



nabp

National Association of Boards of Pharmacy

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TO: Ad Hoc Advisory Committee on the Physician's Assistant

FROM: F. Mahaffey, Executive Director

I greatly appreciate an opportunity to appear before the Committee and discuss some of the apprehensions that NABP and other pharmacy associations have about Physician's Assistants and the dispensing of drugs. As I promised, we enclosed two papers by Dr. Sidney Willig. One paper was presented before the Federation of State Medical Boards of the United States, the others deals directly with Physician's Assistants dispensing drugs and this was prepared for our own Association's convention last April.

The statement that was adopted by the American Pharmaceutical Association House of Delegates is also included and this expresses their recommendations on this subject. A summary of APhA's position policy is included in the American Druggist article.

As I explained to the Committee, I am chairman of an Ad Hoc Group called National Associations Representing Licensing Agencies in the Health Field. At our meeting in June of 1972 there was a great deal of apprehension expressed about the role, function and responsibilities of Physician's Assistants and I am sure that this will again be a topic at our 1973 meeting in September. Our group would appreciate an opportunity to work with you in identifying problem areas concerned with the legal responsibilities of Physician's Assistants working under the supervision of the physician and we would welcome an opportunity for input in your deliberations.

Sincerely,

FM:js

cc - Dr. Richard Penna
Dr. Sidney H. Willig
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Legality of Prescribing by Physician's Assistant

In most discussions with regard to the legal status of a physician's assistant, the major problems are terminology and communication. As to terminology, the question arises as to what is meant by the term physician's assistant. If by any chance this can be established by acceptance of 4 or 5 planes of definition^(G), then the difficulty arises in that for each such definition, that may be contrary to the way a physician, a nurse, a pharmacist or a patient sees it.

In those few states that have granted a form of recognition through a licensing law, to graduates of special programs in physician assistantship, such an individual enjoys some degree of exemption from prosecution via the medical practice act. Exemptions of course are strictly construed in law and the burden of proof that the exemptee enjoys entitlement thereto, is squarely with him or any one legally responsible for his actions. For all intents and purpose any state nursing practice act or the pediatric assistant act in Colorado, or the physician's assistant section within

is as a dispenser of drugs. It is true that in the case of potent drugs the dispensing mechanism must be triggered by the authorization and direction of the physician.^(C) However, a physician might prescribe the simplest of remedies and accompany it with the clearest directions for use and yet not accomplish his prescriptive purpose without the exercise of independent judgements and functions on the part of the pharmacist. It is the latter who assures that the patient receives such a product in unadulterated and non-misbranded condition by dint of his education, methodology and legal requirements comparatively unknown to the physician prescriber.

To return to the physicians' assistants therefore, it is obvious that if they are to enjoy any independent authority, it must be spelled out in the statute. Such a statute, using a well known example, would be that of the pediatric assistant in Colorado, where the limitations as to the physician's assistant's prescribing function are set out, among other parameters of legal conduct.^(G)

However, problems arise as in the part with nurse, where the nurse or physician's assistant seeks to prescribe as a dependent function under color of delegation. That is, where they authorize refill of a pre-

scription originally given by the physician, or actually originate a new prescription without a direct order at the time from the physician so to do. This differs from chart orders in a hospital, or in an office practice,^(E) where the physician seeks to anticipate changes or complications and in advance orders the nurse to provide for the patient, any of a group of drug possibilities clearly dependent on observation of certain facts within the nurse's duties and competence. i.e. temperature, diaphoresis, diuresis etc.

All such dependent "prescribing" authority to only the extent recognized, finds the nurse or other physician's assistant acting within a bonafide physician patient relationship established a priori by the physician. If the physician has not yet established a relationship with a patient by at least elementary diagnosis, patient care may only be initiated by a non-physician within the framework of legality contemplated by the medical practice act; that is then, in an emergency when serious harm or death might ensue and a physician is not available.^{(E)(G)}

On such a basis it would seem that emergency facilities could be staffed solely by non-physicians. That is however medicolegally a non sequitur. An emergency facility since it anticipates the need for

emergency medical services requires medical presence or availability in its plan of operation, otherwise it will attach a violation of illegal practice of medicine to its function and a charge of "aiding and abetting" to those who are in charge or sponsor it.

The analogy to regularly employed physician's assistants can therefore be summarized much as follows:

Physicians' assistants who are permitted within a particular state by their own licensing act, or by a provision in the medical practice act, to undertake independent medical acts such as prescribing medicines or using medical devices in the treatment of patients, must function within the exact limitation of such a statute or statutory exception. Other than that, since they have the legal status of a layman insofar as independent activities are concerned, they would have no right to possession of prescription drugs and devices, no right of prescription and none of administration of same. (E)(G)

Where they are acting as agents of the physician, in functions best labeled as dependent, to carry out tasks delegated by them by the physician, they have no right to originate a prescriptive plan or the administration of drugs or prescription devices, other than as directed by the physician. This is not to

denigrate the use of articles generally regarded as within the sphere of nursing authority when the physician's assistant is a nurse. (E)(G)

Patients for the most part have a right of autotherapy. There are some important exceptions to this of course. Autotherapy is only at best permissible when the drugs or devices self prescribed and administered are not prescription drugs or devices, nor are deemed anti-societal in purpose or result. When autotherapy rights are controvertive to such exceptions, they could be seized from the very home and grasp of a lay user as misbranded. Illegal possession sections in statutes are really misbranding violations. (B)

Therefore in the case of a physician's assistant who undertakes to prescribe as an independent act even non-legend drugs, he is borrowing from the patient's right to autotherapy. He must be suggesting or explaining to the layman, following inquiry by the latter, as to what non-prescription drug might be a satisfactory recommendation.

It should be borne in mind that prescribing authority only exists on the basis of state qualifications. (C) As you will recall, Durham Humphrey merely requires that the prescription to be filled and dispensed legally, must be appropriately authorized by one qualified in

state law to do so. If state law qualifies only a physician who is licensed to practice medicine in that state to have general prescriptive authority, Durham Humphrey abides by that. If state law qualifies other practitioners such as dentists, podiatrists with selective prescriptive authority if they are licensed to practice within that state, Durham Humphrey does not quarrel with that.^(F) Therefore, if state law qualifies non-physicians to prescribe in accordance with a license to practice within such state, Durham Humphrey will abide that as well. Other than that and the exceptions allowed under state law for prescribing authority, such as for federal officials, out of state consultants etc., it is a federal offense to cause misbranded drugs and devices to be distributed and used.^(D) That is what illegal prescribing amounts to.

In cases where persons qualified to prescribe seemingly delegate this authority to persons legally unqualified to prescribe, the measure of statutory acceptability must be found in supervision and direction by the licensed practitioner, superior to the subordinate. This must be by direct oral or written communication to the subordinate. Other than that a physician has no more right to grant prescribing

license to a nurse or a physician's assistant than to a member of his family or a stranger. For the same reason medical boards, pharmacy boards or nursing boards may not grant new privileges nor increase old ones, by regulation. A regulation by a medical board to permit independent prescribing by physician's assistants would be invalid on its face as controverting the medical practice act, unless the latter provided for same.

In terms of civil liability, physicians as individuals and institutional authorities of all kinds in the plural sense, may be willing to assume the legal responsibility for delegating authority to physician's assistants, that includes independent prescriptive authority and independent use of prescriptive devices. However, in the event of patient injury claims therefrom, not only would they be liable for damages, but so would the physician's assistant who might be lulled into a false sense of insecurity by the demeanor of his employer. (A) An injury incurred from a drug or device prescribed or administered in violation of statutory authority to do so would be remediable without any further show of negligence on any of the defendant's part so long as that drug or device was the causative agent

of the patient's damage. (E)

If a physician's assistant is to prescribe legally, such authority must be statutorily endowed, or it is a potential criminal offense in terms of the states' medical practice act, the Federal Food, Drug and Cosmetic Act, and such provisions of state pharmacy and drug laws which replicate the Durham Humphrey language.

For a physician's assistant to feel that he may prescribe as a delegation of authority from the physician, the barest essentials would be:

- (1) that a bonafide physician patient relationship has been previously initiated by the physician from whom the delegation has arisen;
- (2) that by clear and definite instruction as by written or oral orders, (dangerous if such orders represent many drug alternatives), and dependent on observations and findings the physician's assistant is qualified by law and training to make, he can transpose thus the physician's actual prescriptive order as a conduit for the true prescriber;
- (3) that the same considerations be given to prescription devices and the administration thereof;

- (4) that the delegation may not fly in the face of stricter local or federal laws that prohibit same, as in circumstances of transfer of controlled substances or paraphernalia;
- (5) that the delegor have actual authority to prescribe within the state laws;
- (6) that the physician's assistant shall in no way extend the scope of the delegation.

In the event of such delegation, both the delagor and delagee must be prepared in the fact of threatened civil liability to justify the delegation and show it does not contravene existing laws.

A pharmacist who accepts a prescriptive order and dispenses it, is uttering a misbranded drug in terms of federal and state law unless the physician's assistant has satisfactory statutory authority, or acting as agent for a prescriber physician in a legally acceptable manner. (D)

A pharmacist who dispenses a prescription written or ordered by any person not qualified by state law and/or licensure to so prescribe is not only accountable criminally and civilly for causing such misbranded article to go to another, but may also be considered as aiding and abetting the illegal practice of medicine. Obviously he would also be considered an appro-

priate party defendant in a liability action derivatory from the use of the article dispensed which is alleged to have caused patient injury.

Sidney H. Willig
Professor of Law
Temple University

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Should MDs Assistants Be Given The Right To Prescribe Drugs?

If yes, pharmacists should have the same authority, APhA is told

If the new breed of medical personnel usually referred to as "physicians' assistants" acquire any legal right to prescribe medication, pharmacists should have the same right.

The American Pharmaceutical Association will be asked to adopt this policy at its annual convention in Boston later this month. A recommendation to that effect is contained in the report of the association's policy Committee on Professional Affairs. This report, along with those of the Committee on Public Affairs and the Committee on Organizational Affairs, will be voted on by the APhA House of Delegates at the meeting.

Direct supervision: On the subject of physicians' assistants, the professional affairs committee recommended that legislation dealing with prescribing by such personnel "should also consider the dispensing function and provide that it be carried out under the responsibility and direct supervision of a pharmacist."

Moreover, the committee urged, "the legislation should permit pharmacists to prescribe under the same control procedures as those developed for physicians' assistant personnel."

The committee pointed out that legislation pertaining to physicians' assistants has already been enacted in 24 states, and that others are considering it.

Such legislation the committee said "should specifically treat the prescribing function of physicians' assistants—either prohibiting it outright or providing for conditions under

which the function can be performed."

Controls: Any legislation that permits physicians' assistants to prescribe, the committee said, should incorporate "control procedures" such as the following:

"(1) Prescribing carried out only within rigidly defined procedures developed and controlled by an interdisciplinary panel consisting of physicians, pharmacists, dentists, nurses, and other appropriate health professionals.

"(2) Establishing a minimum level of education and training with regard to drug therapy, that would permit physicians' assistants to engage in the prescribing function.

"(3) Physicians' countersigning of prescription medication orders."

More emphasis: In explanation of its stand, committee said that "recent evidence documenting the incidence of adverse drug reactions and interactions, as well as disclosures of the overuse and inappropriate use of antibiotics, indicate that more emphasis needs to be given to rational drug prescribing.

"The question then arises

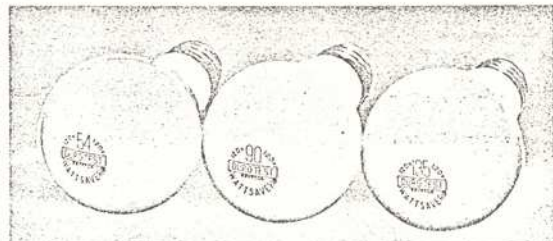
that, if the prescribing function is delegated to individuals with less training and without appropriate control mechanisms, will drug therapy in fact become more irrational? Only when the prescribing professions pay sufficient attention to the prescribing functions can physicians' assistants under their supervision be expected to function effectively."

On continuing education, the professional affairs committee will recommend that the House of Delegates urge states now considering mandatory continuing education legislation to postpone such action until after APhA's 1974 meeting.

In the interim, the committee said, APhA should evaluate the mandatory programs now in effect in five states. Also the committee said, APhA should explore "alternative approaches to motivate pharmacists to participate in continuing education activities."

APhA's leadership has in the past year several times strongly condemned the drive for mandatory continuing education as "premature" and "ill-advised". APhA has also made no secret for its opposition to the action of the National Association of Boards of Pharmacy in adopting a model continuing education law and urging state boards to work for its enactment.

The professional relations



WATSAVER LINE: These bulbs by Duro-Test are marked "54 watt", "90 watt", and "135 watt." They deliver the same life and light as 60, 100, and 150-watt bulbs, respectively. The North Bergen, N.J. manufacturer says its new "WattSaver" line of conventional size bulbs consumes 10% less electrical energy without loss of light output because they use krypton gas. List prices are \$1.69 for the 54- and 90-watt bulb, and \$1.79 for the 135-watt bulb.

committee reported that a survey of the state pharmaceutical associations found that, of 44 states responding, 24 favor mandatory continuing education, 4 oppose it, and 15 have not taken a position.

Dilemma: "The profession is presented with a dilemma," the committee said. "No one will deny the potential value of continuing education, yet in the absence of any data at all on the value of mandatory continuing education in regard to practitioner competence, one must look at the rationale for adopting a national policy encouraging the concept.

"Mandatory continuing education creates a number of serious problems for practitioners, educators and the public. While it is generally agreed that continuing education is professionally desirable, it is the attitude or orientation of the practitioners toward continuing education which is far the more important element. A practitioner favorably discussed to continuing education is already involved in the continuing education experience and does not require legislation to induce him to continue. Legislation mandating continuing education for practitioners not attitudinally attuned is of questionable value.

"Mandatory requirements significantly reduce practitioner flexibility in participating in continuing education. For example, journal reading is not accepted for continuing education credit by some states, yet journals are a substantial source of continuing education. Other states do not accept—or give only partial credit for—correspondence or audio tape programs.

"Restricting the sources of acceptable continuing education may have a detrimental effect on those who produce these programs in that the resulting demand for continuing education may greatly exceed their capacity to produce quality programs. While schools of pharmacy maintain a continuing education effort, this may be insufficient to meet the needs of every practitioner should such

education become mandatory. The only predictable result is decreased availability of 'acceptable' continuing education programs, increased demand, decreased quality and increased costs.

Neglected: "The costs of a mandatory continuing education program have been largely neglected in discussion of the issue, but preliminary calculations indicate that costs would be substantial . . . Assuming 130,000 practitioners spend 20 hours per year in continuing education, this would result in a 2.6 million man-hour effort which, at a cost of \$10 per hour, would cost the public \$26 million annually."

In a minority report, committee member Paul W. Lofholm a California community pharmacist, urged that APhA, instead of waiting a year, take a position now opposing mandatory continuing education for pharmacists.

He also recommended that APhA develop a "national recognition program for a practitioners—who voluntarily participate in continuing education

programs recognized by the association."

Periodic certification: According to Mr. Lofholm, "if the public is to be protected through assurance of pharmacy competency, then that competency should be measured through a system which would provide for periodic certification by examination or a well-defined and developed system of peer review. These are the only methods which can assure that pharmacists possess a minimum level of competency.

"How the pharmacist reaches and maintains that competency is solely his personal and professional prerogative, and no state or professional organization should interfere with that personal prerogative.

"While continued study on the part of the profession and the association will document the value of continuing education in certain aspects of pharmacy practice, no amount of study will document the value of mandatory continuing education, for it is inherently contradictory to the very definition of professionalism."

OTC Review Gives APhA Opportunity To Revive 3rd-Class-of-Drugs Drive

The American Pharmaceutical Association has found in the Food & Drug Administration's o-t-c product review program a new launching pad for its campaign for a "third class" of drugs, available to the public without prescription, but only from pharmacists.

APhA has been urging Congress and/or FDA to establish such a category for almost a decade now, thus far without success.

Richard P. Penna, assistant executive director of APhA for professional affairs, brought up the idea at a hearing of Sen. Gaylord Nelson's (D-Wisc.) subcommittee investigating the drug industry.

The committee devoted a one-day session to FDA's proposed regulation on o-t-c ant-

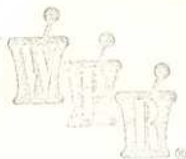
acids, the first product category to finish its progress through FDA's advisory panel review procedure (May 1 ADM).

'Ethical' labeling: Dr. Penna noted that the antacid monograph makes reference several times to "ethical labeling", defined as product labeling provided to physicians, but not to the general public.

Among other things, the advisory panel recommended that "ethical labeling include peptic ulcer, gastritis, and peptic esophagitis as additional indications for certain antacid products. These conditions would not be allowed on labeling intended for the lay public.

For one thing, Dr. Penna said, APhA "feels that designating specific labeling for single

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○ **WHEN TO ACCEPT NURSE'S R ORDER** is a significant legal question. Issue was raised by Temple U's Sidney Willig at recent NABP meeting: What is pharmacist's responsibility for determining the authority on which an MD's assistant -- or more frequently the MD's nurse -- orders medication?

○ **RIGHT OF MD ASSTS./NURSES TO** issue R orders is dependent on state statutes and specific MD delegation of authority. Willig cited Colorado pediatric assistant act and MD's assistant section in the Ariz. medical practice act as specific examples.

○ **PHARMACISTS VIOLATE FEDERAL** law when they dispense an R or refill ordered by a person not authorized to prescribe, Willig warned. He listed the basic requirements necessary when an MD delegates authority "to persons legally unqualified to prescribe." (Story p. 2)

○ **2 BASIC PHARMACIST TYPES DEFINED** and described in meaningful AACP cmt. on academic affairs report, presented at Scottsdale, Ariz. meeting -- the "dispensing pharmacist" and the "consultant pharmacist." Cmt. provided base for sound, pragmatic discussion on whether students are being trained for careers in the real world.

○ **CONSULTANT TYPE PHARMACIST'S** basic function and place of operation "is provide drug information and consultation to other health professionals. . . based primarily in institutional settings," with activities which "would approximate closely an applied clinical pharmacologist."

○ **DISPENSING PHARMACIST'S ROLE** is to prepare/distribute drugs efficiently and safely; counsel and advise patients as "to the correct and safe use of drugs & health aids," report says.

○ **THE "MULTIPURPOSE" PHARMACIST** which educators have historically attempted to mold at

the BS degree level "is apparently undertrained for some types of practice, such as in the hospital, since postgraduate specialty programs are being developed for this purpose," the AACP cmt. report continued. "A need for change of our present approach to the five-year curriculum is indicated.

○ **CHARGES THAT THE 5-YR. PHARMACIST** is too-well trained for community practice "can be challenged," according to the cmt. However, schools "should now begin to consider offering" academic background "leading to specific practice roles rather than attempting to train the same generalist in all schools."

○ **A BS DEGREE PROGRAM** presenting "the minimum core of professional knowledge. . . intended to adequately prepare the pharmacist for entry into dispensing practice or to go on to postgraduate specialty programs," would be one approach for the colleges, the cmt. said.

○ **THE 2nd APPROACH, "BUT POSSIBLY** less desirable," would be to focus individual BS programs toward specific pharmacy practice roles which involve specialty areas. (Story pp. 3 & 4)

○ **"MORNING AFTER" CONTRACEPTIVE** use of DES (Diethylstilbestrol) OKed by FDA "only as an emergency measure -- in situations such as rape, incest, or where in MD's judgement, the patient's physical & mental well-being is in jeopardy." Explicit warnings "against its routine or frequent use" for birth control.

○ **NO CHANGE IN ILOSONE LABELING** or marketing status was recommended by FDA's Anti-Infective Advisory Cmt. The view of FDA and its advisory cmt. apparently is that Ilosone, despite reports of reversible hepatotoxicity, has a useful purpose in the antibiotic armamentarium.

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Wallace Worlds, Editor & Publisher—Associate Editor & Publisher: Wallace Werble Jr.

WHEN IS IT SAFE FOR PHARMACIST TO DISPENSE OR REFILL ON ORDER from an MD's nurse or assistant? This significant legal question, which luckily for pharmacy has not yet become a natl. issue, conceivably could develop into a situation that would create havoc with existing relationships between MD offices and pharmacies, and wreck current prescribing/dispensing patterns in many areas across the country. Natl. problem could be triggered by a "gung ho" pharmacy board, or by a pharmacy board exec who is seeking to create or enhance a reputation, if steps are taken to enforce the letter of the law strictly, without regard to traditional and accepted methods of professional practice.

The ticklish legal issue was raised, somewhat indirectly, in a paper presented by TempleU's Sidney Willig at the recent NABP meeting which approached the problem from the other side -- "Legality Of Prescribing By MD's Assistants." Willig, an acknowledged expert in this field of law, teaches at Temple's schools of medicine, pharmacy and law. In a scholarly legal paper that raised questions, but provided no practical answers, Willig approached the situation from the standpoint of the right of the nurse or the newly-created "MD assistant" to generate an R or refill.

Inherent in the legal issue raised by Willig is the responsibility of the pharmacist for determining the authority on which an MD's assistant -- or more frequently the MD's nurse -- orders medication, or a refill, usually by telephone. Across the country, it is generally accepted pharmacy practice to accept, on good faith, such orders transmitted by telephone -- except in the case of top-controlled BWDD substances -- without questioning legal authority.

RIGHT OF MD ASSTS. OR NURSES TO ISSUE R ORDERS DEPENDS, Willig warned, on the state statutes or on specific delegation of authority from the MD. Various state acts dealing with nursing practice -- or the newer state enactments on MD assts. -- can establish a special basis for ordering Rs or renewals, Willig noted. As specific examples, he cited the Colorado paediatric asst. act and the MD's asst. section in the Ariz. medical practice act, apparently two of the most advanced among the state statutes.

When a pharmacist dispenses an R or a refill, on the order of a person not legally authorized to prescribe, Willig warns, this is a violation of the federal drug law, and also perhaps of comparable state statutes.

When an MD delegates authority "to persons legally unqualified to prescribe, the measure of statutory acceptability must be found in supervision and direction by the licensed practitioner," Willig said. "This must be by direct oral or written communication to the subordinate." In an effort to set a series of guidelines for the legal delegation of prescribing authority from an MD to a nurse or asst., Willig said the basic requirements are that:

① "A bonafide MD-patient relationship has been previously initiated by the physician from whom the delegation has arisen."

② "By clear and definite instruction as by written or oral orders, (dangerous if such orders represent many drug alternatives), and dependent on observations and findings the MD's assistant is qualified by law and training to make, he can transpose thus the MD's actual prescriptive order as a conduit for the true prescriber."

③ "The same considerations be given to R devices and the administration thereof."

④ "The delegation may not fly in the face of stricter local or federal laws that prohibit same, as in circumstances of transfer of controlled substances or paraphernalia."

⑤ "The delegor have actual authority to prescribe within the state laws."

⑥ "That the MD's asst. shall in no way extend the scope of the delegation."

2. Prescribing Practices of "Physician's Assistant"

RECOMMENDATION:

2.1 The Committee recommends that the following guidelines be adopted as a minimum to guide the Association and state associations in supporting or opposing legislation concerning "physician's assistant" personnel:

- (a) Legislation should specifically treat the prescribing function of physicians' assistants, either prohibiting it outright or providing for conditions under which the function can be performed.
- (b) If legislation is to permit physicians' assistants to engage in the prescribing function, specific control procedures should be included such as:
 - (1) Prescribing carried out only within rigidly defined procedures developed and controlled by an interdisciplinary panel consisting of physicians, pharmacists, dentists, nurses, and other appropriate health professionals.
 - (2) Establishing a minimum level of education and training with regard to drug therapy that would permit physicians' assistants to engage in the prescribing function.
 - (3) Physicians' countersigning of prescription medication orders.
- (c) Legislation concerning the prescribing function of physicians' assistants should also consider the dispensing function and provide that it be carried out under the responsibility and direct supervision of a pharmacist.
- (d) The legislation should permit pharmacists to prescribe under the same control procedures as those developed for physicians' assistant personnel.