



Administrative Procedures for the ASHP-Certified Center of Excellence™ in Medication-Use Safety and Pharmacy Practice Program

I. Introduction

The *ASHP Standard for Certification as a Center of Excellence in Medication-Use Safety and Pharmacy Practice*,¹ hereafter referred to as the “Standard”, reflects contemporary best practices for hospital and health-system pharmacy practice. A certification process used by healthcare and other organizations worldwide indicates that an institution has met predetermined criteria through verification. Assessment of an organization’s level of performance in relation to established standards allows the opportunity for implementation of ways to improve continuously.

This voluntary certification process is offered to health-system pharmacy departments with an interest not only in improving patient care and pharmacy services but also in earning this formal recognition of the value provided to their patients and their health system. Pharmacy departments that have achieved excellence apply for and successfully complete a rigorous formal certification process will be designated an “ASHP Certified Center of Excellence in Medication-Use Safety and Pharmacy Practice.”

The term “health-system” is used in the reference Standard and in these administrative procedures, and refers to both hospitals and health systems, defined as both acute and ambulatory settings.

II. Definitions (Certification Status)

- A. Certification:** the act of granting approval to a hospital pharmacy department after it has met established requirements and has been reviewed and evaluated through an official process [document review, site survey, review and evaluation by the Pharmacy Practice Accreditation Commission (PPAC)]. An approved pharmacy department is considered to be in an “ASHP-certified” status.
- B. Site:** the practice location at which the hospital pharmacy department seeks certification.
- C. Multi-site Hospital Pharmacy Department:** an organization at which pharmacy services are provided at multiple locations and the corporate location is responsible for coordinating and managing the pharmacy services. The organization assures the pharmacies meet the core service requirements, there are consistent policies and procedures at all locations, and there is consistent assessment of the quality of pharmacy

services across all locations.

- D. **Lead Surveyor:** an experienced pharmacist, designated by the Office of Practice Advancement (“OPA”), who coordinates and conducts the certification survey in conjunction with a practitioner surveyor. .
- E. **Practitioner Surveyor:** a pharmacist, designated by OPA, who is a subject matter expert and is typically an experienced hospital pharmacist who is trained to assist the lead surveyor in conducting a certification survey.

III. Authority

The program for certification as a Center of Excellence in Medication-Use Safety and Pharmacy Practice (“COE”) is established by authority of the Board of Directors (BOD) of ASHP and is implemented by the PPAC. All matters of policy relating to the certification of pharmacy departments are submitted for approval to the ASHP BOD. The PPAC reviews and evaluates applications for certification and site survey reports submitted, and is authorized to take action on all applications for certification in accordance with the policies and procedures set forth herein. The minutes of the PPAC are submitted to the ASHP Board of Directors for review and action as appropriate.

IV. Certification Procedures

The certification program is conducted as a service of ASHP to any organization voluntarily requesting evaluation of its hospital pharmacy services.

A. Application

1. Application for certification forms are available from ASHP staff. The pharmacist executive of the pharmacy department and the health-system’s administrator must sign the application. Applications should be submitted, along with the supporting documents specified in the application instructions, to ASHP’s Office of Practice Advancement by electronic mail at COE@ashp.org (or mailed to ASHP, Office of Practice Advancement, 4500 East-West Highway, Suite 900, Bethesda, MD 20814, or as directed by ASHP staff. A duplicate copy should be retained for the applicant’s files.
2. Organizations with multiple pharmacy locations must specify which locations are to be evaluated and their addresses.
3. OPA will acknowledge receipt of the application and review it for completeness to make a preliminary judgment about conformance to the basic requirements of the Standard. If the pharmacy department fails to meet the criteria of the Standard in some fundamental way, OPA will notify the signatories of the application accordingly

and will indicate what actions must be taken in order to be accepted.

B. Letter of Agreement and Business Associate Agreement

ASHP will provide a Letter of Agreement for the certification process that includes a description of the certification process, responsibilities of the pharmacy practice and ASHP, the *Administrative Procedures for the ASHP-Certified Center of Excellence in Medication-Use Safety and Pharmacy Practice Program*, and a fee schedule, and may additionally provide a Business Associate Agreement (“BAA”) for signature.

C. Survey Team

1. A survey team is assembled to conduct the evaluation of the pharmacy department. The number of survey team members is determined by OPA in consultation with the assigned lead surveyor.
2. Upon selection of the survey team, surveyors and pharmacy departments must disclose conflicts of interest to OPA and appropriate actions are taken to manage any conflicts.

D. Document Assessment

1. A Document Assessment Checklist is sent to the applicant pharmacy department to self-report policies and procedures, other documents, and data demonstrating compliance with the Standard. The completed Document Assessment Checklist and the referenced supporting documents should be submitted to the applicable ASHP-provided secure cloud file folder within 120 days of receipt of the assessment checklist, unless otherwise coordinated with OPA.
2. The Document Assessment Checklist and supporting documentation is reviewed by the surveyor(s). Within 45 days of receipt of the checklist and documents or as determined by ASHP staff, the lead surveyor provides a written report noting if any documentation is missing or requires clarification. The lead surveyor schedules a conference call with the pharmacist executive and pharmacy team to discuss the report and any questions, as well as to plan for the certification survey.
3. The applicant pharmacy department is eligible for the certification survey as soon as the specified documentation is complete, verified as meeting a minimum number of elements of the Standard, and indicated by the surveyor(s).

E. Certification Survey

1. A survey generally occurs six to eight weeks after notification of survey eligibility. A general desired survey plan will be provided.
2. The survey team will review and tour pharmacy operations and services and patient care areas; review hospital/health-system, pharmacy department and patient records for compliance with policies, procedures, and documentation; observe patient care

services being performed (where appropriate); interview health-system/hospital leaders and staff members; interview pharmacy department personnel concerning their duties and responsibilities for the delivery of pharmacy services to patients, their adherence to policies and procedures, and use of recognized best practices.

3. For multiple-site health-systems, the survey team will collaborate with the pharmacy executive and pharmacy department representatives to determine which sites will be visited during the survey.

F. The Survey Report and Follow-up

1. A written survey report is sent by OPA to the pharmacy department's pharmacist executive within 30 days following the certification survey. The report states whether the survey is complete or whether there are outstanding items to address for compliance with the Standard.
2. Within 75 days of the last day of the survey (45 days of receipt of the survey report), a written response report with a plan of corrective action and timeline for any non-compliant standard elements must be uploaded to the applicable secure cloud file and OPA must be notified by electronic mail. The written response report, action plan and timeline is reviewed by the survey team and may require additional information, with evidence of completion, as determined by the survey team.
3. Additional reports must be provided by applicant pharmacy departments according to designated timelines until action plans have been completed. Failure of the pharmacy department to submit reports as requested may result in certification being withheld.
4. The pharmacy executive is notified when eligible for certification decision.

G. Certification

1. The applicant pharmacy department's survey report and response report, with action plans and timelines, are reviewed by the survey team, OPA, and the PPAC.
2. If appropriate, the PPAC recommends certification of the applicant health-system pharmacy department to the ASHP BOD.
3. The ASHP BOD considers the recommendation and makes a decision regarding certification of the applicant health-system pharmacy department. The BOD's date of decision is the initial date of certification.
4. The certification term is three years.
 - a. A certificate of certification is issued to a pharmacy department that has become certified. However, the certificate remains the property of ASHP and shall be returned to ASHP when certification is withdrawn or if the certification of the pharmacy department is discontinued.

- b. Once the health-system pharmacy department is certified, any reference by the pharmacy department to certification by ASHP in promotional materials (e.g., catalogs, bulletins, web sites, or other form of publicity) and all formal pharmacy department documents including certificates must include the following statement: “The [organization name] Pharmacy Department, [city/province/country], [state] is certified by ASHP.” The ASHP-certified logo may be used in conjunction with the above statements. Refer to the ASHP website for current instructions on logo use.
 - c. If a certified pharmacy department or multi-site hospital pharmacy department wishes to add an additional site to its certification, OPA will follow the outlined process:
5. If a hospital pharmacy department or multi-site hospital pharmacy department desires to add an additional location (hospital) to its certification, OPA will consider the time of notification of the request relative to the current three-year certification cycle and previous certification date.
- a. If notification occurs prior to eighteen months since the most recent survey, OPA will conduct a focused survey of the additional site, including a focused document review and on-site or virtual survey as outlined in steps D, E, F, and G above. Provided certification is granted to the new site, the length of its certification shall be limited to the existing site(s)’ current certification cycle.
 - b. If notification occurs later than eighteen months since the most recent survey, the hospital pharmacy department or multi-site hospital pharmacy department is required to wait until the next scheduled certification re-survey and the new site will be included in the re-certification process at that time.

V. Continuing Certification

- A.** ASHP regards evaluation of certified hospital and health-system pharmacy departments as a continuous process; accordingly, annual reports are required from every certified entity and reviewed by OPA and PPAC; reports that are more frequent may be requested in the judgement of the PPAC.

To maintain certification, pharmacy departments must comply with all requests from ASHP for written reports.

- B.** Pharmacist executives of certified pharmacy departments and those in the certification process must submit written notification of substantive changes to the pharmacy departments to OPA within 30 days of the change. Substantive changes include changes to leadership (e.g. changes in pharmacist executive), major changes in the scope of services, addition of locations or removal of locations for multi-site pharmacies, and changes in organizational ownership. OPA will evaluate the credentials of each new pharmacist

executive (change in leadership) using the requirements outlined in the Standard. Any substantive change in the organization of a pharmacy may be considered justification for re-evaluation of the pharmacy department by report and/or a site survey.

VI. Re-certification

- A.** ASHP-certified pharmacy departments are re-examined by document assessment and site survey every 3 years. Re-certification surveys are scheduled within 12 months of the anniversary date of the original certification survey. Schedule adjustments may be made in order to accommodate the addition of new pharmacy practice sites.
- B.** Records related to the Standard processes (i.e., up to three years) must be maintained and available to the survey team for review. These records may be maintained electronically, as long as they can be easily accessed if requested by the survey team.
- C.** The PPAC, on behalf of ASHP, may request written reports at any time between the 3-year survey intervals. Failure of the pharmacy department to submit reports as requested may result in re-certification, certification being delayed or withheld, or withdrawal of certification.

VII. Quality Improvement

Following a certification survey, OPA will provide a mechanism for the pharmacy department to evaluate the survey team and process. This is an opportunity for the pharmacist executive and staff to provide feedback on the survey process and information for quality improvement of the certification process. Pharmacy departments may submit constructive comments to ASHP at any time to COE@ashp.org or mailed to ASHP, Office of Practice Advancement, 4500 East-West Highway, Suite 900, Bethesda, MD 20814.

VIII. Certification Fees

- A.** The one-time application fee based on number of locations to be certified is established by ASHP and is assessed to the pharmacy department at the time of application.
 - 1. The annual certification fee is based on the calendar year. This fee begins as soon as a pharmacy department has filed an application for certification (it will be pro-rated for the first year, based on the number of months remaining in the calendar year, from point of application.)
 - 2. The annual fee is based on the number of locations to be certified.

IX. Withdrawal of Certification

- A.** Certification of a pharmacy department may be withdrawn by ASHP for any of the reasons stated below.
 - 1. Certified pharmacy departments that no longer meet the requirements of the Standard shall have their certification withdrawn. In the event that a Standard is revised, all ASHP-certified pharmacy departments will be expected to meet the revised Standard within 1 year.
 - 2. A pharmacy department makes false or misleading statements about the status, condition, or category of its certification.
 - 3. A pharmacy department fails to submit periodic written status reports as required or requested.
 - 4. A pharmacy department fails to submit appropriate annual fees as invoiced.
- B.** The pharmacy department may also be disqualified from certification or certification may be withdrawn for any of the reasons stated in the ASHP Letter of Agreement, Section G, signed by the pharmacy department.
- C.** Withdrawal of pharmacy department certification may occur at any point during the certification term per the Letter of Agreement.
- D.** The pharmacy department shall have the right to appeal the final decision of ASHP.
- E.** If certification is withdrawn, the pharmacy department may submit a new application for certification and must undergo re-evaluation to regain certification.
- F.** Pharmacy departments may voluntarily withdraw from the certification process and/or forfeit certification at any time by notifying OPA in writing. When notified, OPA will report these pharmacy departments to the PPAC and the ASHP BOD.

X. Appeal of Decision

A. Notification of intent to appeal

In the event that a pharmacy department is not certified, is not re-certified, or if certification is withdrawn, the pharmacist executive or the organization's administrator (hereafter referred to as the appellants) may appeal the decision to an appeal board on the grounds that the certification decision was arbitrary, prejudiced, biased, capricious, or based on incorrect application of the Standard to the pharmacy department. An appellant must notify OPA of the pharmacy department's intent to appeal, by electronic

mail, within 10 business days after receipt of the notice. The appellant must state clearly the grounds upon which the appeal is being made. The appellant shall then have an additional 30 days to prepare for its presentation to an appeal board.

B. Appeal board

On receipt of an appeal notice, OPA shall contact the ASHP General Counsel. The office of the ASHP General Counsel will proceed to constitute an ad hoc appeal board. The appeal board shall consist of one member of ASHP's BOD, to be appointed by the President of ASHP, who shall serve as Chair, and two experienced pharmacy practitioners from certified hospital pharmacies, neither of whom is a member of the PPAC, one to be recommended by the appellant and one by the Chair of the PPAC. The President of ASHP will appoint a health care administrator in an ex officio, nonvoting capacity. The General Counsel of ASHP shall serve as Secretary of the appeal board. The Senior Vice President, Practice Advancement Office, shall represent the PPAC at the hearing in an ex officio, nonvoting capacity. As soon as recommendations for appointments to the appeal board have been made, the General Counsel will contact all parties to confirm their appointment and the hearing date. The ASHP General Counsel will immediately forward copies of all of the written documentation considered by the PPAC in rendering its decision to the Appeal Board Members.

C. Potential conflict of interest

All members of the appeal board will complete an ASHP "Disclosure Report" form regarding professional and business interests prior to formal appointment to the appeal board. The appeal board Chair will take appropriate action to manage potential conflicts.

D. The hearing

The appeal board shall be convened in no less than 30 days and no more than 60 days from the date of receipt of an appeal notice by OPA. The ASHP General Counsel shall notify appellants and appeal board members, at least 30 days in advance, of the date, time, and place of the hearing. The pharmacy filing the appeal may be represented at the hearing by one or more appropriate officials and shall be given the opportunity at such hearing to present written, or written and oral, evidence and arguments intended to refute or overcome the findings and decision of the PPAC. The appeal board shall advise the appellant organization of the appeal board's decision, by registered or certified mail, or by nationally or internationally recognized courier service, within 10 business days of the date of the hearing. The decision of the appeal board shall be final and binding on both the appellant and ASHP.

E. Appeal board expenses

The appellant shall be responsible for all expenses incurred by its own representatives at the appeal board hearing and shall pay all reasonable travel, living, and incidental expenses incurred by its appointee to the appeal board. Expenses incurred by the board member, PPAC-selected pharmacist executive, and health care administrator shall be borne by ASHP.

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