is described as follows:

> **"[T]he process by which the person with cardiovascular disease, including but not limited to patients with coronary heart disease, is restored to and maintained at his or her optimal physiological, psychological, social, vocational, and emotional status. Intervention is usually prescribed based on four individual treatment phases. Phase I is the hospital inpatient period immediately following the cardiac event or cardiac surgery. It is designed to reduce the deconditioning of prolonged bedrest. Phase II is ideally initiated within three weeks of hospital discharge and includes medically supervised exercise therapy that may involve electrocardiographic monitoring. Phase III and Phase IV are extended outpatient and exercise maintenance stages. These maintenance stages begin when the desired outcome from the exercise therapy in Phase II has been achieved and physiological and cardiovascular responses to exercise have stabilized. (American Association of Cardiovascular & Pulmonary Rehabilitation, 1991).**

As the current system of cardiac rehabilitation has evolved, so, too, has pulmonary rehabilitation (PR).

Chronic obstructive pulmonary diseases (COPDs) such as chronic bronchitis, emphysema, and pneumonia, as a group, constitute a major cause of death and disability and have increased in prevalence dramatically in the 20th century. In the 1980's, COPDs constituted the 5th leading cause of death in the United States. They have been cited as the 3rd leading contributor to death in men aged 55 to 74 and the 5th leading cause in women in the same age group (Ries, 1990).

The application of comprehensive PR programs for patients with COPDs has been demonstrated to reduce health care costs associated with these diseases primarily by decreasing hospitalization days and use of medical resources. Other documented benefits of pulmonary rehabilitation were reduced respiratory symptoms, increased exercise tolerance and level of physical activity, greater independence, and overall improvement in the quality of life resulting from successful pulmonary rehabilitation (Ries, 1991).

As with cardiac rehabilitation, the field has become a specialization area for several disciplines because diagnosis and treatment entail a multidisciplinary approach. The currently accepted definition contends that PR is:

> **An art of medical practice wherein an individually tailored, multidisciplinary program is formulated which through accurate diagnosis, therapy, emotional support, and education, stabilizes or reverses both the**

physio- and psychopathology of pulmonary diseases and attempts to return the patient to the highest possible functional capacity allowed by his or her pulmonary handicap and overall life situation. (Ries, 1990).

The current state of service delivery provides for facilities which specialize in CR and those which also provide for PR almost exclusively based in a hospital or physician's office.

II. Regulation in Other States: Massachusetts, North Carolina, and South Carolina currently regulate outpatient cardiac rehabilitation programs. North Carolina was the first to do so during the late 1970's and the other states patterned their legislation after the North Carolina model.

During the 1970's and into the 1980's no uniformly acceptable accreditation standards were available to determine the safety and effectiveness of cardiac rehabilitation facilities. Therefore, third-party payors such as Medicare, Blue Cross Blue Shield, and others generally would not reimburse these facilities for their services. The North Carolina legislature elected to provide state certification for these facilities solely to facilitate reimbursement for cardiac rehabilitation programs in their state. A certificate program was established through the North Carolina Office of Facility Services, and in 1984, the certification was codified into law. Each year a facility's certification must be renewed through site visits by a multidisciplinary team consisting of a physician, registered nurse, and dietician.

III. Review of Accreditation and Voluntary Standards: Currently, there are no accreditation standards specifically designed for inpatient cardiovascular or pulmonary rehabilitation programs. In a hospital setting, these programs are included under the general oversight of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO also has general standards for ambulatory centers that apply, in part, to outpatient rehabilitation programs. Currently, there is no other *accreditation* mechanism for cardiovascular and pulmonary rehabilitation programs. There are, however, a number of voluntary guidelines and standards available. Private organizations promulgating guidelines include:

* American Heart Association
* American College of Sports Medicine
* American Association of Cardiovascular & Pulmonary Rehabilitation
* American College of Cardiology

The American Association of Cardiovascular & Pulmonary Rehabilitation (AACVPR) guidelines are currently under revision. The new document, complete with the possibility

for voluntary, private accreditation will be available in October 1994.

A federal study on this issue is currently being directed by L. Kent Smith, M.D., M.P.H., an Arizona cardiologist affiliated with the AACVPR. The results of the three year study are scheduled to be released by January 1995. They will be available through the Agency for Health Care Policy Research. Later, practical clinician guidelines are to be crafted from the study.

IV. Review of Complaints: There have been no relevant complaints to the Department of Health Professions concerning this type of rehabilitation generally or to the Department of Health concerning any of the facilities in Virginia that are currently doing this rehabilitation. No evidence of malpractice claims or settlements have been found. St. Paul's Insurance Co., one of the larger medical insurers in the area, makes no special provision for assessing particular risks that might relate to these types of programs, for either inpatient or outpatient settings.

V. Public Hearing and Comment: The public comment period ended September 16, 1994. Only one individual presented at the public hearing held August 31. That individual is a representative of the AACVPR. The information she presented is included above.

Findings & Recommendations

When a health care provider entity seeks to be regulated by the state and the Board of Health Professions has been requested to study the matter, the Board employs a formal set of criteria to evaluate the justification for and level required for regulation. The attached Appendix details each criterion.

Criterion One: Risk of Harm to the Consumer

The first criterion involves the risk of harm to the public's health, safety, or welfare. In order for the Board to recommend regulation of a facility, there must be objective evidence that the public is in jeopardy as a result of the unregulated practices involved at the facility, the characteristics of the clients served, the setting or supervisory arrangements for the delivery of the health service, or some combination of these factors. If jeopardy to the public is demonstrated, the Board normally proceeds to review the matter employing the remaining six criteria. If it is not, the formal review ends.

The study failed to uncover evidence of risk to the public which could not be remedied more readily through means other than regulation of outpatient cardiovascular and pulmonary facilities. The current means of allowing facilities to choose from the various voluntary standards and arrange for payment individually may be inefficient in terms of reimbursement; however, it has not resulted in any determinable public risk. Therefore,

the Board has recommended that outpatient cardiovascular and pulmonary clinics do not require state regulation as a health care entity.

Additional findings: Although Criterion One has not been satisfied, other findings also preclude the need for state regulation. National Voluntary Accreditation Standards will soon be available, nationally recognized specialization certification for individuals is available, and the public has recourse against the unprofessional conduct of licensees of the existing health regulatory boards.

National Voluntary Accreditation Standards

Other than Criterion Five, which evaluates the economic cost to the public of regulating an entity, the Virginia Board of Health Professions does not consider the need to reimburse a facility as sufficient justification for its regulation. However, in the late 1970's, North Carolina, Massachusetts, and South Carolina did consider reimbursement in order to foster greater access to health care for their citizens. In those particular states at the time, third-party payors refused to reimburse facilities for services without an accreditation mechanism in place for quality assurance. State regulation filled the accreditation void.

According to the Virginia Association of Cardiovascular and Pulmonary Rehabilitation, reimbursement has not been an issue for the vast majority of facilities in Virginia. Further, two national voluntary accreditation standards are currently being developed to establish uniform standards for cardiovascular rehabilitation and pulmonary rehabilitation clinics. The American Association of Cardiovascular and Pulmonary Rehabilitation is devising guidelines which are to be published in October 1994. The Commission of Rehabilitation Accreditation is revising its outpatient standards to encompass some pulmonary rehabilitation facilities. The revision is expected to be finalized by July 1, 1995.

It is anticipated that third-party payers throughout the country will be reviewing these accreditation criteria and may be willing to accept accreditation by these organizations in lieu of state regulation.

Nationally Recognized Specialization

Because cardiovascular and pulmonary rehabilitation constitutes a specialty within a number of health professions, certifications for this specialty have become available through a number of national associations. For example, the American College of Sports Medicine certifies physicians and other professionals as specialists, and the American Physical Therapy Association certifies physical therapists in this specialty. The American Nurses Association is expected to provide certification for registered nurses in cardiac rehabilitation in the near future. The first examination is scheduled to be given in October 1994.

Professional Staff Members are Licensed

Many of the health care professionals that are required by the voluntary standards and third-party payers to staff these programs (physicians, nurses, and counselors) are already licensed by the Department of Health Professions. As is the case in any setting, complaints relative to their practice in outpatient cardiovascular and pulmonary rehabilitation clinics could be resolved through the disciplinary proceedings of their respective health regulatory boards.

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APPENDIX

VIRGINIA BOARD OF HEALTH PROFESSIONS
CRITERIA FOR EVALUATING THE NEED FOR REGULATION
Adopted October, 1991

Criterion One: Risk for Harm to the Consumer
The unregulated practice of the health occupation will harm or endanger the public health, safety or welfare. The harm is recognizable and not remote or dependent on tenuous argument. The harm results from: (a) practices inherent in the occupation, (b) characteristics of the clients served, (c) the setting or supervisory arrangements for the delivery of health services, or (d) from any combination of these factors.

Criterion Two: Specialized Skills and Training
The practice of the health occupation requires specialized education and training, and the public needs to have benefits by assurance of initial and continuing occupational competence.

Criterion Three: Autonomous Practice
The functions and responsibilities of the practitioner require independent judgment and the members of the occupational group practice autonomously.

Criterion Four: Scope of Practice
The scope of practice is distinguishable from other licensed, certified and registered occupations, in spite of possible overlapping of professional duties, methods of examination, instrumentation, or therapeutic modalities.

Criterion Five: Economic Impact
The economic costs to the public of regulating the occupational group are justified. These costs result from restriction of the supply of practitioner, and the cost of operation of regulatory boards and agencies.

Criterion Six: Alternatives to Regulation
There are no alternatives to State regulation of the occupation which adequately protect the public. Inspections and injunctions, disclosure requirements, and the strengthening of consumer protection laws and regulations are examples of methods of addressing the risk for public harm that do not require regulation of the occupation or profession.

Criterion Seven: Least Restrictive Regulation
When it is determined that the State regulation of the occupation or profession is necessary, the least restrictive level of occupational regulation consistent with public protection will be recommended to the Governor, the General Assembly and the Director of the Department of Health Professions.