



## ASHP Regulations on Accreditation of Pharmacy Residencies

### I. Introduction

ASHP believes that postgraduate residency programs are the best source of highly qualified pharmacy manpower and that it has an obligation to support residencies through the development of standards and a program of accreditation. To ensure adherence to the principles and philosophy of such standards, ASHP administers an accreditation program. For purposes of accreditation, a pharmacy residency is considered to be a postgraduate program of organized education and training that meets the requirements of applicable standards set forth and approved by ASHP and, as applicable, its partners in residency program development.

### II. Definitions (Accreditation Status)

- A. **Accreditation:** the act of granting approval to a postgraduate residency program after the program has met set requirements and has been reviewed and evaluated through an official process [document review, site survey, review and evaluation by the Commission on Credentialing (COC)]. An approved program is in an “ASHP-accredited” status.
- B. **Pre-candidate:** the status that may be granted to a program that has submitted a completed application indicating intent to seek “candidate” status. Programs may be in a pre-candidate status for no more than two iterations of the Resident Matching Program (RMP). One of the purposes of this status is to assist the program in recruiting a resident through participation in the RMP. If a program in pre-candidate status is not successful in recruiting a resident within two iterations of the RMP, the status may be extended for one additional iteration of the RMP. By the conclusion of this status, the program must have submitted an application for accreditation or this designation will be removed and not granted to the same program again. Programs in this status must submit an application for accreditation when training of the first resident begins.
- C. **Candidate:** the status granted to a program that has a resident(s) in training, has applied to ASHP for accreditation, and is awaiting the official site survey, and review and evaluation by the COC.
- D. **Conditional accreditation:** the status granted to a program that is not in substantial

compliance with the applicable accreditation standard, as usually evidenced by the degree of severity of non-compliance and/or partial compliance findings. Programs must remedy identified problem areas and may undergo a subsequent on-site survey at the discretion of the COC.

### III. Definitions (Program Personnel)

- A. **Preceptor:** an expert pharmacist who gives practical experience and training to a pharmacy resident. Preceptors have responsibility for the evaluation of resident performance.
- B. **Residency program director (RPD):** the pharmacist responsible for direction, conduct, and oversight of the residency program. In a multiple-site residency, the residency program director is a pharmacist designated in a written agreement between the sponsoring organization and all of the program sites.
- C. **Site coordinator:** an individual in a multiple-site residency program who is designated to oversee and coordinate the program's implementation at an individual site that is used for more than 25% of the learning experiences. This individual may also serve as a preceptor in the program. A site coordinator must:
  - 1. be a licensed pharmacist who meets the criteria identified in the appropriate pharmacy residency accreditation standard;
  - 2. implement and adhere to the appropriate residency accreditation standards, regulations and guidance documents in conjunction with the residency program director;
  - 3. practice at the site at least ten hours per week;
  - 4. have the ability to teach effectively in a clinical or administrative practice environment; and
  - 5. have the ability to direct and monitor residents' and preceptors' activities at the site with the RPD's direction.
- D. **Designee:**
  - 1. An individual designated by the RPD to perform duties as allowed by the standard.

### IV. Definitions (Sponsorship and Residency Program Site)

- A. **Sponsoring Organization:** A hospital, health-system, college of pharmacy, corporation or other business entity that assumes ultimate responsibility for coordinating and administering the residency program. The sponsoring organization is charged with ensuring that residents' experiences are educationally sound and are conducted in a quality practice environment. The sponsoring organization is also responsible for submitting the accreditation application and ensuring periodic evaluations of the program are conducted. If several organizations share responsibility for the financial

and management aspects of the residency (e.g., school of pharmacy, health-system, individual site), the organizations must mutually designate one organization as the sponsoring organization. The sponsoring organization may or may not provide financial support. This relationship must be agreed to in writing and signed by all parties (i.e., affiliation agreement) and comply with the Standard 5 of the applicable residency accreditation standard.

- B. **Site:** the actual practice location where the residency training experience occurs.
- C. **Single-site residency:** In a single-site residency, a minimum of 60% of the resident's training program occurs at the main practice site; however, residents may spend time in learning experiences off-site as long as they do not exceed 25% of the residency program at any other site.
  - a. As adapted to community-based programs, in a single-site residency, a minimum of 40% of the resident's training program occurs at the designated home-base site within one organization. If more than 25% of the remainder of the residency is conducted at one different site, the program will be considered a multiple-site program.
- D. **Multiple-site residency:** a residency structure in which multiple organizations or practice sites are involved in the residency program and does not meet the definition for a single site residency program.
  - a. To conduct a multiple-site residency there must be a compelling reason for offering the training in a multiple-site format (that is, the program is improved substantially in some manner). For example:
    1. RPD has expertise, however the site needs development (for example, site has a good variety of patients, and potentially good preceptors, however the preceptors may need some oversight related to the residency program; or services need to be more fully developed);
    2. quality of preceptorship is enhanced by adding multiple sites;
    3. increased variety of patients/disease states to allow wider scope of patient interactions for residents;
    4. increased administrative efficiency to develop more sites to handle more residents across multiple sites/geographic areas;
    5. synergy of the multiple sites increases the quality of the overall program;
    6. allows the program to meet all of the requirements (that could not be done in a single site alone); and
    7. ability to increase the number of residents in a quality program.
  - b. A multiple-site residency program conducted in multiple hospitals that are part of a health-system that is considering CMS pass-through funding should conduct a

thorough review of 42CFR413.85 and have a discussion with the finance department to ensure eligibility for CMS funding.

- c. In a multiple-site residency program, a sponsoring organization must be identified to assume ultimate responsibility for maintaining authority and responsibility for the program's quality. This includes:
  - 1. designating a single residency program director (RPD);
  - 2. establishing a common residency purpose statement to which all residents at all sites are trained;
  - 3. assuring a core program structure and consistent required learning experiences;
  - 4. assuring the core required learning experiences are comparable in scope, depth, and complexity for all residents, if home based at separate sites;
  - 5. assuring a uniform evaluation process and common evaluation tools are used across all sites;
  - 6. assuring there are consistent requirements for successful completion of the program;
  - 7. designating a site coordinator to oversee and coordinate the program's implementation at each site that is used for more than 25% of the learning experiences in the program (for one or more residents); and,
  - 8. assuring the program has an established, formalized approach to communication that includes at a minimum the RPD and site coordinators to coordinate the conduct of the program across all sites.
  
- d. Programs that are managed by one corporate entity but are separated by distances requiring independent site surveys are considered to be separate residency programs and are therefore not multi-site.

## V. Definitions (Survey Team)

- A. **Lead Surveyor:** an expert pharmacist designated by ASHP's Director, Residency Accreditation Services, who coordinates and conducts the accreditation site survey in conjunction with a practitioner surveyor.
  
- B. **Practitioner Surveyor:** a pharmacist who is a subject matter expert and is typically an experienced residency program director in the residency area being surveyed (i.e., PGY1 or PGY2) who is trained to assist the lead surveyor in conducting an accreditation survey.

## VI. Authority

The program for accreditation of postgraduate residency programs is established by authority of the Board of Directors of ASHP and is implemented by the COC. All matters of policy relating to the accreditation of programs will be submitted for approval to the ASHP Board of Directors. The COC 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 COC shall be submitted to the Board of Directors for review and action as appropriate.

## **VII. Accreditation Procedures**

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

### **A. Application**

- a. Application forms are available on the ASHP website ([www.ashp.org](http://www.ashp.org)). The application must be signed by the residency program director, the pharmacist executive of the practice site, and the sponsoring organization's administrator. Applications should be submitted, along with the supporting documents specified in the application instructions, to ASHP's Accreditation Services Office ([asd@ashp.org](mailto:asd@ashp.org)) or mailed to ASHP, 4500 East West Highway, Suite 900, Bethesda, MD 20814. A duplicate copy should be retained for the applicant's files.
- b. The Vice President, Accreditation Services Office, or designee will acknowledge receipt of the application, and review it for completeness and to make a preliminary judgment about conformance to the basic requirements of the applicable accreditation standard(s). If the program fails to meet the criteria of the accreditation standard(s) in some fundamental way, the Vice President or designee will notify the signatories of the application accordingly and advise that the application has not been accepted.
- c. From the time an organization's application for pre-candidate status or for accreditation has been accepted by the Vice President, Accreditation Services Office, or designee, the program will be in either a pre-candidate or candidate status, respectively.
- d. Application for accreditation (candidate status) may be made as soon as a resident has begun training, but not sooner.
- e. Application for pre-candidate status may be made at any time prior to a resident beginning training.

### **B. Initial Site Survey**

- a. An accreditation survey team shall be assembled to conduct a site survey of the program, the organization and the pharmacy services. The survey team

generally consist of at least two individuals, the lead surveyor and the ASHP-designated practitioner surveyor.

- b. Upon the selection of the survey team, surveyors and programs must disclose potential conflict(s) of interest to ASHP's Vice President, Accreditation Services Office, who shall take appropriate actions to manage any conflict(s).
- c. For an initial site survey and at a mutually acceptable time (but not prior to the eighth month of the first residency year) ASHP will send the survey team to review the residency program, organization, and pharmacy services. Instructions for preparation for the site survey (e.g., list of documents to be made available to the survey team and suggested itinerary for the surveyors) will be sent to the residency program director well in advance of the site survey.
- d. Records (to include, residents' applications, residents' acceptance letters, residents' plans, all evaluations, residents' projects, and copies of certificates) for residents trained by an ASHP-accredited program 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.
- e. For multiple-site residency programs, the survey team will determine which sites will be visited during the site survey.
- f. A current resident or immediate past resident must be available during the accreditation survey.
- g. After concluding its site survey evaluation, the survey team will present a verbal report of its findings to the organization's administrator, residency program director, and pharmacist executive.

### **C. Scheduling of Reaccreditation Site Surveys**

- a. Sites with single programs:  
Reaccreditation survey visits will be scheduled within 12 months of the 8-year anniversary of the original site survey.
- b. Sites with multiple programs that submit a new program application:
  - 1. If the application is submitted within 3 years of the most recent survey visit, the survey will be scheduled per normal scheduling procedures (i.e., within the first year of the program's existence) with the survey itinerary to be determined by the lead surveyor assigned to the program. Subsequent site survey visits for the organization will be scheduled to accommodate review of all programs at the site during a single survey visit. Every effort will be made to schedule the combined survey such that no program will be reviewed for reaccreditation earlier than

4 years after their initial accreditation date or 3 years beyond the normal 8-year accreditation cycle.

2. If the application is submitted greater than 3 years after the most recent survey visit, the survey visit will include a review of the new program and all existing programs during a single visit.

#### **D. The Survey Report and Follow-up**

- a. Following the site survey, the survey team will prepare a written report, citing of noncompliance, partial compliance, and consultative recommendations. The written report will be sent to the residency program director, pharmacist and organization's administrator within approximately 30 days of the survey.
- b. The program must prepare and submit to ASHP, within 75 days of the end of the survey, an action plan and supporting documentation outlining how the program will address areas of noncompliance and partial compliance. This action plan will be signed by the residency program director, pharmacist executive, and the organization's administrator.
- c. Any written comments and supporting documentation that individuals from the program wish to make regarding the accuracy of the survey report submitted to the Vice President, Accreditation Services Office, within 10 business days of receiving the report. Comments regarding the report's accuracy must set forth the specific reasons for the disagreement with the survey report.
- d. The program's residency accreditation application file, the surveyors' report, written comments received from the program in response to the surveyors' findings will be reviewed by the COC. Typically, programs surveyed between May 8 and November 30 will be reviewed and evaluated at the following March meeting of the COC, and those surveyed between December 1 and May 7 will be reviewed and evaluated at the following August COC meeting.
- e. Notice of action taken regarding accreditation status will be sent to the residency program director, pharmacist executive, and organization's administrator, as soon as the Board of Directors has reviewed and accepted the COC meeting minutes. The report will indicate that ASHP has acted either:

(a) to accredit the program for a period not to exceed 8 years, (b) to accredit conditionally, or (c) to withhold accreditation. Additional reports to monitor compliance with accreditation standards may be requested at this time.

## **E. Accreditation**

- a. The COC will not recommend accreditation of a program until it has been in operation for one year and has had at least one graduate.
- b. If accreditation is granted, it shall be retroactive to the date on which ASHP's Vice President, Accreditation Services Office, received a valid and complete application for candidate status.
- c. Failure of the program to submit reports as requested may result in accreditation being withheld.
- d. A program granted accreditation will continue in an accredited status until the COC recommends further action.
- e. A certificate of accreditation will be issued to a program 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.
- f. Once the program is accredited, any reference by the program to accreditation by ASHP in residency promotional materials (e.g., catalogs, bulletins, web sites, or other form of publicity) and formal program documents including certificates must include the following statement: The *(residency program type, such as PGY-1 Pharmacy Residency)* conducted by *(organization name, city, and state)* is accredited by ASHP. Programs accredited by ASHP in partnership with other associations, must include the following statement: The *(residency program type, such as PGY-1 Pharmacy Residency)* conducted by *(organization name, city, and state)* is accredited by ASHP, in partnership with *(association name)*. The appropriate ASHP accredited logo may be used in conjunction with the above statements. Refer to the ASHP website for current instructions on logo use.

## **VIII. Continuing Accreditation**

- A. ASHP regards evaluation of accredited residency programs as a continuous process; accordingly, the COC shall request that directors of accredited programs submit periodic written status reports to assist the COC in evaluating the continued conformance of individual programs to the applicable accreditation standard(s).

Each year the residency program director shall be required to submit the Annual Residency Accreditation Report. To maintain accreditation, programs must comply with all requests from ASHP for written reports.

- B. Directors of accredited programs (and also those in the accreditation process: pre-



candidate and candidate) must submit written notification of substantive changes to the residency program to ASHP's Vice President, Accreditation Services Office, within 30 days of the change. Substantive changes include changes to leadership (e.g., changes in residency program director or pharmacist executive), content and construct of the program, and organizational ownership and accreditation. Residency program directors of multiple-site programs must get approval from ASHP's Accreditation Services Office prior to adding or removing a site. Directors of accredited programs must submit written notification of any adverse change in licensure or accreditation statuses with organizations or agencies including, but not limited to, TJC, DNV-GL, BOP, DOH, NCQA, URAQ, CMS, FDA, DEA, etc. Any substantive change in the organization of a program may be considered justification for re-evaluation of the program and/or a site survey.

- C. The COC will evaluate the credentials of each new residency program director using the requirements outlined in the applicable accreditation standard(s), and ASHP will notify the new program director of the results of the evaluation.
- D. When requested annually, residency program directors must provide ASHP's Vice President, Accreditation Services Office, a list of names of residents who have completed the program's requirements that year. This list must be provided through ASHP-approved technology systems (i.e., PharmAcademic).
- E. Unless exempted by the COC, all postgraduate year one and postgraduate year two residency programs in pre-candidate, candidate, conditional accreditation, or accredited status must participate in the Resident Matching Program conducted by ASHP. The COC may make recommendations regarding exemptions to this requirement.
- F. All programs in the accreditation process must use ASHP-approved technology systems to support and maintain the application process (i.e., PhORCAS) and residency program management (i.e., PharmAcademic).

## **IX. Reaccreditation**

- A. Accredited programs will be re-examined by site survey every 8 years. Schedule adjustments may be made in order to accommodate the addition of new programs. (See Section VII.C.)
- B. Records (to include, residents' applications, residents' acceptance letters, residents' plans, all evaluations, residents' projects, and copies of signed and dated certificates) for residents trained by an ASHP-accredited program since the last site survey (i.e., up to eight 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. A current resident or a recent past resident must be available on site during the reaccreditation survey.
- D. ASHP may accredit the program for a period not to exceed 8 years, award conditional accreditation, or withdraw accreditation.
- E. The COC, on behalf of ASHP, may request written reports at any time between the 8-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.

**X. Quality Improvement**

Following a site survey, ASHP's Vice President, Accreditation Services Office, will send the program director a thank-you letter and will provide a mechanism to evaluate the site survey team and process. This is an opportunity for the residency program director and pharmacist executive to provide feedback on the survey process and information for quality improvement of the accreditation process. Programs may submit constructive verbal or written comments to ASHP at any time (see paragraph VII.A.a. above, for address).

**XI. Accreditation Fees**

- A. An application fee shall be established by ASHP and shall be assessed to the program at the time of application for pre-candidate or candidate status.
- B. An annual accreditation fee, established by ASHP, shall be assessed for accredited residency programs and those programs in a pre-candidate, candidate, or conditional status. The annual 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). The fee schedule is posted on the ASHP web site.
- C. When there are multiple residents in a program and they are home-based (i.e., where a resident spends the majority of the year) in separate sites, or if a residency is conducted at multiple sites (sites where residents spend greater than 25% of the program time at one other site), the program will be assessed one-half of the annual fee for one program for each of the additional sites -- in addition to the base fee.
- D. Programs that are managed by one corporate entity but are separated by distances requiring independent site surveys are considered to be separate residency programs and will be assessed annual fees separately.

## **XII. 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 applicable accreditation standard(s) shall have accreditation withdrawn. In the event that an accreditation standard is revised, all accredited programs will be expected to meet the revised standard within 1 year.
  2. Inactive programs:
    - a. For sites with one residency program: accredited programs without a resident in training for a period of three consecutive years shall have accreditation withdrawn at the beginning of the fourth year. Annual accreditation fees must be paid.
    - b. For sites with more than one residency program: a program may remain vacant up to five years and maintain accredited status provided the residency program director for the program without a resident in training remains the same, the organization maintains at least one other ASHP-accredited program actively training residents during this time, and the program pays their annual fees. If the program director does not remain the same, the program shall have accreditation withdrawn at the beginning of the fourth year.
  3. A program makes false or misleading statements about the status, condition, or category of its accreditation.
  4. An accredited program fails to submit periodic written status reports as required or requested.
  5. An accredited program that is required to participate in the Resident Matching Program and fails to do so. ASHP may grant exceptions to the requirement to participate in the Resident Matching Program.
  6. A program that fails to submit appropriate annual accreditation fees as invoiced.
- B. ASHP shall not withdraw accreditation without first notifying the residency program director of the specific reasons. The program shall be granted an appropriate period of time to correct the deficiencies.
- C. Withdrawal of program accreditation may occur at any point during the residency year.
- D. The program shall have the right to appeal the final decision of ASHP.
- E. If accreditation is withdrawn, to regain accreditation the program may submit a new application and must undergo re-evaluation.
- F. Programs may voluntarily withdraw from the accreditation process and/or forfeit

accreditation at any time by notifying the Vice President, Accreditation Services Office, in writing. When notified, the Vice President, Accreditation Service Office, will report these programs to the COC and the ASHP Board.

### **XIII. Appeal of Decision**

- A. Notification of intent to appeal. In the event that a program is not accredited, is not reaccredited, is placed in a conditional status, or if accreditation is withdrawn, the residency program director, 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(s) to the program. An appellant must notify the Vice President, Accreditation Services Office, of the program's intent to appeal, by registered or certified 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 Vice President, Accreditation Services Office, 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 pharmacy residency programs, neither of whom is a member of the COC, one to be recommended by the appellant and one by the Chair of the COC. 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 Vice President, Accreditation Services Office, shall represent the COC at the hearing in an *ex officio*, nonvoting capacity. As soon as recommendations for appointments to the appeal board have been made, 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 COC in rendering its decision to the ASHP Board of Directors. ASHP General Counsel will send the documentation 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 Vice President, Accreditation Services Office. 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 program 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 COC. The appeal board shall advise the appellant organization of the appeal board's decision, by registered or certified mail, 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, COC-selected program director, and health care administrator shall be borne by ASHP.

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