Task Force on Specialties in Pharmacy

The APhA Task Force on Specialties in Pharmacy was created by the APhA Board of Trustees in January 1973 to consider the issue of specialization in pharmacy practice and to recommend a mechanism for recognition of specialties and the certification of specialists. The following is a preliminary report of the Task Force which is being made available to the APhA membership for comment. Please note that the report has not been approved by the APhA Task Force on Specialties and is therefore not a final report. The Task Force is desirous of obtaining the comments of APhA members before it revises its report for the final time and approves it for transmission to the APhA Board of Trustees. APhA members are requested to send their comments to Task Force Chairman Lloyd M. Parks, American Pharmaceutical Association, 2215 Constitution Avenue, N.W., Washington, DC 20037, no later than April 1, 1974.

In 1971 the House of Delegates of the American Pharmaceutical Association adopted a policy statement which contained in part the following provision—"that an organizational mechanism be established within the structure of the Association for the recognition of specialties and certification of specialists."

Following adoption of this statement and following further deliberations and discussions, the Board of Trustees of APhA created a Task Force on Specialties in Pharmacy in the spring of 1973 and directed it with the following charge:

1. To identify existing or potential areas of specialization in pharmacy practice or, alternatively, to determine that currently there are no specialties and/or that the practice of pharmacy does not lend itself to such specialization.
2. To propose the means by which such specialties should be identified if specialties do exist or if it can be concluded that there will be one or more fields of specialization.
3. To develop the means by which individuals should be identified as having met the predetermined criteria for such specialties, including recommendations for continuing education or re-certification.
4. To consider other matters of immediate concern as identified by the Task Force.

In pursuing its assignment the Task Force sought comments and suggestions from members of the profession of pharmacy. It consulted with and obtained statements from representatives of a number of other pharmaceutical organizations. It studied other professions with respect to their policies and practices of specialization and certification. With the assistance of a consultant the members of the Task Force considered all this information, related it to potential developments in the education for and the delivery of health care, and then deliberated in meetings of the Task Force and in meetings of subcommittees.

The Task Force on Specialties in Pharmacy has concluded that:

Whether or not at this time there are areas of practice that could be identified as specialties in pharmacy, it is likely that in the near future one or more areas of practice may qualify as an approved specialty in pharmacy.

Therefore, an official board with independent decision-making authority should now be established and charged with the responsibility of formally recognizing specialties in pharmacy once they are judged to have met approved criteria.

Furthermore, such board should be empowered with the final responsibility of granting certification to individuals who have met the qualifications for certification as specialists in an officially recognized field of specialty.

On the basis of these conclusions the Task Force on Specialties in Pharmacy has developed (1) a statement of criteria which it recommends be employed as the basis for official recognition of an area of specialization in pharmacy, (2) an outline of the structure and responsibilities for the proposed Board of Pharmaceutical Specialties and (3) a list of general qualifications for certification of individual pharmacy specialists.

The Task Force has refrained from identifying any existing areas of specialization in pharmacy on the basis that such decision should more properly be made by the proposed Board of Pharmaceutical Specialties. However, the Task Force has concluded that there are potential areas of pharmacy practice, such as nuclear or radiopharmacy, that may in time be recognized as specialties.

Criteria for Recognition of Specialties in Pharmacy

Certification has been defined as the process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. In the past half century the process has been increasingly employed in the health fields to identify individuals who are considered to be qualified in a specialized area of professional practice or who have attained superior competence in the broad areas of responsibility of a particular profession.

The growth of certification has been encouraged by scientific and technological developments, by increasing numbers of persons seeking health care, by changes in the management and delivery of health care, by growing recognition of the need to protect the public from unqualified personnel, and by the desires of members of the health professions for recognition of special professional competence, as well as for economic and social recognition. All of these factors have been exerting influences on all of the professions, including pharmacy.

To insure that specialty certification, as it may relate to the identification of qualified persons in an identifiable specialized area of pharmacy, is conducted not merely for the benefit of pharmacy but more especially for the benefit of society, the Task Force on Specialties in Pharmacy recommends that the following criteria be met by any group of pharmacists in the United States who wish to have their practice recognized as a specialty in pharmacy. (For purposes of this report the Task Force is relying on the definition of pharmacy, as currently defined by the American Pharmaceutical Association, which states that "pharmacy is defined as that personal health service that assures safety and efficacy in the procuring, storing, prescribing, compounding, dispensing, delivering, administering and use of drugs and related articles.")

Criterion 1—The area of specialization in the practice of pharmacy rests on a specialized knowledge of pharmaceutical sciences, which have their basis in the biological, physical and behavioral sciences, and not on managerial, procedural or technical services, nor on the environment in which pharmacy is practiced.

Criterion 2—The area of specialization shall be one for which specially trained practitioners are needed to fulfill the responsibilities of the profession of pharmacy in improving the health and welfare of the public, responsibilities which may not otherwise be effectively fulfilled.

Criterion 3—The area of specialization shall represent an identifiable and distinct field of practice that calls for special knowledge and skills acquired by education and training and/or experience beyond the basic pharmaceutical education and training.
Industry's Last Opportunity

Statement by the American Pharmaceutical Association Board of Trustees, January 8, 1974.

Several years ago, the American Pharmaceutical Association adopted a policy position which advocated appropriate amendment of state laws in order to restore the pharmacist to his rightful role as the health care practitioner primarily responsible for drug product selection. This action was based upon a number of factors including: (a) general recognition that today legal constraints in this area are not serving the purposes for which they were originally enacted, and indeed the original basis has long ceased to exist; (b) drug industry marketing, distribution, and pricing policies have been largely skewed to take advantage of and to exploit these state laws and regulations; and (c) a general recognition that the pharmacist, more than the physician or any other member of the health care team, is in the best position to judge drug product quality on the basis of his training, experience, and direct contact with the very products involved.

Society was ripe and ready for just such a proposal at the time when APhA introduced it. State and local government agencies, legislative bodies, and consumer groups were only a few of those outside the immediate health care complex that responded with interest and enthusiasm to the position espoused by APhA.

But, alas, most of the drug industry was not prepared to accept this change in what had come to be a very comfortable and generally lucrative system of drug distribution. Virtually all industry advertising and promotion practices had been built up about a marketing system which depended upon the prescriber as the dominant—if not the sole—determiner of both the drug substance to be prescribed, as well as the specific drug product (i.e., manufacturer source) to be dispensed by the pharmacist.

As a consequence, a majority within the pharmaceutical industry made the decision to resist this movement, and vigorously resist it they have. In every forum and field—whether it was professional meetings, journals, conferences, legislative hearings, the public press, smoke-filled rooms, or the lobbies of Congress—opposition from the drug industry has been persistent, consistent, and insistent.

And basically, just what is it that they have opposed so vehemently over these past several years? Simply stated, they have fought a transfer from the physician back to the pharmacist of the primary responsibility of comparing, choosing, and selecting a quality drug product at reasonable cost for the patient. What is involved is not an abrogation of responsibility, but a transfer of responsibility from one health professional to another—that is, to the health professional having the best qualifications and training to perform this particular function.

While busily fighting their battles, however, the drug industry is in danger of losing the war.

The public, consumers, and Congress appear to have grown even more impatient and frustrated than has pharmacy with the obstructionist tactics that have impeded progress to a more effective, efficient, and economical system of drug distribution.

The Nixon Administration, as disclosed in HEW Secretary Weinberger’s recent testimony before the Kennedy Senate Committee, has plans to restrict drug reimbursements under government-administered programs to the lowest cost medications generally available. In essence, the major political forces in both the executive and legislative branches of the federal government now are prepared to abolish all forms of drug product selection whether it be by physician, pharmacist, or government formulary (the latter constituting another frequently made proposal which the drug industry has repeatedly opposed).

Hence, by not accepting drug product selection by the pharmacist as a step forward in orderly and logical progress, the drug industry has spawned a proposal which is less than ideal to pharmacy, to medicine, and, in our opinion, even to the public. At this writing, the precise HEW proposal has not yet appeared in the Federal Register. Therefore, it is impossible to comment upon specific points, and, in fact, APhA itself may well find that certain provisions in the HEW proposal conflict with Association policy position, necessitating the filing of objections regarding any such aspects. However, while pharmacy may be unhappy with certain approaches in the HEW plan on professional grounds, it appears to us that from industry’s economic viewpoint, this latest turn of events means that, despite the skirmishes they may have won, the industry’s entire marketing system now teeters on the brink of total disintegration.

“So the brink” we say, because there still appears to be an opportunity for industry to reverse its position, to support constructive approaches to drug product selection, and to adopt positions which foster both quality and economy in the drug supply. But time is rapidly running out. The industry will need to respond as vigorously and quickly in this positive approach, as it has during the past few years in mobilizing its battle plan of opposition.
Criterion 4—The area of specialization shall be one in which schools of pharmacy and/or other organizations offer recognized education and training programs to those seeking advanced knowledge and skills in the area of specialty practice so that they may perform more competently.

Criterion 5—The area of specialization shall be one in which there is an adequate educational and scientific base to warrant transmission of knowledge through teaching clinics and scientific and technical publications immediately related to the specialty.

Criterion 6—The area of specialization shall be one in which there exists a significant and clear health care demand to provide the necessary public reason for certification.

Criterion 7—The area of specialization shall be comprised of a reasonable number of individuals who devote most of the time of their practice to the specialty area.

Board of Pharmaceutical Specialties

Responsibilities

As previously indicated the Task Force on Specialties in Pharmacy recommends the creation of a Board of Pharmaceutical Specialties, and also recommends that this Board be authorized—

a. to recognize specialties in pharmacy, if and when such specialties meet the criteria for recognition;
b. to approve the qualifications for certification in each recognized field of specialization;
c. to grant final approval for the certification and re-certification of individuals who have met the qualifications for certification as specialists in an officially recognized field of specialization;
d. to issue certificates to certified specialists, and
e. to serve as the coordinating agency and clearinghouse for information among the organizations and groups representing the various recognized fields of specialization.

It is proposed that this Board of Pharmaceutical Specialties be created, as hereinafter recommended, and that the Board function even though there may be no recognized specialties in pharmacy in the immediate future.

Structure

In developing the subsequent recommendations relating to the structure and operations of the proposed Board of Pharmaceutical Specialties, the Task Force adopted certain guiding principles.

Principle 1—Although the Board of Pharmaceutical Specialties must be empowered with independent authority to carry out the responsibilities stated above, it should be provided administrative services and be supported, at least initially, by the American Pharmaceutical Association—the national association that most broadly represents the profession of pharmacy. By such an arrangement services could be provided without the necessity of adding to the already large number of organizations related to pharmacy.

Principle 2—The Board of Pharmaceutical Specialties should be broadly composed since specialization in pharmacy would have an influence on the education of pharmacists and the practice of pharmacy, as well as on the delivery of health care in which other professions, the government and the general public have a direct interest including a major financial interest.

Principle 3—Financing for the Board of Pharmaceutical Specialties should be provided from several sources: the American Pharmaceutical Association, which is expected, at least initially, to provide administrative support; other pharmaceutical associations; each pharmaceutical specialty organization, group or society when the field of specialization is officially recognized; grants from government agencies and independent foundations; and eventually fees from candidates seeking certification or re-certification.

Using these principles as a guide, the Task Force on Specialties in Pharmacy presents the following specific recommendations as to the structure of the Board of Pharmaceutical Specialties.

Composition of the Board

Members of the Board of Pharmaceutical Specialties should be appointed for staggered three-year terms with the privilege of serving no more than two terms in succession. The Board should comprise fourteen (14) members to be appointed in the following manner—

Six (6), broadly representative of the profession of pharmacy, to be appointed by the American Pharmaceutical Association after solicitation of suggested nominees from national pharmaceutical organizations representing practitioners:

One (1) to be appointed by the American Association of Colleges of Pharmacy;
One (1) to be appointed by the National Association of Boards of Pharmacy;
Six (6) to be appointed by the Board itself after solicitation of suggested nominees from appropriate organizations so that of the six, two would be from the general public, one from the federal government, and, on a rotating basis, three from related health professions.

In deciding on the appointment of individuals from related health professions the Board of Pharmaceutical Specialties should seek suggestions from such organizations as the American Dental Association, American Hospital Association, American Medical Association, American Nurses' Association, American Osteopathic Association and National Medical Association.

The chairman of each specialty council (described later in this report), once a pharmaceutical specialty has been recognized and a specialty council for that field of specialty has been created, should serve without vote as an ex-officio member of the Board.

Officers of the Board

The officers of the Board should comprise a Chairman, Vice Chairman and Secretary-Treasurer, each elected on an annual basis by the Board. Each officer should be eligible for election to a maximum of three successive one-year terms.

Committees of the Board

The Board should operate through committees which should include an Executive Committee, a Review Committee for initial consideration of requests from pharmaceutical groups seeking recognition for specialty status, an Appeals Committee for the hearing of appeals from groups unsuccessful in seeking recognition for specialty status and of appeals from individuals who may not have been granted certification in a recognized pharmaceutical specialty, and such other committees as from time to time the Board may deem to be appropriate and necessary.

With the exception of the Appeals Committee all committees may be comprised of both Board members and non-Board members, each to be nominated by the Chairman and approved by the Board. The Appeals Committee should comprise three members, the chairman of which should be appointed by the Board but none should be a member of the Board. The Appeals Committee should be empowered either to uphold the original decision or remand to the Board or the appropriate specialty council for further review.

Meetings of the Board

The Board should be expected to meet at least once each year and at such other times as either it or the Chairman consider advisable.

Approval of Specialties

Recognition of a specialty should require a two-thirds vote of the Board.
Administrative Services for the Board

The American Pharmaceutical Association should provide, at least initially, the administrative support services for the independent Board of Pharmaceutical Specialties. For further assistance the Board should be empowered to employ consultant services as it deems appropriate and necessary.

Financing of the Board

Financing for the Board of Pharmaceutical Specialties should be provided initially by the American Pharmaceutical Association, by other pharmaceutical organizations and by grants from various sources, including both government and independent foundations.

If and when fields of pharmaceutical specialties are recognized and individuals are certified as specialists the fees collected from certified individuals will be an increasing source of income. The establishment of the amount of individual fees for initial certification and of annual fees for re-certification should be a responsibility of the Board. Such fees should be modest and yet sufficient to assist adequately in financing the functions of certification of specialists.

Reports of the Board

The Board of Pharmaceutical Specialties should be expected on an annual basis to make reports of its activities to the American Pharmaceutical Association, American Association of Colleges of Pharmacy, National Association of Boards of Pharmacy, and to each organization, group or society representing a recognized field of pharmaceutical specialty.

Specialty Councils of the Board for Pharmaceutical Specialties

For each pharmaceutical specialty that has been officially recognized, the Board of Pharmaceutical Specialties should create a specialty council responsible to the Board and charged to perform certain functions.

Functions of the Specialty Councils—In conformity with policies established by the Board of Pharmaceutical Specialties and subject to final approval by the Board, each Specialty Council should be expected to fulfill the following functions—

1. develop and codify requirements for individual specialty and certification and re-certification, which proposed requirements should be publicly available for adequate widespread consideration before presentation to the Board for adoption;
2. develop and administer examinations, at least once each year, to determine the competency of candidates for certification and re-certification;
3. evaluate the qualifications of individuals seeking certification or re-certification, and submit to the Board the names of candidates recommended for certification or re-certification; and
4. recommend policies with respect to such matters as length of time of continued certification before qualifications for re-certification must be met, time interval permitted between the filing of an application for certification and successful completion by the candidates of all requirements, and the number of attempts permitted a candidate for the passing of an examination or meeting of other requirements.

Composition of the Specialty Councils—the majority of the members of each Specialty Council, whose size should be established by the Board, should be appointed or elected by the appropriate national pharmaceutical specialty organization, or group, whose membership would be comprised primarily of individuals who are specialists in that field of pharmaceutical specialty.1

Other members of the Specialty Council should include individuals engaged in related practice of pharmacy and be appointed by the Board of Pharmaceutical Specialties after consultation with appropriate representatives of these other areas of practice. The Board should have the power to decide on the numbers to be appointed to each Specialty Council, and the numbers may vary among fields of specialty.

All members of Specialty Councils should be appointed or elected for staggered three-year terms subject to serving no more than two successive terms. The chairman and other officers should be elected annually by the section and be eligible for election to a maximum of three successive one-year terms.

Qualifications for Certification of Individual Specialists

The qualifications for certification of individuals as specialists should be developed initially by each appropriate Specialty Council subject to final approval by the Board of Pharmaceutical Specialties. These qualifications or requirements should include such factors as ethical and moral standing, level of education, extent of training, practical experience, successful passing of an oral and/or written examination, license to practice and payment of fees. Citizenship and membership in professional organizations or societies should not be qualifications for certification.

Approval of By-Laws

The adoption of by-laws for the Board of Pharmaceutical Specialties, or any revisions in them should be subject to the approval of the Board of Trustees of the American Pharmaceutical Association.

Creation of Board of Pharmaceutical Specialties

It is recommended that, concurrent with the acceptance and approval of this report by the House of Delegates of the American Pharmaceutical Association, the House also authorize the appointment by the APHA Board of Trustees of a small committee to draft the bylaws and establish the detailed plans for the creation by July 1, 1975 of the Board of Pharmaceutical Specialties and for the implementation of the recommendations of this report, subject to the approval of the APHA Board of Trustees.

A subsequent organization and the election of officers of the Board of Pharmaceutical Specialties, one of its first orders of business would be the development and adoption of procedures by which pharmaceutical groups seeking specialty status might be considered for official recognition.

Review of the Board of Pharmaceutical Specialties

It is further recommended that no later than five years from the date of creation of the Board of Pharmaceutical Specialties a review should be undertaken of the Board's structure, operations and financing, with special attention given to the composition of the Board. The review should be undertaken by a special committee created for this purpose and comprised of five (5) individuals—one (1) appointed by the American Pharmaceutical Association, one (1) appointed by the American Association of Colleges of Pharmacy, one (1) appointed by the National Association of Boards of Pharmacy, and two (2) nonpharmacists, one of whom shall be chairman, appointed jointly by the three above-named organizations.

Similar reviews should subsequently be conducted at periodic intervals. In such reviews provisions should be made to retain a proportion of nonpharmacists on the Board at least no less than that provided initially.

November 29, 1973

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1 The members of the Task Force have assumed that in addition to the responsibility of appointing or electing officials to serve on a Specialty Council, each such pharmaceutical specialty organization, or group, would perform other activities, such as encourage the study, elevate the standards, promote and improve the practice of the pharmaceutical specialty with which it is directly concerned, and stimulate the development of adequate training standards for the specialty.