Duke University Medical Center
DURHAM, NORTH CAROLINA

DIRECTOR OF MEDICAL EDUCATION

POSTAL CODE 27706
TELEPHONE 919—684-3528

Sunday, Oct. 26
2 p.m.
Statler Hilton

October 2, 1969

E. Harvey Estes, Jr., M.D.
Professor and Chairman
Department of Community Health Sciences
Duke University Medical Center

Dear Henry:

Thank you for your letter of September 24 regarding the program for October 26. It looks like an important meeting and I shall do my best to attend.

Sincerely yours,

Thomas D. Kinney, M.D.
Director of Medical Education

TDK:sfl

Duke University Medical Center
DURHAM, NORTH CAROLINA

DEPARTMENT OF COMMUNITY
HEALTH SCIENCES

September 24, 1969

POSTAL CODE 27706
TELEPHONE 919—684-6127

Dr. Thomas D. Kinney
Duke University Medical Center
Durham, North Carolina

Dear Tom:

We are having a conference here at Duke on the 26th of October, from 2:00 p.m. to 5:00 p.m., to discuss the various alternate ways of handling the problems of defining the legal status of new health manpower categories. D. A. McLaurin has suggested that the members of the Committee on Medical Education may wish to attend, since the committee will be making some decisions with regard to such categories. From our standpoint, we would heartily welcome such participation, and cordially invite you to attend and enter into the discussion.

The conference will be held at the Statler Hilton Inn and will adjourn promptly at 5:00 p.m. so that those who wish to do so can return home before the end of the day. There will be several consultants present from the legal profession, including several who have contributed significantly to the published literature on this topic.

The general plan is to prepare and distribute a summary of the several alternate paths open to us with a brief summary of the pros and cons of each. This is to be prepared by Mrs. Martha Ballenger, a recent graduate of the University of Virginia Law School, who is working with our department this year and coordinating this study. The conference will be directed at a discussion of these various alternates, from which we hope to obtain some indication of the most reasonable one or two alternates for North Carolina.

There will be a follow-up meeting of the legal consultants the following morning (October 27th), along with D. A., Ed Beddingfield and others who may be especially interested in the legal aspects, for the purpose of discussing legal aspects of these alternates, and what steps might be taken to implement them. There will be a report sent regarding this meeting, and there will be a further conference in about March, 1970 to discuss progress and obtain further suggestions.

We would be most pleased to have you join us on October 26th. The preliminary material, plus a return card indicating your plans for attendance will be sent in a week or so.

With best regards,

Very truly yours,

E. Harvey Estes, Jr., M.D.
Professor and Chairman

EHEjr:fs

Duke University Medical Center
DURHAM, NORTH CAROLINA

October 9, 1969

DEPARTMENT OF COMMUNITY HEALTH SCIENCES
PHYSICIANS ASSISTANT PROGRAM

POSTAL CODE 27706
TELEPHONE 919—684-6127

Dr. Thomas D. Kinney
Duke University Medical Center
Durham, North Carolina 27706

Dear Dr. Kinney:

Enclosed you will find the informational paper which will serve as background for discussion at our conference on the legal status of the Physician's Assistants. As Dr. Estes wrote you earlier, the conference is scheduled for October 26th and 27th at the Statler Hilton Inn in Durham. A general meeting will be held from 2:00 to 5:00 p.m. on the 26th, at which the various alternatives available to us will be discussed. We hope to be able to arrive at some consensus as to the best approach at that meeting. A follow-up session will be held on the morning of the 27th, for further discussion of the practical considerations involved in implementing the plan decided upon.

We hope that you will be able to attend one or both of these meetings. It would be quite helpful to us if you would indicate on the enclosed postcard whether you plan to participate in the conference, so that we will have some idea of the number of people to expect. Also enclosed is a Statler Hilton reservation card. If you plan to attend and will need over-night accommodations, we would appreciate your filling out this card and mailing it directly to the Inn.

Again, we hope that you will be able to join us for the conference.

Sincerely yours,

Martha Ballenger

(Mrs.) Martha Ballenger

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. 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. 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. All extragovernmental 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, enabling them to perform only those health care functions for which they were qualified by training and experience.

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). 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 develop-

ment of new types of personnel to help alleviate the physician shortage.

The Physician's Assistant Program is an example of an innovational manpower program, developed in recognition of the fact that if additional qualified personnel were available to handle tasks not requiring the judgment and ability of a physician, the health care potential of the physician could be increased both quantitatively, in terms of the number of patients treated, and qualitatively, through time freed for continuing education. The program has operated thus far in reliance on an opinion of the North Carolina Attorney General that the performance of the projected physician-supervised activities does not contravene the licensure laws of the State. This opinion, however, is merely advisory. As the program enters its fifth year, we feel it necessary to explore more fully its legal implications, in the interest of protecting the public, the other health professionals affected, and the PAs who graduate each year, and to determine by what means the PAs, and subsequent innovational categories, can best become established as legitimate members of the health care team. The purpose of the scheduled conference is to provide an opportunity for discussion of the alternatives that have occurred to us, to garner additional suggestions, and to determine the direction our future activities should take. Statements of the alternatives we currently visualize are set forth below, with a brief summary of their respective merits and weaknesses. These alternatives have been developed largely from a survey of current writings of those concerned with the problem, notably Dr. Edward Forgotson, Mr. Nathan Hershey, Mr. Arthur Leff, and Dr. Carl Wasmuth, who we hope will indulge the borrowing of their ideas and conclusions without specific acknowledgment.

I. The Status Quo

The first alternative is to maintain the status quo and take no formal action with respect to the PAs. If it were intended that they perform any independent functions, some form of explicit exception to the Medical Practice Act would of course be required, as in the case of midwives.[1] Because, however, the proposed functions are solely dependent, under the supervision of a physician, it would be possible to rely on developing custom and usage in the profession to provide legal sanction. This is true because in view of the expertise required in the practice of medicine-- an expertise which legislatures and courts do not have-- the profession is virtually able to set its own standards by reference to the ordinary practices of the profession.[2] As will be seen, however, this approach is uncertain and may produce needless vulnerability for the individual physician, should action be taken against him.

The principal problems with maintaining the status quo relate to possible liability of the physician. Under the doctrine of respondeat superior, commonly known as the master-servant doctrine, the physician is responsible for negligent actions of any person in his employ.[3] Of course, liability based on respondeat superior inheres regardless of licensure or any other formal arrangement as long as an employment relationship exists.[4] The additional risks of liability that would follow from doing nothing at this point relate to possible malpractice attacks against the physician for delegating functions to the PA at all, because even if the PA is not negligent the delegation itself may be found improper.[5] Relying on custom and usage to legitimize the delegation is risky for several reasons. First, until the use of PAs becomes widespread enough to be regarded as an ordinary practice, this affords no protection at all. Second, even when PAs 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.[6] Finally, the physician is generally judged against a "locality" standard. In North Carolina, for example, cases indicate that his practices will probably be measured against those of physicians "similarly situated."[7] At present, most of the PAs are employed in the Duke Medical Center community, 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.[8] A more formal sanction could, therefore, dispel many of the uncertainties attendant with the custom and usage test.

Even if PAs become widely used and accepted, the very existence of other licensure laws poses an additional danger. In a recent Washington case,[9] action by an unlicensed nurse, viewed against the background of the State's licensure scheme, gave rise to an inference of negligence against which custom and usage was not even admissible for jury consideration. In many other states, the absence of a license is admissible as evidence to be weighed against custom and usage.[10] In North Carolina, the law currently seems to be that the failure to be licensed is immaterial on the issue of negligence. The last case asserting this, however, was decided in 1949,[11] and in view of more recent cases elsewhere there is possibility of change. If North Carolina courts should follow Washington, the physician may be vicariously liable if lack of a license establishes employee negligence, or possibly directly liable for delegating to unlicensed personnel. Aside from the question of civil liability, action by an unlicensed person may subject him to criminal action for the unlicensed practice of medicine and leave the delegating physician open to similar criminal action for aiding and abetting.[12] Even the 1949 North Carolina decision acknowledges the possibility that such

criminal action may be brought. Although custom and usage might furnish a good defense if the PA was performing a dependent function under 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.[13] This may also pose problems with malpractice insurance coverage, as most policies have exclusions for instances in which the liability of the physician arises out of the performance of an unlawful act.[14]

Aside from the uncertainties with respect to the physician's civil and criminal liability, the present situation may be unfair to the PA, who may find his expectations and time and energy investments shattered in a suit against him for unlicensed practice and/or the reluctance of physicians to employ him in view of the uncertainty with respect to their own liability. There would seem to be a definite ethical obligation to the PAs to provide some assurance that there will be a legitimate place for them in the medical community. It is also true that the status quo provides no formal public protection in the form of standards and qualification requirements for persons used in this capacity. As PAs become established and more schools seek to institute training programs similar to Duke's, some form of definite quality controls may be necessary to assure uniformity of the manpower product.

From the standpoints of the physician, the PA, and the public, therefore, there are definite drawbacks to maintaining the status quo.

II. Licensing PAs As A New Category

If it is decided that some form of action is desirable, one obvious possibility is to license Physician's Assistants 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 PA, though, of course, 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 the PAs as an occupational category and protecting the public through the specification of minimum qualifications and official delineation of the PA's functional sphere.

There are also problems with choosing this approach. The principal difficulty would be in defining the scope of operation of the PA so that it is a meaningful limitation, without preventing the necessary accretion of functions as more activity comes to be within the competence of these sub-physician professionals. Although custom and usage can be useful in legitimizing these accretions, as is pointed out above, the actual wording of the licensure laws cannot be ignored.[15] There would also be the problem, partially "political," of framing the definition in such a way that it does not unduly compound the jurisdictional boundary disputes currently waged among those professionals already licensed.[16]

Some authorities feel that further formalized fragmentation of the health care team through the licensure of new dependent personnel groups would have only self-serving advantages for those groups, at the expense of efficient care delivery.[17] The consequences of licensure for the innovational categories themselves are not all positive, however. Aside from the possibility that functional spheres may be frozen at unrealistic levels, licensure may unnecessarily impede geographical and occupational mobility. The geographical mobility problem may persist regardless of the solution we select for North Carolina until such time as concerted action is taken by the states to make their laws uniform in this regard. The occupational mobility aspect, on the other hand, is susceptible to more localized solution. A formal licensure scheme would undoubtedly include specification of education or training requisites. By building "license walls" around many separate groups whose practitioners are presently or potentially,

after further experience, capable of performing many of the same functions, these practitioners are forced either to operate in a frustrating and inefficient manner or to satisfy the formal, and practically unnecessary, basic training requirements of the other licensed group. This impedes both efficiency and advancement with scant justification, because with respect to these dependent personnel, the quality of performance is theoretically otherwise assured by proper supervision.

In view of these difficulties and the problems which current licensing laws pose for efforts at needed innovation, the mere addition of another licensed category may eventually be more of an aggravation than an aid. At best it does not look beyond the immediate problem.

III. License Practitioners Using PAs

Because the PA performs solely dependent functions, acting under the direction and supervision of the physician, the possibility for abuses by the physician may be greater than by the PA himself. Another possibility would, therefore, be the licensing of physicians or institutions using such personnel.[18] A responsible licensing board could be charged with investigating the ability of the particular physician to supervise, the feasibility of using such personnel in his type of practice, and the professional integrity of the physician, so as to assure that the PA will 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. Possibly, provisional licenses could be granted, with final determination 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 will rest on the

mere use of unlicensed personnel in the face of a licensure scheme, since the legislature will have voiced approval of such use by specially licensing the physicians. There will still be a problem of whether to define the limits of the use physicians may 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 can 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 Part V herein, thus allowing the specially licensed physicians to utilize personnel for functions approved by the Committee on Manpower Innovations. This would provide further protection for the physician because permissible delegations would be specified and would give some assurance to the Committee that all physicians participating in manpower innovation experimentation have been screened to some extent.

IV. Statute Authorizing General Delegations

Four states at present have general statutory provisions authorizing supervised delegation of functions, with slight variations as to who may delegate and to whom delegations may be made.[19] 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.[20]

Such statutes have the advantage of great flexibility but appear to provide only minimal protection for the public, as the guidelines are vague and there are apparently no formal checks. There may still be dangers for physicians with such an approach if specification is 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 medical practice acts per se, and would leave questions of good medical practice in given instances to judicial or executive interpretation, as would be the case in all but the most precisely defined scheme. The flexibility of this approach does much to commend it over some of the more precise schemes that are vulnerable to early obsolescence by over-specification.

V. Establish Committee on Health Manpower Innovations

The final alternative that has occurred to us is the legislative establishment of a Committee on Health Manpower Innovations, under the auspices of and responsible to the Board of Medical Examiners.[21] It would be composed of representatives of all health professions concerned with problems of manpower shortage, such as physicians, nurses, and hospital administrators, and possibly a representative of the general public. Any group wishing to initiate a program for training a new manpower category would submit a written proposal for Committee consideration, detailing its objectives, curriculum, faculty, and facilities. It should be prepared to show that the program is responsive to a need that is not satisfied by existing personnel and that patient safety has 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 unsatisfactory ones, and the modification of programs as the need arises. It obviously would have implications beyond the immediate problem with PAs and would facilitate innova-

tion 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 is 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.

The Medical Practice Act presently has exemptions for certain categories of practitioners.[22] This act could be amended to include an additional exemption in a form similar to the type discussed for supervised delegations, 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 is 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.

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

* * * *

We hope that the possibilities discussed here will provide at least a spring-board for discussion at the conference. We trust that you will be freely critical and will contribute additional ideas for alternatives that may seem more feasible to you.

1. N.C. GEN. STAT. §90-18 (7) (1965 Repl. Vol.).

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

3. It is even possible that a physician may be liable for the negligence of hospital personnel if charitable immunity of non-profit hospitals presents an obstacle to patient recovery. There is, however, no charitable immunity for hospitals in North Carolina. Rabon v. Rowan Memorial Hospital, Inc., 269 N.C. 1, 152 S.E.2d 499 (1967).

4. Leff, supra note 2, at 366.

5. Id. at 363.

6. Forgotson, Roemer, and Newman, Licensure of Physicians, in II REPORT OF THE NATIONAL ADVISORY COMMISSION ON HEALTH MANPOWER 285, 293, citing People v. Whittaker, No. 35307, Justice Court of Redding Judicial District (Shasta County, Cal., Dec. 1966).

7. Belk v. Schweizer, 268 N.C. 50, 149 S.E.2d 565 (1966).

8. Leff, supra note 2, at 343.

9. Barber v. Reinking, 68 Wash. 2d 122, 411 P.2d 861 (1966).

10. Leff, supra note 2, at 387.

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

12. 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).

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

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

15. Forgotson, Roemer, and Newman, supra note 6, at 292.

16. Hershey, Comments on the Legal Status of the Physician's Assistant, a paper presented at Duke Conference on Current Status and Development of Physician's Assistant Program, Oct. 28, 1968, Durham, N.C.

17. Id.

18. Id.

19. 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).

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

21. This is basically the idea espoused in Forgotson and Cook, Innovations and Experiments in Uses of Health Manpower-- The Effect of Licensure Laws, 32 Law & Contemp. Problems 731, 747 (1967).

22. N.C. GEN. STAT. § 90-18 (1965 Repl. Vol.).