

ASHP Administrative Procedures on Accreditation of International Hospital and Health-System Pharmacy Services

I. Introduction

The American Society of Health-System Pharmacists (ASHP) believes that accreditation specific to pharmacy services can foster further development of pharmacy-delivered patient care services and advance practice. ASHP also believes that it has an obligation to support international hospital and health-system pharmacy services through the development of practice standards and a program of accreditation. To ensure adherence to the principles and philosophy of such standards, ASHP administers an accreditation program.

The term “hospital” is used in the accreditation standard and in thesions, and refers to both hospitals and health-systems, defined as both acute and ambulatory settings.

II. Definitions (Accreditation Status)

- A. **Accreditation:** the act of granting approval to a hospital pharmacy service after the service has met established requirements and has been reviewed and evaluated through an official process [document review, site survey, review and evaluation by the International Accreditation Commission (IAC)]. An approved program is considered to be in an “ASHP- accredited” status.
- B. **Site:** the actual practice location at which the hospital pharmacy service seeks accreditation.
- C. **Multi-site Hospital Pharmacy Service:** 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, who coordinates and conducts the accreditation site survey in conjunction with a practitioner surveyor.
- E. **Practitioner Surveyor:** a pharmacist who is a subject matter expert and is typically an experienced hospital pharmacist who is trained to assist the lead

surveyor in conducting an accreditation survey.

III. Authority

The program for accreditation of international hospital and health-system pharmacy services is established by authority of the Board of Directors of ASHP and is implemented by the IAC. All matters of policy relating to the accreditation of programs will be submitted for approval to the ASHP Board of Directors. The IAC shall review and evaluate applications and site survey reports submitted, and shall be authorized to take action on all applications for accreditation in accordance with the policies and procedures set forth herein. The minutes of the IAC shall be submitted to the Board of Directors for review and action as appropriate.

IV. Accreditation Procedures

The accreditation program shall be conducted as a service of ASHP to any organization voluntarily requesting evaluation of its hospital pharmacy services.

A. Proposal for Accreditation

1. ASHP will send a proposal for international hospital pharmacy services accreditation which includes
 - A one-time application fee
 - An annual accreditation fee

B. Application

1. Application forms are available on the ASHP website (www.ashp.org). The application must be signed by the pharmacist executive of the pharmacy services and the hospital's administrator. 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 (global@ashp.org) or mailed to ASHP, Office of Practice Advancement, 4500 East West Highway, Suite 900, Bethesda, MD 20814. 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. The Director, Pharmacy Accreditation, Office of Practice Advancement, will acknowledge receipt of the application and review it for completeness to make a preliminary judgment about its conformance to the basic requirements of the accreditation standard.
4. If the pharmacy services fail to meet the criteria of the certification standard in some fundamental way, OPA will notify the signatories of the application accordingly and will provide information as to those actions that must be taken in order for the application to be accepted.

5.

C. Survey Team

1. An accreditation survey team shall be assembled to conduct the evaluation of the pharmacy services. The Director, Pharmacy Accreditation in consultation with the assigned lead surveyor, determines the number of survey team members.
2. Upon selection of the survey team, surveyors and pharmacy services must disclose conflicts of interest to the Director, Pharmacy Accreditation, Office of Practice Advancement and appropriate actions will be taken to manage any conflicts.

D. Document Assessment

1. A Document Assessment Checklist is sent to the pharmacy to self-report policies and procedures demonstrating compliance with the standard. The completed Document Assessment Checklist and the referenced supporting documents must be submitted to the applicable cloud file folder within 120 days of receipt of the assessment checklist.
2. The checklist and other supporting documentation is reviewed by the surveyor(s). Within 45 days of receipt of the checklist and documents, 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 pharmacy director and pharmacy team to discuss the report and any questions, as well as to plan for the accreditation survey.
3. The pharmacy is eligible for the accreditation survey as soon as the documentation is complete, verified as meeting the standard, and indicated by the surveyor.

E. Accreditation Survey

1. A survey will generally occur within two to six weeks after notification of survey eligibility and a general survey plan will be provided.
2. The survey team will review and tour pharmacy operations and patient care areas; review patient records for compliance with policies, procedures, and documentation; observe patient care services being performed (where appropriate); interview pharmacy practice 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 pharmacies, the survey team will determine which sites will be visited during the site survey.

F. The Survey Report and Follow-up

1. A written survey report is sent by the Director, Pharmacy Practice Accreditation within 30 days following the site survey. The report states

whether the survey is complete or whether there are outstanding items to address for compliance with the standard.

2. Within 30 days of receipt of the report, a written response with a plan of corrective action and timeline for any non-compliant standard elements must be submitted to the applicable secure cloud file and the Director, Pharmacy Practice Accreditation must be notified. 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. Action plan reports must be provided, according to the accepted timeline, until the action plans have been completed. Failure of the pharmacy service to submit reports as requested may result in accreditation being withheld.
4. The pharmacy director is notified when eligible for accreditation decision.

G. Accreditation

1. The pharmacy's survey findings, final action plan with responses, and timeline are reviewed by the survey team, Director, Pharmacy Accreditation, and the ASHP International Accreditation Commission (IAC).
2. If appropriate, the IAC will recommend accreditation of the pharmacy services to the ASHP Board of Directors.
3. The ASHP Board of Directors (the "Board") will consider the recommendation and make their decision regarding accreditation of the pharmacy services. The Board's date of decision will constitute the initial date of certification.
4. The accreditation term is three years.
 - a. A certificate of accreditation will be issued to a pharmacy services that has become accredited. However, the certificate remains the property of ASHP and shall be returned to ASHP when accreditation is withdrawn or the program is discontinued.
 - b. Once the pharmacy service is accredited, any reference by the pharmacy service to accreditation by ASHP in promotional materials (e.g., catalogs, bulletins, web sites, or other form of publicity) and formal pharmacy services documents including certificates must include the following statement: "The [organization name] Pharmacy Service, [city/province/country], [state] is accredited by ASHP." ASHP accredited logo may be used in conjunction with the above statements. Refer to the ASHP website for current instructions on logo use.

V. Continuing Accreditation

- A. ASHP regards evaluation of accredited hospital pharmacies as a continuous process; accordingly, annual reports are required from every accredited entity and reviewed by the Director, Pharmacy Accreditation, and IAC; more

frequent reports may be requested in the judgement of the IAC.

To maintain accreditation, pharmacy services must comply with all requests from ASHP for written reports.

- B. Pharmacy Directors of accredited pharmacy services and those in the accreditation process must submit written notification of substantive changes to the pharmacy services to Director, Pharmacy Accreditation 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 multisite pharmacies, and changes in organizational ownership. The Director, Pharmacy Accreditation will evaluate the credentials of each new pharmacist executive (change in leadership) using the requirements outlined in the certification standard. Any substantive change in the organization of a pharmacy may be considered justification for re-evaluation of the pharmacy services and/or a site survey.

VI. Reaccreditation

- A. Accredited pharmacy services will be re-examined by document assessment and site survey every 3 years. Reaccreditation survey visits will be scheduled within 12 months of the anniversary of the original accreditation survey. Schedule adjustments may be made in order to accommodate the addition of new pharmacy practice sites.
- B. Records related to the accreditation standard (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 IAC, on behalf of ASHP, may request written reports at any time between the 3-year site survey intervals. Failure of the program to submit reports as requested may result in reaccreditation being delayed or withheld, conditional accreditation, or withdrawal of accreditation.

VII. Quality Improvement

Following a site survey, the Director, Pharmacy Accreditation will provide a mechanism for the pharmacy services to evaluate the survey team and process. This is an opportunity for the pharmacy director and staff to provide feedback on the survey process and information for quality improvement of the accreditation process. Programs may submit constructive comments to ASHP at any time to PracticeAccreditation@ashp.org or mailed to ASHP, Office of Practice Advancement, 4500 East West Highway, Suite 900, Bethesda, MD 20814.

VIII. Accreditation Fees

- A. The one-time application fee based on number of locations to be certified shall be established by ASHP and shall be assessed to the pharmacy at the time of application.
 - 1. The annual accreditation fee is based on a calendar year. This fee begins as soon as a program has filed an application for accreditation (it will be prorated 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 accredited.

IX. Withdrawal of Accreditation

- A. Accreditation of a program may be withdrawn by ASHP for any of the reasons stated below.
 - 1. Accredited programs that no longer meet the requirements of the accreditation standard shall have accreditation withdrawn. In the event that an accreditation standard is revised, all ASHP-accredited pharmacy services will be expected to meet the revised standard within 1 year.
 - 2. A pharmacy service makes false or misleading statements about the status, condition, or category of its accreditation.
 - 3. A pharmacy service fails to submit periodic written status reports as required or requested.
 - 4. A pharmacy service fails to submit appropriate annual accreditation fees as invoiced.
- B. ASHP shall not withdraw accreditation without first notifying the hospital pharmacy director of the specific reasons. The program shall be granted an appropriate period of time to correct the deficiencies, which may also result in an investigation or an additional on-site, or virtual survey.
- C. Withdrawal of pharmacy services accreditation may occur at any point during the accreditation term.
- D. The pharmacy services shall have the right to appeal the final decision of ASHP.
- E. If accreditation is withdrawn, the pharmacy service may submit a new application for accreditation and must undergo re-evaluation to re-gain accreditation.
- F. Pharmacy services may voluntarily withdraw from the accreditation process and/or forfeit accreditation at any time by notifying the Director, Pharmacy Accreditation, Office of Practice Advancement, in writing. When

notified, the Director, Pharmacy Accreditation, Office of Practice Advancement will report these pharmacy services to the IAC and the ASHP Board of Directors.

X. Appeal of Decision

A. Notification of intent to appeal

In the event that a pharmacy services is not accredited, is not reaccredited, or if accreditation 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 accreditation decision was arbitrary, prejudiced, biased, capricious, or based on incorrect application of the standard to the program. An appellant must notify the Director, Pharmacy Accreditation Office of Practice Advancement of the pharmacy services' 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, the Director, Pharmacy Accreditation, Office of Practice Advancement 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 Board of Directors, to be appointed by the President of ASHP, who shall serve as Chair, and two program directors of accredited hospital pharmacies, neither of whom is a member of the IAC, one to be recommended by the appellant and one by the Chair of the IAC. 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 IAC at the hearing in an ex officio, nonvoting capacity. As soon as recommendations for appointments to the appeal board have been made, the ASHP 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 IAC 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 the Office of Practice Advancement. 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 IAC. 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.

F. 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, IAC-selected hospital pharmacy executive, and health care administrator shall be borne by ASHP.

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