Accommodating a New Medical Profession:
The History of Physician Assistant Regulatory Legislation in North Carolina

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In 1967, the first graduates of the Duke University Physician Assistant Program received their certificates and began their practice. The Duke program was the first in the country to train this new professional group.[1] There was no legal framework in place for their practice, other than a ruling from the Attorney General of North Carolina that performance of delegated, physician-supervised activities by a physician assistant did not contravene the licensure laws of the state.[2,3] Other institutions were beginning programs of their own, some using the Duke model, and others a very different structure. National interest in this new manpower innovation was high, as was interest in the new profession by prospective students.[4]

Recognizing their obligation as the innovators and pioneers in physician assistant education, the parent department of the program at Duke University Medical Center, the Department of Community Health Sciences undertook the process of studying the unique problems of regulation of this new professional group and designing model legislation to implement this regulation.[1,2,5]

The process by which this model legislation was designed was unique, as was the regulatory framework which resulted. Following the development of the model, it was framed as a legislative act and considered by the North Carolina General Assembly the following year. It was passed with no major opposition.[6] This framework has served the state, the medical profession, and the physician assistant profession well for over three decades and has been the model for similar legislation in a number of other states.[7]

The purpose of this paper is to describe the process, some of the options that were considered, and some of the factors that led to a new and very unique basis for regulation of physician assistants. At the same time, it will highlight some of the characteristics of the process by which the proposed regulatory system was studied and developed. In retrospect, these appear to have heavily contributed to the favorable reception of the new regulatory process by the medical community within the state. The authors feel that recognizing these characteristics, and duplicating them, can be very useful to those with the responsibility for designing new licensure and regulatory statutes for medical occupations that may evolve in the future.

The Environment and Early Preparation

The Duke Physician Assistant Program arose from the awareness that many areas of the state, especially rural areas, were suffering from a growing shortage of physicians. The first class began in 1965, with a curriculum that resembled a shortened medical school curriculum: 12 months of pre-clinical sciences and 15 months of clinical instruction taught by medical school faculty. Interest in the program was immediate. Other medical institutions began programs of their own, some using the Duke model, and others a very different design, such as the Medex Program at the University of Washington. Entrepreneurial interest was also evident, with for-profit programs offering a certificate after only a few weeks of training. The need for standards for educational and clinical preparation of physician assistants was seen as an urgent priority, as was a framework for licensure and regulation.[5,7]

The Duke Physician Assistant Program was conceived and begun by Dr. Eugene A. Stead, then the Chair of the Department of Medicine.[8] He retired from this position in 1966, just after Duke University formed a new department—the Department of Community Health Sciences (later Community and Family Medicine)—with the first author of this paper as its chairman. The new Physician Assistant Program fit more easily into the mission and interests of this new department, and it was transferred to the new department late in 1966, before the graduation of the first class of students. This department initiated a number of studies of the new profession and also began to explore other required steps for its inclusion as a recognized component of the medical community. In addition to the looming problem of licensure and regulation, there was

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the need for accreditation of educational programs and a process for testing the educational preparation of graduating students. Drs. Estes, Stead, and D. Robert Howard, Director of the Physician Assistant Program, became the planning group for these activities, with the Department of Community Health Sciences as the organizational seat of the activity.[1,9] This paper will only consider those activities related to licensure/regulation.

The federal government recognized the need for uniform standards for the profession, and early in 1969 the Department of Health, Education, and Welfare awarded a contract to the Duke Department of Community Health Sciences to develop model legislation for the regulation of physician assistants. One of the first steps in carrying out the contract was to select a project operating officer, Martha Ballenger, JD, who immediately began to review published information about licensure of medical personnel. Her findings became the basis for a *white paper*, which was used for project planning and as background information for participants in the series of conferences that followed.[2]

This white paper pointed out that the responsibility for physician and other medical occupational licensure is a state prerogative, and there are differences from state to state. Legislation for physician licensure arose in the late 19th and early 20th century to control the rampant quackery and poor medical education characteristic of that time. These licensure acts were framed in very broad and general terms, permitting physicians to carry out any act or task taught in medical school, with no restrictions. As new health professions evolved and gained acceptance, their members were granted more circumscribed licenses, enabling them to perform only those specific functions for which they were qualified by training and experience.

The paper also pointed out that the process of awarding independent licensure for a new professional group was often hotly contested by those professional groups whose professional territory was being invaded. The result was an array of professional groups within healthcare (each with a sharply defined set of authorized functions) with frequent scope-of-practice conflicts as they sought to expand their functions.

Five options were identified for discussion and debate, each with advantages and disadvantages. The "status quo" option was a continuation of the existing policy. Physicians would delegate functions to their assistant, and custom and useage would validate the process over time. This option was seen as leaving both the employing physician and the assistant vulnerable to legal action for improper delegation. Independent licensure of physician assistants was the second option. Difficulty in precisely defining the duties to be permitted was seen as a major problem with this option. The third option was to license the physician or institution that wished to utilize a physician assistant. This was seen as a new function of the Medical Board. The fourth option was create a new statute authorizing general delegation by physicians. Four states were found to have some features of legislation authorizing general delegation within their medical practice acts. Lack of protection for the public was an identified problem with this approach. The fifth and last option was to create a Committee on Health Manpower Innovations, which would report to the medical board. The Committee would evaluate and pass judgment on new types of health workers, based on the need and the ability of the applicant individual or institution to support and supervise the innovation. The need for representation by all health professions on the new Committee was recognized, but at the same time, it was predicted that each of the representatives would tend to be protective of their own turf.

No judgment was offered on the relative merits of each of these options, since this was to be the subject of open discussion and debate in the series of conferences planned for the future. The purpose of presenting options was to encourage consideration of possibilities beyond those in use at the time and to present the unique challenges of the task ahead. Chief among these was the need for flexibility while meeting the responsibility to protect the patient and the public interest.

Drafting the North Carolina Statute for Licensure and Regulation of New Medical Professionals

The next step in the process was to hold a conference on licensure/regulation of new medical professions, with physician assistants as the principal focus.[10] Representation was sought from all groups seen as having a significant interface with the new professional group. The invited participants included:

- Nationally recognized experts on licensure of health personnel, identified from their contribution to the literature on this subject;
- Representatives from medicine, nursing, and hospital administration in North Carolina, including both practicing members of these professions and members of their legal staff;
- Members of the North Carolina legislature, the North Carolina Institute of Government, and the regulatory boards governing medicine and nursing;
- Educational representatives from Duke University School of Medicine and the Physician Assistant Program;
- Members of the newly graduated classes of Physician Assistants and their employing physicians; and
- A representative of the United States Department of Health, Education, and Welfare.

The first conference was held in Durham, North Carolina, on October 26 and 27, 1969. The previously listed options were presented and discussed during the first day. It was the consensus of those present that the best approach would include a combination of several options, most closely resembling option four—a statute authorizing general delegation of functions to an assistant. For the protection of the public, it was felt that this delegatory authority should be restricted to assistants functioning under credentials and constraints reviewed and approved by the North Carolina Board of Medical Examiners. Following the conference, a group of legal consultants met to prepare a first draft of a model statute, which was circulated to all those who attended, with a request for added comments and

suggested revisions. Following a rewrite incorporating several of these suggestions, the revised version was again circulated to all who had attended.

A second conference was held in Durham, North Carolina on March 1, 1970, to discuss the product of these revisions, and to discuss in detail a modification proposed by one of the legal consultants. After lengthy discussion, the "October Proposal" was endorsed by the group, and became the proposal forwarded to those responsible for framing new legislation. It was enacted into law, essentially as proposed, in the 1971 session of the North Carolina General Assembly.[6]

At the time of the previously mentioned actions, the North Carolina General Statutes, Section 90, paragraph 18, after prescribing penalties for the unlicensed practice of medicine, read:

> "Any person shall be regarded as practicing medicine or surgery within the meaning of this article who shall diagnose or attempt to diagnose, treat or attempt to treat, operate or attempt to operate on, or prescribe for or administer to, or profess to treat any human ailment, physical or mental, or any physical injury to or deformity of another person: Provided, that the following cases shall not come within the definition above recited."

This was followed by a series of permitted exceptions, including the use of home remedies within the family, the practice of dentistry by a licensed dentist, the practice of pharmacy by a licensed pharmacist, etc. The proposal was exception (14) to this definition of the practice of medicine. It read as follows:

> "(14) Any act, task or function performed at the direction and under the supervision of a physician licensed by the Board of Medical Examiners, by a person approved by the Board as one qualified to function as a physician assistant when the said act, task, or function is performed in accordance with rules and regulations promulgated by the Board."

This proposal established a two-stage method of control. Before the physician assistant could have the benefit of the protection afforded by the statute, he or she must have gained the approval of the Board, through graduation from a recognized educational program. Once approved, the assistant might subsequently demonstrate incompetence or unwillingness to perform within the limits set by the physician, or the physician might be shown to be using his assistant in an inappropriate manner. Thus, there was an implicit power of the Board to deny or revoke approval at a later time. The final clause of the exception requires the Board to promulgate rules as needed.

The model legislation had several attractive features. It avoided specificity in definition of functions allowed by assistants. The functions permitted are, in effect, any functions delegated by the physician. It placed the promulgation of rules in the hands of the Board of Medical Examiners, not the General Assembly, thereby making changes possible without the formal action of an elected body.

Since its adoption in 1971, the afore mentioned approach has had the desired effect of permitting and supporting the function of physician assistants, while safeguarding the safety of the public. It has required very minimal alteration over time, and most changes have been accomplished through changes in the rules and regulations rather than the statute.[12,13] After its enactment, a similar approach was used to permit the medical acts of nurse practitioners. Recognizing that the nurse practitioner is already acting under another licensing authority, the North Carolina Board of Nursing, the legislation added nurse practitioners to the list of exceptions to the unauthorized practice of medicine. Legislation also established a joint committee of both boards to promulgate rules and regulations for nurse practitioners, specifying that both boards must approve these rules.

Still more recently, the same model has been used to permit the function of clinical pharmacist practitioners, who are now permitted to prescribe and manage illness under rules established by a committee with membership from both boards.

The model legislation proposed in 1969-1970 thus proved its merit through its adoption in North Carolina and many other states, and it has proved a very workable and flexible in action. It has also been used as a model for other professional groups that have joined physician assistants in performing medical acts. Physician assistants now work in every medical specialty, and their functions have been accommodated as new tasks have been developed and implemented, in ways that could not have been predicted when the legislation was developed.

The Process of Development of Model Legislation

The development of the model legislation for physician assistants was a very intense process with much debate and exchange of opinion. Yet, at the end, the resulting legislation passed the North Carolina General Assembly with very little dissent. This result has caused the authors to examine the process by which it developed in more detail, and to speculate cause and effect. Several characteristics of the process of development are identified as important in achieving the successful outcome. These are presented and discussed in the following section, with the hope that they will be useful to others who wish to achieve accommodation of a new professional group into the health professions.

The following characteristics are identified as important to the outcome:

- All professional groups identified as being impacted by the new professional group, physician assistant, were represented in the group invited to develop the model legislation;
- Identified national experts, from outside the medical profession, were invited to participate and contribute to the development of ideas;
- The process emphasized, at all stages, that a major objective for the model legislation was protection of the public and the individual patient, not preservation of professional turf;
- The process permitted all participants to review prior work;

submit their own new ideas, and revise old ideas through several iterations of the developing model; and
- The process produced near unanimous agreement on the details of the model before it was sent forward.

It was obvious that the new physician assistant would interact with every other major medical professional group: nurses, hospital administrators, pharmacists, etc. For this reason, an effort was made to include each of these groups in the conference and subsequent discussions. This proved very useful in allaying anxiety and suspicions and in informing all about the provisions of the model legislation.

Physician support was an essential requirement. It was fortuitous that the president of the North Carolina Medical Society was a family practitioner from a rural area, who had seen the need for the new profession firsthand. He was also a very perceptive and innovative individual who had a very warm relationship with many members of the North Carolina General Assembly. This individual, Edgar Beddingfield, MD, had served for many years as the head of the Legislative Committee of the Medical Society of the State of North Carolina (later the North Carolina Medical Society). He was also very active as a delegate and elected officer in the American Medical Association and was very helpful later in establishing a mechanism for accreditation of physician assistant education programs through that organization.

Nursing was represented by Dr. Eloise Lewis, a senior stateswoman in this profession, and the dean of a highly respected School of Nursing. The legal counsel to the North Carolina Nurses Association was also included.

The regulatory boards for both medicine and nursing were also included, with both members and legal counsel from each. This inclusion insured that the point of view of each of these boards was expressed and understood by the other, and the usual suspicions of ill intent, based on fragmentary or distorted information, were avoided.

The inclusion of national experts on licensure of medical personnel had several important effects. Their writings were known from the preliminary research, but their presence as a part of the discussion and deliberation broadened the approach. Their presence also provided an assurance to all participants that all major issues had been considered and that the work of the committee was important. They were also tenacious defenders of the public protection requirements of the model legislation, and their presence lent authority and validity to the product developed.

The emphasis on protection of the public was unifying in many ways. Each professional group could understand that this was not an attempt to restrict or diminish other professional groups, but to serve all interests as, together, we serve our patients.

The last two points can be considered together. Every participant was invited to comment, criticize, revise, object, and contribute to the development of the model. When differences were discovered, these were discussed in detail, and a consensus obtained. When the process was finished, all felt that they had contributed and felt ownership of the product. The group included legislators who were very effective in answering questions from fellow legislators during the debates and at avoiding conflict as the North Carolina General Assembly proceeded toward passage of the measure.

Summary

The first physician assistant program in the United States was at Duke University Medical Center. This program served as a model for other institutions to begin similar educational programs, and the profession has quickly become a major source of medical services throughout the country. Less well-known is the role of Duke University and North Carolina in the development of a unique regulatory system, which also became a national model. This system has been effective in protecting the public and the patient, and has had the flexibility to adapt to changing medical practice and changing standards. The process by which this regulatory system was developed was unique, and its unique characteristics are felt to have been a significant factor in its success. Duplication of these characteristics is recommended for those who wish to incorporate new medical occupations into the larger medical community. **NCMJ**

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REFERENCES

1 Carter R, Strand J. Physician assistants: A young profession celebrates the 35th anniversary of its birth in North Carolina. NC Med J 2000;61(5):249-256.
2 Ballenger MD, Estes EH. Model Legislation Project for Physician's Assistants. 1969. Department of Community Health Sciences, Duke University School of Medicine. Durham, NC.
3 Department of Community Health Sciences, Duke University School of Medicine. Duke Physician's Associate Program: Legal status and insurance, 1972. Durham, NC: Informational Pamphlet Series. Available at: http://www.pahx.org/archives_detail. asp?ID=132&searchterm.
4 Carter RD, Gifford JF, Jr. The emergence of the physician assistant profession. In Perry HB and Breitner B (eds). Physician Assistants: their contribution to health care. New York, NY: Human Science Press, 1982;19-50.

5 Estes EH, Howard D. Potential for newer classes of personnel: experiences of the Duke physician's assistant program. J Med Educ 1970;45:149-155.
6 North Carolina Statutes: Section 1. GS 90-18, July 1971.
7 Fasser CE, Andrus P, Smith, Q. Certification, registration and licensure of physician assistants. In Carter RD, Perry HB (eds). Alternatives in health care delivery: Emerging roles for physician assistants. St. Louis, MO: Warren H. Green, Inc., 1984;78-93.
8 Stead EA. Conserving costly talents–providing physicians new assistants. JAMA 1966;194(10):1108-1109.
9 Howard DR. A proposal for guidelines for education essentials for physician assistants. Paper presented at Conference on Current Status and Development of Physician's Assistant Program, October 28, 1968; Department of Community Health Sciences, Duke University Medical School, Durham, NC.
10 Department of Community Health Sciences, Duke University School of Medicine. A resume on proceedings of the conference on legal status of physician's assistants, October 1969. Durham, NC. Available at: http://www.pahx.org/archives_detail.asp?ID=310#Images.
11 Department of Community Health Sciences, Duke University School of Medicine. The third annual Duke conference on physician's assistants: conference proceedings November 1970. Durham, NC.
12 Paris BD, Jr. The regulation of physician extenders in North Carolina. 1979; Federation Bulletin 66(2):43-45.
13 Davis A. Putting state legislative issues in context. JAAPA 2002;15(10):27-32.