MODEL LEGISLATION PROJECT

FOR

PHYSICIAN'S ASSISTANTS

Department of Community Health Sciences
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I. Introduction

In 1965 Duke University Medical Center inaugurated a training program for a new type of health professional designated "physician's assistants." As the name suggests, personnel trained in this program function in a direct, personal relationship with a physician, performing many of the tasks which have traditionally been performed exclusively by the physician but which realistically do not require the extensive--and expensive--complete medical training necessary for the physician. It was felt that the addition of a highly trained assistant to the health team would be beneficial in increasing both the quantity and quality of those aspects of care dependent on physician services.[1] It is a matter of common knowledge that the United States today is faced with an acute shortage of physicians and that the current and projected output of medical schools is inadequate to offer any significant relief. Personnel trained to assume some of the more routine tasks which occupy much of the physician's day could free time for the physician to perform a greater number of those functions which require his unique talents and training. These functions presumably lie primarily in the realm of judgmental decision-making and the performance of the most complex and infrequently required procedures. The available supply of physician services would,

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therefore, hopefully be augumented by allowing physicians to use their time with maximum efficiency. In addition, the physician shortage and the consequent demands for their services make it increasingly difficult for "continuing education"--in the form of attendance at medical center-based refresher courses and of reading current medical literature--to be more than a fine ideal for many physicians. It is probable that some of the time freed by physician's assistants will be devoted to continuous improvement of the quality of medical care by way of continued education of physicians.

Armed with these expectations for the potential contribution of physician's assistants, the Department of Community Health Sciences at Duke developed a twenty-four month curriculum which is divided into two phases--didactic and clinical.[2] Those accepted into the program are required to have had previous experience in health care as assurance of their desire to pursue a career in this field. In the initial didactic portion of the program the trainees build on their background knowledge through intensive courses in the basic medical sciences. The subsequent clinical phase is designed to provide further experience in the techniques and procedures of patient care under the supervision of the faculty. Upon completion of the training program, the graduates are awarded certificates of accomplishment by the Medical School, signifying that they are ready to assume a place on the physician's health team.

The extent of the need and real demand for these assistants, even in this early stage of its development, is demonstrated by the steady flow of requests from physicians seeking to employ graduates.[3] That there is an immense pool of manpower eager to assume such a role is demonstrated by the increasing volume of applications for admission

to the program.[4] That the concept is becoming accepted by educators as a viable approach to at least a partial resolution of the critical physician shortage is demonstrated by the current development of new training programs in institutions around the country.

Those responsible for the Duke Physician's Assistant Program have recognized their obligation as a pioneer in the training of these assistants to continuously evaluate the results of their efforts, to analyze and attempt to resolve perceived problems, and generally to make their program as immediately responsive to the needs of physicians and the realities of health care delivery as possible. As part of this on-going self-examination, two conferences were held at Duke in 1968 for in-depth consideration of various aspects of the program in an attempt to determine the areas in which future efforts should be concentrated. Both conferences were attended by people from across the nation who were interested in the program and who were authorities on various considerations relevant to the development of a new type of paramedical personnel. The participants included physicians, lawyers, nurses, educators, hospital administrators, and other health officials.

One of the primary areas of concern, emphasized particularly by the lawyers in attendance, was the question of the position of these emerging professionals with respect to the existing legal framework of health care delivery. They delineated many of the potential problems which might be encountered with the introduction of new manpower groups into an industry which has traditionally been license-oriented with respect to its personnel.

II. Legal Implications of Manpower Innovation

The problems which the lawyers participating in the 1968 conferences foresaw with respect to the legality of the performance of physician's

assistants are attributable in large part to the predominant role which licensure has played in the regulation of the manpower inputs into the process of health care delivery. Licensure of health manpower is a function of State rather than Federal government under the power of the State to legislate for the protection of the health, safety, and morals of its citizens.[5] State medical societies were successful in securing the enactment of licensure laws in the late 19th and early 20th centuries--a time when the laissez-faire philosophy was flourishing and the "freedom to contract" doctrine had doomed many other attempts at occupational licensure.[6] These statutes, requiring licensure of all persons practicing medicine, were enacted in an effort to combat the widespread incompetence and quackery existing in the profession at that time.[7] All extra-governmental means of control, including efforts by medical societies as well as individuals, had proved ineffective against this threat. Because the early laws originated at a time when there were few health manpower categories, the statutes were phrased to authorize qualifying physicians to perform all health care functions. As new categories of health professionals developed and gained acceptance, their members were granted more circumscribed licenses, providing them with a degree of professional status but enabling them to perform only those health care functions for which they were qualified by training and experience.[8] At the present time, there are approximately twenty-five health professions and occupations licensed by one or more of the States.[9]

The quality control which these laws insure is, of course, vital; but in view of the existing acute medical manpower shortage, they are a mixed blessing. Laws licensing health personnel have typically progressed from permissive (merely preventing the use of a given title

by the unlicensed) to mandatory (making criminal any action within the scope of a licensed profession by one not licensed by that profession)[10] Spheres of action are defined by statute, and boundaries are jealously guarded by each licensed group against encroachment from the outside. As more functions have come within the practical competence of personnel below the level of the physician and as health care demands have grown, these laws have created problems with regard to the allocation of new functions to existing allied health personnel and to the development of new types of personnel to help alleviate the physician shortage.[11]

It was pointed out that in view of the existing licensure framework, new types of personnel may perform <u>independent</u> functions only if they are authorized to do so by a licensing statute or by some other explicit exception to the medical practice act of the state. If, however, as in the case of physician's assistants, the proposed functions of a new personnel category are solely <u>dependent</u>, to be performed only under the supervision of a physician, custom and usage in the medical profession may eventually provide legal sanction.[12] Legislatures and courts have recognized that they do not have the medical expertise possessed by physicians and have relied, therefore, on the ordinary practices of the profession in determining the requisite standard of practice in situations in which the physician maintains supervision.[13] Under such circumstances it is assumed that the safety of the patient is protected by the physician's professional training.[14] Although relying on custom and usage may be easier, in that it avoids the time and expense involved in developing and promoting legislation, as will be seen, it has certain inherent uncertainties and may produce needless vulnerability for the individual physician and physician's assistant, should action be taken against them.

When legal problems do arise, they are generally in the form of civil suits based on an injury suffered by the patient during the treatment process. Under the doctrine of respondeat superior, commonly known as the master-servant doctrine, the physician is responsible for the negligent acts of any persons in his employ. Of course, liability based on respondeat superior inheres regardless of licensure or any other formal arrangement as long as an employment relationship exists.[15] In this respect, the physician's liability for a physician's assistant, who is currently unrecognized by the law, is similar to his liability for the licensed nurses he hires for his office. Beyond liability for the frankly negligent acts of employees, there is, however, an additional danger in hiring an unlicensed assistant that arises from delegating tasks to such a person at all. Nurses are licensed by the State, their qualifications are established, and their sphere of activity is defined to various degrees. As long at the physician restricts the nurse to this defined sphere, he has a presumption on his side that he is delegating to competent, qualified personnel.[16] But if the legislature has not spoken at all with respect to a given category of assistants, either to establish qualifications or to define a sphere of activity, the physician delegating to this type of personnel does not have such a presumption on his side. If a patient launches a malpractice attack against the physician alleging that he was negligent in delegating or that the particular task delegated was beyond the competence of the particular assistant, the physician must rely solely on a custom and usage defense. This means of legitimizing a delegation is risky for several reasons. Until the use of this type of assistant (or the delegation of a particular task to such an assistant) becomes sufficiently widespread to be regarded as an ordinary practice, there is no "custom

and usage" and therefore no protection. However, to establish a custom and usage defense, it is not necessary that all or even a majority of the physicians in an area actually employ or use this type of assistant. As long as a respectable group does so, this protection could exist. It should be noted that the physician is often judged against a "locality" standard. At present, the number of physician's assistants is small, and they are widely dispersed around the country. Such concentrations as there are are primarily in large medical center communities, and the ordinary practice in a large training hospital may afford little protection to the rural doctor in a different set of circumstances. Although it is forecast that improvements in travel and communication may end the "locality" approach, this is uncertain as yet and may give rise to non-innovational pockets in precisely the areas most in need of this new type of manpower.[17] Even when the particular assistants are used more generally, whether the "custom and usage" is sufficient to legitimize the practice is a question for the jury to determine in the particular case, and thus there will still be uncertainty and the possibility of inconsistent decisions.[18]

Even if professional physician's assistants become widely used and accepted, the very existence of other licensure laws poses an additional danger in civil litigation. In addition to the fact that the physician does not have the presumption of competence on his side when he delegates to unlicensed personnel, at least one court has actually indulged a presumption against a physician who made such a delegation. In the case of Barber v. Reinking,[19] decided by the Washington Supreme Court, a licensed practical nurse in the physician's office was giving a small child an injection, when the child moved suddenly and the needle broke off, necessitating its removal by surgery. The court said that because

the state's nursing practice act provided that only a licensed professional nurse can give innoculations, as a licensed practical nurse the assistant acted beyond the scope of her license in giving the shot, and they refused to allow a custom and usage defense. The rationale for this decision was that the legislature, by licensing personnel and prescribing their scopes of practice, has determined what is permissible, and that permitting expansions by custom and usage would be against public policy. In some other states, the absence of a license is admissible as evidence to be weighed against custom and usage.[20] At the present time, however, the law in most states, including North Carolina, appears to be that failure to be licensed is immaterial on the issue of negligence.[21]

Aside from the question of civil liability, if the physician delegates to an unlicensed assistant tasks which could be considered as within the "practice of medicine," the assistant may be prosecuted criminally for the unlicensed practice of medicine, and the delegating physician may be similarly prosecuted for aiding and abetting.[22] Although custom and usage might furnish a good defense if the assistant was performing a dependent function under the supervision of a physician, the time, expense, and possible injury to reputation attendant to litigation are not to be reckoned with lightly. Were the physician found guilty of aiding and abetting the unlicensed practice of medicine, he would be subject to disciplinary action, possibly even license revokation, for unprofessional conduct.[23] This may also pose problems with professional liability insurance coverage, as policies may have exclusions for instances in which the liability of the physician arises out of the performance of an unlawful act.[24]

III. Impact of the Current Legal Framework on Health Care Delivery

It would indeed be myopic to place primary responsibility for the current manpower crisis in health care delivery on the strictures involved in the legal framework of that industry. The need for more and expanded training facilities and the need for improved wages and working conditions are only a few of the many other concerns. Yet it cannot be denied that the process for regulating the personnel input has a significant impact on the operation of the system.[25]

Perhaps the principal detrimental effect of the licensure scheme lies in the area of manpower utilization. Scopes of practice in the licensure laws of the various professions and occupations determine the at least theoretical boundaries of performance of these groups. In some cases the statutes are quite specific in setting forth the tasks which may and may not be performed by the licensed group.[26] In view of the rapid strides in medical knowledge and technology which characterize the present age, it is likely not only that an expanded spectrum of activity will be within the capabilities of non-physician personnel equipped with intricate and accurate mechanical aids, but also that it will, in fact, be necessary to utilize such personnel in many areas formerly considered beyond their ken if physicians and other such highly trained professionals are to be freed to realize their new potentials in ministering to health needs. Rigid definitions are, therefore, subject to speedy obsolescence both in terms of personnel capabilities and in terms of the needs of the system. One response to such definitions would of course be frequent resort to the legislature for modification. This, however, may entail great delays in making the necessary adjustments and might place the final judgment in a forum not in fact equipped with the expertise and experience which should

underlie such a decision. The alternatives to modification are to use personnel inefficiently or to ignore the scope of practice restrictions. The former seems impractical in view of current demands; the latter raises serious questions from a legal standpoint and may challenge the viability of the licensure scheme itself.

In contrast to the specific definitions mentioned above, the scopes of practice in some licensure statutes, notably most nursing practice acts, are formulated in broad and somewhat vague terms, presumably to facilitate the necessary expansion and accretion of functions over time. The potential advantage of these broad definitions has not been realized, however, because of the uncertainty as to the boundaries of activity encompassed thereunder. With respect to nursing practice acts, it has been noted that "the very necessity of interpretation of the definitions, as well as uncertainties regarding possible reinterpretation, may inhibit innovations in professional nursing."[27] The incidence of malpractice litigation and the size of awards are on the increase in the United States today,[28] and physicians are becoming increasing--and understandably--wary of innovational activity that might carry them beyond the protections accorded to conventional practices.[29] Relying on progressive interpretations not legally binding (as those of attorneys general) involves hazards well-perceived by physicians, who are aware that their practices may ultimately be judged by a lay jury against a custom and usage standard, which "may not correspond to wisdom, logic, the realities of patient safety, or good medical care."[30]

Not only may the current licensure scheme inhibit efficient and practically justifiable use of licensed personnel, it has strong implications for the development and use of new types of health personnel. The potential dangers from this type of activity have been

discussed above. A practical example of how the inhibitions have operated in fact may be instructive. In the summer of 1969, a graduate of the Duke Physician's Assistant Program went to work in a California clinic staffed by nine physicians. After effectively functioning for some months, without incident, and to the satisfaction of his employing physicians in performing those tasks for which he had been trained, he was informed by the business manager of the hospital where his employing physicians practiced that it had been deemed advisable, because of potential hospital liability, to seek a formal legal opinion as to what tasks he could and could not perform under California law. The opinion of legal counsel was as follows:

> It is our opinion that regardless of the training which the individual may have had at Duke University, the laws of California make no provision for the recognition of such a person performing any acts which might otherwise require licensure. In other words, the acts of the so-called physician's assistant cannot infringe upon the activities requiring MD licensure, RN licensure, LVN licensure, or any other license under the laws of the state of California. The courts of California have clearly indicated that the mere fact that the person may be acting under the supervision of a physician does not grant that person the right to act without license. The famous Magit case, in which the license of the supervising physician was challenged on this ground, is clear indication of the attitudes of the courts.
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> For these reasons, it would be our opinion that the person involved would be limited to those activities permitted to an aide or an orderly. (Emphasis added.)[31]

Subsequent to the rendering of this opinion, the directors of the clinic where the physician's assistant was employed determined that they could not assume the risks of the assistant's continuing to perform tasks not sanctioned by that opinion, and he was restricted to the activities of an aide or an orderly in both the hospital and the clinic. Although efforts are underway in California at present to remedy this situation through the enactment of a licensure law for

physician's assistants, it is noteworthy that many months of valuable service to the physicians have been lost because the system is not geared to accommodate innovations in health manpower.

The current licensing structure also affects the career mobility of people in the health field. Licensure statutes typically specify formal educational prerequisites to entry into the profession or occupation. A person at one level or with one particular license who wishes to move up the career ladder or to expand his range of performance may be required to "begin a new formal educational process anew without receiving much, if any, credit for his former education and experience."[32] This may in fact preclude advancement for those whose financial responsibilities prevent their reassuming a student status. The obstacle to advancement thus imposed will often be logically unjustifiable in view of the skills and knowledge which have been acquired in the course of work experience. For those able to comply with the formal educational requisites, there is likely to be much duplication and therefore an inefficient use of educational and training resources.[33]

Concern has also been expressed that the proliferation of licenses results in the fragmentation of health care delivery. This has been of particular concern to hospitals, where the various licensed interest groups can exert much the same influence as unions and may therefore have a substantial impact on personnel utilization.[34] The jealous guarding of jurisdictional boundaries may culminate in the necessity for a health worker to have several licenses in order to perform in what is, in truth, a single profession.[35] This in turn may lead to increased costs for medical care if salary demands continue to increase in reflection of the additional formal training and concommitant expenses involved in securing the various licenses.[36] Keeping supply short

through licensure in itself drives salaries up in a time of increasing demand such as this.[37] Although licensure laws do serve a function in measuring at least initial qualifications, it can certainly be argued that the disadvantages of the current scheme outweigh the benefits in view of the other quality controls (such as program accreditation) which were not in existence when the licensure scheme originated.[38]

IV. Background on the Project Itself

In view of the uncertainties inherent in the current situation, it was the opinion of the participants in the 1968 conferences that clarification of the legal position of physician's assistants, perhaps through some type of legislative pronouncement, would be to the advantage of the public, the physician's assistants, and the physicians. In view, however, of the possible negative effects of licensure on the delivery of optimal medical care today, it was felt that much thought should be devoted to the question of whether this traditional means of legalization should be pursued in this instance.

The Department of Community Health Sciences at Duke, in accordance with its desire to assist in the resolution of as many of the problems related to physician's assistants as possible, applied for and received funds from the Department of Health, Education, and Welfare[39] to conduct a year-long study, with the objective of designing a means whereby physician's assistants might be most advantageously accommodated into the legal framework of health care delivery. Although the immediate focus of concern has been on the physician's assistant in North Carolina, the objective of the study has been the development of a model legislative proposal which will be adaptable to other emerging health manpower categories and to other states.

The philosophy of the project has centered around the fact that the delivery of medical care requires the coordinated and cooperative effort of many types of personnel, the totality of which is often referred to as the "health team." It was recognized that introducing a new member into this team would affect, directly or indirectly, other members of the team. In addition, it was recognized that those people presently working in the health care system are most aware of the needs of that system and of the realities in relation to which any legislation must operate. It was decided, therefore, that effort should be concentrated on securing the participation of representatives of the health team in order that the benefit of their experience might be obtained and in order that the final product might be most acceptable to them and might be one which they would be willing to lend their support to in the political arena.

Because the educational institutions in North Carolina have pioneered in the development of this category of personnel and because there has, as a result, been significant exposure to assistants in this state, it was felt that North Carolina provided the optimal experiential and informational resources to warrant its being used as the laboratory or focus of this project. Effort has been made, therefore, to center the project around the participation of representatives of the health team in North Carolina--primarily physicians, nurses, and hospital administrators--and to enlist the aid of informed legal consultants from within and without the State of North Carolina.

The first step in the project was, of course, deciding on the general type of legislation which would be most advantageous and acceptable to the interested parties. To this end a conference was held at Duke on October 26th and 27th, 1969. Prior to this conference an informational paper was prepared for distribution to the participants

outlining several alternatives which had previously been advanced as possible means of regularizing the activities of new types of physician-dependent personnel. This paper served as background for discussion at the conference, which was attended by members of the North Carolina State Medical Society's Committee on Medical Education, members of the State Board of Medical Examiners, and interested physicians, nurses, and lawyers from around the state, as well as by several legal consultants from other states who possessed particular expertise in this area. The general alternatives considered at that conference will be briefly discussed below.

V. General Alternatives Considered

A. Maintain the Status Quo

The first alternative discussed was preserving the status quo and taking no formal action with respect to physician's assistants at this time. Because these assistants will perform in a dependent relationship with physicians, it would be possible to gain eventual protection through developing custom and usage in the profession. Such an approach, however, entails the legal risks cited above and primarily for this reason was unanimously rejected by the conference participants. Although it was acknowledged that liability should continue to attach in instances of actual negligence, it was felt that the possibility of incurring a penalty for mere delegation to or performance of a task by people not formally recognized should be eliminated. Aside from recognition that the parties presently involved should be relieved of undue financial and professional risks inherent with the lack of legislative sanction, concern was expressed that the possibility of such additional liability might in practical fact preclude the physician's assistant from effectively utilizing his training and making the anticipated contribution

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to health care delivery. Some physicians might be reluctant to employ such assistants under these conditions, and those who did employ them might be unwilling to utilize them in the most effective way. In view of the time and energy investments required for completion of a training program, there would seem to be a definite ethical obligation to the physician's assistants to provide some assurance that there will be a legitimate place for them in the medical community. It is also true that at present, there is no formal public protection in the form of standards and qualification requirements for persons used in this capacity. As the physician's assistant concept becomes more established and more schools seek to institute training programs, some form of definite quality control would seem inevitable.

B. License Physician's Assistants as New Category

The most obvious means of regularizing physician's assistants is to license them in a manner similar to the licensure of other health personnel. This would alleviate some of the dangers of civil and criminal liability discussed above for the physician and the assistant, though liability would still attach on a finding of actual negligence or operation beyond the scope of the license. Licensure would have the additional advantages of enhancing the status of physician's assistants as an occupational category and of protecting the public through the specification of minimum qualifications and the official delination of the assistant's functional sphere.

The general problems related to the current licensure scheme have been discussed above, however, and the conference participants felt that it would be unwise to extend this scheme unnecessarily. They felt that its tendency to fragment health care delivery, to freeze roles at

what later become unrealistic levels, and to impede occupational mobility and entry into the field by imposing rigid and specific formal educational requirements were significant disadvantages. The primary justification for licensure is the attendant assurance of the competence of practitioners, at least at the outset. It was felt that the problem of incompetence of physician's assistants would be minimal since they would not function independently but rather under the supervision of a physician, whose vicarious liability for the assistant's negligence should be incentive for him, the physician, to adequately monitor competence.

An additional argument against licensure is posed by the very concept of the physician's assistant. The physician's assistant functions in a personal relationship with a physician. Although the assistant receives a core of basic background knowledge and skills through participation in the formal training program, it is intended that his education should continue throughout his work experience under his physician's supervision. New skills would certainly be acquired over time and new understandings gained as the assistant becomes more familiar with the practice of his particular physician. A scope of practice specified for the recent program graduate might impose an unjustifiable ceiling on the graduate with a number of years' experience. Similarly, the skills taught one assistant by his employing physician might be very different from those taught another assistant whose employing physician practiced a different specialty or simply chose to use his assistant in another way. In other words, if defined by the sets of functions performed (scopes of practice), there could be as many types of physician's assistants as employing physicians. Training

programs are even permitting a measure of concentration in particular areas, which may result in an assistant's having greater expertise in his area of concentration even at the time of graduation than do most of his contemporaries. This diversity of experience and the consequent diversity in capability would pose a significant obstacle to the formulation of a universally realistic definition of a scope of practice for physician's assistants.

In addition to the consensus that licensure would not be a desirable solution to the problem of physician's assistants, there was speculation that the time is near for a full-scale re-evaluation of the efficacy of licensure even for those health professions currently regulated in this way. It was acknowledged that in view of the vested interests in the existing system, any major change would likely meet with great opposition from many vocal health professions and occupations. A fundamental change affecting established groups must probably, therefore, await a worsening of the situation in order that the resistence from within might be overcome. Any legislative action on behalf of physician's assistants at this time will in all probability be an interim measure pending a broader-based revamping of the whole system of health manpower regulation.

C. License Users of Physician's Assistants

Because the physician's assistant performs solely dependent functions, acting under the direction and supervision of a physician, the possibility for abuses by the supervisor-employer were thought to be greater than by the assistant himself. Another possibility would, therefore, be specially licensing physicians or institutions to use such personnel. A responsible licensing board could be charged with

investigating the ability of a particular physician to supervise an assistant, the feasibility of using such an assistant in his type of practice, and the professional integrity of the physician, so as to insure that the assistant would not be used as a de facto physician. The most apparent obstacle to this scheme is the difficulty of establishing licensing criteria and finding workable means of evaluating the physician with respect to these criteria. It would perhaps be possible to grant provisional licenses, with final determination to be made on the basis of actual performance and with periodic review to insure against subsequent abuse. Such a scheme should alleviate the danger that liability could rest on the mere use of unlicensed personnel in the face of a licensure scheme, since the legislature would have voiced approval of such use through the issuance of these licenses to physicians or institutions. There would still be a problem of whether to define the limits of the use physicians might make of these personnel or to rely on the development of custom and usage (both of which involve difficulties discussed previously) to resolve practical "good practice" questions that could continue to arise in malpractice cases in which improper delegation is alleged by plaintiffs who feel that the license has been abused or exceeded. It would be possible to couple this type of licensure with the scheme proposed in Section D. (infra), thus allowing the specially licensed physicians to utilize personnel for functions approved by a Committee on Manpower Innovations. This would provide further protection for the physician because permissible delegations would be specified, and it would give some assurance to the Committee that all physicians participating in manpower innovation experimentation had been screened to some extent.

A somewhat similar approach which emerged at the conference and which enjoyed greater enthusiasm among the participants would require that the prospective user of personnel submit to his licensing board (board of medical examiners, board of nursing examiners, hospital licensing board, etc.) job descriptions for the various positions to be filled in his particular setting. These descriptions could specify the set of tasks or functions which would be performed by personnel occupying the positions and the degree and nature of the supervision which would be provided. The board would consider the submitted descriptions and if it granted its approval would specify the qualifications necessary for persons assuming the jobs. The user could then employ personnel with the requisite qualifications and enjoy the sanction of the board in delegating tasks encompassed under the approved job descriptions. If the user later desired to alter the set of tasks performed by a given person, he could submit an appropriate request to the board for consideration.[41]

This approach has the advantage of flexibility, in that it avoids the necessity of naming classifications of personnel and allows modification--either expansion or contraction--of roles as the need arises, without resort to the legislature. It also has the advantage of defining the scope of practice in terms of the particular situation and avoids the necessity of establishing a separate board to control the use of physician-dependent personnel. Concern was expressed by those with legislative experience in North Carolina, however, that such a proposal would stand little chance of success in the legislature at the present time. It was felt that requiring each individual position to be approved would create a mammouth job for the Board of Medical Examiners and would

therefore entail significant delays between submission of the description and its approval. It was predicted that such a proposal could not gain the support of the medical profession at this time, and a united front by the profession will be virtually essential to securing this type of legislation. It should be noted, however, that although this approach was rejected at the October conference, it received renewed support by some participants at the second conference, in March, 1970, and emerged basically as one of the favored alternatives. The reasons for this will be discussed at a later point in this paper.

D. Establish a Committee on Health Manpower Innovations

Another approach discussed would be to seek legislative establishment of a Committee on Health Manpower Innovations, under the auspices of and responsible to the Board of Medical Examiners of the State. Such a committee could be composed of representatives of all health professions concerned with problems of manpower shortage, such as physicians, nurses, and hospital administrators, and a representative of the general public. Any group wishing to initiate a program for training a new type of manpower would submit a written proposal for Committee consideration, detailing its objectives, curriculum, faculty, and facilities. It would have to be prepared to show that the program was responsive to a need that was not satisfied by existing personnel and that patient safety had been assured. If tentatively approved, the program could be put into operation, but periodic follow-up reports, including evaluations by those using members of the new category would be required. After two years of successful operation under such observation, the program would be eligible for approval but would be subject

to continuing review at five-year intervals. This would facilitate the perpetuation of categories that prove successful, the elimination of unsuccessful ones, and the modification of programs as the need arises. It obviously would have implications beyond the immediate problem with physician's assistants and would facilitate innovation with respect to new roles for established personnel as well as the creation of new manpower categories. Such an approach would further the public interest by insuring that experimentation would be controlled and by encouraging more efficient medical care delivery through the removal of some of the obstacles that even responsible innovation meets today. It would eliminate the necessity of going to the legislature with each new category or role innovation and the attendant problem of developing workable definitions not subject to speedy obsolescence.

Medical practice acts presently have exemptions for certain categories of practitioners. They could be amended to include an additional exemption in a form similar to the type discussed for supervised delegations (Section E, infra), with specification that the delegations be of a nature and to personnel approved by the committee. This, coupled with the fact that the Committee itself would be legislatively established, should give sufficient legislative sanction to the use of these personnel to minimize the chance of civil and criminal liability based solely on violations of the licensing laws. Although negligence and malpractice questions might still arise with respect to particular delegations, the careful supervision by a responsible Committee should go far in establishing that the use of new personnel and new roles is being conducted in a manner consonant with good medical practice until such time as it is validated by custom and usage.

One criticism advanced with respect to this proposal related to the suggested composition of the Committee. Being constituted primarily of representatives of various existing health professions, there would be a danger that the Committee would be overly concerned with protecting the respective provinces of the group they represent. In other words, there would be danger that self-interest might obscure the primary concerns of need and patient safety. It would be hoped that supervision by the Board of Medical Examiners could afford some protection against this.

Although this approach was viewed favorably as a means of regulation at some future time, it was pointed out that at present there is in North Carolina widespread dissatisfaction with the multiplicity of administrative boards and agencies at the state level. It was the opinion of the conference participants that an attempt to establish a Committee of this type at the present time would encounter significant opposition in view of the current movement to streamline the administrative machinery. It was decided, therefore, that such a proposal would not be feasible for resolving the situation in the immediate future.

E. Enact a Statute Authorizing General Delegations

Four states at present have general statutory provisions authorizing delegation of functions to be performed under supervision, with slight variation as to who may delegate and to whom delegations may be made.[42] These provisions are framed as exemptions from the medical practice acts of the states. Typical of these is the Oklahoma statute, which reads as follows:

> ...(N)othing in this article shall be so construed as to prohibit...service rendered by a physician's

> trained assistant, a registered nurse, or a licensed practical nurse if such service be rendered under the direct supervision and control of a licensed physician.[43]

Although these statutes were apparently not enacted with physician's assistants in mind, it would appear that they could legitimize the activities of such personnel as long as requisite supervision is maintained. Such statutes have the advantage of great flexibility but appear to provide only minimal protection for all concerned, as the guidelines are vague and there are apparently no formal checks.[44] There would still be dangers for physicians with such an approach if specification was not made regarding such questions as who exactly qualifies as a delegatee and what exactly may be delegated, because when litigation arises and the court has only these vague outlines, it will again have to resort to custom and usage to determine negligence *vel non* with respect to the particular delegation in the particular circumstances. This type of law would, apparently, prevent running afoul of the licensure laws *per se* and would leave questions of good medical practice in given instances to judicial or executive interpretation, which is likely to be the case to some extent in all but the most precisely defined scheme.

It was felt that the flexibility of this approach has much to commend it over some of the more precise schemes that are vulnerable to early obsolescense by over-specification. It was also felt, however, that additional authoritative guidelines should be provided for the operation of such statutes in the interest of protecting the patient, the physician, and the delegatee.

VI. General Approach Decided Upon

After a discussion of the merits and disadvantages of the several alternatives, it was the concensus among those assembled that the best approach would involve elements of alternatives C,D, and E, above. It was felt that the first step in legitimizing the activities of physician's assistants should be the enactment of an exception to the Medical Practice Act, specifying that acts performed by a trained assistant under the direction and supervision of a licensed physician should not be construed as within the prohibited unlicensed practice of medicine. This is similar to the statutes discussed above in Section E.

From the standpoint of the physician and his assistant, it was felt that such an exception would reduce the risk of criminal prosecution for the unlicensed practice of medicine by the assistant and for aiding and abetting by the physician, as long as the tasks delegated are in fact supervised by the physician. It was also anticipated that the statute would preclude the drawing of an inference of negligence in a civil suit from the mere delegation of tasks to or the performance of tasks by unlicensed personnel. It was felt that liability should inhere only on a showing of actual negligence, either on the physician's part, in delegating to an assistant he knew or should have known was not competent to perform the task delegated, or on the assistant's part, as demonstrated by his failing to satisfy the requisite standard of care in performing the task. In the event actual negligence could be established, the assistant would continue to be liable to the injured patient, and the physician would continue to be vicariously liable under the doctrine of respondeat superior.

As was noted above, however, concern was expressed that such a statute does not specify the type of delegations which are permissible nor define the term "trained physician's assistant" for purposes of determining exactly which persons might accept delegations. There was also general feeling that regulation of assistants should not be vested solely in the hands of the individual physician but that the organized profession should exercise some control. In response to these concerns therefore, variations of alternative C, special licensure of physicians, were considered. As originally conceived, under this approach the physician wishing to employ such an assistant would be specially evaluated with respect to his ability to supervise, the feasibility of using an assistant in his type of practice, and his professional integrity. He would then be granted a special license authorizing him to utilize an assistant. Although this type of formal additional licensure was rejected, it was felt that because the assistant is in reality extending the service potential of the physician, control should be exerted through the mechanism set up to regulate medical practice, namely the State Board of Medical Examiners. It was decided, therefore, that the protection of the statute should extend only to cases in which the basic qualifications of an assistant to function in this relationship with a physician have been reviewed and approved by the Board of Medical Examiners. There was some concern that physicians might be lax in seeking approval of their employees, but it was pointed out that since such approval would be necessary to avoid the additional liability which could inhere merely for improper delegation, the insurance carriers for the practitioners might in practical fact perform an informal policing function.

Unlike traditional licensure statutes, it was felt that initially under this proposal there should be no specification as to the permissible scope of practice for the physician's assistant. Rather, it would be for the individual physician to determine what his assistant can or cannot do, upon consideration of his needs and the particular qualifications of his assistant. Questions could still arise, therefore, as to whether a particular delegation would be proper, and recognition that an improper delegation would continue to be actionable should inject caution into the actual delegation practices of the individual physician. This flexibility was felt desirable, however, in view of the variations both in types of practice and in capabilities of assistants.

From the standpoint of the public, such a statute, by removing the fear of unwarranted civil and criminal liability, would likely encourage the development and effective use of new types of personnel so badly needed in view of the existing and forecast physician shortage. Public protection should be assured by the physician's liability in instances of actual negligence and his knowledge that if he does not in fact exercise direction and supervision he will not benefit from the exception's protection at all.

It was recognized that experience with this system might disclose a need for a more formal definition of scope of practice or more formal guidelines as to what constitutes proper delegation. It was proposed that at that time a committee be organized under the State Board of Medical Examiners to develop such a definition. This would be essentially the second phase of a regulatory program. A determination was not made at the conference as to whether this would require additional

legislation or whether it could be accomplished under the Board's general rule-making power. Because the definition of scopes of practice has traditionally been an aspect of licensure, effected by the legislature, it is possible that specific delegation of this task by the legislature, along with general standards to govern the development of a definition, would be necessary.

Under the above scheme it appears that the problems of the physician's assistant per se could be resolved. It was recognized, however, that the basic issue is broader than the question of how to fit this particular emerging category into the health care framework. Because of expanding knowledge, the population increase, and the reorientation from "medical care" for those who can afford services to "health care" for society as a whole, it may be forecast that in the coming years many new types of paramedical personnel will be entering the picture. The sentiment in the country today seems to be against extending the licensure scheme to accommodate these new groups of personnel. It was suggested at the conference that the eventual resolution of the problem might lie in the establishment of an independent board or committee similar to that discussed in Section D, charged with regulating the practice of all allied health professionals. Such a body would be responsible for determining the qualifications and scope of practice for all auxilliary personnel and for generally coordinating the activities of the various groups. This type of board would provide the flexibility necessary for keeping the roles of the personnel groups more immediately responsive to their capabilities and the needs of health care delivery over time. Composed primarily of representatives of health professions, the board would have the expertise required for making such judgements. No agreement was reached as to whether the

board should formally license members of the various groups, certify them or merely approve their general activities and maintain supervision. The creation of this board was regarded as the third step in the development of a regulatory program, and some participants felt that it should be established at the national level rather than by the individual states.

It was decided that the present project should be concerned primarily with developing the first stage of regulation, namely a general statute authorizing supervised delegations and vesting the responsibility for determining proper delegatees in the State Board of Medical Examiners. It was acknowledged that in practical fact this limited legislation might prove adequate and that it might not be necessary to proceed further. It was suggested, however, that in drafting this initial legislation as much consideration as possible should be given to questions which might arise pertaining to the development of further regulation, should that prove necessary, in the interest of coordinating activities and avoiding unnecessary duplication of effort.

VII. Inter-Conference Activity

Following the October conference, attention was directed to the preparation of an initial draft of a legislative proposal. Two considerations seemed to be of primary importance to those participating in these meetings. First, because the concept of physician's assistants is relatively new and the potentials of these assistants are not yet clearly defined, any legislation should provide sufficient flexibility to allow optimal development and use of these personnel, consonant with insuring the safety of the patient. Second, because

these assistants work directly with physicians who assume responsibility for their actions and who are in the best position to be aware of their abilities and limitations, regulation of these personnel should be in the hands of the medical profession. With these considerations in mind, a draft of an exemption statute and explanatory notes was written and circulated among those who had participated in the October conference, as well as among others who had indicated an interest in the project. Those to whom the draft was distributed were requested to submit their comments, criticisms and suggestions for changes. On the basis of the responses to the initial draft, a second draft was prepared, incorporating several suggestions made by the reviewers. This draft was in turn distributed and reactions solicited.

The responses to both drafts indicated approval of the general approach of the proposed statute, which is set forth and explained in the next section. It was felt at that point, however, that another meeting should be held for further discussion of the issues, in terms both of the draft of the October proposal and questions which had arisen with respect to it, and of new ideas regarding approaches to the problem. A meeting was, therefore, scheduled for March 1, 1970, to which the previous conference participants and other interested parties were invited.

Those attending the March meeting still appeared to favor the basic approach of an exception to the Medical Practice Act, and discussion focussed on the original proposal suggested in October, a variation of that proposal suggested and developed by one of the legal consultants on the project, Clark C. Havighurst, and an alternate approach suggested in October by another of the legal consultants, Nathan Hershey. The basic difference among the three approaches

centers around the degree and nature of control to be exerted by the organized medical profession, as represented by the Board of Medical Examiners.

VIII. The Proposals

A. The October Proposal

This proposal was formulated on the basis of the discussion which took place at the October conference and on the basis of responses to the circulated drafts. The explanation herein will be more lengthy than for the remaining two proposals for the reason that many of the aspects are common to all three and do not require re-iteration. Discussion of the Havighurst and Hershey proposals will focus primarily on the aspects in which they differ from the October proposal.

S90-18 of the North Carolina Statutes, after prescribing the penalty for the unlicensed practice of medicine, reads:

> 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.

The proposal would be exception (14) to this definition of the practice of medicine. The proposal based on suggestions made at the October conference and subsequent correspondence reads as follows:

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

Framing the authorization for delegations as an exception to the Medical Practice Act is in keeping with the form in the four states (Arizona, Colorado, Kansas, and Oklahoma) which have attempted, although not specifically on behalf of physician's assistants, to provide protection short of licensure. Nor is the concept entirely new to North Carolina. Exception (7) to the Dental Practice Act reads as follows:

> Any act or acts performed by an assistant to a licensed dentist when the said act or acts are authorized and permitted by and performed in accordance with rules and regulations promulgated by the Board (of Dental Examiners).

Although the method of regulation differs with respect to delegations by dentists, the basic objectives of this exception and the above proposal are the same: to allow the licensed professional to receive assistance without fear that liability will be incurred by either him or his assistant simply because delegations are made to unlicensed personnel.

In accordance with the determination that regulation should be in the hands of the medical profession, the proposal would establish a two-stage method of control. Organized medicine would participate in the regulation process in three principal ways, through the Board of Medical Examiners. First, before a physician or his assistant could have the benefit of the protection afforded by the statute, the assistant must have gained the approval of the Board of Medical Examiners, signifying that he has in some way demonstrated his qualification to perform under a physician's supervision. Determining precisely what criteria would govern the granting or denial of this approval will be the responsibility of the Board. It is anticipated that the Board might evaluate the curriculum, faculty, and facilities of the various programs and approve graduates of ones that

it finds acceptable. (It is hoped that an accreditation mechanism will soon be developed for this type of program which could relieve the Board of the program-evaluation task.) Having a presumption in favor of graduates of acceptable programs would reduce the burden of having to consider closely the qualifications of each individual applicant and would give assurance to persons entering approved programs that they will be able to function legitimately upon graduation. The consensus of the group was that the Board should also consider, presumably on an ad hoc basis, the qualifications and abilities of persons without the benefit of a formal program but who have received appropriate training in some other manner. This would insure that academic credentials not be the sole criterion for approval to perform in this capacity.

Second, it was recognized that an assistant, once approved, might subsequently demonstrate incompetence or unwillingness to perform within the confines of the physician's direction and supervision. Similarly, it might later appear that the responsible physician is using his assistant in an inappropriate manner, with the assistant consenting by remaining in the situation. It was felt, therefore, that implicit in the board's power of approval should be the power to deny or revoke approval under circumstances and in a manner prescribed by rules and regulations promulgated by the Board. The initial draft specified that the assistant should be "currently approved," but legal consultants on the project advised that "currently" was not necessary to imply such a power and the word was, therefore, omitted in the subsequent draft.

Third, the final clause would require the Board to consider what safeguards should surround an assistant's performance and to promulgate rules accordingly. An example of a rule which might be adopted under this clause is one requiring that the patient be adequately apprised of the assistant's status, as by an identifying name tag. This provision would also allow the Board to cope with other questions that might arise with the operation of the statute. For example, the degree and nature of direction and supervision required of the physician is not specified in the statute. In recognition of the variety of tasks which could be delegated and the diverse capabilities of the individual assistants, it was felt that specificity would be unwise. The intent of the proposal is that the required degree and nature of direction and supervision should be that appropriate to the particular situation and circumstances. While immediate oversight by the physician might be necessary when complex procedures are performed, general instructions and subsequent review by the physician would be sufficient for routine duties. Further definition of these terms--either to broaden or to restrict their meaning--would render the proposed statute inappropriate for a variety of situations, and it was felt that physicians themselves must give the terms meaning in relation to particular circumstances. As long as there is no further definition, questions--should they arise--may have to be resolved in court, quite likely on the basis of expert testimony as to what type of supervision was appropriate to the circumstances. It may become apparent after experience with assistants, however, that some guidelines can be drawn with respect to certain typical situations.

Such guidelines could subsequently be embodied in rules and regulations promulgated under the final clause. This clause did not appear in the first draft which was circulated but was suggested by a legal consultant and approved as a desirable addition.

The second stage of regulation would be in the hands of the individual physician, who would have two primary functions. First, it would be his responsibility to evaluate the particular skills of his assistant and to determine what tasks are and are not within his competence. Second, he must direct and supervise the activities of his assistant in order to bring such activities within this exception. As was stated previously, he should have adequate incentive to exercise caution and proper control since he will be vicariously liable for the negligent acts of his assistant and possibly directly liable if he knew or should have known that the assistant was not competent to perform the task delegated. In this area of professional activity, negligence includes more than mere carelessness. Because the assistant will be undertaking some tasks traditionally performed by the physician, he will presumably be held to the same standard of care and have to demonstrate the same knowledge and skill as the physician with respect to these tasks. This seems to be the approach the North Carolina courts have taken in the past.[45] In the area of civil liability, therefore, it should be noted that such an exception would do nothing more than preclude the drawing of an inference of negligence from the mere delegation to an unlicensed person.

It should also be noted that the proposed statute would not strictly require an employment relationship between the physician and the assistant. Rather, to be protected the assistant must be

approved and must be acting under the direction and supervision of a licensed physician. It is conceivable that the assistant's salary could be paid by a hospital, if he in fact functions as a physician's assistant, under a physician's direction and supervision.

It was felt that the wording of this proposal makes a limitation regarding diagnosis and prescription of treatment both unnecessary and unwise. Such a limitation received some discussion at the October conference because it was felt that these activities represented the essential ingredients of medical practice and should therefore be beyond the sphere of a non-physician. This proposal, however, provides an exception only for dependent activity--activity directed and supervised by a licensed physician. It will not permit the assistant to function as an independent practitioner, even within the office of a physician. To state that independent diagnosis and prescription of treatment is not protected by a statute which is explicitly limited to dependent activity would seem to be restating the obvious. If the limitation provided that the assistant could not engage in dependent diagnostic or prescriptive activity, directed and supervised by a physician, it would severely limit the potential contribution of the physician's assistants as they are being trained today. As has been stated previously, one of the primary purposes in enacting a statute of this type is to prevent liability based solely on the delegation of tasks to or the performance of tasks by unlicensed personnel. There are three primary elements of medical practice under the North Carolina definition quoted above: diagnosis, prescription, and treatment. If this limitation were imposed, the physician's assistant and his supervising physician would be protected

only if the tasks delegated related to the treatment process. The taking of histories and collection of physical data, for instance, would not be protected because these occur prior to treatment and are part of the diagnostic process. Yet it is by performing exactly these tasks that the physician's assistants are proving most useful to the physician. The wording of this proposal reflects a feeling that the physician's discretion and supervision must be relied upon regarding all phases of the assistant's activities. If his integrity--buttressed by his financial responsibility--is adequate protection against improper delegation of treatment tasks, it should also prevent abuse with respect to delegations more closely related to diagnosis and prescription. None of the other states with statutes of this type have a limitation regarding diagnosis and prescription of treatment, and correspondence with their State Medical Societies indicates that there has been no adverse experience with these statutes.[46]

Two suggestions for changes in the October proposal emerged at the March meeting. First, it was pointed out that consideration should be given to changing the term "licensed physician" to "physician licensed by the Board of Medical Examiners," since the general term "licensed physician" has been interpreted to include chiropractors.[47] There was no objection to this change. Second, for reasons which will be discussed subsequently, it was suggested that the term "physician's assistant" be changed to "assistant to a physician." This suggestion was also generally approved. In response to these recommendations, following the March 1 meeting the draft was revised to read as follows:

(14) Any act, task or function performed by an assistant to a physician licensed by the Board of Medical Examiners, provided that

a) such assistant is approved by the Board as one qualified by training or experience to function as an assistant to a physician, and

b) such act, task or function is performed at the direction and under the supervision of such physician, in accordance with rules and regulations promulgated by the Board.

Possible rules and regulations for the administration of such a statute appear as Appendix II to this report.

B. The Havighurst Proposal

The proposal advanced by Mr. Havighurst is also for an exception to the Medical Practice Act and reads as follows:

(14) Any act, task, or function performed at the direction and under the supervision of a licensed physician by a person qualified by formal or informal training and experience to perform such act, task, or function when the said act, task, or function is performed in accordance with such rules and regulations as may be promulgated by the Board of Medical Examiners.

Obviously, this proposal has much in common with the proposal which emerged from the October conference. It employs the above-discussed regulation by the physician, in terms of vesting in him the responsibility for evaluating the competence of the person to perform a particular task and for directing and supervising the performance of tasks judged to be within such competence. As with the October proposal, the physician would remain liable for instances of actual negligence, either in the performance of the delegatee or in his delegating to unqualified personnel, but would presumably be protected against an inference of negligence based solely on lack of a license. Likewise, the possibility of criminal prosecution would continue to exist if the physician removed himself from the statute's

protection by delegating to a person not in fact qualified to perform the delegated task, by failing to maintain direction and supervision, or by failing to observe the rules and regulations to be promulgated by the Board. Beyond the guidelines to be provided by such rules and regulations, further questions as to the definition of such terms as "direction and supervision" would in all likelihood have to be resolved in court with the assistance of expert testimony. Determination of a particular delegatee's qualification to perform a particular task, if challenged, could possibly be made on the basis of testimony by those responsible for his training experience.

This proposal would also charge the Board of Medical Examiners with providing safeguards in the form of rules and regulations to surround physician-delegated activity. It differs in two principal respects from the October proposal, the implications of which will be discussed below as the proposals are compared. First, it does not give the Board the power and responsibility of initially approving the qualifications of the individual delegatee. Primary reliance for the public's protection is placed on (1) the physician's ethical and professional judgment, (2) the deterrent effect of the malpractice risk attending the use of unqualified personnel, and (3) supervision by physicians' and hospitals' malpractice insurers. It was also proposed that, should these be regarded as inadequate safeguards, the Board of Medical Examiners might be charged with investigating complaints concerning delegation to incompetents. The Board could be empowered to issue administrative cease and desist orders when, after notice and a hearing in which the burden of proof was on the delegating physician, it found that a particular assistant had

been assigned functions beyond his competence. Under such a system, investigation could be initiated by the Board on its own motion or by complaints submitted by others to whose attention abuses have come, presumably physicians or aggrieved patients.[48] Unlike traditional license revokation, this would not necessarily deprive the physician or the delegatee of a livelihood while the facts are being determined because they could continue to function in areas in which competence had not been challenged. It was pointed out that health departments are at present generally authorized to issue such administrative injunctions in situations where delay may result in harm to the public. The specific example given was the power of public health agencies in many states to close restaurants and food storage places in instances where there is danger that food has become tainted. It was emphasized that protection against harassment by irresponsible patients or competing physicians might be provided by requiring sworn affidavits alleging grounds for belief that abuses have occurred and by giving the Board discretion to refuse to initiate a proceeding if the complaint appears to be unfounded. It was also postulated that a physician might be given the right to have an employee's competence certified in such a proceeding on his own motion.

Second, under this proposal the term "physician's assistant" is eliminated altogether, for reasons which will be set forth below.

C. The Hershey Proposal[49]

The regulatory scheme advanced by Mr. Hershey in October and revived in March could, again, be formulated as an exception to the Medical Practice Act, reading basically as follows:

> (14) Any act, task, or function performed at the direction and under the supervision of a licensed physician by a person who is working in accordance with a job description approved by the Board of Medical Examiners and who possesses the qualifications which have been established by the Board for the described job.

Under such a statute, a physician desiring to employ an assistant who does not have some type of license or who will be performing tasks beyond the scope of his license may submit a job description to the Board of Medical Examiners. The description should include a list of the tasks and functions which would be delegated to the assistant, a statement as to the amount and nature of supervision to be provided by the physician, specification of the physician's qualifications to supervise the performance of such tasks and functions by an assistant, and any other information deemed relevant by the physician. The Board would review the submitted description and information, and if it appeared that the proposed job would not exceed what is conceptually beyond the capacity of a non-physician[50] the Board would approve the job and specify the qualifications necessary for a person assuming the position.[51] In October, it was postulated that the physician could include a statement of suggested qualifications with the description submitted, which could also be considered and, if necessary, modified by the Board before approval. This would possibly relieve the Board of some of the burden of initially formulating qualifications since it could focus on and evaluate the considered suggestions of the physician. Upon approval of the job

description and determination of the necessary qualifications by the Board, the physician could then employ a person possessing the specified qualifications and forward such person's name and resume to the Board. The physician would then be authorized to delegate the tasks set forth in the job description to this person. When delegating in accordance with this scheme, the physician would enjoy basically the same type of protection from civil and criminal liability discussed above for the October and Havighurst proposals. It is likely, however, that the protection could be somewhat greater since the delegation of the particular tasks would have been approved, thereby resolving some of the uncertainties as to what constitutes a proper delegation to a person with certain qualifications. It is possible that functioning within the approved job description would give rise to the same presumption of competence with respect to the tasks delegated that presently exists for performance within the practice scope of a license. This might allay some of the fears regarding proving the competence of an assistant should such competence be challenged. Liability dangers would continue to exist for actual negligence and for delegation or performance beyond the scope of the approved job description.

This approach would allow great flexibility by focussing on the situation in the particular physician's office or institutional setting. The job set could be expanded or contracted over time, with Board approval, in accordance with technologic development, changes in the physician's needs and capacity for supervision, and changes in the supply and qualifications of available personnel. Some fear was expressed in October that consideration of all such jobs in all phy-

sician's offices would be a task of such magnitude for the Board that significant delays would result. It was pointed out, however, that although each physician would have to submit his own descriptions, there would probably be much duplication among categories of physicians, and once a description had been approved, approval of subsequent descriptions of the same type would likely be pro forma. It was also suggested that physicians could be aided in the formulation of acceptable job descriptions by a periodic publication of those descriptions currently approved by the Board.[52]

It was pointed out that although the above proposal and discussion focuses on the physician and his licensing board, a scheme such as this is adaptable to other areas of the health care system. For example, a similar procedure could be developed for the regulation of positions within institutions or for the regulation of personnel performing under the direction and supervision of health professionals other than physicians by requiring submission of job descriptions to the respective licensing boards of the institutions or professionals to be responsible.

Ix. Comparison of Aspects

A. Public Protection

The primary consideration involved in developing any proposal, of course, is that the safety of the public be adequately provided for, and the proposals above evidence different evaluations as to how this can best be accomplished. All three proposals reflect agreement that regulation should be in the hands of the medical profession, and their differences are based primarily on disagreement as to the type and extent of quality control which can

realistically be expected to issue from the Board of Medical Examiners, as representatives of the organized profession.

Under all three proposals it would be the physician's responsibility to direct and supervise the actual performance of his assistant. Under the October and Havighurst proposals, it would also be for the physician to determine what specific tasks the assistant can and will perform. The Havighurst proposal explicitly states that the person must be competent to perform the particular task delegated; but this is also implicit in the October proposal. If the physician delegates and the assistant performs a task which the delegatee is not qualified to perform, both could likely be deemed negligent, and such actual negligence would not be protected. It should be remembered that either proposal if enacted would be an exception from the prohibition against the unlicensed practice of medicine and would be useful in a civil suit only to prevent the drawing of an inference of negligence from the mere delegation to unlicensed personnel. Actual competence and negligence issues would have to be determined on the facts of the particular case. It was suggested that under the October proposal the incentives of the individual physician and his malpractice insurer for carefully monitoring the competence of the assistant may be weakened because they may relax in reliance on the initial approval given by the Board. There is room for disagreement on this point, however, since Board approval would offer no protection when actual negligence (which may consist of delegating at all) is involved.

It was postulated that under the Havighurst proposal professional liability insurance carriers may be relied upon to exercise some degree of supervision in situations involving physician use of unlicensed personnel, for the simple reason that they have a significant financial stake in the competence of the auxiliary personnel. Some

participants disagreed with this, however, largely on the basis of the additional energy and expense which would be required from insurers engaging in such a policing function. It was pointed out that insurance companies are currently not enthusiastic about their professional coverage and that putting them in the position of being expected to assume additional supervisory functions might be sufficient inducement for them to pull out of this area of service altogether. It was also pointed out that because of the nature of their financial stake, insurers are inherently conservative and may exert a negative influence on the development and use of badly needed new personnel.

Under the October proposal, protection in addition to that afforded by the direction, supervision, and ultimate responsibility of the individual physician would be provided by the Board of Medical Examiners through a system of approval and disapproval of those who intend to function as assistants to physicians. Fear was expressed by some that considering the financial and staff limitations of the Board, it may be unrealistic to think that the Board could effect any significant degree of regulation. Others, however, felt it preferable to increase the resources of the Board if necessary rather than to abandon this aspect of the proposal. Criteria upon which approval would be granted or withheld would be determined by the Board on the basis of its particular expertise and would be embodied in its rules and regulations. Some concern was expressed as to what criteria could be used for the general approval of such assistants. It was pointed out that some of the training programs have been seeking the establishment of a national program accreditation

mechanism, under the auspices of the Association of American Medical College and/or the American Medical Association. It is hoped that this will be developed in the near future to assure the quality of training programs.[53] Standards developed for such accreditation could be useful to the Board in performing its evaluation function. No suggestions emerged as to how applicants who had not had the benefit of a formal program could be evaluated but an equivalency examination, perhaps developed in cooperation with the training programs, would appear to be one reasonable means. It has been speculated that the provision for ad hoc approval for non-graduates may in effect operate much as does the grandfather clause in many licensure laws since it is hoped that as more programs are developed around the country and as present programs are expanded, the supply of graduates will meet the demand for assistants, obviating the need for physicians to undertake the task of basic training themselves.

It was, however, pointed out that in view of the variety of functions assistants are and will be performing and concommitant differences in the types of training necessary, it may be difficult for the Board to grant or deny approval except in the context of the particular tasks to be performed, which may themselves change over time as new skills are acquired. The October proposal as presently constituted does not provide for the submission of a job description with the application for approval. Some participants, therefore, favored the Hershey proposal as providing more complete information and a more valid basis for the evaluation by the Board.

Under the Havighurst proposal there could also be provision for participation by the Board of Medical Examiners in the regu-

lation of such persons beyond the enactment of safeguarding rules and regulations. Rather than having the Board attempt to determine the competence of assistants ab initio, it would charge the Board with investigating complaints concerning delegation to incompetent personnel. It was suggested that the Board be empowered to issue cease and desist orders in situations discussed above. This would insure that if the physician were in fact abusing the privilege of delegation, organized medicine would not be powerless to stop the activity. The basic premise of the proposal appears to be, however, that if it is realistic to trust the physician with the important function of directing and supervising the activities of his assistant and, under the October proposal, of determining what tasks that assistant can perform, it should also be realistic to trust him with evaluating the basic qualifications of the assistant in the first place, making Board approval a needless and burdensome procedure.

The Havighurst proposal, therefore, differs from the other two in eliminating the requirement of some type of Board approval prior to the authorized functioning of a delegatee. The Hershey and October proposals differ on the basis of disagreement as to the type of approval which can most effectively operate to insure the public's protection. All three proposals would provide on-going supervision by the organized profession, the October proposal by rules and regulations surrounding performance and the possibility of withdrawing approval, the Havighurst proposal by rules and regulations surrounding performance and the power to issue cease and desist orders, and the Hershey proposal by requiring Board approval of changes in previously approved job descriptions.

B. Categorization

Concern was expressed that use of the term "physician's assistant" in the October draft, even though not capitalized, creates in fact a new category of health personnel. Many felt that by creating such a category, a unitary concept would be developed, embodying a fixed group of skills, presumably roughly equivalent to those possessed by graduates of the Duke and Bowman Gray programs. They argued that if this occurred, there would be a severe restriction of manpower, since approval would not practically be available to those who had not had the benefit of a formal program. This might also have the potential of tending to make newly developing programs adhere strictly to the format of the established ones, perhaps impeding innovative experiments in new training techniques and for somewhat different types of personnel. It was for this reason that the Havighurst proposal eliminates the term "physician's assistant" and instead focusses exclusively on the delegatee's competence to perform a particular function.

The group assembled at the March 1 meeting agreed that the October proposal did present a potential danger in this respect, since the term "physician's assistant," though basically descriptive, has been associated with the existing formal programs and their graduates. It was emphasized that this proposal is not intended to be addressed to a particular category but rather relates to a variety of assistants, from the registered nurse to the informally trained person from the community, who are performing under a physician's direction and supervision tasks which have traditionally been performed only by the physician himself. It was

apparently the sentiment of the group that the term "physician's assistant" should be changed to "assistant to the physician," which is descriptive of the relationship without carrying the strong connotation of being identified exclusively with program graduates. This change has been made in the most recent draft of the October proposal.

Quite obviously, the danger of categorization does not exist under the Hershey proposal, which focuses closely on the particular tasks to be performed by an assistant and restricts approval in relation to qualifications deemed necessary for the performance of the particular job. For example, persons performing limited technical tasks may not be required to possess the broad background in the general medical sciences which characterizes graduates of the Duke and Bowman Gray programs.

C. Situation for Present Personnel

There was some disagreement as to the effect the October proposal would have on unlicensed people who are now being delegated tasks by physicians but who do not apply for or are unable to get Board approval. It was the contention of some participants that the existence of a mechanism whereby approval could be granted would give rise to an inference against many persons performing valuable services in the physician's office who for some reason are not approved. Such fears regarding the October proposal would also be applicable to the Hershey proposal in situations where a physician permitted personnel to function otherwise than pursuant to an approved job description when an approval mechanism exists. This possible danger to unapproved personnel was cited as a major

reason for the elimination of the Board-approval aspect from the Havighurst proposal.

Others felt that no practical danger would be presented in this respect. As far as civil suits are concerned, North Carolina courts have not to date allowed an inference to be drawn against a person performing acts within the scope of practice of a licensed profession merely because that person was not licensed.[54] The approval system advanced in the October and Hershey proposals would appear to give less basis for the drawing of an inference against those not covered than would the more formal licensing schemes. As far as criminal prosecution is concerned, it was pointed out that this would be an exception to the Medical Practice Act and would only be addressed to those assistants arguably practicing medicine to some degree. The only "acts, tasks, or functions" or job descriptions which need to be excepted at all are those which fall within the definition of medical practice. If someone other than a licensed physician or a person falling under another exception performs these acts at the present time, he is probably performing illegally unless he is protected by established custom and usage. There was an apparent difference of opinion as to whether present custom and usage protections for various personnel would survive the enactment of a proposal establishing an approval system. It was suggested that perhaps the intent that such a statute not affect persons already protected by custom and usage might be expressed in rules and regulations promulgated under the statute.

Whether there would be created by the existence of an approval mechanism additional dangers to unapproved personnel or to personnel functioning otherwise than under an approved job description remained a matter of disagreement. There was also disagreement as to whether if such additional danger did exist, it would necessarily be a negative factor, since presumably approval would be granted where patient safety permitted and the burden attendant to securing approval would not be undue.

D. Constitutionality

The final issue discussed concerned whether the October proposal would constitute an unconstitutional delegation of legislative power because clear standards for approval would not be specified in the statute. This discussion is also relevant to the Hershey proposal which likewise does not specify standards for the approval of job descriptions. Although the issue of "adequate standards" has seemingly lost its importance at the national level, it continues to play a role in many states.[55] It was felt that at this stage in the development of the concept of physician's assistants it would be unwise, if not impossible, to formulate specific standards to be embodied in legislation. It was felt that the Board of Medical Examiners are the best judges of the standards against which such people (or job descriptions) should be measured and could be more immediately responsive to changing needs and developments with regard to physician-dependent personnel. They would also have the benefit of developing custom and usage over time in determining their standards and exercising their discretion. It

is perhaps noteworthy at this point that no penalties are intended to attach to non-approval of an assistant or job description by the Board. The proposals are intended only to provide an added protection which does not exist at present. This may somewhat alleviate the need for the more precise standards often required. It was suggested that although the "adequate standards" doctrine may present a problem, specificity should be avoided at this point. It was felt that if a good set of possible regulations were available at the time a proposal is introduced, the Legislature might be more inclined to make this delegation. It was recognized that at a later time the statute might be challenged, and a court might declare it void for lack of sufficient standards. If this occurs, the statute can then be rewritten, and hopefully the intervening experience with assistants to physicians will make specification of more definite standards possible.

Although it may be preferable to avoid the specification of standards and although they may not be considered necessary in some states, it is recognized that in other states it might be impossible to secure the enactment of such a statute absent some type of standards. Where this is true, perhaps a general statement of purpose could be included in the statute which might be construed as providing adequate standards. For instance, a sentence such as the following might be added to the October proposal:

> The Board shall grant approval of an assistant, if such appears to be in the interest of the public, after considering such factors as the education and experience of the assistant and the unfulfilled needs of the public.

The following proviso might be added to the Hershey proposal:

> A job description shall be approved by the Board if such appears to be in the public interest upon consideration of such factors as the unmet needs of the public and the physician, patient safety, and the availability to non-physicians of training appropriate to the performance of the acts, tasks, or functions described therein.

Although such standards are quite general and leave great discretion with the Board, they might be considered sufficient to uphold the constitutionality of the statute when such constitutionality might otherwise be doubtful.

X. Conclusion

No final agreement was reached on March 1 as to the single best approach for North Carolina. All three proposals would appear to accomplish the basic purpose of accommodating physician's assistants into the legal framwork of health care delivery, varying primarily in the degree and nature of the restriction which would be placed on the individual physician. The Havighurst proposal is obviously the least restrictive of the three, placing the power and responsibility for choosing the assistant and defining his role exclusively with the physician. The Hershey proposal is the most restrictive, providing for Board approval of the job descriptions and Board determination of necessary qualifications for persons performing under such job descriptions. The October proposal is intermediate in the degree of restrictiveness, in that it requires Board approval of the assistant but leaves the determination of permissible functions with the physician. The disagreement at the March meeting centered on which of these proposals would best meet the specific needs of this State. It was pointed

out that this is a problem which most immediately affects the physicians of the State and that further consideration of the alternatives might best be undertaken by the Medical Society. At its annual meeting in May, the House of Delegates of the Medical Society of the State of North Carolina passed a resolution empowering their Committee on Legislation to consider this issue and to help develop and request appropriate legislation. The three alternatives discussed above will be submitted to this Committee, and it is hoped that a satisfactory proposal will be ready for introduction to the North Carolina General Assembly when it next convenes, in January, 1971.

One fact which has become quite apparent in the course of this project is that it may be difficult from a political standpoint to secure the enactment of a uniform proposal in all states on this matter. In some states, for example, where the incidence of malpractice litigation is particularly high, physicians may prefer to sacrifice a degree of flexibility in their use of personnel for a more definite assurance that the particular use they make of the personnel is condoned. Another variable may be the degree of control over his activities that the individual physician is willing to relinquish to the Board of Medical Examiners of his State. Another obvious factor to consider is the time and resources which the Board is willing or able to devote to the regulation of subphysician personnel. Consideration of variables such as these will--and should be--important in selecting a realistic and acceptable means to regularize practice activities in a particular state. It is felt that each of the three alternatives discussed

above has merit and that, in view of the variety afforded, one of the three should satisfy the needs of any state. Final selection should be based on a careful evaluation of these needs and the realities of the situation in each state.

Although this project has been primarily concerned with legalizing the physician's assistant, it is felt that the basic approaches outlined above are adaptable to new categories of personnel functioning under direction and supervision other than that afforded by a physician. For example, new aides to nurses or other such licensed professionals could be accommodated by provisions similar to these in the respective licensing acts of the primary profession, as long as the performance of the new category remained dependent. The Hershey proposal would also appear to be quite adaptable to the institutional setting, since a properly constituted hospital licensing board could be empowered to approve job descriptions and establish qualifications for positions within the hospital.

It is recognized that there are many widespread doubts as to the efficacy of the health manpower licensing system as it exists today. There are proposals abroad for a full-scale reevaluation of the entire system with hopes that a more viable means of regulation, even for traditional manpower categories, might be developed. It is also recognized, however, that many groups have vested interests in the preservation of the current system and that, therefore, a radical restructuring will probably not be possible until the situation becomes critical enough to still or overcome the objections of these vocal and often powerful interest groups. The alternatives

discussed in this report are presented as means of accommodating new categories into the system as it currently exists, and it is recognized that they may, therefore, be only interim measures. It is felt, however, that some such action is needed to provide protection until such time as a more comprehensive restructuring is feasible.

Footnotes

1. See generally Estes and Howard, The Physician's Assistant in the University Center, NEW YORK ACADEMY OF SCIENCES, February 1970, pp. 37-44; Estes and Howard, Potential for Newer Classes of Personnel: Experiences With The Duke Physician's Assistant Program, JOURNAL OF MEDICAL EDUCATION; Powers and Howard, The Feasibility of an Assistant to the Physician, 31 N.C. MEDICAL JOURNAL 79-83 (1970).

2. See BULLETIN OF DUKE UNIVERSITY: PHYSICIAN'S ASSISTANT PROGRAM -- 1970-71.

3. Dr. Robert Howard, Director of the Duke Program, indicates that there are approximately six available positions for each graduate.

4. Inquiries from prospective applicants to the Duke Program are being received at the rate of 250 per week, which is a five-fold increase over last year.

5. Forgotson, Roemer, and Newman, Legal Regulation of Health Personnel in the United States, in II REPORT OF THE NATIONAL ADVISORY COMMISSION ON HEALTH MANPOWER 279 (1967) (hereafter cited as REPORT OF NATIONAL ADVISORY COMMISSION).

6. See Friedman, Freedom of Contract and Occupational Licensing 1890-1910: A Legal and Social Study, 53 CALIF. L. REV. 487 (1965).

7. R. Shryock, MEDICAL LICENSING IN AMERICA, 1650 - 1965, Chapter II, p. 43 et seq. (1967).

8. Forgotson and Cook, Innovations and Experiments in Uses of Health Manpower--The Effect of Licensure Laws, 32 LAW AND CONTEMPORARY PROBLEMS 731, 735 (1967).

9. M. Pennell and P. Stewart, STATE LICENSING OF HEALTH OCCUPATIONS 1 (1967).

10. Forgotson and Cook, supra note 8.

11. REPORT OF THE NATIONAL ADVISORY COMMISSION at 291.

12. Resume of Conference on Ethical and Legal Implications of Health Manpower Innovations, pp. 45-47, Duke University, March 31 and April 1, 1968.

13. Leff, Medical Devices and Paramedical Personnel: A Preliminary Context for Emerging Problems, 1967 WASH. U.L.Q. 332, 340-41.

14. REPORT OF THE NATIONAL ADVISORY COMMISSION at 426.

15. Leff, supra note 13, at 366.

16. Anderson, Licensure of Paramedical Personnel, 6, Address before 65th Annual Meeting of the Federation of State Medical Boards of the United States, February 7, 1969.

17. Leff, supra note 13, at 343.

18. REPORT OF THE NATIONAL ADVISORY COMMISSION at 293, citing People v. Whittaker, No. 35307, Justice Court of Redding Judicial District (Shasta County, Cal., Dec. 1966).

19. 68 Wash. 2d 122, 411 P. 2d 861 (1966).

20. Leff, supra note 13, at 387.

21. See, e.g., Grier v. Phillips, 230 N.C. 672, 55 S.E. 2d 485 (1949).

22. E.g., N.C. GEN. STAT. §90-18 (1965 Repl. Vol.). See Magit v. Board of Medical Examiners, 57 Cal. 2d 74, 366 P. 2d 816, 17 Cal. Rptr. 488 (1961); People v. Whittaker, No. 35307, Justice Court of Redding Judicial District (Shasta County, Cal., Dec. 1966).

23. See Board of Medical Examiners v. Gardner, 201 N.C. 123, 159 S.E. 8 (1931).

24. Leff, supra note 13, at 393. See Glesby v. Hartford Accident & Indemnity Co., 44 P.2d 365 (1935).

25. Roemer, Licensing and Regulation of Medical and Medical-Related Practitioners In Health Service Teams, presented at Conference on The Role of Law in Medical Progress, Boulder, Colorado, March 20, 1970.

26. See Curran, New Paramedical Personnel -- to License or Not to License, 282 NEW ENGLAND JOURNAL OF MEDICINE 1085 (1970).

27. REPORT OF THE NATIONAL ADVISORY COMMISSION at p. 423.

28. AMERICAN MEDICAL NEWS, p. 1 (April 13, 1970).

29. AMERICAN MEDICAL NEWS, p. 1 (April 20, 1970).

30. REPORT OF THE NATIONAL ADVISORY COMMISSION at p. 424.

31. Letter from James E. Ludlam, Law Firm of Musick, Peeler & Garrett, Los Angeles, California, to Paul J. Brauch, Business Manager, George L. Mee Memorial Hospital, King City, California (March 12, 1970).

32. Duffy, A Legislator Looks at Health Manpower, 56, Report of the Allied Health Conference, California, July 1968.

33. Id.

34. Lloyd, The Future of Licensure of Health Professions and Occupations In the State of New Jersey 10 (1969).

35. See Anderson, supra note 16, at 4; Shine, Licensing or Certifying Allied Health Occupations and the Role of Professional and Vocational Standards, 91, Report of the Allied Health Conference, California, July 1968.

36. Anderson, supra note 16, at p. 4.

37. Shine, supra note 35.

38. Roemer, supra note 25, at p. 6.

39. Contract No. HSM 110-69-242.

40. See footnote 31 and accompanying text.

41. This proposal was advanced at the October conference by Nathan Hershey, Research Professor of Health Law, Graduate School of Public Health, University of Pittsburgh. Mr. Hershey was a legal consultant on this project.

42. ARIZONA REV. STAT. §32-1421 (Supp. 1969); COLO. REV. STAT. §91-1-6(3) (m) (1963); KANSAS STAT. §65-2872(g) (1964); OKLA. STAT. tit. 59, §492 (Supp. 1968-69). The texts of these statutes appear as Appendix I to this report.

43. OKLA. STAT. tit. 59, §492 (Supp. 1968-69).

44. Correspondence with Bruce E. Robinson, Assistant Executive Director, The Arizona Medical Association (December 8, 1969); Don Blair, Executive Director, The Oklahoma State Medical Association (October 20, 1969); Oliver E. Ebel, Executive Director, the Kansas Medical Society (December 4, 1969).

45. Grier v. Phillips, 230 N.C. 672, 55 S.E. 2d 285 (1949).

46. See Appendix I and note 44, supra.

47. Opinion of N.C. Attorney General, dated December 12, 1955.

48. It is possible that some states may have cease and desist order provisions which can be incorporated by reference into the delegation statute. For states, such as North Carolina, which do not have such provisions, a more detailed specification regarding the power to issue such orders may be necessary. Appendix III sets forth a possible formulation of additional sections under which such a power might be conferred.

49. This concept has been developed by Mr. Hershey as a possible means of regularizing the position of physician's assistants in West Virginia, at the request of Alderson-Broaddus College. The formal proposal, formulated by Mr. Hershey and a group of his students, has not been endorsed by Alderson-Broaddus College, and no plans have been made for introducing it into the West Virginia Legislature at this time. The wording of the proposal appearing in this report is not identical to that proposed by Mr. Hershey and his students but is intended to accomplish the same result.

50. There was no specification as to what would be conceptually beyond the capacity of a non-physician. Presumably non-delegable duties would lie in the area of judgmental decision-making.

51. Benyak, Hoffman, McGinley and Strassburger, A Legislative Proposal To Incorporate Physicians' Assistants Within The Medical Care System of West Virginia, 10,Seminar Report, School of Law, University of Pittsburgh, January 1970.

52. Possible rules and regulations under which this proposal could be administered are set forth in Appendix IV.

53. A special Task Force of the Association of American Medical Colleges and the Board on Medicine of the National Academy of Sciences have recently developed reports setting forth possible guidelines for training programs.

54. Grier v. Phillips, 230 N.C. 672, 55 S.E. 2d 485 (1949).

55. See, e.g., South Carolina Highway Department v. Harbin, 226 S.C. 585, 86 S.E.2d 466 (1955).

APPENDIX I

Exceptions to Medical Practice Acts to enable physicians to delegate tasks.

Any person acting at the direction or under the supervision of either a doctor of medicine or under the supervision of one included in the paragraphs numbered 7 or 8 of this section, so long as he is acting in his customary capacity, not in violation of any statute, and does not hold himself out to the public generally as being authorized to practice medicine.

ARIZONA REV. STAT. § 32-1421 (Supp. 1969)

The rendering of services under the personal and responsible direction and supervision of a person licensed under the laws of this state to practice medicine or to practice a limited field of the healing arts, but nothing in this exemption shall be deemed to extend the scope of any license.....

COLO. REV. STAT.§ 91-1-6(3) (m) (1963)

Persons whose professional services are performed under the supervision or by order of or referral from a practitioner who is licensed under this act.

KANSAS STAT. § 65-2872(g) (1964)

Nothing in this article shall be so construed as to prohibit.... service rendered by a physician's trained assistant, a registered nurse, or a licensed practical nurse if such service be rendered under the direct supervision and control of a licensed physician.

OKLA. STAT. tit. 59, § 492 (Supp. 1968-69)

APPENDIX II

Regulations for the October Proposal

The following are submitted as possible rules and regulations according to which the October proposal could be administered.

Rule I
Definitions

Section 1. The term "Board" as herein used refers to the Board of Medical Examiners of North Carolina.

Section 2. The term "Secretary" as herein used refers to the Secretary of the Board of Medical Examiners of North Carolina.

Section 3. The term "assistant to a physician" as herein used refers to auxiliary, paramedical personnel who are functioning in a dependent relationship with a physician licensed by the Board and who are performing tasks or combinations of tasks traditionally performed by the physician himself. Examples of such tasks would include history taking, physical examination, and treatment, such as the application of a cast. The regulations are not intended to cover or in any way prejudice the activities of assistants not engaged in direct patient contact or the performance of assistants with tasks well-defined by statute or recognized custom of medical practice.

Section 4. The term "applicant" as used herein refers to the assistant upon whose behalf an application is submitted.

Rule II
Application for Approval

Section 1. Application for approval of an assistant must be made upon forms supplied by the Board and must be submitted by the physician with whom the assistant will work and who will assume responsibility for the assistant's performance.

Section 2. Application forms submitted to the Board must be complete in every detail. Every supporting document required by the application form must be submitted with each application.

Section 3. If for any reason an assistant discontinues working at the direction and under the supervision of the physician who submitted the application under which the assistant is approved, such assistant shall so inform the Board and his approval shall terminate until such time as a new application is submitted by the same or another physician and is approved by the Board.

Rule III
Requirements for Approval

Section 1. Before being approved by the Board to perform as an assistant to a physician, an applicant shall:

(1) Be of good moral character and have satisfied the requirements of Rule IV hereof;

(2) Demonstrate in one of the following ways his competence to perform at the direction and under the supervision of a physician tasks traditionally performed by the physician himself:

(a) By giving evidence that he has successfully completed a training program recognized by the Board under Rule V hereof;

(b) By standing and passing an equivalency exam administered by a training program recognized by the Board under Rule V hereof;

(c) By standing and passing an exam administered by the Board;

Section 2. Initial approval may be denied for any of the reasons set forth in Rule VI Section 1 hereof as grounds for termination of approval, as well as for failure to satisfy the Board of the qualifications cited in Section 1 of this Rule.

Section 3. Whenever the Board determines that an applicant has failed to satisfy the Board that he should be approved, the Board shall immediately notify such applicant of its decision and indicate in what respect the applicant has so failed to satisfy the Board. Such applicant shall be given a formal hearing before the Board upon request of such applicant filed with or mailed by registered mail to the Secretary of the Board at Raleigh, N. C., within 10 days after receipt of the Board's decision, stating the reasons for such request. The Board shall within 20 days of receipt of such request notify such applicant of the time and place of a public hearing, which shall be held within a reasonable time. The burden of satisfying the Board of his qualifications for approval shall be upon the applicant. Following such hearing, the Board shall determine on the basis of these regulations whether the applicant is qualified to be approved, and this decision of the Board shall be final as to that application.

Section 4. In hearings held pursuant to this rule the Board shall admit and hear evidence in the same manner and form as prescribed by law for civil actions.

Rule IV
Moral Character

Section 1. Every applicant shall be of good moral character, and the applicant shall have the burden of proving that he is possessed of good moral character.

Section 2. All information furnished to the Board by an applicant, and all answers and questions upon forms furnished by the Board, shall be deemed material and such forms and information shall be and become a permanent record of the Board.

Section 3. All investigations in reference to the moral character of an applicant may be informal, but shall be thorough, with the object of ascertaining the truth. Neither the hearsay rule, nor any other technical rule of evidence need be observed.

Section 4. Every applicant may be required to appear before the Board to be examined about any matter pertaining to his moral character.

Rule V
Requirements for Recognition of Training Programs

Section 1. Application for recognition of a training program by the Board shall be made by letter and supporting documents from the director of the program and must demonstrate to the satisfaction of the Board that such program fulfills the requirements set forth in Sections 2 through 8 of this Rule.

Section 2. The training program must be sponsored by a college or university with appropriate arrangements for the clinical training of its students, such as a hospital maintaining a teaching program. There must be evidence that the program has education as its primary orientation and objective.

Section 3. The program must be under the supervision of a qualified director, who has at his disposal the resources of competent personnel adequately trained in the administration and operation of educational programs.

Section 4. Adequate space, light, and modern equipment must be provided for all necessary teaching functions. A library, containing up-to-date textbooks, scientific periodicals, and reference material pertaining to clinical medicine, its underlying scientific disciplines, and its specialties, shall be readily accessible to students and faculty.

Section 5. The curriculum must provide adequate instruction in the basic sciences underlying medical practice to provide the trainee with an understanding of the nature of disease processes and symptoms, abnormal laboratory tests, drug actions, etc. This must be combined with instruction, observation and participation in history taking, physical examination, therapeutic procedures, etc. This should be in sufficient depth to enable the graduate to integrate and organize historical and physical findings. The didactic instruction shall follow a planned and progressive outline and shall include an appropriate mixture of classroom lectures, textbook assignments, discussions, demonstrations and similar activities. Instruction shall include practical instruction and clinical experience under qualified supervision sufficient to provide understanding of and skill in performing those clinical functions which the assistant may be asked to perform. There must be sufficient evaluative procedures to assure adequate evidence of competence. Although the student may concentrate his effort and his interest in a particular specialty of medicine, the program must insure that he possesses a broad general understanding of medical practice and therapeutic techniques.

Section 6. Although some variation may be possible for the individual student, dependent on aptitude, previous education, and experience, the curriculum shall be designed to require two or more academic years for completion.

Section 7. The program must have a faculty competent to teach the didactic and clinical material which comprises the curriculum. The faculty shall include at least one instructor who is a graduate of medicine, licensed to practice in the location of the school, and whose training and experience enable him to properly supervise progress and teaching in clinical subjects. He shall be in attendance for sufficient time to insure proper exposure of the student to clinical teaching and practice. The program may utilize instructors other than physicians, but sufficient exposure to clinical medicine must be provided to insure understanding of the patient, his problem, and the diagnostic and therapeutic responses to this problem.

Section 8. The program must through appropriate entrance requirements insure that candidates accepted for training possess 1) an ability to use written and spoken language in effective communication with physicians, patients, and others, 2) quantification skills to insure proper calculation and interpretation of tests, 3) behavioral characteristics of honesty and dependability, and 4) high ethical and moral standards, in order to safeguard the interests of patients and others.

Section 9. To retain its recognition by the Board, a recognized program shall:

1) make available to the Board yearly summaries of case loads and educational activities done by clinical affiliates, including volume of outpatient visits, number of inpatients, and the operating budget;
2) maintain a satisfactory record of the entrance qualifications and evaluations of all work done by each student, which shall be available to the Board;
3) notify the Board in writing of any major changes in the curriculum or a change in the directorship of the program.

Section 10. Recognition of a program may be withdrawn when, in the opinion of the Board, the program fails to maintain the educational standards described above. When a program has not been in operation for a period of two consecutive years, recognition will automatically be withdrawn. Withdrawal of recognition from a program will in no way affect the status of an assistant who graduated from such program while it was recognized and who has been approved by the Board.

Rule VI
Termination of Approval

Section 1. The approval of an assistant shall be terminated by the Board when, after due notice and a hearing in accordance with the provisions of this Rule, it shall find:

a) that the assistant has held himself out or permitted another to represent him as a licensed physician;
b) that the assistant has in fact performed otherwise than at the direction and under the supervision of a physician licensed by the Board;
c) that the assistant has been delegated and performed a task or tasks beyond his competence;
d) that the assistant is an habitual user of intoxicants or drugs to such an extent that he is unable safely to perform as an assistant to the physician;
e) that the assistant has been convicted in any court, state or federal, of any felony or other criminal offense involving moral turpitude;
f) that the assistant has been adjudicated a mental incompetent or whose mental condition renders him unable safely to perform as an assistant to a physician; or
g) that the assistant has failed to comply with any of the provisions of Rule VII hereof.

Section 2. Before the Board shall terminate approval granted by it to an assistant, it will give to the assistant a written notice indicating the general nature of the charges, accusation or complaint preferred against him and stating that the assistant will be given an opportunity

to be heard concerning such charges or complaints at a time and place stated in such notice, or to be thereafter fixed by the Board, and shall hold a public hearing within a reasonable time. The burden of satisfying the Board that the charges or complaints are unfounded shall be upon the assistant. Following such hearing, the Board shall determine on the basis of these regulations whether the approval of the assistant shall be terminated.

Section 3. In hearings held pursuant to this Rule the Board shall admit and hear evidence in the same manner and form as prescribed by law for civil action.

Rule VII
Method of Performance

Section 1. An assistant must clearly identify himself as an assistant to a physician, a physician's assistant, or by some other appropriate designation in order to insure that he is not mistaken for a licensed physician. This may be accomplished, for example, by the wearing of an appropriate nametag.

Section 2. The assistant must generally function in reasonable proximity to the physician. If he is to perform duties away from the responsible physician, such physician must clearly specify to the Board those circumstances which would justify this action and the written policies established to protect the patient.

Section 3. The assistant must be prepared to demonstrate upon request, to a member of the Board or to other persons designated by the Board, his ability to perform those tasks assigned to him by his responsible physician.

APPENDIX III

Havinghurst Proposal

For those states not having cease and desist order provisions susceptible to incorporation into the statute, the following provisions are suggested for conferring on the Board of Medical Examiners the cease and desist order power discussed under the Havighurst proposal.

"§90-18. Practicing without license; practicing defined; penalties. - No person shall practice medicine or surgery, or any of the branches thereof, nor in any case prescribe for the cure of disease unless he shall have been first licensed and registered so to do in the manner provided in this article, and if any person shall practice medicine or surgery without being duly licensed and registered, as provided in this article, he shall not be allowed to maintain any action to collect any fee for such services. The person so practicing without license shall be guilty of a misdemeanor, and upon conviction thereof shall be fined not less than fifty dollars ($50) nor more than hundred ($100), or imprisoned at the discretion of the court for each and every offense.

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;

...

(14) Any act, task, or function performed at the direction and under the supervision of a licensed physician by a person qualified by formal or informal training and experience to perform such act, task, or function when the said act, task, or function is performed in accordance with such rules and regulations as may be promulgated by the Board of Medical Examiners and is not in violation of a cease and desist order issued by the Board under sections 90-18.1 through 90-18.3 of this article.

§90.18.1. Investigation of unauthorized performance, hearing; evidence admissible. - If it comes to the attention of the Board, by formal complaint or otherwise, that a person may be performing, at the direction and under the supervision of a physician licensed by the Board, an act, task, or function which he is not qualified by formal or informal training and experience to perform, the Board shall investigate

to determine if there is good cause for believing that such unauthorized performance has occurred. If it determines that such good cause does exist, the Board shall immediately notify such person of this determination and give him written notice indicating the nature of the alleged unauthorized performance and stating that he will be given an opportunity to be heard concerning such allegations at a time and place stated in the notice, or to be thereafter fixed by the Board, and shall hold a public hearing within a reasonable time. The burden of satisfying the Board of his qualification to perform the act, task, or function alleged as being beyond his competence shall be upon the person whose qualification is challenged. In proceedings held pursuant to this section the Board shall admit and hear evidence in the same manner and form as prescribed by law for civil actions. A complete record of such evidence shall be made, together with other proceedings incident to such hearing.

§90-18.2. Cease and desist orders and modifications thereof. - a) If, after such hearing the Board shall determine that the person has been delegated and has performed any act, task or function beyond his competence, the Board shall reduce its findings to writing and shall issue and cause to be served upon the person charged an order requiring such person to cease and desist in the interest of public safety from performing such act, task, or function.
b) Until the expiration of the time allowed under §90-18.3 (a) of this article for filing a petition for review (by appeal) if no such petition has been duly filed within such time, or if a petition for review has been filed within such time, then until the transcript of the record in the proceeding has been filed in the superior court, as hereinafter provided, the Board may at any time, upon such notice and in such manner as it shall deem proper, modify or set aside in whole or in part any order issued by it under this section.
c) After the expiration of the time allowed for filing such a petition for review if no such petition has been duly filed within such time, the Board may at any time, after notice and opportunity for hearing, reopen and alter, modify or set aside, in whole or in part, any order issued by it under this section, whenever in its opinion conditions of fact or law have so changed as to require such action or if the public interest shall so require.

§90-18.3. Judicial review of cease and desist order. - a) Any person required by an order of the Board under §90-18.2 to cease and desist from performing any act, task, or function may obtain a review of such order by filing in the superior court of Wake County, within thirty days from the date of the service of such order, a written petition praying that the order of the Board be set aside. A copy of such petition shall be forthwith served upon the Board, and thereupon the Board forthwith shall certify and file in such court a transcript of the entire record in the proceedings, including all the evidence taken and the report and order of the Board. Upon such filing of the petition and transcript such court shall have jurisdiction

of the proceeding and of the question determined therein, shall determine whether the filing of such petition shall operate as a stay of such order of the Board, and shall have power to make and enter upon the pleadings, evidence, and proceedings set forth in such transcript a decree mofifying, affirming or reversing the order of the Board, in whole or in part. The findings of the Board, as to the facts, if supported by substantial evidence, shall be conclusive.

b) To the extent that the order of the Board is affirmed, the court shall thereupon issue its own order commanding obedience to the terms of such order of the Board. If either party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Board, the court may order such additional evidence to be taken before the Board and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Board may modify its findings of fact, or make new findings by reason of the additional evidence so taken, and it shall file such modified or new findings which, if supported by substantial evidence shall be conclusive, and its recommendations, if any, for the modification or setting aside of its original order, with the return of such additional evidence.

c) A cease and desist order issued by the Board under §§90-18.2 shall become final:

(1) Upon the expiration of the time allowed for filing a petition for review if no such petition has been duly filed within such time; except that the Board may thereafter modify or set aside its order to the extent provided in §§90-18.2(b);

(2) Upon the final decision of the court if the court directs that the order of the Board be affirmed or the petition for review dismissed.

d) No order of the Board under this article or order of a court to enforce the same shall in any way relieve or absolve any person affected by such order from any liability under any other laws of this State.

APPENDIX IV

Regulations for the Hershey Proposal

These regulations are modelled on regulations developed by Mr. Hershey and his students for use in another state.

Procedure for employment of a physician's assistant.

1. Any physician licensed by the Board of Medical Examiners desiring to employ a physician's assistant may submit a job description to the Board of Medical Examiners. The job description shall include: (a) a list of specific tasks and functions that will be assigned to the physician's assistant; (b) the amount and nature of supervision to be provided by the physician; (c) qualifications of the physician to supervise the performance of tasks and functions by the physician's assistant; and (d) any other information the physician submitting the job description deems pertinent.

2. The Board of Medical Examiners shall review the job description and respond within thirty days by a statement of approval or disapproval. Where the Board does not grant approval, the reasons shall be set forth. With approved job descriptions, the Board shall submit a statement of qualifications which must be met by any person who will be employed to perform tasks and functions within the job description.

3. Within fourteen days after employment, the physician shall submit the name of the physician's assistant, and a resume of his relevant education and experience.

4. The Board, if it determines, upon receipt of notification of employment of a physician's assistant, that the person so employed does not meet the established qualifications, shall within fourteen days, by registered mail, so inform the physician. If no rejection is received by the physician within fourteen days, the employment of the person as a physician's assistant is deemed approved.

5. Immediately upon receipt of notification from the Board that the person employed does not meet the established qualifications, employment as a physician's assistant shall be terminated.

6. Substantial changes in tasks or functions, or in the nature or extent of supervision of an approved physician's assistant, require the submission and approval of a new job description, and

the establishment of qualifications consistent with the job as newly described.

7. The Board may revoke job description approval or revise required qualifications in the interests of public health, safety or welfare.