



## Accreditation Council for Pharmacy Education International Services Program

### Guiding Principles for Policies and Procedures for Certification and Precertification of Professional Degree Programs in Pharmacy in Countries other than the United States and Its Territories

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This document summarizes the guiding principles that help to shape the policies and procedures that are used by ACPE to certify and precertify professional degree programs in pharmacy (“programs”) in countries other than the United States and its territories. This document is intended to provide only a broad overview of the certification process, while the full Policies and Procedures (available at <https://www.acpe-accredit.org/pdf/ISP/PoliciesandProcedures.pdf>) describe in detail the specific requirements and processes. This document also highlights those aspects of the certification and precertification processes that are unique and somewhat different from the elements found in ACPE’s current policies and procedures used to accredit professional degree programs (PharmD degrees) of U.S. colleges and schools of pharmacy. Readers should refer to the Certification and Precertification Policies and Procedures for the official and more comprehensive descriptions of the certification and precertification processes and requirements. The Policies and Procedures document also includes a Glossary of Terms. The relevant paragraphs of the Policies and Procedures document are indicated in parentheses below.

Guiding principles within the **certification and precertification processes** include (important concepts are *italicized*):

- Certification and Precertification applies only to *professional degree programs* (those granting eligibility to practice as a pharmacist) outside the United States and its territories.
- The primary *purpose* of ACPE’s certification program is to assist schools, colleges and faculties of pharmacy outside the United States (hereinafter “schools”) in their quality assurance and improvement efforts.
- Certification and Precertification are *not* intended to infer or grant eligibility for licensure or registration to practice as a pharmacist in any jurisdiction.
- The intent behind ACPE’s certification program is *not* to impose U.S. systems and models for pharmacy education and quality assurance on other countries. Rather, the certification program is intended to help assure that professional degree programs in pharmacy are designed and implemented in accordance with quality principles and criteria that have been developed through a broad-based, transnational consensus process.
- A professional degree program’s compliance with the Certification Quality Criteria (available at <https://www.acpe-accredit.org/pdf/ISP/QualityCriteria.pdf>) will be evaluated in the *context* of the health and education systems, government structures, regulation, language and culture of the school or institution’s country.
- One of the outcomes of the certification program is to provide a list (“Directory”) of professional degree programs with Certification Status from ACPE.

- Only programs and institutions meeting the Certification and Precertification Eligibility Criteria will be considered for Certification and Precertification; for example, the professional degree program must be part of an independent school of pharmacy, a school of pharmacy within a university, or another structure approved by the ACPE Board of Directors (Board). (6)

Guiding principles regarding the **Quality Criteria** include:

- The certification and precertification processes use the Quality Criteria that are designed to be applicable to a *range* of professional degree programs and to assure that the program is relevant, contemporary, socially accountable, and appropriate to the needs and health systems of the country in question.
- The Quality Criteria reflect professional and educational qualities identified by ACPE through international dialogue, consensus, and feedback.
- The Quality Criteria establish certain *expectations* of quality within all the essential components of academic pharmacy, namely: mission, planning, and evaluation; organization and administration; curriculum; students and academic policies; staff resources; and facilities and resources.
- The Board, upon the recommendations of the International Commission (IC), determines *compliance* with the Quality Criteria and the likelihood of continued compliance with such Quality Criteria.
- The Quality Criteria are revised periodically (likely every six to eight years) in keeping with changes in pharmacy education and pharmacy practice globally. However, ACPE may revise the Quality Criteria more frequently if warranted.

Guiding principles regarding the types of **certification and precertification actions** taken by the Board, the types of **Certification Status** that may be held by a program, and related issues: (*numbers refer to the relevant paragraph in the Policies and Procedures*)

- **Certification Status**: The type of public recognition granted or continued by ACPE; the possible types are:
  - Certification/Certified
  - Precertification/Precertified
  - Provisional Certification (Category 1)/Provisionally Certified (Category 1)
  - Provisional Certification (Category 2)/Provisionally Certified (Category 2)
  - Certification with Probation/Certified with Probation.

Schools must disclose the Certification Status of their program in an accurate and complete manner; and may use the ACPE International Logo only when they have active Certification Status. (8)

- **Precertification**: The status of public recognition that ACPE grants to a new pharmacy degree program (i.e., for which there has not yet been a graduating cohort of students) for a limited period of time that signifies that the program is progressing towards Certification and is likely to attain Certification before the expiration of that time period. The term of Precertification of the program shall be limited to a maximum of twelve (12) months beyond the anticipated date of graduation of the program's first cohort of students, unless the Board, for good cause and at its sole discretion, grants an extension to the Precertification term. (7.1)
- **Provisional Certification/Provisionally Certified**: The Certification Status of a program that has been granted either Provisional Certification (Category 1), Provisional Certification (Category 2), or Provisional Certification (Category 1 and 2).
- **Provisional Certification (Category 1)/Provisionally Certified (Category 1)**: The Certification Status that may be granted by ACPE to a Professional Degree Program in a country other than the United States and its territories that may have factors that compromise compliance with Quality Criteria,

but that has initiated appropriate plans to address such factors, and meets all ACPE's requirements for such recognition. (7.3, 7.5, 8.4, 8.6, 10.10, 11.4 – 11.9, 11.13, 11.15, 13.1, 13.5, and 15.3)

- *Provisional Certification (Category 2)*: The Certification Status that may be granted by ACPE to a Professional Degree Program in a country other than the United States and its territories that demonstrates compliance with all or most Quality Criteria and meets all ACPE's requirements for such recognition. Provisional Certification (Category 2) may be granted following the conduct of a Virtual Site Visit evaluation when the Board has determined that an on-site evaluation visit is not possible or advisable for reasons of security, health, safety, or other circumstance identified by the Board. Provisional Certification (Category 2) is envisioned as a temporary Certification Status, and the program is expected to advance to Certification at the earliest opportunity, subject to meeting all requirements and conditions set by ACPE. (7.4, 7.5, 8.5, 8.6, 10.10, 11.4, 11.5, 11.8 – 11.10, 11.13, 11.15, 13.1, 13.5, and 15.3)
- *Administrative Warning*: Administrative Warning is a status assigned by ACPE Staff to a Professional Degree Program when a school does not comply with administrative requirements for maintaining its Certification Status. (7.7)
- *Certification with Probation*: The Certification Status granted to a Certified Professional Degree Program that has been identified by ACPE as being partially or non-compliant with one or more of the Quality Criteria and that has not made adequate progress towards bringing the Criterion/Criteria into compliance. A status of Certified with Probation is disclosed to the public and listed as such in the Directory. (8.7 and 11.14)
- *Denial of Certification and Precertification*: Certification and Precertification will be denied when, during the review process of an application for Certification or Precertification, evidence exists that the program exhibits substantial deficiencies that prevent compliance with the Quality Criteria. (15.2)
- *Withdrawal of Certification Status*: Certification Status will be withdrawn when there is documented evidence that a program that is Certified, Precertified, Provisionally Certified, or Certified with Probation exhibits ongoing deficiencies in achieving or maintaining compliance and that the deficiencies are sufficiently serious to raise concerns regarding overall programmatic quality. (15.3, 15.3.1, 15.3.2)
- *Immediate Withdrawal of Certification Status*: Regardless of the Certification Status of a program, rapid and precipitous deterioration of the quality of the program may be sufficient grounds for the immediate withdrawal of Certification Status, whether or not a period of Certified with Probation or other opportunity to remedy issues of Partial or Non-compliance with the Quality Criteria has been provided. 15.3.3)
- *Appeals Process*: A school may appeal only the following Adverse Certification Actions: (1) awarding of the status Certified with Probation; (2) denial of Certification and Precertification, or (3) withdrawal of Certification Status as a result of a decision by the Board. (16)
- *Voluntary Discontinuation of Certification and Precertification*: A school may at any time elect to discontinue the Certification or Precertification Status of its program. (24)

Guiding principles within the **application process** include (see accompanying flowchart as well):

- ACPE may refuse to accept an application for Certification or Precertification of a program, which otherwise meets the Eligibility Criteria, where exceptional circumstances, such as a U.S. imposed embargo and strained international relationships, prevent ACPE from doing so. (6)
- To initiate the process of applying for Certification or Precertification, a school must submit a non-binding Letter of Intent. Documentation submitted with the Letter of Intent is evaluated to confirm that the school, institution, and program satisfy the Eligibility Criteria. (10.1, 11.1)

- Prior to the formal submission of an application, a school must consult with ACPE Staff to ensure that it understands the policies, procedures, expectations, and obligations of Certification. (10.2, 11.2)
- To apply for Certification or Precertification, a school must submit an official application (“Invitation to Evaluate”), a *self-study report* of the program, the required application fee (paid in U.S. Dollars), and any additional materials required by ACPE. (10.3, 11.3)
- ACPE Staff will complete an initial review of the application to ensure its completeness and adequacy. (10.3, 11.3)
- At any stage in the application process, an application can be referred back to the school for revision and re-submission. (10.3, 11.3)
- At any stage in the application process, the school or institution can voluntarily withdraw the application or request ACPE to postpone action on the application. (10.3, 11.3)
- A team comprising a member of the ACPE Staff or a consultant appointed for the purpose and one member of the ACPE International Commission will complete a *preliminary review* of the application to determine whether or not the program meets the Eligibility Criteria and assess if the program has a strong likelihood of achieving Certification or Precertification, and thus should be granted an evaluation visit. The Certification or Precertification Threshold Rubric, as applicable, is used for this purpose. The preliminary review team will make a recommendation to the IC, which shall in turn make its recommendation to the ACPE Board. The Board decides whether or not to authorize an evaluation visit. (10.3, 11.3)
- If not granted an evaluation visit, the school will be advised to *defer* its application and to submit a revised application. A recommendation to defer and resubmit an application is not an Adverse Certification Action and is not appealable. (10.3, 11.3)
- A *revised application* must be submitted within twelve (12) months of the recommendation for deferral or the school will be charged an application re-submission fee. (10.4, 11.4)
- If approved by the Board, the evaluation visit team (typically comprising four members) will conduct an *evaluation visit* using an established evaluation instrument (“rubric”) and procedures. The school will pay ACPE the applicable evaluation visit fee and will cover all expenses. Following the visit, the team will prepare an *Evaluation Team Report (ETR)* that will be reviewed by the IC and Board. Based on the collected evidence, the ETR, any supplementary information provided by the school, and any communications with the school, the IC will make a *recommendation* to the Board regarding the granting of Certification Status. (10.3, 11.3)
- The Board will consider the IC’s recommendation along with all available evidence and will either grant Certification, grant Precertification, grant Provisional Certification, advise the school or institution to defer its application and to resubmit an appropriately revised application, deny Certification, deny Precertification, or take such action as it may deem to be appropriate. An Actions and Recommendations Letter (A&R) will be approved by the Board and sent to the school. (10.3, 11.3)
- Denial of Certification or Precertification is an *Adverse Certification Action* and is subject to appeal. (10.8, 11.12, 15,2; 15; 16)
- For programs denied Certification or Precertification, the school may re-apply for Certification or Precertification but must wait for a minimum period of twelve months from the date of denial. During this re-application process, the school must repeat all steps in the application process, including payment of application fees. (10.6, 11.11)
- Programs granted Certification will have an *initial term* of two years. Prior to the expiration of the two-year term, a focused evaluation visit will be conducted to evaluate *continued compliance* with all Quality Criteria. The school will pay ACPE the applicable evaluation visit fee and will cover all expenses. Any focused evaluation visit requires a written report to be

submitted prior to the visit. In addition, a one-year progress report must be submitted by the school. (11.6)

- Programs granted Provisional Certification (Category 1) will have a term of two years. Prior to the expiration of the two-year term, a focused evaluation visit will be conducted to evaluate compliance with all Quality Criteria. The school will pay ACPE the applicable evaluation visit fee and will cover all expenses. Any focused evaluation visit requires a written report to be submitted prior to the visit. Depending on the timing of the focused visit, the school may be required to submit a one-year progress report. (11.7)
- For programs granted Provisional Certification (Category 1): within the two-year term the Board must either grant Certification or, if the program has failed to satisfy the expectations of the Board, Provisional Certification will be withdrawn at the end of the two-year term. The Board may, however, grant an extension of the term of Provisional Certification if the school can demonstrate “good cause.” (11.7)
- Programs granted Provisional Certification (Category 2), will be awarded an initial certification term of two (2) years. The Board will define all monitoring and future evaluation requirements, and may set additional terms and conditions as it deems appropriate and necessary. Prior to the expiration of the two-year term, ACPE will communicate with the school to schedule a focused evaluation visit for the purpose of evaluating compliance with all Quality Criteria. No less than six (6) weeks prior to the evaluation visit, the school must submit a written report to ACPE, in the required format, that summarizes progress and achievements made by the school and program and provides evidence of compliance with all Quality Criteria. The school or institution shall pay the applicable fee and cover all expenses related to the evaluation visit. Based on the ETR following the focused evaluation visit, any additional data or documentation provided by the school, and the recommendations of the IC, the Board shall consider the program for continued Provisional Certification (Category 2) and take a certification action in. Following the initial two-year term, the standard term for a program that is in compliance with the Quality Criteria, is four (4) years, to bring the program onto the standard review cycle of six (6) years.
- For a program to be considered for advancement from Provisional Certification (Category 2) to Certification, an on-site Verification Visit (VV) must be held within the awarded Certification Term. For a program to be granted Certification, the VV must, at a minimum with regard to compliance, affirm the findings and conclusions from the VSV. If the VV does not, at a minimum with regard to compliance, affirm the findings and conclusions from the VSV or the VV evaluation team identifies new concerns or issues of compliance, the Board will take an action in accordance with its established decision-making process, which may include the withdrawal of the Certification Status.
- For programs granted Provisional Certification (Category 1 and 2), the provisions of Paragraph 11.7 may also be applied, as deemed appropriate by the Board.
- The standard review cycle for Certified programs is six years. Thus, following the initial two-year term, a Certified program may have its Certification continued for four years - if it maintains compliance with the Quality Criteria - to bring the program onto the standard review cycle (6 years). If the two-year focused visit reveals significant issues, the program may be given a *shorter Certification Term* and appropriate *monitoring procedures* will be implemented. (11.6)
- ACPE may review programs for purposes of continued Certification at any time within the six-year cycle. Shorter Certification Terms may be granted to monitor progress on specific issues. (11.13)

Guiding principles within some of the **operational procedures** include:

- If ACPE is precluded from undertaking an on-site evaluation (for example, because of security or health concerns, as outlined in ACPE's Global Travel Policies), then ACPE and the school will strive to identify an *alternative venue or format* for conducting the evaluation in a timely manner. (11.16)
- Business will be conducted in *English* although ACPE will endeavor to accommodate other languages, for example, by using evaluators with relevant language skills. (13.1)
- *Conflict of interest* and *confidentiality* policies have been established and will be followed to avoid compromising the certification process. (12; 13.3)
- Evaluation team members and ACPE Staff will be trained to appreciate *cultural differences* in the various countries and regions visited. Prior to deployment, team members will be trained regarding the Quality Criteria, Policies and Procedures, evaluation techniques, and respective roles in the evaluation process. Team members will be provided guidelines for how to conduct meetings and interviews, including for virtual site visits, and how to use the criterion-by-criterion evaluation instrument ("Rubric"). (13.1, Addendum 7)
- Ordinarily, the evaluation visit involves *two to four* days and includes interviews with the key academic leaders, academic staff, preceptors, students, and other key stakeholders. An inspection is made of physical facilities, educational resources, and sites utilized for pharmacy practice experiences. (13.3)
- ACPE may refer to *assessments* made by national or regional accrediting/quality assurance agencies concerning such issues as the basic science and general education components of the program. (13.3)
- Schools may be asked to submit *interim reports*, and *focused visits* may be scheduled to monitor compliance with Quality Criteria. (10.7, 11.6; 13.3)
- ACPE will require *annual reporting* of key indicators by schools and will review all *substantive changes* to determine whether or not there are factors that affect the quality of the program. (13.6; 14)
- Any *litigation* instituted by (i) any school of pharmacy against ACPE or (ii) ACPE against any school shall be brought in Cook County, Illinois, USA, in the Circuit Court of Cook County or in the Federal District Court for the Northern District of Illinois. (17)

ACCREDITATION COUNCIL FOR PHARMACY EDUCATION

INTERNATIONAL SERVICES PROGRAM

FLOWCHART FOR APPLICATION, GRANTING, DENIAL, APPEAL & RE-APPLICATION FOR CERTIFICATION

