

Board of Pharmacy Specialties

Petitioner's Guide for Recognition of a Pharmacy Practice Specialty

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Board of Pharmacy Specialties

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CRITERIA FOR THE RECOGNITION OF A PHARMACY PRACTICE SPECIALTY

I. INTRODUCTION

The Board of Pharmacy 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 Pharmacy Specialties by visiting the BPS web site: www.bpsweb.org.

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

BPS Executive Director
2215 Constitution Avenue NW
Washington, DC 20037
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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 amended in 2012 by the Board of Pharmacy 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. The Criteria for Recognition were reconfirmed through a stakeholder survey in 2013. 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 should summarize and discuss the linkage of supporting documentation to the petition criteria with appropriate references. Attachment of the source articles or other documents is not required or encouraged if the narrative links the documents to the criteria and they are referenced properly.

BPS recommends constructing an Annotated Literature Review that includes the following sections:

- Citation
- Summary
- Conclusion
- Relevance to BPS Criteria for Recognition of a Pharmacy Specialty

The Annotated Literature Review can be utilized to address each Criterion and should include a concise interpretive narrative or succinct discussion of the Guidelines for each Criterion. The total number of references should not exceed forty (40). The petitioners will need to deem these 40 (or less) citations to be representative of the proposed specialty areas and of sufficient quality to meet the intent of the Criterion (Appendix A provides a sample Annotated Literature Review). An Annotated Literature Review or other literature citations provides the evidence base in support of the petition for the proposed pharmacy specialty but does not replace the need for interpretation and discussion of the citations in the petition.

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. If these needs are currently being met by another BPS Specialty, 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.
2. Specify how the functions performed by pharmacists in the proposed specialty address these

specific needs of the public's health and well-being such as improved safety, cost, quality of life and outcomes. Included in this discussion should be a description of how the public's health and well-being may be at risk if the services of practitioners in the proposed specialty are not provided.

3. 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 Vision for Pharmacists' Practice adopted by the Joint Commission of Pharmacy Practitioners in January 2014 when defining the responsibilities of the profession:

Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare.

Commentary/Suggested Evidence and Documentation

In addressing the criterion for Need, the petitioner(s) should support their narrative with data and appropriate references to the extent that is possible. Suggested evidence can include journal articles, government reports, as well as reports and data from professional, patient, consumer and/or healthcare organizations. Original research or surveys conducted by the petitioner(s) are also appropriate for this purpose as long as the methodology is sound and described in the response. These citations can be referenced as part of the Annotated Literature Review.

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 the services of a Board Certified Pharmacist.

Guidelines for Petitioners

1. Include statements of support by stakeholder organizations and other entities, other than petitioners, that attest to the demand for pharmacists with training and knowledge to provide services in the proposed specialty. Stakeholder organizations can include non-pharmacist health professional organizations, public and private health care entities, and consumer organizations.
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, if possible. Describe the sources and methods used to determine these estimates.

Commentary/Suggested Evidence and Documentation

Suggested evidence to support meeting the criterion includes the statements of support described in Guideline B1 as well as other articles, reports, statements, surveys or data from appropriate sources that support the Criterion for Demand.

CRITERION C

The area of specialization shall include a reasonable number of individuals who devote most 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 Guideline C1, 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.

Commentary/Suggested Evidence and Documentation

Suggested evidence to support meeting Criterion C and the Guidelines includes membership surveys and other data from pharmacist organizations that represent the proposed specialty, data on PGY2 residencies in the specialty area as well as other data, reports and surveys from additional public or private sources. Citation of the data contained in the Role Delineation Study is appropriate to meet Guideline C2. If applicable, the number of PGY2 positions could be a data source for meeting Guideline C3.

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.

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.

Commentary/Suggested Evidence and Documentation

If BPS has conducted a Role Delineation Study for the potential pharmacy specialty and has issued a Call for Petition in that specialty area, the petitioning organization(s) does not need to complete this section. If BPS has **not** conducted the Role Delineation Study, the petitioning organization(s) must provide a complete Role Delineation Study, conducted within the last three years and address the Guidelines above in order for the petition to be considered.

CRITERION E

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

This criterion refers to **SPECIALIZED TASKS/SKILLS**.

Guidelines for Petitioners

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

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

Commentary/Suggested Evidence and Documentation

If BPS has conducted a Role Delineation Study for the potential pharmacy specialty and has issued a Call for Petition in that specialty area, the petitioning organization(s) does not need to complete this section. If BPS has **not** conducted the Role Delineation Study, the petitioning organization(s) must provide a complete Role Delineation Study, conducted within the last three years and address the Guidelines above in order for the petition to be considered.

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, post-graduate training programs and/or experience required to acquire the specialized knowledge and skills. Discuss how such education, post-graduate training programs and/or experience differ from the education, post-graduate training programs 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 the programs, sponsoring organizations or institutions, locations and individuals in charge.

Commentary/Suggested Evidence and Documentation

The following statement from the BPS Strategic Plan should be considered;

“..... especially important is documentation of an accepted, widely disseminated, well-structured process for specialty training that goes beyond the doctor of pharmacy program and is the basis for the growth and proliferation of the specialty area. BPS believes this process is best demonstrated through the American Society of Health-System Pharmacists (ASHP) Accreditation Standard for PGY2 Pharmacy Residency Programs and that consideration of new pharmacy specialties should be generally consistent with, but not exclusive to, the evolution of ASHP-accredited PGY2 programs.”

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 directly 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 select bibliography of published abstracts, articles, positions papers, and white papers in the professional literature dealing with the proposed specialty.
3. Reference and summarize selected experimental and quasi-experimental, peer-reviewed articles demonstrating the value of the proposed specialty (if available and appropriate).
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 the average total attendance at such programs.

Commentary/Suggested Evidence and Documentation

Guidelines G2 and G3 can be met by the Annotated Literature Review that can be used to support the overall petition, assuming that the review is complete and thorough.

III. PROCEDURES FOR CONSIDERING PETITIONS

The following sequence is a procedural outline regarding consideration of petitions by BPS. The petition review process is organized in three stages:

Stage 1 – Completeness

A preliminary screening will be conducted by BPS staff for completeness of petition. A preliminary review will be conducted 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. 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.

Stage 2 – Public Comment

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.

BPS will determine the methods to solicit input from the pharmacy profession, other health professions, third-party payers, and the public. These methods can include written, electronic and live forums and/or the use of any other media deemed appropriate to receive comments.

Stage 3 – Review and Decision

Final evaluation and decision will take place during the first meeting of the full Board, following the public comment period. 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.

An approximate timeline will be developed for each petition once it is received. The Board has set a preliminary timeline for the completion of these three stages to be six months. It should be noted that this timeline may be revised.

The BPS Board of Directors reserves the right to request the petitioning organization(s) to submit additional written information to help clarify or supplement the petition.

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 sixty (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.

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 discuss, reference and/or cite 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 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

The petitioner shall include, as part of the petition, the proposed name for the proposed specialty and the definition of the proposed specialty

E. Submission of the Petition

All petitions must be submitted electronically following the guidelines below:

1. The full petition must be submitted via e-mail to the Board of Pharmacy Specialties c/o the

Executive Director.

2. The full petition and any attachments must be sent in one PDF file. Attachments must be appropriately labeled using the bookmark feature.

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 expenses associated with the conduct of open hearings will be borne by the petitioner.

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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V. APPENDIX

APPENDIX A SAMPLE Annotated Literature Review Pediatric Pharmacists

Need for Pediatric Pharmacy Specialists – Criterion A

Citation	Summary	Conclusion	Relevance to BPS Petition
<p>Bhatt-Mehta V, Buck ML, Chung AM, Farrington EA, Hagemann TM, et. al. Recommendations for meeting the pediatric patient’s need for a clinical pharmacist: a joint opinion of the pediatrics practice and research network of the American College of Clinical Pharmacy and the Pediatric Pharmacy Advocacy Group. <i>Pharmacotherapy</i>. 2013;33(2):243-51.</p>	<p>This joint opinion paper outlines strategies and recommendations for expanding the quality and capacity of pediatric clinical pharmacy practitioners by elevating the minimum expectations for pharmacists entering pediatric practice, standardizing pediatric pharmacy education, expanding the current number of pediatric clinical pharmacists, and creating an infrastructure for development of pediatric clinical pharmacists and clinical scientists.</p>	<p>The Joint Opinion Group believes that a strategic approach is needed to increase the workforce and collective capacities of our profession for providing pediatric clinical pharmacy services. The recommendations outlined are to encourage focused collaboration among schools of pharmacy, health care facilities, and professional organizations to enrich the quality of health care and improve access to pediatric clinical pharmacist care for all children.</p>	<p>This paper outlines the need for expansion of clinical pediatric pharmacists and suggests ways the profession can ensure that there are trained and qualified pharmacists to provide the direct patient care needs of pediatric patients.</p>
<p>Gazarian M. Training pediatric clinical pharmacology and therapeutics specialists of the future: the needs, the reality, and opportunities for international networking. <i>Paediatr Drugs</i>. 2009.</p>	<p>In recent years there has been a rapid and marked increase in global recognition of the need for better medicines for children, with various initiatives being implemented at global and regional levels. These exciting developments are matched by recognition of the need to build greater capacity in the field of pediatric clinical pharmacology and therapeutics to help deliver on the promise of better medicines for children.</p>	<p>A range of pediatric medicines researchers, educators, clinical therapeutics practitioners, and experts in drug evaluation, regulation, and broader medicines policy are needed on a larger scale, in both developed and developing world settings. The current and likely future training needs to meet these diverse challenges, the current realities of trying to meet such needs, and the opportunities for international networking to help meet future training needs are discussed from a global perspective.</p>	<p>This article references the global need for pediatric specialists and outlines the needs for training and networking that are required to adequately expand this workforce.</p>

Education and Training of Pediatric Pharmacy Specialists– Criterion F

Citation	Summary	Conclusion	Relevance to BPS Petition
<p>Elliott J, Koerner P, Heasley J, and Kamal K. Impact of elective active learning courses in pregnancy/lactation and pediatric pharmacotherapy. <i>Amer J Pharm Ed.</i> 2012;76(2):1-8.</p>	<p>To implement and evaluate the impact of two elective courses, Pregnancy & Lactation and Pediatrics on student acquisition of knowledge and development of lifelong learning skills related to these special populations. Two 3-credit elective courses were implemented using various student-driven learning techniques, such as case-based exercises, group presentations, pro-con debates, and pharmacist “grab bag” questions. Strong emphasis was placed on medication literature retrieval and analysis, and a wiki was used to create an electronic resource for longitudinal use.</p>	<p>The combination of student-directed learning techniques used in two pediatric-concentration courses is an effective teaching model.</p>	<p>Demonstrates effective teaching modules for development of lifelong learning skills in pediatrics.</p>
<p>Aucoin R, Buck M, Dupuis L, Dominguez K, and Smith K. Pediatric pharmacotherapeutic education: current status and recommendations to fill the growing need. <i>Pharmacotherapy.</i> 2005;25(9):1277-1282.</p>	<p>Millions of prescriptions are written for infants and children each year, and relatively few pharmacists practice in environments devoid of pediatric patients. To fulfill the stated mandate, professional pharmacy curricula must include adequate content dedicated to pharmaceutical care of the pediatric patient. Current pediatric curricula are inadequate and must be improved.</p>	<p>Pediatric topics should be introduced early in the curriculum to increase students’ awareness of the special needs of this vulnerable population. Other recommendations include the provision for at least 25 hours of didactic instruction in core pediatric areas and at least one pediatric clinical rotation to all students. Pharmaceutical care of pediatric patients can also be improved by offering pediatric rotations to all pharmacy practice residents and encouraging their participation.</p>	<p>There is a growing need for the expanded care of pediatric patients. Education in pediatrics must be expanded to include didactic and experiential exposure.</p>
<p>Low JK, Baldwin JN. Pediatric pharmacy education for U.S. entry-level doctor of pharmacy programs. <i>Am J Pharm Educ</i> 1999;63:323–7.</p>	<p>This article reports on a survey of U.S. pharmacy colleges requesting information about pediatric didactic content, reading assignments, clerkships, and amount of time dedicated to these experiences in entry-level PharmD programs.</p>	<p>An average of 16.7 hours was devoted to pediatric content in required courses. This content varied extensively; only seven topics (otitis media, immunizations, meningitis, cystic fibrosis, pharmacokinetics, asthma, and fluid and electrolyte therapy) were included by greater than 70 percent of programs. Fifty of the 54 reporting</p>	<p>Didactic and experiential training in pediatrics is not standardized. However, the article reinforces the need for all pharmacy graduates to be prepared to care for the</p>

		<p>programs (93 percent) offered at least an elective pediatric clerkship and all planned to. Eleven programs (20 percent) required pediatric clerkships. Forty-one percent of students enrolled in these 50 colleges would complete a pediatric clerkship. Pharmacy colleges should assure that their didactic and experiential curricula adequately prepare their graduates to provide appropriate pharmaceutical care to the neonatal-through-adolescent population.</p>	<p>neonatal-through-adolescent population.</p>
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