



ACCREDITATION STANDARD FOR POSTGRADUATE YEAR ONE (PGY1) MANAGED CARE PHARMACY RESIDENCY PROGRAMS

**Prepared jointly by the American Society of Health-System Pharmacists
and the Academy of Managed Care Pharmacy**

Part I - Introduction

Definition: Postgraduate year one of pharmacy residency training is an organized, directed, accredited program that builds upon knowledge, skills, attitudes, and abilities gained from an accredited professional pharmacy degree program. The first-year residency program enhances general competencies in managing medication-use systems and supports optimal medication therapy outcomes for patients with a broad range of disease states.

Purpose of this Standard: The *ASHP Accreditation Standard for Postgraduate Year One (PGY1) Managed Care Pharmacy Residency Programs* (hereinafter the Standard) establishes criteria for systematic training of pharmacists for the purpose of achieving professional competence in the delivery of patient-centered care and in pharmacy operational services in managed care settings. Its contents delineate the requirements for ASHP-accreditation of PGY1 residencies that build upon the educational foundation provided through completion of an accredited Doctor of Pharmacy degree program. Completion of a PGY1 pharmacy residency serves as one of the prerequisites for postgraduate year two (PGY2) residencies and fellowships.

Purpose of PGY1 Managed Care Pharmacy Residencies: Residents in PGY1 residency programs are provided the opportunity to accelerate their growth beyond entry-level professional competence in patient-centered care and in pharmacy operational services, and to further the development of leadership skills that can be applied in any position and in any practice setting. PGY1 residents in managed care pharmacy are trained to deliver pharmaceutical care utilizing three practice models: 1) individual patient care in which the pharmacist communicates findings and recommendations to those health care providers who provide care directly to the patient; 2) care provided to targeted groups of patients in which the pharmacist designs, conducts, monitors and evaluates the outcomes of organized and structured programs; and 3) population care management in which the pharmacist develops and implements medication-use policy. Residents in integrated managed care settings are also trained for proficiency in the direct patient care model of practice. PGY1 residents acquire substantial knowledge required for skillful problem solving, refine their problem-solving strategies, strengthen their professional values and attitudes, and advance the growth of their clinical judgment. The instructional emphasis is on the progressive development of clinical judgment, a process begun

in the advanced pharmacy practice experiences (APPE or clerkships) of the professional school years but requiring further extensive practice, self-reflection, and shaping of decision-making skills fostered by feedback on performance. The residency year provides a fertile environment for accelerating growth beyond entry-level professional competence through supervised practice under the guidance of model practitioners. Specifically, residents will be held responsible and accountable for acquiring these outcome competencies: managing the drug distribution process; designing and implementing clinical programs; ensuring the safety and quality of the medication-use system; providing medication and practice-related information, education, and/or training; designing effective benefit structures; exercising leadership and practice management skills; and demonstrating project management skills.

Organization and Application of the Standard: Seven guiding principles provide the framework for the Standard. Each principle is restated at the beginning of the applicable segment of the Standard that outlines the specific requirements corresponding to the principle. The requirements serve as the basis for evaluating a residency program for accreditation and are followed by an interpretive narrative for those requirements needing more explanation.

Throughout the Standard use of the auxiliary verbs *will* and *must* implies an absolute requirement, whereas use of *should* and *may* denotes a recommended guideline.

The Standard sets forth the criteria used in the evaluation of practice sites that apply for accreditation. The accreditation program is conducted under the authority of the ASHP Board of Directors and is supported through a formal partnership with the Academy of Managed Care Pharmacy (AMCP). The *ASHP Regulations on Accreditation of Pharmacy Residencies*¹ sets forth the policies governing the accreditation program and describes the procedures for seeking accreditation.

Part II - Overview of the Principles of PGY1 Managed Care Pharmacy Residencies

Principle 1: The resident will be a pharmacist committed to attaining professional competence beyond entry-level practice.

Principle 2: The pharmacy residency program will provide an exemplary environment conducive to resident learning.

Principle 3: The resident will be committed to attaining the program's educational goals and objectives and will support the organization's mission and values.

Principle 4: The resident's training will be designed, conducted, and evaluated using a systems-based approach.

Principle 5: The RPD and most preceptors will be professionally and educationally qualified pharmacists. Some preceptors may be non-pharmacists who are content matter experts. The RPD and all preceptors must be committed to providing effective training of residents.

Principle 6: The organization conducting the residency will meet accreditation standards, regulatory requirements, and other nationally applicable standards and will have sufficient resources to achieve the purposes of the residency program.

Principle 7: The practice environment will be organized effectively and will deliver comprehensive, safe, and effective services.

Part III - Interpretation of the Principles

Principle 1: Qualifications of the Resident (The resident will be a pharmacist committed to attaining professional competence beyond entry-level practice.)

Requirement:

- 1.1 Residency applicant qualifications will be evaluated by the residency program director (RPD) through an established, formal procedure that includes an assessment of the applicant's ability to achieve the educational goals and objectives selected for the program. Further, the criteria used to evaluate applicants must be documented and understood by all involved in the evaluation and ranking process.

Interpretation of Requirement 1.1: A formal, criteria-based process to evaluate and rank program applicants must be in place. Possible criteria should include, but might not be limited to: assessment of the applicant's academic performance; attainment of appropriate knowledge, skills, attitudes, and abilities needed to achieve the stated educational goals and objectives selected for the residency program; and, letters of recommendation from faculty and employers. On-site personal interviews should be conducted. Ultimately, it is the responsibility of the RPD to assess the applicant's baseline knowledge, skills, attitudes, and abilities to determine that the applicant has met the qualifications for admission to the residency program.

- 1.2 The resident should be a graduate of an Accreditation Council for Pharmacy Education (ACPE)-accredited Doctor of Pharmacy degree program.

Interpretation of Requirement 1.2: For PGY1 pharmacy residencies it is clear that the Doctor of Pharmacy degree provides the applicant with the level of knowledge, skills, attitudes and abilities needed to meet program requirements. However, it is permissible to accept applicants who have graduated from ACPE-accredited Bachelor of Science (B.S.) in pharmacy degree programs.

- 1.3 The applicant must be licensed, or be eligible for licensure, in the state or jurisdiction in which the residency program is conducted. Consequences of failure to obtain appropriate licensure must be addressed as a policy issue by the organization conducting the residency.

Interpretation of Requirement 1.3: Since residency training is predicated upon accepting full responsibility and accountability for the care of patients, residents must obtain licensure to practice as a pharmacist, consistent with the requirements for pharmacists within the organization conducting the residency. Therefore, licensure must be obtained either prior to beginning the residency program or very soon afterwards.

- 1.4 Residents making application to residency programs that have applied for accreditation or that are accredited by ASHP must participate in and adhere to the rules of the Resident Matching Program (RMP) process.

Principle 2: Obligations of the Program to the Resident (The pharmacy residency program will provide an exemplary environment conducive to resident learning.)

Requirements:

- 2.1 Programs must be a minimum of twelve months and a full-time practice commitment or equivalent.
- 2.2 The residency program director (RPD) must ensure that neither the educational outcomes of the program nor the welfare of the resident or the welfare of patients are compromised by excessive reliance on residents to fulfill service obligations. Providing residents with a sound academic and clinical education must be planned and balanced with concerns for patient safety and resident well-being. Programs must comply with the current duty hour standards of the Accreditation Council for Graduate Medical Education (ACGME)².

Interpretation of Requirement 2.2 (added April 2011): Alternatively, from July 1, 2011 through June 30, 2013, programs will be granted a temporary exemption waiver from the current ACGME standard, and allowed to follow ACGME Common Program Requirements, VI – Resident Duty Hours in the Learning and Working Environment, effective July 1, 2007.

Interpretation of Requirement 2.2 (added April 2012): Effectively July 1, 2013 programs must comply with the Pharmacy Specific Duty Hours Requirements for the ASHP Accreditation Standard for Pharmacy Residencies approved in April 2012 (Duty Hours Appendix). Program will no longer be required to comply with the Accreditation Council for Graduate Medical Education (ACGME) duty hour standards.

- 2.3 Residency programs that are in pre-candidate, candidate, preliminarily accredited, and conditionally accredited status or are ASHP-accredited must adhere to the rules of the Resident Matching Program (RMP) process set forth in Rules for the Resident Matching Program).
- 2.4 The RPD must provide residents who are accepted into the program with a letter outlining their acceptance to the program. Information on the terms and conditions of the appointment must also be provided in a manner consistent with that provided to pharmacists within the organization conducting the residency. Acceptance by residents of these terms and conditions must be documented prior to the beginning of the residency.
- 2.5 The residency program must provide a sufficient complement of professional and technical pharmacy staff to ensure appropriate supervision and preceptor guidance to all residents.
- 2.6 The residency program must provide residents an area in which to work, access to appropriate technology, access to extramural educational opportunities (e.g., AMCP national meetings, ASHP Midyear Clinical Meeting, other pharmacy association meetings, a regional residency conference), and sufficient financial support to fulfill the responsibilities of the program.
- 2.7 Policies concerning professional, family, and sick leave and the effect such leaves would have on the resident's ability to complete the residency program must be documented.
- 2.8 The residency program must be capable of providing population and individual patient care activities necessary for development of residents' competence in the outcomes required in Principle 4 of this Standard.
- 2.9 The RPD will award a certificate of residency to those who complete the program. Reference must be made in the residency certificate that the program is accredited by ASHP in partnership with AMCP. The certificate must be issued in accordance with the provisions of the *ASHP Regulations on Accreditation of Pharmacy Residencies*¹ and signed by the RPD and the chief executive officer (or designee) of the organization. A certificate must not be issued to anyone who does not complete the program's requirements.

Interpretation of Requirement 2.8: For large corporate entities in which it is impractical to involve the chief executive officer in signing residency certificates, it is the intent of this requirement that an appropriate executive with ultimate authority over the residency join the RPD in signing the certificate of residency.

- 2.10 The RPD must ensure the program's compliance with the provisions of the current version of the *ASHP Regulations on Accreditation of Pharmacy Residencies*¹.

Principle 3: Obligations of the Resident to the Program (The resident will be committed to attaining the program's educational goals and objectives and will support the organization's mission and values.)

Requirements:

- 3.1 Residents' primary professional commitment must be to the residency program.

Interpretation of Requirement 3.1: A residency is a full-time obligation. Residents must manage their activities, external to the residency, so as not to interfere with the program defined in this Standard. It is permissible to admit on a part-time basis a resident who is employed by the residency site, another employer, or enrolled concurrently in a degree program, provided a clear distinction can be made between employment or academic responsibilities and the requirements of the residency. AMCP and ASHP assume no authority for evaluation of an academic program taken concurrently with a residency program. In any case, residents are responsible for making any changes necessary to meet the requirements for successful completion of the residency.

- 3.2 Residents must be committed to the values and mission of the organization conducting the residency program.
- 3.3 Residents must be committed to completing the educational goals and objectives established for the program.
- 3.4 Residents must seek constructive verbal and documented feedback that directs their learning.
- 3.5 Residents must be committed to making active use of the constructive feedback provided by residency program preceptors.

Principle 4: Requirements for the Design and Conduct of the Residency Program

(The resident's training will be designed, conducted, and evaluated using a systems-based approach.)

To ensure training efficiency and effectiveness, the program must use a systems-based approach to training design, delivery, and evaluation. Such an approach requires that there be a direct correlation among the expectations of resident performance, the type of instruction provided, and the evaluation of resident performance. The requirements in Principle 4 specify the products of a systems-based approach that may be examined during an onsite accreditation

survey but, beyond specifying broad RPD and preceptor participation in program decisions do not specify a particular process for producing these products. RPDs are free to develop their own systems-based approach to training or rely on the guidance and tools in the ASHP-endorsed *Residency Learning System (RLS)* and associated materials.^{3,4}

Requirements:

4.1 Program Design. The RPD and, when applicable, program preceptors will collaborate to design the residency program. The resulting design will include the following elements:

- a. The program will document its purpose (the type of practice for which the residents are to be prepared); its outcomes (the residency graduates' capabilities); its educational goals (broad, sweeping statements of abilities); and educational objectives (observable, measurable statements of resident performance, the sum of which ensure achievement of the educational goal) for each educational goal. The program's purpose will be reflected in the program's choice of outcomes. For each outcome there must be goals that further explain the capabilities specified by the outcome. For each goal there must be a set of educational objectives that specifies the resident performance to be measured.

- b. Programs must select all outcomes required by this standard. The required outcomes are as follows:
 - (1) Manage the drug distribution process for the organization's members.
 - (2) Design and implement clinical programs to enhance the efficacy of patient care.
 - (3) Ensure the safety and quality of the medication-use system.
 - (4) Provide medication and practice-related information, education, and/or training.
 - (5) Collaborate with plan sponsors to design effective benefit structures to service a specific population's needs.
 - (6) Exercise leadership and practice management skills.
 - (7) Demonstrate project management skills.

Programs must include all of the associated educational goals and educational objectives listed with these outcomes. The list of outcomes with their educational goals and educational objectives is published elsewhere.⁵ Programs may establish additional program outcomes with associated educational goals that emphasize program strengths. The same reference includes some potential additional (elective) program outcomes with associated educational goals and educational objectives.

Interpretation of Requirement 4.1.b: The published Residency Learning System (RLS) lists of outcomes, educational goals, and educational objectives also include instructional objectives to assist, when needed, in teaching. Instructional objectives are not required and are not meant to be evaluated.

- c. The program will create a structure (the designation of types, lengths, and sequence of learning experiences) that facilitates achievement of the program's educational

- goals and objectives. The structure must permit residents to gain experience in diverse patient populations, a variety of disease states, and a range of complexity of patient problems as characterized by a generalist's practice. Residents' experiences must include participation in the development of clinical plans for populations and for individual patients, with adequate time to acquire the individual patient-centered care objectives. Residency programs that are based in certain managed care practice settings (e.g., health maintenance organizations, pharmacy benefits management organizations, health plans) must ensure that the program's learning experiences meet the above requirements for diversity, variety, and complexity. No more than one-third of the twelve-month PGY1 pharmacy residency program may deal with a specific patient population or practice area (e.g., drug policy development, formulary management, drug information). The educational goals and objectives, including those for the project, will be assigned for teaching to a single learning experience or a sequence of learning experiences to allow sufficient practice for their achievement by residents. Programs may market the practice strengths they seek to develop as defined by their choice of program structure.
- d. Preceptors will create a description of their learning experience, and a list of activities to be performed by residents in the learning experience that demonstrates adequate opportunity to learn the educational goals and objectives assigned to the learning experience.
 - e. The program will create a competency-based approach to evaluation of resident performance of the program's educational goals and objectives, resident self-assessment of their performance, and resident evaluation of preceptor performance and of the program. The strategy will be employed uniformly by all preceptors. This three-part, competency-based approach will include provisions for the following:
 - (1) Preceptors conduct and document a criteria-based, summative assessment of each resident's performance of each of the respective program-selected educational goals and objectives assigned to the learning experience. This evaluation must be conducted at the conclusion of the learning experience (or at least quarterly for longitudinal learning experiences), reflect the resident's performance at that time, and be discussed by the preceptor with the resident and RPD. The resident, preceptor, and RPD must document their review of the summative evaluations.
 - (2) Each preceptor provides periodic opportunities for the resident to practice and document criteria-based, formative self-evaluation of aspects of their routine performance and to document criteria-based, summative self-assessments of achievement of the educational goals and objectives assigned to the learning experience. The latter will be completed on the same schedule as required of the preceptor by the assessment strategy and will include an end-of-the-year component.
 - (3) Residents complete an evaluation of the preceptor and of the learning experience at the completion of each learning experience (or at least quarterly in longitudinal learning experiences.) Residents should discuss their evaluations with the preceptor and must provide their evaluations to the RPD.

- 4.2 Program Delivery. To achieve systems-based training the program's design must be implemented fully, with ongoing attention to fulfillment of both preceptor and resident roles and responsibilities. In delivering the program the following must occur and be documented:
- a. The RPD and, when applicable, preceptors will conduct essential orientation activities. Residents will be oriented to the program to include its purpose, the applicable accreditation regulations and standards, designated learning experiences, and the evaluation strategy. When necessary, the RPD will orient staff to the residency program. Preceptors will orient residents to their learning experiences, including reviewing and providing written copies of the learning experience educational goals and objectives, associated learning activities, and evaluation strategies.
 - b. The RPD and, when applicable, preceptors will customize the training program for the resident based upon an assessment of the resident's entering knowledge, skills, attitudes, and abilities and the resident's interests. Any discrepancies in assumed entering knowledge, skills, attitudes, or abilities will be accounted for in the resident's customized plan. Similarly, if a criteria-based assessment of the resident's performance of one or more of the required educational objectives is performed and judged to indicate full achievement of the objective(s), the program is encouraged to modify the resident's program accordingly. This would result in changes to both the resident's educational goals and objectives and to the schedule for assessment of resident performance. The resulting customized plan must maintain consistency with the program's stated purpose and outcomes. Customization to account for specific interests must not interfere with achievement of the program's educational goals and objectives. The customized plan and any modifications to it, including the resident's schedule, must be shared with the resident and all preceptors.
 - c. Preceptors will provide ongoing, criteria-based verbal and, when needed, documented feedback on resident performance. Documented feedback will be used if there is limited direct contact with the preceptor (e.g., when non-pharmacist preceptors are utilized for learning experiences late in the residency) or verbal feedback alone is not effective in improving performance.
 - d. Preceptors will ensure that all aspects of the program's plan for assessment of resident performance, preceptor performance, and resident self-evaluation are completed.
 - e. RPDs and, when applicable, preceptors will establish a process for tracking residents' progress toward achievement of their educational goals and objectives. Overall progress toward achievement of the program's outcomes, through performance of the program's educational goals and objectives, will be assessed at least quarterly, and any necessary adjustments to residents' customized plans, including remedial action(s), will be documented and implemented.

- 4.3 Program Evaluation and Improvement. Program evaluation and improvement activities will be directed at enhancing achievement of the program's choice of outcomes. RPDs will evaluate potential preceptors based on their desire to teach and their aptitude for teaching (as differentiated from formal didactic instruction) and provide preceptors with opportunities to enhance their teaching skills. Further, RPDs will devise and implement a plan for assessing and improving the quality of preceptor instruction including, but not limited to, consideration of the residents' documented evaluations of preceptor performance. At least annually, RPDs and, when applicable, preceptors will consider overall program changes based on evaluations, observations, and other information.
- 4.4 Tracking of Graduates: The RPD should evaluate whether the residency produces the type of practitioner described in the program's purpose statement. (Information tracked may include initial employment, changes in employment, board certification, etc.)

Principle 5: Qualifications of the Residency Program Director (RPD) and Preceptors (The RPD and most preceptors will be professionally and educationally qualified pharmacists. Some preceptors may be non-pharmacists who are content matter experts. The RPD and all preceptors must be committed to providing effective training of residents.)

Requirements of the residency program director:

- 5.1 The RPD must be a licensed pharmacist who has either: a) completed an ASHP-accredited residency and have a minimum of three years of pharmacy practice experience, or b) has five or more years of practice experience with demonstrated mastery of the knowledge, skills, attitudes, and abilities expected of one who has completed a residency.
- 5.2 The RPD serves as the leader of the program, responsible not only for ensuring appropriate training overall and for precepting residents, but also for the evaluation and development of all other preceptors in the program. Therefore, the RPD must have documented evidence of his/her own ability to teach effectively in the managed care practice environment (e.g., through student and/or resident evaluations).
- 5.3 Each residency program must have a single RPD who must be a pharmacist from a practice site involved in the program or from a sponsoring organization.
- 5.4 A single RPD must be designated for multiple-site residencies or for a residency offered by a sponsoring organization in cooperation with one or more practice sites. The responsibilities of the RPD must be defined clearly, including lines of accountability for the residency and to the residency training site. Further, the designation of this individual to be RPD must be agreed to in writing by responsible representatives of each participating organization.

- 5.5 The RPD must have demonstrated ability to direct and manage a pharmacy residency program (e.g., previous involvement as a preceptor in an ASHP-accredited residency program, management experience, and previous academic experience as a course coordinator).
- 5.6 The RPD must have a sustained record of contribution and commitment to pharmacy practice that must be characterized by a minimum of four of the following:
- a. Documented record of improvements in and contributions to pharmacy practice.
 - b. Appointments to appropriate drug policy and other committees of the organization.
 - c. Formal recognition by peers as a model practitioner (e.g., board certification, fellow status).
 - d. A sustained record of contributing to the total body of knowledge in pharmacy practice through publications in professional journals and/or presentations at professional meetings.
 - e. Serving regularly as a reviewer of contributed papers or manuscripts submitted for publication.
 - f. Demonstrated leadership in advancing the profession of pharmacy through active service in professional organizations at the local, state, and national levels.
 - g. Demonstrated effectiveness in teaching (e.g., through student and/or resident evaluations, teaching awards).

Requirements of preceptors: (The RPD should document criteria for pharmacists and non-pharmacist content matter experts to be preceptors. The following requirements may be supplemented with other criteria.)

- 5.7 Preceptors must be licensed pharmacists who have either: a) completed an ASHP-accredited residency followed by a minimum of one year of pharmacy practice experience, or b) must demonstrate mastery of the knowledge, skills, attitudes, and abilities expected of one who has completed a PGY1 residency plus have a minimum of three years of pharmacy practice experience.
- 5.8 Preceptors must have training and experience in the area of pharmacy practice for which they serve as preceptors, must maintain continuity-of-practice in that area, and must be practicing in that area at the time residents are being trained.
- 5.9 Preceptors must have a record of contribution and commitment to pharmacy practice characterized by a minimum of four of the following:
- a. Documented record of improvements in and contributions to the respective area of advanced pharmacy practice or other area of expertise (e.g., implementation of a new service, active participation on a committee/task force resulting in practice improvement, development of treatment guidelines/protocols).
 - b. Appointments to appropriate drug policy and other committees of the department/organization.

- c. Formal recognition by peers as a model practitioner (e.g., board certification, fellow status).
 - d. A sustained record of contributing to the total body of knowledge in pharmacy practice or other area of expertise through publications in professional journals and/or presentations at professional meetings.
 - e. Serving regularly as a reviewer of contributed papers or manuscripts submitted for publication.
 - f. Demonstrated leadership in advancing the profession of pharmacy or other area of expertise through active participation in professional organizations at the local, state, and national levels.
 - g. Demonstrated effectiveness in teaching (e.g., through student and/or resident evaluations, teaching awards).
- 5.10 Preceptors must demonstrate a desire and an aptitude for teaching that includes mastery of the four preceptor roles fulfilled when teaching clinical problem solving (instructing, modeling, coaching, and facilitating). Further, preceptors must demonstrate abilities to provide criteria-based feedback and evaluation of resident performance. Preceptors must continue to pursue refinement of their teaching skills.
- 5.11 To develop a resident's practice competency it is critical that learning experiences be supervised by pharmacist preceptors who model pharmacy practice skills and provide regular criteria-based feedback. In selected learning experiences in the managed care environment (e.g., sales and marketing, contracting, pharmacoeconomic analysis) the most expert preceptor may be a non-pharmacist. In these limited situations it is permissible to use practitioners who are not pharmacists (e.g., physicians, actuaries, analysts, medical economists) as preceptors. In these instances, the RPD or pharmacist-designee must work closely with the non-pharmacist preceptor to select the educational goals and objectives as well as participate actively in the criteria-based evaluation of the resident's performance. Clinical learning experiences that are precepted by non-pharmacists must be conducted only at a point in the residency when the RPD and preceptors agree that the resident is ready for independent practice.

Principle 6: Minimum Requirements of the Site Conducting the Residency Program (The organization conducting the residency will meet accreditation standards, regulatory requirements, and other nationally applicable standards and will have sufficient resources to achieve the purposes of the program.)

Requirements:

- 6.1 As appropriate, residency programs must be conducted only in practice settings that have sought and accepted outside appraisal of facilities and patient care practices. The external appraisal must be conducted by a recognized organization appropriate to the practice setting.

- a. A health-system (inclusive of all components of the system that provide patient care) that offers or that participates in offering a pharmacy residency must be accredited by applicable organizations [e.g., The Joint Commission, American Osteopathic Association (AOA), National Committee for Quality Assurance (NCQA), Det Norske Veritas (DNV)].
- b. A college of pharmacy that participates in offering a pharmacy residency must be accredited by the Accreditation Council for Pharmacy Education (ACPE).
- c. Other practice settings that offer a pharmacy residency must have demonstrated substantial compliance with applicable professionally developed and nationally applied standards.

Interpretation 6.1 (added April 2011): If a hospital is state-certified as a Medicare and/or Medicaid single provider institution, the state's review process will meet the intent of this section.

- 6.2 Residency programs must be conducted only in those practice settings where management and professional staff have committed to seek excellence in patient care, demonstrated substantial compliance with professionally developed and nationally applied practice and operational standards, and have sufficient resources to achieve the educational goals and objectives selected for the residency program.
- 6.3 Two or more practice sites, or a sponsoring organization (e.g., college of pharmacy, health system) working in cooperation with one or more practice sites, may provide a pharmacy residency.
 - a. Pharmacy residencies are dependent on the availability of a sufficient patient population base and professional practice experience to satisfy the requirements of the residency program.
 - b. Sponsoring organizations must maintain authority and responsibility for the quality of their residency programs.
 - c. A mechanism must be established that designates and empowers an individual to be responsible for directing the residency program and for achieving consensus regarding the evaluation and ranking of applicants for the residency.
 - d. Sponsoring organizations and practice sites must have contractual arrangement(s) or signed agreement(s) that define clearly the responsibilities for all aspects of the residency program.
 - e. Each of the practice sites that provide residency training must meet the requirements set forth in Requirement 6.2 and the pharmacy's service requirements in Principle 7.

Interpretation of Requirement 6.3: Application for accreditation of a health-system or corporate-based, multiple-site pharmacy residency must be submitted in the name of the principal practice site (i.e., the practice site in which the majority of the residency program is centered).

In the case of a sponsoring organization (e.g., college of pharmacy, health system) that has a contractual arrangement with one or more practice settings to provide residency training, the application must be completed by the sponsoring organization.

The sponsoring organization, in making application for accreditation, must submit with the application the signed agreement(s) with the practice site(s) that define clearly the relationship, the governance, and the responsibility that will be borne by the organization and the practice site(s) for all aspects of the residency program.

Since the sponsoring organization may delegate day-to-day responsibility for the residency program to the practice site(s), the site(s) will be required to submit routine reports to the sponsoring organization. Some method of on-site inspection by a representative of the sponsoring organization must be in place to insure that the terms of the agreement are being met.

All reports and inspections must be documented and signed by representatives of all parties bound by the agreement and will be made available to the accreditation survey team.

Principle 7: Qualifications of the Practice Environment (The practice environment will be organized effectively and will deliver comprehensive, safe, and effective services.)

The most current edition of the ASHP *Best Practices for Health-System Pharmacy*, available at www.ashp.org, (and, when necessary, other pharmacy association guides to professional practice that apply to specific practice environments) will be utilized in evaluating any practice environment providing pharmacy residency training.

Requirements:

- 7.1 The practice environment must be led and managed by a professionally competent, legally qualified pharmacist who is responsible for insuring compliance with requirements for the practice environment as outlined in this Principle.
- 7.2 The pharmacy services must be an integral part of the pharmacy practice site in which the residency program is offered, as evidenced by the following (as appropriate to the practice environment):
 - a. The scope of pharmacy services provided to patients at the practice site is based upon an assessment of pharmacy functions needed to provide care to all patients served by the practice site.
 - b. The services are of a scope and quality commensurate with identified patient needs.
 - c. Pharmacy personnel are involved in the overall planning of patient care services for the practice setting.

- d. Pharmacy services extend to all areas of the practice site in which medications for patients are prescribed, dispensed, administered, and monitored.
 - e. Pharmacists are responsible around-the-clock for the procurement, preparation, distribution, and control of all medications used, including those that are investigational.
- 7.3 The pharmacist who has ultimate responsibility for the residency practice site/pharmacy environment in which the residency program is conducted must provide effective leadership and management for the achievement of short- and long-term goals of the practice environment and the organization relating to medication use and medication-use policies. This pharmacist must ensure that the following elements associated with a well-managed practice environment are in place (as appropriate to the practice environment):
- a. A pharmacy services mission statement.
 - b. A written document describing the scope and depth of pharmacy services.
 - c. A well-defined pharmacy organizational structure.
 - d. A description of pharmacy services provided.
 - e. Documented short- and long-term pharmacy services goals.
 - f. Current policies and procedures that are readily available to staff participating in service provision.
 - g. Position descriptions for all categories of pharmacy personnel.
 - h. Systems to document pharmacy workload, financial performance, and patient care outcomes data.
 - i. Pharmacy personnel involvement with key committees involving medications and patient care.
 - j. A quality improvement plan.
- 7.4 The practice environment:
- a. Complies with all applicable federal, state, and local laws, codes, statutes, and regulations governing pharmacy practice.
 - b. Demonstrates substantial compliance with national practice standards and guidelines.
 - c. Regularly reviews and develops plans to conform to new practice standards or guidelines.
 - d. Has sought and accepted outside appraisals of its facilities and patient care practices (as appropriate to the practice environment.)
- 7.5 Any pharmacy utilized for resident training must provide a safe and effective drug distribution system for all medications used within the practice environment. This system must include the following components (as applicable to the practice environment):
- a. A unit-dose drug distribution service that includes packaging equipment adequate to prepare medications for unit-dose dispensing or compliance packaging.
 - b. An intravenous admixture and sterile product service.

- c. An investigational drug service.
- d. An extemporaneous compounding service.
- e. A system for the safe use of drug samples.
- f. A system for the safe use of emergency medications.
- g. A controlled substance floor-stock system.
- h. A controlled floor-stock system.
- i. An outpatient drug distribution service.
- j. A system for the safe handling of vaccines.
- k. A system for the safe handling of emergency-preparedness medications.

7.6 The practice environment must provide the necessary population and patient care services in a manner consistent with practice environment capabilities and patient needs.

- a. The following activities must be provided in collaboration with other health-care professionals to optimize medication therapy for patients:
 - (1) Membership on interdisciplinary teams in healthcare areas associated with the residency program.
 - (2) Development of treatment protocols, critical pathways, order sets, and other systems approaches involving medications for patients.
 - (3) Participation in collaborative practice agreements with other providers and management of patients following collaborative practice agreements, treatment protocols, critical pathways, etc.
 - (4) Prospective participation in the development of clinical plans for populations and individual patients.
 - (5) Identification of medication-related problems.
 - (6) Mechanisms for review of the appropriateness and safety of medication orders or prescriptions.
 - (7) Design and implementation of medication-therapy monitoring plans.
 - (8) Documentation of all significant patient care recommendations and resulting actions, treatment plans, and/or progress notes in the appropriate section of the organization's clinical information system.
 - (9) Written and oral consultations regarding medication-therapy selection and management.
 - (10) Patient disease and/or drug therapy management programs consistent with laws, regulations, and practice site policy.
 - (11) Medication administration consistent with laws, regulations, and practice site policy.
 - (12) Preventive and wellness programs.
 - (13) A system to ensure and support continuity-of-care.
- b. Essential drug information activities that must be provided by pharmacy staff and the residents include, but are not limited to, the following (as applicable to the practice environment):
 - (1) Developing and maintaining a formulary.

- (2) Publishing periodic newsletters or bulletins for health-care providers on timely medication-related matters and medication policies.
- (3) Preparing medication therapy monographs based on an analytical review of pertinent biomedical literature, including a safety assessment and a comparative therapeutic and economic assessment of each new agent for formulary addition or deletion.
- (4) Establishing and maintaining a system for retrieving drug information from the literature.
- (5) Responding to drug information inquiries from health-care providers.
- (6) Conducting educational programs about medications, medication therapy, and other medication-related matters for health-care providers.
- (7) Participating in the development or modification of policies related to: (a) medications; (b) medication-use evaluation; (c) adverse drug event prevention, monitoring, and reporting; and (d) appropriate methods to assess ongoing compliance with such policies.

7.7 Pharmacy staff must provide leadership and participate with other health professionals in the following systems to ensure safe and effective patient care outcomes and to continuously improve the medication-use system used in the practice environment (as applicable to the practice environment):

- a. A system to support and actively participate in decision-making concerning the pharmacy and therapeutics function, including the preparation and presentation of drug-therapy monographs.
- b. A system to review medication-use evaluations and to implement new policies or procedures to improve the safe and effective use of medications.
- c. A system to review adverse drug event reports and to implement new policies and procedures to improve medication safety.
- d. A system to evaluate routinely the quality of pharmacy services provided.

7.8 The practice environment must have personnel, facilities, and other resources to carry out the scope of pharmacy services applicable to the practice environment. The pharmacy's:

- a. Facilities are constructed, arranged, and equipped to promote safe and efficient work.
- b. Automated medication systems and software support a safe medication-use system.
- c. Computerized systems support a safe medication-use system.
- d. Professional and technical staff is sufficient in number and of the diversity to ensure that the department can provide the level of service required by all patients served. In instances where resources limit the delivery of pharmacy services to all patients receiving medication therapy, mechanisms are in place to identify those patients who might benefit most from these services, and a plan is in place to work toward meeting these needs.
- e. Professional staff members seek professional enrichment and demonstrate their interest in continuing competence.

- f. Technical and clerical staff complement is sufficient to handle all functions that can be assigned appropriately to them.

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The effective date for implementation of this standard is commencing with the entering resident class for 2008.

GLOSSARY

Certification. A voluntary process by which a nongovernmental agency or an association grants recognition to an individual who has met certain predetermined qualifications specified by that organization. This formal recognition is granted to designate to the public that the individual has attained the requisite level of knowledge, skill, or experience in a well defined, often specialized, area of the total discipline. Certification usually requires initial assessment and periodic reassessments of the individual's qualifications.⁶

Customization. The process by which a residency's generic plan for training (program outcomes; educational goals; educational objectives; structure; learning activities; extent of modeling, coaching, and facilitation; and, assessment strategy for preceptor and self-evaluation) are modified to account for the strengths, weaknesses, and interests of the resident to help ensure that each resident's training is optimal.

Drug distribution process in the managed care setting. The pharmacist in the managed care setting manages the drug distribution process through one of four approaches:

1. Through the managed care organization's pharmacies. Some managed care organizations operate their own pharmacies. These in-house pharmacies often provide enhanced pharmaceutical services because they are members of a fully integrated patient care system. Managed care pharmacists ensure that the services delivered by these "in-house" pharmacies are of the highest quality.
2. Through community pharmacies. Managed care organizations contract with broad-based networks of participating pharmacies to fill the prescriptions of their members. Managed care pharmacists manage the pharmacy network, perform drug utilization reviews, minimize fraud and abuse and initiate quality assurance programs to ensure that the organization's members have local access to high quality, affordable pharmacy services.
3. Through mail order or online services. Some managed care organizations own or contract with mail order and/or online pharmacies. Managed care pharmacists manage these services to ensure quality.
4. Through collaboration with physicians and other health care professionals. Pharmacists within managed care organizations review patients' drug profiles to help safeguard against unintended side effects in new and existing prescriptions. They work with prescribers and other health care professionals to ensure that the drugs prescribed are: eligible for coverage, of high quality, affordable, and projected to do no harm. The managed care organization has access to several databases of information that lead to a coordinated and safe drug distribution process.

Interdisciplinary team. A team composed of members from different professions and occupations with varied and specialized knowledge, skills, and methods. The team members integrate their observations, bodies of expertise, and spheres of decision making to coordinate, collaborate, and communicate with one another in order to optimize care for a patient or group of patients. (Institute of Medicine. Health professions education: a bridge to quality. Washington, DC: The National Academy Press; 2001.)

Multiple-site residency. a residency site structure in which multiple organizations or practice sites are involved in the residency program. Examples include programs in which: residents spend greater than 25% of the program away from the sponsoring organization/main site at another single site; or there are multiple residents in a program and they are home-based in separate sites.

1. To run 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:
 - a. 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);
 - b. quality of preceptorship is enhanced by adding multiple sites;
 - c. increased variety of patients/disease states to allow wider scope of patient interactions for residents;
 - d. increased administrative efficiency to develop more sites to handle more residents across multiple

- sites/geographic areas;
 - e. synergy of the multiple sites increases the quality of the overall program;
 - f. allows the program to meet all of the requirements (that could not be done in a single site alone); and
 - g. ability to increase the number of residents in a quality program.
2. 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.
 3. In a multiple-site residency program, a sponsoring organization must be identified to assume ultimate responsibility for coordinating and administering the program. This includes:
 - a. designating a single residency program director (RPD);
 - b. establishing a common residency purpose statement to which all residents at all sites are trained;
 - c. assuring a core program structure and consistent required learning experiences;
 - d. assuring the core required learning experiences are comparable in scope, depth, and complexity for all residents, if home based at separate sites.;
 - e. assuring a uniform evaluation process and common evaluation tools are used across all sites;
 - f. assuring there are consistent requirements for successful completion of the program;
 - g. 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,
 - h. 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

Patient-centered care in the managed care setting. The managed care setting embraces four practice models for the delivery of patient-centered pharmaceutical care.

1. Direct patient care. There is a 1:1, face-to-face (or over the phone) interpersonal relationship between the pharmacist and the patient.
2. Individual patient care. The pharmaceutical care activities performed by the pharmacist do not all occur in direct collaboration with the patient and are typically implemented through others (by communicating findings and recommendations to those health care providers who are providing care directly to the patient). The pharmacist works with comprehensive clinical data sets belonging to a single patient., identifies drug-related problems, modifies existing or establishes new evidence-based therapeutic regimens, designs patient education strategies and monitoring plans, then implements the plans and strategies either directly or through other health care providers. Medication Therapy Management programs under Medicare Part D often take this form.
3. Care provided to targeted groups of patients. This model includes activities such as the design, conduct, monitoring, and evaluation of outcomes of a variety of organized and structured programs including those targeted at specific disease states or at-risk populations (e.g. the elderly or patients taking 10 or more chronic medications). Pharmacists practicing in the model may develop, implement, and monitor case-finding strategies; conduct risk assessments, develop practice guidelines, drug therapy algorithms and strategies; evaluate effectiveness and outcomes; communicate strategies between providers; and maintain relationships with payers to assure coverage.
4. Population care management. Pharmacists are involved in formulary management; drug use policy development and application; automatic prescription refill programs accompanied with adherence/persistence assessment methodologies; and drug benefit design and evaluation.

Preceptor. an expert pharmacist who gives practical experience and training to a pharmacy resident. Preceptors have responsibility for the evaluation of resident performance.

Plan sponsor. The company that assumes financial responsibility for an insured group. A plan sponsor can be an insurance company, third-party administration, or the company itself, if the company is self-insured. (AMCP. Glossary of managed care terms. AMCP web site accessed October 19, 2006

<http://amcp.org/amcp.ark?c=stu&sc=glossary>.)

Residency program director. 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.

Service commitments. Clinical and operational practice activities. May be defined in terms of the number of hours, types of activities, or a set of educational goals and objectives.⁷

Single-site residency. a residency site structure in which the practice site assumes total responsibility for the residency program. In a single-site residency, a minimum of 60% of the resident's training program occurs at the site (that is, the locations must be within walking distance and be part of the same health system); however, residents may spend assigned time in short elective learning experiences off-site (that is, a one-month rotation offsite does not make a program a multiple-site residency). Conversely, 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.

Site. the actual practice location where the residency experience occurs.

Site Coordinator. a preceptor 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 minimum requirements to serve as a preceptor (meets the criteria identified in Principle 5.9 of the appropriate pharmacy residency accreditation standard);
2. practice at the site at least ten hours per week;
3. have the ability to teach effectively in a clinical practice environment; and
4. have the ability to direct and monitor residents' and preceptors' activities at the site (with the RPD's direction).

Sponsoring organization. The organization assuming ultimate responsibility for the coordination and administration of the residency program. The sponsoring organization is charged with ensuring that the resident 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 are conducted. If several organizations share responsibility for the financial and management aspects of the residency (e.g., school of pharmacy, health-system, and individual site), the organizations must mutually designate one organization as the sponsoring organization.

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Pharmacy Specific Duty Hours Requirements For the ASHP Accreditation Standards for Pharmacy Residencies

This applies to requirement 2. 2 in the following ASHP Accreditation Standards:

Postgraduate Year One (PGY1) Pharmacy Residency Programs

Postgraduate Year One (PGY1) Community Pharmacy Residency Programs

Postgraduate Year One (PGY1) Managed Care Pharmacy Residency Programs

Postgraduate Year One (PGY1) Pharmacy Residency Programs – International

Postgraduate Year Two (PGY2) Pharmacy Residency Programs

Definitions:

Duty Hours: Duty hours are defined as all scheduled clinical and academic activities related to the pharmacy residency program. This includes inpatient and outpatient care, in-house call, administrative duties, scheduled and assigned activities, such as conferences, committee meetings, and health fairs that are required to meet the goals and objectives of the residency program. Duty hours must be addressed by a well-documented, structured process.

Duty hours do not include: reading, studying, and academic preparation time for presentations, journal clubs; or travel time to and from conferences; and hours that are not scheduled by the residency program director or preceptor.

Scheduled duty periods: Assigned duties, regardless of setting, that are required to meet the educational goals and objectives of the residency program. These duty periods are usually assigned by the residency program director or preceptor and may encompass hours which may be within the normal work day, beyond the normal work day, or a combination of both.

Moonlighting: Voluntary, compensated, pharmacy-related work performed outside the organization (external), or within the organization where the resident is in training (internal), or at any of its related participating sites. These are compensated hours beyond the resident's salary and are not part of the scheduled duty periods of the residency program.

Continuous Duty: Assigned duty periods without breaks for strategic napping or resting to reduce fatigue or sleep deprivation.

Strategic napping: Short sleep periods, taken as a component of fatigue management, which can mitigate the adverse effects of sleep loss.

DUTY HOURS

Residents, program directors and preceptors have the professional responsibility to ensure they are fit to provide services that promote patient safety. The RPD must ensure that there is not excessive reliance on residents to fulfill service obligations that do not contribute to the educational value of the residency program or that may compromise their fitness for duty and endanger patient safety. Providing residents with a sound training program must be planned, scheduled and balanced with concerns for patient safety and resident's well-being. Therefore, programs must comply with the following duty hour requirements:

I. Personal and Professional Responsibility for Patient Safety

- A. Residency program director must educate residents and preceptors concerning their professional responsibilities to be appropriately rested and fit for duty to provide services required by the patients and health care.
- B. Residency program directors must educate residents and preceptors to recognize signs of fatigue and sleep deprivation, and adopt processes to manage negative effects of fatigue and sleep deprivation to ensure safe patient care and successful learning.
- C. Residents and preceptors must accept personal and professional responsibility for patient care that supersedes self interest. At times, it may be in the best interest of the patient to transition the care to another qualified, rested provider.
- D. If the program implements any type of on-call programs, there must be a written description that includes:
 - The level of supervision a resident will be provided based on the level of training and competency of the resident and the learning experiences expected during the on-call period
 - Identification of a backup system, if the resident needs assistance to complete the responsibilities required of the on-call program.
- E. The residency program director must ensure that residents participate in structured handoff processes when they complete their duty hours to facilitate information exchange to maintain continuity-of-care and patient safety.

II. Maximum Hours of Work per Week and Duty Free Times

- A. Duty hours must be limited to 80 hours per week, averaged over a four-week period, inclusive of all in-house call activities and all moonlighting.

- B. Moonlighting (internal or external) must not interfere with the ability of the resident to achieve the educational goals and objectives of the residency program.
 - 1. All moonlighting hours must be counted towards the 80-hour maximum weekly hour limit.
 - 2. Programs that allow moonlighting must have a documented structured process to monitor moonlighting that includes at a minimum:
 - a. The type and number of moonlighting hours allowed by the program.
 - b. A reporting mechanism for residents to inform the residency program directors of their moonlighting hours.
 - c. A mechanism for evaluating residents overall performance that may affect residents' judgment while on scheduled duty periods or impact their ability to achieve the educational goals and objectives of their residency program and provide safe patient care.
 - d. A plan for what to do if residents' participation in moonlighting affects their judgment while on scheduled duty hours.
- C. Mandatory time free of duty: residents must have a minimum of one day in seven days free of duty (when averaged over four weeks). At-home call cannot be assigned on these free days.
- D. Residents should have 10 hours free of duty between scheduled duty, and must have at a minimum 8 hours between scheduled duty periods.
- E. If a program has a 24 hour in-house call program, residents must have at least 14 hours free of duty after the 24 hours of in-house duty.

III. Maximum Duty Period Length

- A. Continuous duty periods of residents should not exceed 16 hours. The maximum allowable duty assignment must not exceed 24 hours even with built in strategic napping or other strategies to reduce fatigue and sleep deprivation, with an additional period of up to two hours permitted for transitions of care or educational activities.
- B. In-House Call Programs
 - 1. Residents must not be scheduled for in-house call more frequently than every third night (when averaged over a four-week period).
 - 2. Programs that have in-house call programs with continuous duty hours beyond 16 hours and up to 24 hours must have a well-documented structured process that oversee these programs to ensure patient safety, resident well-being, and provides a supportive, educational environment. Well-documented, structured process must include at a minimum:
 - a. How the program will support strategic napping or other strategies for fatigue and sleep deprivation management for continuous duty beyond 16 hours.

b. A plan for monitoring and resolving issues that may arise with residents' performance due to sleep deprivation or fatigue to ensure patient care and learning are not negatively affected.

C. At-Home or other Call Programs

1. At-home call must not be so frequent or taxing as to preclude rest or reasonable personal time for each resident.
2. Program directors must have a method for evaluating the impact on residents of the at-home or other call program to ensure there is not a negative effect on patient care or residents' learning due to sleep deprivation or serious fatigue.
3. Program directors must define the level of supervision provided to residents during at-home or other call.
4. At-home or other call hours are not included in the 80 hours a week duty hour's calculation, unless the resident is called into the hospital/organization.
5. If a resident is called into the hospital/organization from at-home or other call program, the time spent in the hospital/organization by the resident must count towards the 80-hour maximum weekly hour limit.
6. The frequency of at-home call must satisfy the requirement for one-day-in-seven free of duty, when averaged over four weeks. No at-home call can occur on the day free of duty.

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