

# INNOVATIONS AND EXPERIMENTS IN USES OF HEALTH MANPOWER—THE EFFECT OF LICENSURE LAWS\*

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## INTRODUCTION

Present trends indicate that growth in the output of personal health services will exceed the growth in population.<sup>1</sup> At the same time, the relative and absolute physician shortage will, in all probability, continue to deteriorate.<sup>2</sup> These apparently contradictory predictions are evidence of fundamental problems confronting personal health care delivery systems.

To understand this paradox it is necessary to examine the nature and distribution of available personal health care. Such an examination reveals that there is a national crisis in the provision of medical care, characterized by spiraling costs, inadequacies in services rendered to the disadvantaged, and widespread discontent with the restricted availability of professional health services despite greater numbers of health workers and more medical facilities per capita than ever before.<sup>3</sup>

In part, these shortages and higher costs may be traced to a lack of skilled health personnel.<sup>4</sup> But they also reflect to an important degree the extraordinarily inefficient manner in which existing health manpower resources are currently used.<sup>5</sup> Organizational changes must be made in the health care delivery system. Until such changes are accomplished, health care will cost more than it should, and it will not be possible to estimate with accuracy the need for additional health manpower in the future.<sup>6</sup> As medicine develops new methods of treatment requiring specialized skills, innovations in functions for existing health personnel must be authorized, and

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<sup>1</sup> 1 NAT'L ADVISORY COMM'N ON HEALTH MANPOWER, REPORT OF THE NATIONAL ADVISORY COMMISSION ON HEALTH MANPOWER 6-23 (1967) [hereinafter cited as HEALTH MANPOWER REPORT].

<sup>2</sup> *Id.*

<sup>3</sup> *Id.* at 7.

<sup>4</sup> *Id.* at 6.

<sup>5</sup> *Id.*; NAT'L COMM'N ON COMMUNITY HEALTH SERVICES, HEALTH IS A COMMUNITY AFFAIR 77-100, 211-15 (1966).

<sup>6</sup> See HEALTH MANPOWER REPORT 6.

new kinds of auxiliary personnel must be created. The National Advisory Commission on Health Manpower recommended in November 1967 that the federal government give high priority to the support under university direction of experimental programs which would train and utilize new categories of health professionals.<sup>7</sup>

Current professional and occupational licensure laws pose major impediments to the expansion of the functions of existing categories of health personnel and even to the implementation of experiments to develop new ways of employing such manpower or to create new categories of health workers. For these reasons, this discussion will focus particularly on these laws, placing special emphasis on those legal standards defining the allocation of tasks among members of the health service industry.

## I

### OFFICIAL LICENSURE LAWS

The principal professed objective of licensure laws<sup>7a</sup> is the promotion of high quality personal health care through the regulation of inputs of the health care delivery system.<sup>8</sup> These laws restrict the personnel, facilities, medications, and equipment that may be employed in the health service industry on the assumption that high quality outputs can be obtained by regulating inputs. Whether the regulatory system should be redesigned to focus more on outputs—as malpractice law now does and as a process of continuing supervision might someday do—is a problem that is beyond the scope of this discussion. Nevertheless, such a redesign may someday be appropriate, and the concept and its feasibility should be the subject of continuing research.

State licensure of individuals in the health professions and occupations, setting minimum qualifications and performance standards for entry into or retention in the profession or occupation, is the basic but by no means the sole legal control over the quality of health services and the allocation of patient care tasks among members of the health service industry. The courts also exercise quality and task allocation control through the exercise of jurisdiction in malpractice suits, actions for declaratory judgments, and criminal proceedings for illegal practice.<sup>9</sup> State and federal governments control quality through licensure of hospitals and other health

<sup>7</sup> *Id.* at 31.

<sup>7a</sup> Licensing laws may also reflect the licensed profession's desire to restrict entry into its ranks as a means of limiting competition. See pp. 748-50 *infra* for a discussion of this aspect of medical practice acts in the context of an assessment of prospects for professional support of the reforms recommended in this article.

<sup>8</sup> The word *system* is used as a convenient term to describe the health services industry and is not meant to imply the existence of an organized planned undertaking.

<sup>9</sup> *E.g.*, *Crees v. California State Bd. of Medical Examiners*, 213 Cal. App. 2d 195, 28 Cal. Rptr. 621 (1963) (criminal prosecution); *Mitchell v. Louisiana State Bd. of Optometry Examiners*, 128 So. 2d 825 (La. Ct. App. 1961) (declaratory judgment); *Barber v. Reinking*, 68 Wash. 2d 139, 411 P.2d 861 (1966) (malpractice); CAL. BUS. & PROF. CODE §§ 2141, 2141.5 (West Supp. 1967).

facilities and through financing of health programs requiring providers of care to meet certain individual or institutional standards. Professional and other nongovernmental organizations exert quality controls through accreditation of hospitals, certification of medical and dental specialties, and approval of training programs. Within hospitals, moreover, there are professional controls imposed by medical staff organizations, such as those governing hospital staff appointments and those regulating surgery and medical audits.

Nongovernmental standards are essential to promote high and constantly improving standards of excellence for patient care. Occupational licensing is and must probably remain merely a mechanism for the enforcement of minimum standards. At present, nongovernmental regulation is more important in assuring high quality care because it generally specifies higher standards than official licensure. In addition, nongovernmental regulation directly or indirectly affects more factors relevant to the delivery of medical care than do licensure laws, by virtue of its control over activities not regulated by licensure, such as qualification to practice a medical or dental specialty or the number of consultants required where hospitalized patients are not progressing satisfactorily. Finally, many nongovernmental regulatory systems have been given official status by incorporation into licensure provisions.<sup>10</sup>

Official occupational licensure will be the principal subject of this analysis because it almost exclusively controls the allocation of tasks and responsibilities among members of the health manpower matrix;<sup>11</sup> it is therefore also most relevant to experimental programs which would train and utilize new categories of health professionals. Moreover, such laws tend to be less flexible than nongovernmental standards in responding to changes in the social, economic, and technological context of the delivery of medical care.

#### A. Description

State licensure statutes enacted under the police power to legislate for public health, welfare, and safety are designed to protect the public from incompetent, unethical, and unscientific practitioners.<sup>12</sup> To this end, the statutes define the functions that each occupational group is authorized to perform and specify the requirements of character, education, and training that licensed practitioners must meet. Entrance into practice is further regulated by statutory provisions for approval of educational institutions and examination of licensure candidates. In controlling the continuing eligibility of licensees to practice, the legislatures provide grounds and procedures for renewal, suspension, revocation, and reinstatement of licenses. To enforce these

<sup>10</sup> For example, the statutes of several states specifically require graduation from a medical school approved by the American Medical Association or the Association of American Medical Colleges.

<sup>11</sup> See generally E. Forgotson, R. Roemer & R. Newman, *Legal Regulation of Health Personnel in the United States*, Sept. 1967, ch. 2 (mimeo.) [hereinafter cited as *Regulation of Health Personnel*].

<sup>12</sup> See *Dent v. West Virginia*, 129 U.S. 114 (1889).

standards, the statutes establish licensing agencies with administrative, adjudicative, and rule-making powers.

An analysis of occupational licensure laws of the fifty states and the District of Columbia reveals significant problems affecting all health professions and occupations. The licensure process regulates physicians, osteopaths, chiropractors, professional and practical or vocational nurses, professional nurse-midwives, physical therapists, optometrists, podiatrists, dentists, and dental hygienists in all jurisdictions in the United States. Some jurisdictions license psychologists, dispensing opticians, x-ray technologists, and medical technologists.<sup>13</sup> Occupational therapists and dental assistants are not licensed in any jurisdiction. Hitherto unrecognized categories of health manpower, such as the "physician's assistants" now being educated at the Duke University School of Medicine,<sup>14</sup> are of course not licensed in any jurisdiction.

Since the original enactment of most occupational licensure acts in substantially their present form shortly after the beginning of the twentieth century, vast social and scientific changes have taken place.<sup>15</sup> Even though the substrate upon which licensure laws must act has changed, creating new problems and increased demand for health services, there have been no fundamental changes in licensure laws with respect to the allocation of health service tasks and responsibilities among the various members of the health service industry. The changing character of personal health care has brought into being a number of new categories of ancillary health personnel, some of which did not exist as recently as ten years ago.<sup>16</sup> In spite of these developments, laws regulating the practice of medicine primarily recognize only the physician with twelve to fourteen years' of education and training after high school and the professional nurse who may have had as little as two years of formal education after high school.<sup>17</sup> There is a similar problem in the practice of dentistry in which the professional dentist and the dentist hygienist, who has marked restrictions on her activities, are the only two legally recognized manpower categories. These inadequate classifications of health manpower have resulted in inefficient use of other highly trained personnel.

Some understanding of the nature and number of ways in which licensure statutes

<sup>13</sup> E.g., CAL. BUS. & PROF. CODE §§ 2900-2984 (West 1962, Supp. 1967) (psychologists); *id.* §§ 2250-2558 (registered dispensing opticians); *id.* §§ 1200-1322 (clinical laboratory technology).

<sup>14</sup> The Duke program is discussed in Stead, *At Duke: A New Approach to the Doctor Shortage*, *RESIDENT PHYSICIAN*, Feb. 1967, at 84; Stead, *Conserving Costly Talents—Providing Physicians' New Assistants*, 198 J.A.M.A. 1108 (1966).

<sup>15</sup> See generally H.E. SIGERIST, *The History of Medical Licensure*, in HENRY E. SIGERIST ON THE SOCIOLOGY OF MEDICINE 308, 316-18 (M. Roemer ed. 1960).

<sup>16</sup> HEALTH MANPOWER REPORT 31; The Allied Health Professions Personnel Training Act of 1966, Pub. L. No. 89-751, 80 Stat. 1222 (codified in scattered sections of 12, 42 U.S.C.), has greatly stimulated the growth of new categories of ancillary health personnel. Interview with William Parson of the Division of Allied Health Manpower, Bureau of Health Manpower, United States Public Health Service, Jan. 15, 1968.

<sup>17</sup> See HEALTH MANPOWER REPORT 31.

influence allocation of health service tasks and functions among members of the health service industry may be obtained by inspection of the history and evolution of present licensure statutes. Licensure of health personnel was virtually nonexistent until 1881; previously anyone was entitled to practice any profession or engage in any business because of the influence of the tenet of unimpeachable freedom of contract.<sup>18</sup> Until that time, the only meaningful professional standards were those established by the professions themselves. After 1881, the professional standards were partially incorporated into state licensure laws as minimal governmental standards. These early licensure laws, which were in many cases permissive, merely protected titles and left to the public the task of determining the distinction between licensed and unlicensed medical practitioners. In general, there has been an orderly progression from voluntary nongovernmental standards to permissive licensure and eventually to mandatory governmental licensure, which requires minimal qualifications as a condition of entering or remaining in practice.

The institution of medical manpower licensure began with licensure of medical practitioners to protect the public from incompetent, untrained, unethical, and commercial practitioners.<sup>19</sup> To this end, licensure of medical practitioners was eventually made mandatory, which necessitated statutory definition of the practice of medicine from which unlicensed persons were excluded. These statutory definitions universally defined the practice of medicine in such broad terms that all personal health service functions were encompassed. Subsequent to the enactment of the medical practice acts, other categories of health manpower sought recognition through licensure. Legal recognition of these new categories of manpower through licensure made necessary the carving out of limited exceptions to the broad medical practice acts. The scope of these exceptions was limited to those tasks and duties specifically defined by law.<sup>20</sup> Under the present licensure system, the physician has an unlimited license, while other licensed health personnel have limited licenses to perform tasks which had previously been within the exclusive province of the physician. Personal health care services not specifically recognized by other licensure laws as appropriately rendered by allied and auxiliary health personnel can be rendered only by the physician.

The history of licensure also reveals that enactment of the present occupational licensure statutes was based on considerations not necessarily related to optimal allocations of responsibilities among the allied or auxiliary health professions and occupations or to different productive delivery of health and medical care to the entire population as a "civil right" of the people. Optimal allocation of health resources and expanded accessibility of health and medical care are now recognized as proper

<sup>18</sup> See generally L. Friedman, *Freedom of Contract and Occupational Licensing 1890-1910: A Legal and Social Study*, 53 CALIF. L. REV. 487 (1965).

<sup>19</sup> See H.E. SIGERIST, *supra* note 15, at 317.

<sup>20</sup> E.g., CAL. BUS. & PROF. CODE § 2141 (West Supp. 1967).

subjects of governmental concern.<sup>21</sup> A design for optimal allocation should be developed by viewing the health service professions and occupations as a matrix in which duties and responsibilities should be allocated on the basis of actual capabilities for performing specific tasks, measured by education, training, and experience, and demonstrated capacity rather than by possession of a categorical title.

New allocations of roles in the health care industry and experiments to determine which innovations are safe and effective are beset with serious legal difficulties. Present occupational licensure laws tend to preserve the status quo, discouraging new allocations of responsibilities within the health manpower matrix and inhibiting experiments to test the safety and effectiveness of new manpower uses. While this is probably the most significant problem that occupational licensure laws present relative to new programs designed to advance achievement of our national health goals, there are other significant problems as well. These other problems include (1) whether present licensure laws provide even adequate minimum standards and (2) the effect of these laws on innovations in the education of physicians and other health personnel.

## B. Adequacy of Minimum Standards

### 1. *Educational Obsolescence*

In providing minimum standards, regulatory programs must contain realistic provisions to minimize activities which can endanger the public. Licensure laws evolved at a time when the amount of knowledge concerning delivery of personal health care was clearly finite. These laws were enacted before the technological and information explosion which began in the late 1930s and consequently did not, as a general rule, recognize that development of new information would render a person's initial qualifications to practice obsolete unless they were upgraded periodically by a program of continuing education. The laws regulating medicine, dentistry, professional and practical nursing, and physical therapy have no requirements aimed at preventing skills from becoming outdated. Aside from dealing with serious incompetence manifested by something such as gross malpractice warranting license revocation, the licensure process does little or nothing to guard against educational obsolescence. In twelve states osteopaths are required to pursue yearly continuing education programs approved by their state osteopathic associations, but those courses need not be designed to instruct the osteopaths in the latest advances in all of the clinical specialties or basic sciences.<sup>22</sup> Nevertheless, these twelve provisions could be an important first step in the development of legal requirements

<sup>21</sup> See Heart Disease, Cancer, and Stroke Amendments of 1965, Pub. L. No. 89-239, 79 Stat. 926. See generally NAT'L COMM'N ON COMMUNITY HEALTH SERVICES, *HEALTH IS A COMMUNITY AFFAIR* (1966).

<sup>22</sup> These states are Arizona, Florida, Maine, Michigan, Nevada, New Mexico, North Dakota, Ohio, Oklahoma, Tennessee, Vermont, and West Virginia. In these states attendance at the annual educational program conducted by the state osteopathic association, or its equivalent, satisfies the requirement of continuing, refresher education. Regulation of Health Personnel, ch. 1, at 50.

that can begin to cope realistically with the serious problem of educational obsolescence.

The report of the National Advisory Commission on Health Manpower recommended in November 1967 that either (1) satisfactory completion of periodic programs of continuing medical education or (2) passage of a periodic examination by those not completing such educational programs be made a mandatory condition of renewal of licenses by all physicians graduating from medical school after the time of enactment of such requirements.<sup>23</sup> Implementation of this recommendation would require official approval of the duration and content of the periodic educational programs and of the length, contents, emphasis, and administration of the periodic examinations. Nevertheless, this is a significant recommendation which could lead to overcoming a serious deficiency of present licensure laws.

## 2. *Hospital Staff Privileges*

It must be noted that it is a nongovernmental process not involving certification or accreditation that probably is the mechanism which most effectively insures the adequacy of the services rendered by personnel, particularly physicians, in hospitals. This process is the granting and maintaining of staff privileges for physicians.

Hospital staff privileges are nongovernmental and do not involve systematic nationwide standards. The standards generally are applied on an institution-by-institution basis, and governmental process becomes involved only in adjudications relating to procedural matters in granting and maintaining staff privileges and denials of equal protection of the law where racial or religious discrimination is alleged.<sup>24</sup> The staff privilege regulatory process affects daily operations of health personnel, involves peer group evaluation of performance of physicians, and can deal with such questions as (1) ordinary incompetence in the exercise of skills, (2) lack of specialized skills, (3) diminution of skills as a result of age, debilitation, drug addiction, or alcoholism, and (4) educational obsolescence. Since it does not involve invocation of quasi-penal provisions such as those presented by cases involving alleged violations of licensure laws,<sup>25</sup> supervision of practices can be more flexible, and procedural standards of proof of improper practices need not be as stringent. Such subprocesses as utilization review, tissue committee review, medical audit,

<sup>23</sup> HEALTH MANPOWER REPORT 40-42. The anticompetitive nature of a provision exempting persons already licensed is as clear as the fact that such a provision eliminates the class of physicians most in need of an educational "refresher." Such a "grandfather clause," while seriously subversive of the goals sought to be attained, probably will be necessary to gain for the measure the support of the regulated professions. This appeared to the author to be the major reason for the limitation to newly licensed physicians. The author observed one session of the Commission when this came up.

<sup>24</sup> See *Hamilton County Hosp. v. Andrews*, 227 Ind. 217, 84 N.E.2d 469 (1949); *Levin v. Sinai Hosp. of Baltimore City*, 186 Md. 174, 46 A.2d 298 (1946), for the general rule. See *Simkins v. Moses H. Cone Memorial Hosp.*, 323 F.2d 959 (4th Cir. 1963), *cert. denied*, 376 U.S. 938 (1964), for the rule of the courts in cases involving illegal racial discrimination.

<sup>25</sup> See *Shively v. Stewart*, 65 Cal. 2d 514, 421 P.2d 65, 55 Cal. Rptr. 217 (1966), in which the analogy of the criminal law to cases involving potential revocation of licensure was stated.

and professional activity surveys can be incorporated into the over-all process of supervision of staff privileges, and considerable peer group control and professionalism is possible. Since the hospital is an integral element in the health care delivery system and effective medical or surgical practice is not possible without hospital privileges, the importance of this process cannot be understated.

However, the system of staff privileges regulates only physicians directly, though it affects other personnel indirectly by regulating how physicians relate to them in hospital operations. Furthermore, it does not regulate nonhospital-related activities of physicians or other personnel unless they affect hospital operations. And while the system operates in most voluntary nonprofit and public or tax-supported hospitals, it may not provide the same protections in proprietary hospitals. Finally, the staff privilege system does not prevent physicians denied such privileges from practicing at a low level of competence and ethics and perhaps adversely to the health and safety of a significant percentage of the population. Thus, important as they are, staff privileges do not solve the major problems presented by licensure laws.

### 3. *Cultism*

Licensure laws regulating the practice of medicine clearly have failed in one most important respect, namely, the control of cultism and unscientific schools of practice. Chiropractic, by far the most important category of cultist healers, has grown to include over 35,000 practitioners and is licensed in all states except Louisiana and Mississippi, having been legalized in New York in 1963 and Massachusetts in 1966.<sup>26</sup> It has been clearly demonstrated that chiropractic lacks a scientific basis. Faculty members of chiropractic "colleges" have been demonstrated to be clearly without sufficient education and other qualifications to teach scientific medicine.<sup>27</sup> The states have attempted to control this unscientific school by regulating it with official licensure laws coupled with basic science examinations.<sup>28</sup> Licensure and basic science examinations have not, in fact, controlled chiropractic, which contends that it can and should treat all diseases, and have not upgraded the scientific content of chiropractic education and practice, as evidenced by the quality of chiropractic college faculties and the unscientific claims of practicing chiropractors.<sup>29</sup> Licensing can never give an unscientific system a scientific basis, but it can give it a cloak of legal respectability.

### C. Obstacles to Innovations in Education and Training

Professional licensure laws can constrain innovations in education of members of the health professions and occupations. A highly significant question is whether

<sup>26</sup> For a review of the licensure statutes, see *Regulation of Health Personnel*, ch. 1, at 58-62.

<sup>27</sup> AMA Dep't of Investigation, *Educational Background of Chiropractic School Faculties*, 197 J.A.M.A. 999 (1966).

<sup>28</sup> See *Regulation of Health Personnel*, ch. 1, at 61.

<sup>29</sup> ANDERSON REPORT, *ISSUES CONFRONTING THE DELEGATES AND MEMBERS OF THE AMERICAN CHIROPRACTIC ASSOCIATION AS THEY SEEK TO SOLVE THE PROBLEMS OF CHIROPRACTIC EDUCATION* 8-10 (1964); AMERICAN MEDICAL ASSOCIATION, *CHIROPRACTIC: THE UNSCIENTIFIC CULT* 5 (1966).



current medical licensure laws, which in many jurisdictions specify course and curricular requirements, unduly hamper medical education and training.<sup>30</sup> An educational curriculum which because of rigid legal restrictions cannot be made more responsive to new technology, scientific progress, the information explosion, and changing patterns of medical care, is not serving the public's best interests.

In the case of medicine, many specific statutory curricular requirements were prescribed in the pre-Flexner era to give physicians some exposure to certain pre-clinical and clinical subjects. Most specific requirements, however, were the product of implementation of the recommendations of the Flexner report and were designed to close down or improve inadequate medical schools, diploma mills, and commercialized educational programs. However, those problems have long since been resolved, and other problems, such as requirements for curricular innovation in subjects ranging from medical genetics to community medicine, have arisen. Meanwhile, the statutes have been neither modified substantively nor interpreted with the flexibility needed to respond to changing requirements.<sup>31</sup>

Similarly, the statutory requirement for licensure of physicians in over thirty jurisdictions specifying the internship as a separate entity rather than as part of a program of graduate medical education can operate as a barrier to innovations in graduate medical education and to more effective coordination of undergraduate and graduate medical education.<sup>32</sup> This has been pointed out in the report of the Commission on the Graduate Education of Physicians.<sup>33</sup>

## II

### INNOVATIONS IN USES OF MANPOWER

Innovations in uses of health manpower and experimental programs to train and utilize new categories of health professionals require new allocations of patient care tasks among members of the health professions and occupations and a regulatory program to permit experiments to demonstrate the safety and effectiveness of new kinds of health workers and of new uses for existing kinds of health manpower.

#### A. New Allocations of Patient Care Tasks

##### 1. *Expansion of Tasks Performed by Present Categories of Allied and Auxiliary Manpower*

Expansion of the tasks performed by present nonphysician manpower categories requires legal authorization by legislative, administrative, or judicial action. In view of past experience, legislative expansions would appear to be unlikely because of

<sup>30</sup> See generally Regulation of Health Personnel, ch. 1, at 20-21. See also address by Ruhe, Federation of State Medical Boards of the United States, in Chicago, Ill., Feb. 11, 1967.

<sup>31</sup> Regulation of Health Personnel, ch. 1, at 21-22.

<sup>32</sup> See generally *id.*, at 23-26.

<sup>33</sup> CITIZENS COMM'N ON GRADUATE MEDICAL EDUCATION, THE GRADUATE EDUCATION OF PHYSICIANS 61-63 (1966). For further elaboration of the problems of graduate medical education, see L. COGGESHALL, PLANNING FOR MEDICAL PROGRESS THROUGH EDUCATION (1965).

reluctance to expand tasks performed by present categories until there has been antecedent demonstration of the safety and effectiveness of the new allocation practice by the profession or occupation. However, such antecedent demonstration is curbed by the threat of civil and criminal sanctions for exceeding the statutory scope of practice.<sup>34</sup> Consequently, innovations in uses of present categories of health manpower must be sanctioned by expansive judicial and administrative interpretation of existing licensure laws. The difficulties encountered in achieving such expansions through interpretation can be illustrated by taking a typical "model" statutory definition of professional nursing and speculating on the judicial responses to the scope-of-nursing-practice problems presented by such a statutory definition.

Definitions of the practice of professional nursing address themselves to the two basic types of services that can be rendered by professional nurses—nursing duties which must be performed under orders of a physician and those which the nurse can perform without supervision of a physician. Most nursing practice acts provide in substance that (1) under no circumstances can a nurse diagnose or prescribe therapeutic measures; (2) under orders of a doctor, a nurse can "administer medication and treatments"; and (3) a nurse can independently supervise and teach other personnel, observe care given to and counsel the ill, maintain health, and prevent illness if limitations (1) and (2) are observed. The definition most commonly used provides as follows:<sup>35</sup>

The term "practice of professional nursing" means the performance, for compensation, of any acts in the observation, care and counsel of the ill, injured or infirm or in the maintenance of health or prevention of illness of others, or in the supervision and teaching of other personnel, or the administration of medications and treatments as prescribed by a licensed physician or a licensed dentist; requiring substantial specialized judgment and skill and based on knowledge and application of the principles of biological, physical and social science. The foregoing shall not be deemed to include acts of diagnosis or prescription of therapeutic or corrective measures.

The most difficult problems concern those activities that lie between the traditional practices of nursing and medicine. For example, do the medical and nursing practice acts permit specially trained nurses, working under standing orders from a physician, to administer cardiopulmonary resuscitation by means of a Pacemaker machine to patients suffering from cardiac arrests? Good patient care may require that this function be performed by nurses and others in many instances, but legal authority for this practice has not been defined clearly.

Resolution of such problems requires an analysis of the purposes and meaning

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<sup>34</sup> See cases cited note 9 *infra*.

<sup>35</sup> The quoted definition has been adopted as a "model definition" by the American Nurses Association. It has been adopted into the laws of Alabama, Alaska, Colorado, Delaware, Hawaii, Idaho, Illinois, Kansas, Kentucky, Montana, New Hampshire, North Dakota, South Carolina (regulation), Utah, and Washington. Variations of the model definition exist in Arizona, Florida, Maine, Nevada, North Carolina, and Oregon.

of the phrase "administration of medications and treatments" and also the phrase "the foregoing shall not be deemed to include acts of diagnosis or prescription of therapeutic or corrective measures." These phrases often give little help in resolving an interpretative problem, such as that concerning the use of a Pacemaker machine by a professional nurse. It is apparent that literal interpretation can produce results which impede innovations in health services and which are not required by considerations of patient safety. For instance, the latter phrase is too restrictive since it is clear that professional nurses can prescribe and do apply certain therapeutic or corrective measures, such as rendition of first-aid and minor treatments in occupational and industrial medical programs. The purpose of this attempted limitation on the scope of nursing practice is to distinguish nursing from medical practice by excising from nursing practice certain types of *acts*. However, it fails to point to the real distinction between a nurse and a physician—namely, the nature of the medical judgments that each is capable of making.<sup>36</sup>

The difficulty with the present statutory definitions is that they attempt to resolve difficult scope-of-practice issues through the use of vague and ambiguous classifications without establishing guidelines by which the public, the courts, administrative agencies, and the professions themselves can determine scope-of-practice issues not specifically resolved by statute.<sup>37</sup> Without further statutory definitions and standards, such terminology is subject to a variety of inconsistent administrative and judicial interpretations. Even within individual states, considerable judicial and administrative interpretation will be necessary to establish with reasonable certainty the content of the criteria. On the other hand, of course, legislative semantic precision is not necessarily desirable because of the inflexibility it could produce.

The primary attempts by the courts to clarify scope-of-practice problems on a case-by-case basis have not been satisfactory. Scope-of-practice issues can come before the courts in the form of malpractice suits, actions for declaratory judgments, and criminal prosecutions for illegal practice.<sup>38</sup> In general, the decisions in such actions have been based on rigid and narrow construction of the statutes rather than upon broad policy considerations involving optimal allocation of tasks among health workers and expanded accessibility of medical care.<sup>39</sup> Moreover, the decisions tend to turn on very narrow points, such as definition of prevailing custom and usage.<sup>40</sup>

Strict construction of these statutes can, of course, be justified on the policy premise that mandatory licensure is designed to protect the public from persons not

<sup>36</sup> See Hershey, *Scope of Nursing Practice*, 66 AM. J. NURSING 117 (1966).

<sup>37</sup> Committee on Industrial Nursing of the Council on Industrial Health, *The Legal Scope of Industrial Nursing Practice*, 169 J.A.M.A. 1072 (1959).

<sup>38</sup> See cases cited note 9 *supra*.

<sup>39</sup> See, e.g., *Magit v. Board of Medical Examiners*, 57 Cal. 2d 74, 366 P.2d 816, 17 Cal. Rptr. 488 (1961); *People v. Whittaker*, Civil No. 35307, Justice Court of Redding Judicial District (Shasta County, Cal., Dec. 1966); *Barber v. Reinking*, 68 Wash. 2d 139, 411 P.2d 861 (1966).

<sup>40</sup> See, e.g., *People v. Whittaker*, Civil No. 35307, Justice Court of Redding Judicial District (Shasta County, Cal., Dec. 1966).

meeting appropriate standards of ethics, education, and training.<sup>41</sup> Accordingly, it can be argued that the performance of medical functions by nonphysicians should be permitted only when expressly authorized by statutory exceptions. Under this approach, responsibility for developing legal rules and standards regarding delegation of medical tasks is left to the legislature rather than to the courts or administrative agencies or to supervising physicians.<sup>42</sup> While failing to provide needed flexibility and the opportunity to apply a broad public interest standard, such an approach by the courts is understandable and may be even proper inasmuch as the courts lack the necessary experience to make qualified judgments on the broader questions.<sup>43</sup>

The extent to which various licensing agencies deal with scope-of-practice issues is not known, but some tentative conclusions on the administrative approach to scope-of-practice problems can be drawn from a review of the licensure statutes, administrative regulations, and cases.<sup>44</sup> Administrative agencies have seldom used their power to "promulgate rules and regulations"<sup>45</sup> to clarify scope-of-practice problems.<sup>46</sup> Although this hesitancy to encourage more flexible and efficient uses of health manpower through administrative rules is probably based on the perceived original purposes of licensure statutes, administrative agencies should reconsider their position in view of changed policies and needs of the public. The present procedures for authorization of innovations in uses of health manpower have thus produced a significant responsibility gap. This gap is characterized on the one hand by legislative inaction until innovations have been adopted into regular medical practice and on the other hand by judicial and administrative deference to existing legislation. Certainly the greatest criticism should be directed at the administrative agencies, which have failed to recognize the problem and their power to deal with it.

Because of the many variables, both medical and legal, involved in the propriety of delegations, it is difficult to resolve the issue through statutory standards and the accumulation of case law criteria. Ideally, the problem warrants a tripartite solution: first, broad statutory provisions in which the legislature strikes a balance between policies of public protection and manpower use; second, formulation of specific but flexible administrative regulations by a specialized administrative agency applying new broad policies to health service delivery practices; and third, an adjudicative process in which the administrative agency primarily and the courts

<sup>41</sup> See *Indiana State Bd. of Dental Examiners v. Davis*, 69 Ind. App. 109, 121 N.E. 142 (1918).

<sup>42</sup> "The history of legislation discloses that in this, as in many other states, there has been developed gradually a policy to commit to boards of experts the question of what persons are qualified and competent and should be permitted to practice in professions and engage in callings that bear directly upon the public health." *Id.* at 128, 121 N.E. at 148.

<sup>43</sup> *Id.* at 128-31, 121 N.E. at 148-49.

<sup>44</sup> See generally Regulation of Health Personnel, ch. 2.

<sup>45</sup> See, e.g., CAL. BUS. & PROF. CODE § 2119 (West 1962); IND. STAT. ANN. § 63-907 (1961).

<sup>46</sup> The administrative regulations typically fail to elaborate upon the statutory scope of practice definitions. See, e.g., Cal. Ad. Reg., tit. 16, ch. 14 (1966); 4 Burns Ind. Ad. Rules & Reg., tit. 63, ch. 9 (1967).

secondarily may construe and enforce the statutes and regulations.<sup>47</sup> Early consideration of such a solution is necessitated by the real possibility that, until the issue of delegation is clarified, new and desirable uses of present categories of health manpower may be inhibited by legal uncertainties.

## 2. *Creation of New Categories of Health Manpower*

In addition to expansion of the scope of present categories of health manpower, optimal allocation of health services requires creation of new categories of health manpower. Merely expanding the scope of present categories is insufficient because in medicine, for example, present legally defined categories of nonphysician manpower are not broad enough to encompass the many medical care tasks which are evolving as new technologies and processes are incorporated into preventive, curative, and rehabilitative services.

Present licensure statutes make no provision for the orderly and systematic creation of new categories of health manpower. Consequently, recognition and widespread use of new categories of manpower will normally be enacted only if such a category of personnel exists and seeks licensure. Obviously, such categories are unlikely to develop without legal recognition because of fear of criminal or civil penalties for engaging in illegal practice.

Legal barriers to the creation of new categories of health manpower through custom and usage arise because the practice of medicine encompasses all health service functions.<sup>48</sup> Consequently, rendition of health care without a medical license violates the medical practice acts unless such services are performed pursuant to the limited license of an allied or auxiliary occupation or profession. Thus, where unlicensed personnel, even working under the direct supervision and control of a licensed physician, are used to perform new functions, the medical practice acts are violated, and enforcement of the licensure statutes could result in any or all the following: disciplinary action against and possible revocation of the licenses of those physicians utilizing such personnel;<sup>49</sup> revocation or suspension of the licenses of any physicians assisting or abetting such utilization;<sup>50</sup> criminal (both misdemeanor and felony) prosecution of personnel rendering the services;<sup>51</sup> criminal (felony) conspiracy prosecution of persons involved in planning the utilization of such services;<sup>52</sup> and injunctive relief restraining further activities in violation of the licensure laws. Needless to say, the threat of such consequences, or even of proceedings seek-

<sup>47</sup> If the administrative agencies were structured to properly protect the public interest, consideration should be given to limiting judicial review to due process questions.

<sup>48</sup> Regulation of Health Personnel, ch. 1, at 2.

<sup>49</sup> *E.g.*, *Newhouse v. Board of Osteopathic Examiners*, 159 Cal. App. 2d 728, 324 P.2d 687 (1958) (suspension of license for thirty days); *see Magit v. Board of Medical Examiners*, 57 Cal. 2d 74, 366 P.2d 816, 17 Cal. Rptr. 488 (1961) (revocation of license by Board of Medical Examiners set aside as abuse of discretion).

<sup>50</sup> *E.g.*, CAL. BUS. & PROF. CODE §§ 2361, 2372 (West Supp. 1967); § 2392 (West 1962).

<sup>51</sup> *E.g.*, CAL. BUS. & PROF. CODE §§ 2141, 2141.5 (West Supp. 1967).

<sup>52</sup> *E.g.*, *People v. Marsh*, 58 Cal. 2d 732, 376 P.2d 300, 26 Cal. Rptr. 300 (1962).

ing to impose them, constitutes a great obstacle to the creation of new categories of health manpower.

The recent California case of *People v. Whittaker*<sup>53</sup> illustrates some of the legal problems of using new categories of health manpower. The case involved a neurosurgeon's use in brain surgery of a trained surgical assistant as an "extra pair of hands." The assistant operated a cranial drill and Giegle saw positioned by the surgeon to bore holes and excise skull flaps during operations. The jury found the assistant guilty of practicing medicine without a license and the surgeon guilty of aiding and abetting an unlicensed person to practice medicine.

The situation is further complicated by a recent decision of the Supreme Court of the State of Washington. In *Barber v. Reinking*,<sup>54</sup> the plaintiff brought an action against a physician and his practical nurse to recover for injury caused by the negligence of the nurse in administering a hypodermic injection. Since the state licensure statute provided that such an injection could be administered only by a licensed professional nurse, the court held that the practical nurse would be liable if she did not have the knowledge and skill possessed by a licensed registered nurse. Her failure to be so licensed raised an inference, which the jury was allowed to consider, that she did not possess this required degree of knowledge and skill. Additionally, evidence that it was the custom and practice in the community for practical nurses to administer such injections was held inadmissible. This case departs from prior decisions holding that evidence of violation of a licensure statute is irrelevant and has no direct bearing upon the skill or care of the defendant.<sup>55</sup> Although the physician's liability in *Barber* was presumably based on *respondeat superior*, the decision increases the possibility of a successful malpractice claim based on the negligent delegation of authority and thus provides an added deterrent to the use of trained but unlicensed health personnel.

## B. Experiments to Demonstrate the Safety and Effectiveness of New Manpower Uses

### 1. *Removing the Legal Impediments*

Clearly, there are substantial legal barriers to experimental programs to develop, train, and use new categories of health manpower. The present legal climate fails to encourage experimentation in the uses of manpower largely because interpretations of licensure standards have neglected broad policy considerations. Such current problems in the delivery of medical care as manpower shortages, the spiraling costs of care, the gap between the kinds of care that *can* be given and the kinds that actually *are* given, and the distribution of care to urban ghetto dwellers and the rural

<sup>53</sup> Civil No. 35307, Justice Court of Redding Judicial District (Shasta County, Cal., Dec. 1966).

<sup>54</sup> 68 Wash. 2d 139, 411 P.2d 861 (1966).

<sup>55</sup> See *Brown v. Shyne*, 242 N.Y. 176, 151 N.E. 197 (1926); Gregory, *Breach of Criminal Licensing Statutes in Civil Litigation*, 36 CORNELL L.Q. 622 (1951).

poor have not entered into the making and administration of licensure laws. Furthermore, innovations and experiments are subject to the risks of penal and quasi-penal sanctions as well as malpractice civil liability involving large sums of money, and even if there were a basis for confidence that sanctions and damage judgments could be avoided by lengthy litigation, the cost and strains of such litigation is a mammoth deterrent to engaging in such innovations in the first place.

The existing inhibitions against innovations in patterns of delivery of personal health and medical care, in tasks performed by health and medical personnel, and in kinds of health and medical personnel used are not the result of deliberate and planned legislative action. They developed during the evolution of the present occupational licensing statutes when other policy considerations, namely protection of the public against unethical and incompetent practitioners and commercial deception by providers of medical care, were predominant. Removal of these inhibitions is necessary in the light of the conclusion of the President's National Advisory Commission on Health Manpower that the present crisis in the provision of medical care cannot be averted or effectively ameliorated without substantial innovations in the patterns of delivery of health care, even if massive increases in the number of health personnel could be achieved.<sup>56</sup>

Any changes in present licensure laws should balance the public's need for protection from commercial abuses and from research that is scientifically or ethically improper against the need for innovations in the delivery of personal medical care. Commercialized efforts at shortcutting personnel standards would probably continue to be deemed objectionable under the same principles that underlie existing licensure laws, and even where the commercial motive is absent, regulation may be required to guide the pace and direction of innovation and to protect the public against uncontrolled efforts. Even with legislation authorizing new manpower uses on an experimental basis, programs implementing that authorization would continue to be subject to the legal controls applicable to clinical investigation generally; most importantly, this means that the patient's informed consent must be obtained before he is employed as an experimental subject.<sup>57</sup> That clinical investigation is involved seems clear, since manpower experiments are nothing less than the introduction into the medical care process of a new input the value and effectiveness of which have not been demonstrated and which presents potential risks to the health and safety of the patient. Additional legal controls over such experiments may be deemed essential or desirable.

What may be needed is a regulatory program that does the following things:

- (1) permits experimental programs by universities and other qualified institutions and individuals for the purpose of developing and demonstrating the

<sup>56</sup> HEALTH MANPOWER REPORT 2.

<sup>57</sup> See generally Fletcher, *Human Experimentation: Ethics in the Consent Situation*, in this symposium, p. 620; Stason, *The Role of Law in Medical Progress*, *id.*, pp. 563, 580-95.

safety and effectiveness of new categories of and new uses for existing categories of health manpower;

- (2) regulates such programs so that patients will be protected against irresponsible and dangerous experiments and so that hazards to patient safety which develop during the course of such experimental programs can be controlled; and
- (3) permits the translation of those innovations that have been demonstrated to be safe and effective into regular patterns of medical care.

Such a program of regulation could be created only by legislation.

A federal program, if it were feasible, would be the most expeditious means of reform. However, political realism makes this course seem unpromising at this time. Moreover, a serious question exists as to whether the federal government's interest in the provision of medical care, growing out of its commitment to the Medicare program, is sufficient to support constitutionally the encroachment on state police powers that would be entailed. Nevertheless, such a law, perhaps restricted to authorizing activities at hospitals participating in Medicare, might pre-empt state legislation, thereby permitting experimentation, training, and employment of federally licensed persons in states where licensure acts would otherwise prove an obstacle. A general sort of precedent for the type of regulation that might be adopted can be found in the Kefauver-Harris amendments to the Food, Drug, and Cosmetic Act in 1962, which govern drug experiments with human subjects.<sup>58</sup>

The Kefauver-Harris amendments illustrate that the public can benefit from the fruits of experimentation and still be protected from uncontrolled and harmful research.<sup>59</sup> Before a drug manufacturer can clinically test a new drug in patients, it must first justify testing the drug on humans and obtain authorization from the Food and Drug Administration. Among other things, the sponsor of the test must (1) demonstrate that adequate animal, chemical, and other tests indicate clinical tests on humans can be initiated with reasonable safety; (2) demonstrate that adequate provision has been made for protection of the public on such matters as selection of qualified investigators, supervision of all patients, and obtaining of the consent of all subjects; and (3) maintain detailed records including the names and addresses of all subjects. The length of the investigational period is limited, and the FDA has the power to terminate the investigation or require it to be modified if there is evidence that the drug is unsafe. Only when the sponsor can produce substantial evidence that the drug is safe and effective is authority to distribute the drug commercially granted by the FDA.<sup>60</sup> While substantial dissimilarities exist

<sup>58</sup> Pub. L. No. 87-781, 76 Stat. 780 (1962).

<sup>59</sup> For a more detailed discussion of the Kefauver-Harris amendments, see Rankin, *Progress on Investigational Drugs*, 19 FOOD DRUG COSM. L.J. 237 (1964); Comment, *The Drug Amendments of 1962*, 38 N.Y.U.L. REV. 1082 (1963).

<sup>60</sup> 21 U.S.C. § 355 (1964).



between drug experimentation and experimentation with new manpower uses, adaptation from this system of regulation could prove both desirable and feasible.

State legislation is a more promising goal than federal intervention in an area that in its major aspects is traditionally one of state concern. If one or a few states would amend their licensure laws to permit controlled experimentation in manpower uses, progress could at least begin. Demonstrable success might then lead to further amendments to licensing laws to regularize the employment of new categories of personnel or to broaden the functions of established categories. Work should now begin on a uniform or model health manpower act which could be presented to the states for legislative consideration, as will soon be done in the area of gifts of human tissues for transplantation purposes.<sup>61</sup>

If states choose to regulate experimentation with manpower uses, the federal program for regulating drug experiments might prove to be a useful model. Alternatively, a more modest program might be established to provide something like the following:

- (1) that experimentation and training involving unauthorized uses of health manpower might be conducted in university hospitals if a comprehensive plan of the experiment or training program was submitted to and approved by an appropriate hospital committee and filed with the state licensing authority. Particular conditions might be imposed, such as requirements for physician supervision and for written consent from all patients whose care was delegated to nonphysicians as part of the program.
- (2) that new functions for existing categories of medical personnel could be created by the state licensing authority upon a showing that experimental results and medical manpower requirements warranted a finding that such action was in the public interest.
- (3) that persons trained in such training programs could be licensed on an ad hoc basis, to perform only those functions enumerated in the license, upon certification of competence by the hospital and a showing that experimental results and medical manpower requirements warranted a finding that such action was in the public interest.

This hypothetical program is merely one example of how the issue might be handled, and its exposition here reflects no conclusion that this is the preferable approach. Such a conclusion must await further study and a careful evaluation of the degree of risk that attends programs of the sort that must be created. The author's current involvement in a study of this kind leads him to expect that a recommended legislative solution can soon be devised.<sup>62</sup>

<sup>61</sup> Stason, *The Role of Law in Medical Progress*, in this symposium, pp. 563, 571-72.

<sup>62</sup> See references cited note 14 *supra*.

## 2. *Designing the Research*

While legal reform is essential to wide-scale employment of new categories of health personnel and to the expansion of the functions of the existing categories, the first objective must be legal authorization of necessary research. Experimentation must be allowed to supply the lacking performance and operational data upon which new legal standards can be based. The medical profession must be prepared to meet this need for experimental data, and thought must now be given to the technical and ethical facets of the experiments to be performed.

The technical facets of manpower experiments will involve planning and designing the program in the way most likely to amplify the quantity and quality of physician-directed medical care. Perhaps the major challenge is the selection of the particular innovations to be attempted. This can be done through the use of pre-experimental models and simulations so that the innovations' cost and potential value can be determined. Criteria for evaluating the performance of individuals and classes of individuals must be developed, and methods for measuring or otherwise determining safety and effectiveness must be incorporated in the research plan. Medical knowledge must be drawn on to establish the necessary scope of the training of specialists for particular tasks, and methods of instilling limited technical capacity and understanding in persons lacking substantial technical training will be essential.

The ethical facets of such experiments must also be considered. These relate to protecting the health, safety, and welfare of the patient from irresponsible, dangerous, and unnecessary experiments. Such problems as the patient's informed consent and the physician's supervisory responsibility must be faced in the context of the legal and ethical considerations applicable to human experimentation generally. Attention must also be given to the difficult problem of striking a balance between patient safety and the potential social value of the innovations being attempted. Whether or not a regulatory framework enforcing these various requirements is developed, the physician's responsibility for adherence to high standards in dealing with these matters will be the same.

## III

### POLITICAL PROSPECTS: CAN ANTICOMPETITIVE LICENSING LAWS BE LIBERALIZED?

It has been contended that "[l]icensure is the key to the control that the medical profession can exercise over the number of members."<sup>63</sup> If current licensing is, in fact, valued by the medical profession as an anticompetitive device, attainment of the legislative revisions discussed above, which ultimately will amplify the quantity and reduce the cost of physician-directed medical care, may be virtually impossible.

<sup>63</sup> Milton Freedman, untitled lecture at Wabash College, summer 1959, quoted in Moore, *The Purpose of Licensing*, 4 J. LAW & ECON. 93 (1961).