

Board of Pharmaceutical Specialties

Petitioner's Guide for Recognition of a Pharmacy Practice Specialty

- I. Introduction
- II. Criteria for Specialty Recognition
- III. BPS Procedures for Considering Petitions
- IV. Instructions to Petitioners

Board of Pharmaceutical Specialties

1100 Fifteenth Street, NW, Suite 400

Washington, DC 20005

202-429-7591

202-429-6304 FAX

bps@mail.aphanet.org

<http://www.bpsweb.org>

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CRITERIA FOR THE RECOGNITION OF A PHARMACY PRACTICE SPECIALTY

I. INTRODUCTION

The Board of Pharmaceutical Specialties (BPS) was created in 1976 to serve the profession by formally recognizing areas of specialty practice and certifying pharmacists in those areas. BPS bylaws outline four primary responsibilities:

1. Recognize specialties in pharmacy practice,
2. Set standards for certification and recertification,
3. Objectively evaluate individuals seeking certification and recertification, and
4. Serve as a source of information and coordinating agency for pharmacy specialties.

The Board provides the information contained in the Guide to assist those interested in developing and submitting a petition for recognition of a pharmacy practice specialty. Procedures for the review of petitions (see Section III of this document) are designed to provide for a reasoned consideration of submissions. These procedures allow for communication from other pharmacists and other health professionals who might be directly affected by the recognition of a new pharmacy practice specialty. In addition, these procedures allow for communication from the public who might benefit from such recognition and who would ultimately bear its cost.

Potential petitioners should familiarize themselves with the organization and operation of the Board of Pharmaceutical Specialties by visiting the BPS web site: www.bpsweb.org and consulting other available resources that are available upon request from the Board.

Questions concerning BPS and the petitioning process should be directed to:

BPS Executive Director
1100 Fifteenth Street, NW, Suite 400
Washington, DC 20005
202-223-7192
202-429-6304 FAX
bps@mail.aphanet.org
<http://www.bpsweb.org>

II. CRITERIA FOR RECOGNITION

These Criteria were adopted by the American Pharmacists Association (APhA) House of Delegates in April 1975 and amended in 1997. This document was most recently amended in 2006 by the Board of Pharmaceutical Specialties, following discussions with its constituents and outside experts, in an effort to reflect contemporary pharmacy practice and to make the petitioning process more user-friendly. Following each criterion is a set of guidelines. These guidelines are meant to assist petitioners in addressing the criteria by suggesting areas of information, assessments and documentation that BPS, the public and the profession might find useful when evaluating a petition. The guidelines are neither exhaustive in scope nor mandatory in nature. Petitioners are encouraged to submit all documentation thought to be pertinent to the petition, whether indicated in the guidelines or not.

CRITERION A

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

This criterion addresses NEED.

BPS defines NEED as a condition of requiring supply.

Guidelines for Petitioners

1. Identify specific public health and/or patient care needs which are not being met currently and which pharmacists in the proposed specialty can meet effectively.
2. Specify how the functions performed by pharmacists in the proposed specialty address these specific needs of the public's health and well being.
3. Describe and document with references how the public's health and well being may be at risk if the services of practitioners in the proposed specialty are not provided.
4. Describe how functions provided by the practitioners in the proposed specialty will fulfill the responsibility of the profession of pharmacy in improving the public's health.
Petitioners may use the following mission statement for pharmacy when defining the responsibilities of the profession:
The mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes.
5. Describe the reasons why the needs as described above are not or cannot be met by pharmacists who do not have specialized education and training.
6. Describe in detail how the needs as described above are not or cannot be met by pharmacists in those pharmacy specialties already recognized by BPS.
7. Describe the reasons why the needs as described above are not or cannot be met by other health professionals.
8. If these needs are currently being met by other areas of pharmacy practice, or by other health professionals, describe how these needs can be met more effectively by pharmacists in the proposed specialty.

CRITERION B

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

This criterion emphasizes DEMAND.

BPS defines DEMAND as a willingness and ability to purchase a commodity or service.

Guidelines for Petitioners

1. Include statements by at least two individuals in each of the categories listed below regarding the demand for pharmacists with specialized training and knowledge to provide specialized services in the proposed specialty:
 - a. non-pharmacist health professional leaders, planners and/or administrators,
 - b. pharmacist practitioners who are not practicing in the proposed specialty,
 - c. members of the public.

NOTE: To the extent possible, such statements should emphasize objective quantification of demand.
2. Include estimates of positions for pharmacists with specialized training and knowledge in the proposed specialty that are currently filled and those that are currently unfilled. Identify these positions by practice settings. Describe the sources and methods used to determine these estimates.
3. Include estimates of filled and unfilled positions in each of the past three (3) years in order to demonstrate a sustained or increased demand for pharmacists with specialized knowledge and training. Describe the sources and methods used to determine these estimates.

CRITERION C

The area of specialization shall include a reasonable number of individuals who devote most of the time of their practice to the specialty area.

This criterion relates to the NUMBER of practitioners and the amount of TIME spent in the practice of the specialty.

NOTE: This criterion also helps insure that the expenses connected with the development and administration of the certification and recertification processes will be economically justifiable for the public and the profession.

Guidelines for Petitioners

1. Estimate the number of pharmacists currently practicing in the proposed specialty. Identify the types of practice settings for these pharmacists (e.g., academic, hospital, managed health care, community). Describe the sources and methods used to determine these estimates.

2. For the pharmacists identified in 1. (immediately above). estimate the percentage of time they devote exclusively to the practice of the proposed specialty. Describe the sources and methods used to determine these estimates.
3. Estimate the number of pharmacists who would likely seek board certification in the proposed specialty during the first five years in which board certification would be available. Describe the sources and methods used to determine these estimates.

CRITERION D

The area of specialization shall be based on specialized knowledge of one or more of the pharmaceutical sciences and the biological, physical, behavioral, and administrative sciences which underlie them. Procedural or technical services and the specific environment in which pharmacy is practiced are not applicable to this criterion.

This criterion relates to SPECIALIZED KNOWLEDGE.

Guidelines for Petitioners

1. Describe in detail the specialized knowledge of pharmaceutical sciences required for the proposed specialty.
2. Explain fully the relationship of this specialized knowledge to the biological, physical and behavioral sciences.
3. Discuss in detail how this specialized knowledge differs from the knowledge base of a recent graduate with a Doctor of Pharmacy degree.
4. Discuss in detail how this specialized knowledge differs from the knowledge base of those specialty areas already recognized by BPS (see Criterion E, note on Role Delineation).

NOTE: In this section of the petition, respondents are requested to focus commentary on the areas of specialized knowledge rather than on how this knowledge is attained.

CRITERION E

The area of specialization shall represent an identifiable field of pharmacy practice which requires specialized functioning by the practitioner and which is distinct from other BPS-recognized pharmacy specialties.

This criterion refers to SPECIALIZED FUNCTIONS.

Guidelines for Petitioners

1. Specify and describe in detail, specialized functions performed routinely by practitioners in the proposed specialty which are not performed by pharmacists in general.
2. Describe the special skills required to perform functions specified above.
3. Discuss in detail how these specialized functions differ from the functioning of a recent graduate with a Doctor of Pharmacy degree.

4. Discuss in detail how these specialized functions differ from the functions required in those pharmacy specialties already recognized by BPS (see note below on Role Delineation).

NOTE: A role delineation is required of all petitioners in order to clearly and adequately address Criteria D and E. This information must be incorporated into the petition and will be used by BPS in reaching a decision. BPS will assist the petitioner, as requested, in determining appropriate methods to collect such information.

Also, petitioners are requested to focus commentary on describing the specialized functions within the proposed specialty, rather than on how the knowledge and skills are attained to be able to carry out these functions.

CRITERION F

The area of specialization shall be one in which schools and colleges 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.

This criterion addresses EDUCATION and/or TRAINING.

Guidelines for Petitioners

1. Describe in detail the education, training and/or experience required to acquire such specialized knowledge and skills. Discuss how such education, training and/or experience differ from the education, training and/or experience of a recent graduate with a Doctor of Pharmacy degree.
2. Describe in detail the nature of training programs in the area of specialty practice including their length, content and objectives.
3. Provide a comprehensive listing of such programs, detailing sponsoring organizations or institutions, locations and individuals in charge.

CRITERION G

The area of specialization shall be one in which there is an adequate transmission of specialized knowledge through professional, scientific and technical literature immediately related to the specialty area.

This criterion refers to the TRANSMISSION OF KNOWLEDGE.

Guidelines for Petitioners

1. Identify journals and other periodicals dealing specifically with the proposed specialty.
2. Provide a comprehensive bibliography of articles in the professional literature dealing with the proposed specialty published during the three most recent calendar years.

3. Include copies of sample peer-reviewed articles dealing with the proposed specialty.
4. Describe methods of knowledge transmission through symposia, seminars, workshops, etc., and enclose representative programs concerning these activities.
5. Provide the number of such events, included in #4 above, which occur on an annual basis, and estimate average and total attendance at such programs.

III. PROCEDURES FOR CONSIDERING PETITIONS

The following sequence is a procedural outline, with projected time lines, regarding consideration of petitions by BPS. The Board, in consultation with the petitioner may adjust time lines.

- A. Preliminary screening by BPS staff for completeness of petition (within 10 days of receipt of petition in BPS office).
- B. Preliminary review by BPS to determine if the petition clearly addresses all criteria so that the petition may be released to the profession and the public for comment and further consideration (within 90 days of receipt of petition in BPS office). The purpose of this review is not to pass judgment on the petition as a whole, or on any of its parts, but to assure that there is sufficient information upon which the public and the profession may comment.
- C. If the petition is released for comment, appropriate news releases and correspondence are generated by the Board requesting comments in support of or in opposition to the petition (within 120 days of receipt of petition in BPS office).
- D. Possible petitioner interview (within 300 days of receipt of petition in BPS office).
- E. At least two open hearings will be held to solicit input from the pharmacy profession, other health professions, third-party payers, and the public (within 300 days of receipt of petition in BPS office).
- F. Final evaluation and decision will take place during the first meeting of the full Board, once the requisite open hearings have been held. The Board will review all matters of record concerning the petition, including any supplemental material submitted by the petitioner upon request of the Board or at the petitioner's own discretion. Submission of supplemental materials may cause the Board to pose additional questions to the petitioners.

Approval of a petition is based on a balancing of all factors pertinent to the criteria. Compliance with several criteria may balance deficiencies in another criterion. The vote of the Board will be carried out in accordance with its governing policies.

In the event that the Board decides not to recognize the proposed area as a specialty, the petitioner will be informed of the Board's decision and advised that within 60 days, an announcement of the Board's decision will be released to the public and the profession. The petitioner will also be advised that within sixty (60) days of this notification, a request for reconsideration or an appeal of the decision may be made to BPS, in accordance with its governing policies.

- G. In the event that a petition is denied and the time for reconsideration/appeal has expired, a period of at least one (1) year must elapse before BPS will consider another petition for the same specialty.

IV. INSTRUCTIONS TO PETITIONERS

A. Who May Petition

Any individual or group of individuals may petition BPS to recognize a specific area of pharmacy practice as a specialty. Any individual or group interested in filing a petition with BPS is encouraged to communicate with all individuals in the proposed specialty area who may have an interest in filing a similar petition, to consolidate resources and coordinate information so that one complete and comprehensive petition is submitted for a proposed specialty.

In the event that more than one petition is submitted to BPS regarding the same area of pharmacy practice, BPS will accept the first complete petition received as the "petition of record" and refer all subsequent petitioners to the originator of the "petition of record" for support, coordination, and any necessary modification.

B. Structure of Petition

The petition should address each of the Criteria and their associated guidelines, in the order outlined in Section II of this Guide. The petition should clearly demonstrate to BPS that the proposed specialty meets all the criteria by providing all of the documentation as stipulated in the guidelines. Petitioners are encouraged to submit all documentation thought to be pertinent to the petition, whether indicated in the guidelines or not.

The Procedures and Instructions listed in Sections III and IV of this Guide should also be followed.

C. Signatures

The petition shall be accompanied by no less than twenty-five (25) signatures or letters of support from individuals practicing in the proposed specialty area. Signatures must be identified by address, title, and place of practice. Each signer's name should also appear in printed format.

D. Definitions for the Proposed Specialty

1. The petitioner shall include the following as part of the petition:
 - a.) Name for the proposed specialty
 - b.) Definition of the proposed specialty
 - c.) Title for the specialist
2. The petitioner shall indicate a preferred group for designation by BPS as the "Representative Body" for the practitioners in the proposed specialty. This Representative Body may be the sponsor of the petition or any other practitioner-based group, whose membership includes a significant number of pharmacists practicing in the proposed specialty. The responsibilities of this Representative Body include:
 - a.) Appointing two-thirds of the members of the Specialty Council,
 - b.) Acting as the lead agency in promoting and publicizing the value and availability of the certification and recertification processes for the specialty,
 - c.) Acting as the lead agency in developing educational programs that assist pharmacists in attaining and maintaining competency in the specialty.
 - d.) Directly providing or helping to secure funding for the development and implementation of the certification and recertification processes.

E. Copies of the Petition

1. The petitioner shall submit twenty-five (25) copies of the petition and the Executive Summary to the Board of Pharmaceutical Specialties (see address below).
2. The petitioner also shall be responsible for providing copies of the petition and/or the executive summary to all interested parties upon their request.

F. Costs

1. A filing fee of \$7,500 must accompany the submission of a petition.
2. All costs associated with the development of the petition, including the role delineation study, will be borne by the petitioner, unless other approved arrangements have been made by BPS.
3. All costs associated with producing and providing copies of the petition and executive summary to BPS and interested individuals will be borne by the petitioner.
4. All expenses associated with appearing at interviews and/or open hearings will be borne by the petitioner.
5. Should the petition be approved, the petitioner will be responsible for directly providing or helping to secure funding for the development and implementation of the certification and recertification processes.

G. Questions, Clarifications

Potential petitioners are invited to contact the Board with any questions or requests for clarifications concerning the information in this Guide. Questions concerning policy or complex procedural issues should be submitted in writing.

The Board's hours of operation are Monday through Friday, 8:30am-5:00pm (eastern time).

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