GUIDANCE DOCUMENT FOR THE
ASHP ACCREDITATION STANDARD FOR POSTGRADUATE YEAR TWO (PGY2) PHARMACY RESIDENCY PROGRAMS

Guidance Updated March 2021

Guidance Document Introduction

Interpretation for many sections of the Standard is provided in this Guidance Document in boxes following each section of the Standard. The interpretation is provided to help programs better understand their level of compliance with the Standard and describes how compliance with the Standard will be evaluated by accreditation surveyors. Accreditation decisions are made based on integration of all components of the Standard and their relationship to each other; however, programs that follow the descriptions provided are most likely to have a successful accreditation survey.

The “How It Will Be Surveyed” sections in the Guidance Document provide information about how surveyors will review programs during accreditation surveys. In general, programs are surveyed using three processes: (1) review of documentation; (2) discussion with the RPD, preceptors, residents and others; and, (3) observation, such as during a tour of facilities, or other observations. These sections of the Guidance Document include information about documentation that will be reviewed, types of discussions, and observations and tours that will take place.

Introduction

Purpose of this Standard: the ASHP Accreditation Standard for Postgraduate Year Two (PGY2) Pharmacy Residency Programs (hereinafter the Standard) establishes criteria for systematic training of pharmacists in advanced areas of pharmacy practice. Its contents delineate the requirements for PGY2 residencies, which build upon the foundation provided through completion of an accredited Doctor of Pharmacy degree program and an accredited postgraduate year one (PGY1) pharmacy residency program.

PGY2 Program Purpose: PGY2 pharmacy residency programs build on Doctor of Pharmacy (Pharm.D.) education and PGY1 pharmacy residency programs to contribute to the development of clinical pharmacists in specialized areas of practice. PGY2 residencies provide residents with opportunities to function independently as practitioners by conceptualizing and integrating accumulated experience and knowledge and incorporating both into the provision of patient care or other advanced practice settings. Residents who successfully complete an accredited PGY2 pharmacy residency are prepared for advanced patient care, academic, or other specialized positions, along with board certification, if available.

Application of the Standard: the requirements serve as the basis for evaluating PGY2 pharmacy residency programs for accreditation.

PGY2 pharmacy residencies are offered in a variety of practice environments and may focus on specific practice areas, patient populations, and/or disease states. Therefore, a corresponding set of educational goals and objectives1 has been developed for many of the practice settings and areas of practice (e.g., critical care, drug information, geriatrics, oncology, health-system pharmacy administration, ambulatory care). Each takes into account the unique elements of the practice site and the focused area of practice. To structure the PGY2 residency, the program must use the set of educational goals and objectives that
best corresponds to the practice site and the focused area of practice. These educational goals and objectives must be used with this Standard, and the appropriate selection and use of them will be evaluated in site surveys for accreditation.

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 describes the criteria used in 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 formal partnerships with several other pharmacy associations. The ASHP Regulations on Accreditation of Pharmacy Residencies describes the policies governing the accreditation program and procedures for seeking accreditation.

Overview of the Standards for PGY2 Pharmacy Residencies

Standard 1: Requirements and Selection of Residents
PGY2 residents must be pharmacists having sufficiently broad knowledge, skills, attitudes, and abilities in pharmacy practice necessary for further professional development at an advanced level of pharmacy practice.

Standard 2: Responsibilities of the Program to the Resident
It is important that pharmacy residency programs provide an exemplary environment for residents’ learning. This area indicates policies that must be in place to help protect residents and organizations during unusual situations that may arise with residency programs (e.g., extended leaves, dismissal, duty hours).

Standard 3: Design and Conduct of the Residency Program
It is important that residents’ training enables them to achieve the purpose, goals, and objectives of the residency program. Residents should develop into more mature, clinically competent, and independent practitioners able to address patients’ needs. Proper design and implementation of programs helps ensure successful residency programs.

Standard 4: Requirements of the Residency Program Director and Preceptors
The residency program director (RPD) and preceptors are critical to the residency program’s success and effectiveness. Their qualifications and skills are crucial. Therefore, the RPD and preceptors will be professionally and educationally qualified pharmacists who are committed to providing effective training of residents and being exemplary role models for residents.

Standard 5: Requirements of the Site Conducting the Residency Program
It is important that residents learn to incorporate best practices into their future roles; therefore, the organization conducting the residency must meet accreditation standards, regulatory requirements, and other nationally applicable standards and will have sufficient resources to achieve the purposes of the residency program.

Standard 6: Pharmacy Services
When pharmacy facilities and services provide the learning environment where residents are trained, it is important that they train in exemplary environments. Residents’ expectations as they leave residency programs should be to strive for exemplary pharmacy services to improve patient care outcomes. Pharmacy’s role in providing effective leadership, quality improvement efforts, appropriate organization, staffing, automation, and collaboration with others to provide safe and effective medication-use systems
are reviewed in this section. This section encourages sites to continue to improve and advance pharmacy services and should motivate the profession to continually improve patient care outcomes.

**Standard 1: Requirements and Selection of Residents**

1.1 The applicant must be participating in, or have completed, an ASHP-accredited PGY1 pharmacy residency program or one in the ASHP accreditation process (i.e., one with candidate or preliminary accreditation status).

1.2 The RPD or designee must evaluate the qualifications of applicants to pharmacy residencies through a documented and formal procedure based on predetermined criteria, which includes an assessment of applicants’ ability to achieve the educational goals and objectives selected for the program.

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<td><strong>1.1</strong> is a critical factor (see Glossary for definition of “critical factor”). This procedure may appear in the residency manual or other readily available pharmacy department documents. The procedure needs to be documented but it does not need to be a formal pharmacy department policy. Predetermined criteria used to evaluate applicants are documented. Process of verifying that residents accepted into the program completed a PGY1 residency is defined.</td>
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<td>Review of:</td>
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<td>• formal, documented procedure.</td>
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<td>• predetermined criteria used to select applicants to interview and rank.</td>
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<td>• review of PGY1 residency certificates.</td>
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1.3 The predetermined criteria and procedure used to evaluate applicants’ qualifications must be used by all involved in the evaluation and ranking of applicants.

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<td>Review of procedure and criteria</td>
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<td>Discussion with preceptors/RAC members.</td>
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1.4 Applicants to pharmacy residencies must be graduates of an Accreditation Council for Pharmacy Education (ACPE) accredited degree program (or one in process of pursuing accreditation) or have a Foreign Pharmacy Graduate Equivalency Committee (FPGEC) certificate from the National Association of Boards of Pharmacy (NABP). At a minimum, the program must be a five-year pharmacy degree program.

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<td>This information is included in the criteria required in Standard 1.1 (criteria to evaluate qualifications of applicants).</td>
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<td>Review of residents’ Academic and Professional Records and the documented procedure described above in Standard 1.1.</td>
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1.5 Applicants to pharmacy residencies must be licensed or eligible for licensure (or equivalent designation for the country conducting the residency, e.g., registered) in the state, country,
or jurisdiction in which the program is conducted.

**Guidance**
Jurisdiction pertains only to federal facilities (e.g., VA, DOD, PHS, IHS, BOP) in which pharmacists may practice as long as they maintain license in any state or U.S. territory.

1.6 Consequences of residents’ failure to obtain appropriate licensure either prior to or within 90 days after the start date of the residency must be addressed in written policy of the residency program.

**Guidance**
1.6 is a critical factor (see Glossary for definition of “critical factor”). The policy can appear in the residency manual or other readily available pharmacy department documents.

Program documents how resident’s plan will be modified if the resident isn’t licensed prior to, or within, 90 days. (Examples: dismiss, extend, suspend and restart when licensed).

Programs ensure a minimum of 2/3 of residency is completed as a pharmacist licensed to practice in the program’s jurisdiction.

1.7 Requirements for successful completion and expectations of the residency program must be documented and provided to applicants invited to interview, including policies for professional, family, and sick leave; consequences of any such leave on residents’ ability to complete the residency program; and for dismissal from the residency program.

1.7.a. These policies must be reviewed with residents once they have started the program and be consistent with the organization’s human resources policies.

**Guidance**
Program policies, requirements for successful completion of the program, and expectations of residents in the program are provided (either in print or electronically) to interviewees prior to or on the interview date.

Program policies appear in the residency manual (written or electronic) or other readily available pharmacy department documents.

The following policies and procedures are documented:
- Dismissal policy
  (Dismissal or disciplinary policy must address consequences of failure to progress)
- Licensure
- Moonlighting
- Duty hours
- Tracking of duty hours and moonlighting
- Professional, family, sick and extended leave. Consequences of professional, family, sick and extended leave on residents’ ability to complete the residency program must include whether the leave will result in dismissal from the program or if the program allows for extension of the program in order to allow residents to complete all program requirements, including the requirement for a minimum of twelve months of training.

Programs have a list of requirements and expectations for completion of the residency program that address at minimum:
- Achievement of the program’s educational goals and objectives (e.g., designate % achieved, specify objectives that must be achieved, or as defined by the program)
- List of required duties and responsibilities
- List of products requiring completion
• List of required presentations
The list of requirements for successful completion must match the list used to document resident’s completion of program requirements (see guidance for 2.7a).
Policies and procedures must be consistent with human resources policies and procedures, and must be consistent among themselves and what is provided to the resident.

**How it will be surveyed**
Review of documents given to applicants invited to interview to determine inclusion of items listed in the Standard.

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**Standard 2: Responsibilities of the Program to the Resident**

2.1 Programs must be a minimum of twelve months and a full-time practice commitment or equivalent.

2.1.a. Non-traditional residency programs must describe the program’s design and length used to meet the required educational competency areas, goals, and objectives.

**Guidance**
Residents taking leave greater than the paid leave (i.e., vacation, sick, holiday) allowed by the organization cannot be awarded a certificate of completion unless that additional leave is made up.

Program policies address whether or not the program will be extended and if the extension will be paid or unpaid. If the organization is not able to extend the program, the policy states that the resident will not receive a certificate of completion.

**How it will be surveyed**
Review of:
- residents’ schedules
- extended leave policy
- residency terms and conditions
- documentation of changes to the program duration for residents’ successfully completing the program when leave has exceeded paid leave allowed by the organization

Discussion with RPD and residents about how extended or excessive leave during residency is managed.

2.2 Programs must comply with the *ASHP Duty-Hour Requirements for Pharmacy Residencies*.

**Guidance**
Programs provide a link or documentation to residents of the *ASHP Duty-Hour Requirements for Pharmacy Residencies* policy published on the ASHP website.
Programs document in program materials whether or not moonlighting is allowed.
Programs have a process for monitoring compliance with the *ASHP Duty-Hour Requirements for Pharmacy Residencies* policy.

**How it will be surveyed**
Review of:
- documentation related to duty hours and the moonlighting policy.
- documentation of work hours/schedules, if available.
Discussions related to duty-hour practices and procedures.

2.3 All programs in the ASHP accreditation process must adhere to the *Rules for the ASHP Pharmacy Resident Matching Program*, unless exempted by the ASHP Commission on Credentialing.
Guidance
The following are approved exemptions:
- Indian Health Service (IHS) residency positions.
- Residency positions offered to members of the active forces of the uniformed services (i.e. Army, Navy, Air Force, Marines, and Coast Guard)
- Residency positions offered to commissioned officers of the Public Health Service (PHS)

Residency programs which are exempt from the Match are required to report the number positions filled annually to the ASHP Accreditation Services Office by April 1st. This may be done by each individual program or collectively for programs utilizing the same process for hiring exempt residency positions (i.e., IHS). The date by which applicants must accept or decline residency positions offered through the IHS match process must occur prior to the initial date applicants may submit Rank Order Lists for Phase I of the Match.

How it will be surveyed
Review of residents’ Academic and Professional Records.
Discussion related to participation in the matching program.

2.4 The RPD must ensure that residents who are accepted into the program are provided with a letter outlining their acceptance to the program.

2.4.a. Information on the pre-employment requirements for the organization (e.g., licensure and human resources requirements, such as drug testing, criminal record check) and other relevant information (e.g., benefits, stipend) must be provided.

2.4.b. Acceptance by residents of these terms and conditions, requirements for successful completion, and expectations of the residency program must be documented prior to the beginning of the residency.

Guidance
Residents accept and sign the offer letter (including pre-employment requirements) and signify that they understand the list of requirements and expectations (as listed in standard 1.7 guidance) of the residency program prior to the beginning of the residency. This may be accomplished within the offer letter (if possible) or within a separate document created by the program. Transmittal and execution of a contract or agreement constitutes acceptance, and would be acceptable in place of a signed offer letter.

How it will be surveyed
Review of acceptance letter and attachments or review of executed contract.

2.5 The residency program must provide qualified preceptors to ensure appropriate training, supervision, and guidance to all residents to fulfill the requirements of the standards.

Guidance
2.5 is a critical factor (see Glossary for definition of “critical factor”). There is a sufficient number of preceptors available to facilitate achievement of the competencies, goals, and objectives and to guide (model, coach, facilitate) residents for each learning experience.

How it will be surveyed
Review of:
- the residency program’s structure documents and learning experience descriptions.
- review of preceptors’ roster and academic and professional record form.
- residents’ evaluations of preceptors and learning experiences.
Discussions with residents and preceptors.
2.6 The residency program must provide residents an area in which to work, references, an appropriate level of relevant technology (e.g., clinical information systems, workstations, databases), access to extramural educational opportunities (e.g., a pharmacy association meeting, a regional residency conference), and sufficient financial support to fulfill the responsibilities of the program.

**Guidance**
Residents are provided with an area to work and access to computer technology. Work area is conducive to concentrating. Residents are made aware of financial support to meet requirements of the program (e.g., travel to professional meeting, registration for meetings, statistical support for projects, poster production).

**How it will be surveyed**
Observation by tour of residents’ work area, reference materials, available technology. Discussion with residents and preceptors about extramural educational opportunities and financial support.

2.7 The RPD will award a certificate of residency only to those who complete the program’s requirements.

2.7.a. Completion of the program’s requirements must be documented.

**Guidance**
2.7 and 2.7.a. are critical factors (see Glossary for definition of “critical factor”). See Standard 2.4b for guidance on “requirements for completion.”

**How it will be surveyed**
Review of:
- methodology for documentation of residents’ satisfactory completion.
- current and past residents’ documentation to determine if requirements were met.
- summative evaluations; exit evaluations; residents’ work products/records/files; electronic tracking system; or other methods, such as a checklist of program requirements.

2.8 The certificate provided to residents who complete the program’s requirements must be issued in accordance with the provisions of the *ASHP Regulations on Accreditation of Pharmacy Residencies*, and signed by the RPD and the chief executive officer of the organization or an appropriate executive with ultimate authority over the residency.

2.8.a. Reference must be made in the certificate of the residency that the program is accredited by ASHP.

**Guidance**
For programs in candidate status, certificates issued to residents indicate that the program is in candidate status. Once the program achieves accredited status, new certificates are issued to these residents indicating completion of an accredited residency. Accreditation is retroactive to the date that ASHP received the program’s application for accreditation (candidate status, not pre-candidate status). Use of ASHP logos are encouraged and, if used, follow all applicable rules and the ASHP Style Guide as published by ASHP on the accreditation website (see Residency Accreditation Tools: Program Logo). PGY2 programs must follow *ASHP Regulations on Accreditation of Pharmacy Residencies* regarding naming of their program (see additional guidance under Standard 2.9).

**How it will be surveyed**
Review of certificate for signatures and wording. Candidate status programs must provide a draft of current certificate and also a draft of certificate to be issued once accreditation is conferred.
2.9 The RPD must maintain the program’s compliance with the provisions of the current version of the *ASHP Regulations on Accreditation of Pharmacy Residencies* throughout the accreditation cycle.

**Guidance**

2.9 is a critical factor (see Glossary for definition of “critical factor”). PGY2 programs should include the name of the advanced practice area of residency training as listed in the respective competency areas, goals, and objectives for the advanced area (e.g., PGY2 Oncology Pharmacy Residency Program).

PGY2 programs are allowed to provide additional information about their program in promotional or program materials but the description should be limited to the practice setting, types of patients seen, or other special characteristics of the program. For example, a program set in an ambulatory clinic is allowed to describe their practice or note that the program is in an ambulatory setting in the program description. As another example, if a program is set in a pediatric hospital, that can also be described in the program description. However, it cannot be part of the program title.

Per *ASHP Regulations on Accreditation of Pharmacy Residencies*:

Regulation (VIII.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).*”

Required use of PharmAcademic for residency program management includes:

- Building and maintenance of learning experience descriptions
- Summative, preceptor, and learning experience evaluations;
- Documentation and sharing of resident development plans;
- Close-out procedures to notify ASHP regarding completion/non-completion of enrolled residents, including graduate tracking.
- Upload program certificates.

Regulation (VII.B.): “*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 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.*”

**How it will be surveyed**

Review of Application Procedures

Review of Pharm Academic

May review records of past residents to determine if they have been maintained for the appropriate length of time as specified in the regulations.

Regulations: “*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 since the last site survey (i.e., up to six 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.*”

**Standard 3: Design and Conduct of the Residency Program**
3.1 Residency Purpose and Description

3.1.a. The residency program must be designed and conducted in a manner that supports residents in achieving the following purpose and the required educational competency areas, goals, and objectives described in the remainder of the standards.

3.1.b. PGY2 Program Purpose: PGY2 pharmacy residency programs build on Doctor of Pharmacy (Pharm.D.) education and PGY1 pharmacy residency programs to contribute to the development of clinical pharmacists in specialized areas of practice. PGY2 residencies provide residents with opportunities to function independently as practitioners by conceptualizing and integrating accumulated experience and knowledge and incorporating both into the provision of patient care or other advanced practice settings. Residents who successfully complete an accredited PGY2 pharmacy residency are prepared for advanced patient care, academic, or other specialized positions, along with board certification, if available.

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<td>The program documents the required PGY2 purpose statement in program materials.</td>
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<td>The program’s design is consistent with the program purpose statement.</td>
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<td>The program may develop a <strong>SUPPLEMENTAL</strong> brief description of their program that aligns with the purpose statement of a PGY2 residency and elaborates on any unique aspects of their program.</td>
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**How it will be surveyed**

Review of purpose statement, description (if applicable), and the design of the program.

3.2 Competency Areas, Educational Goals and Objectives

3.2.a. The program’s educational goals and objectives must support achievement of the residency’s purpose.

3.2.b. At the beginning of the resident’s program, RPDs must document an individualized set of program competency areas, educational goals, and educational objectives for each resident. In doing so, PGY2 residencies in advanced areas of pharmacy practice must draw upon the program competency areas, educational goals, and educational objectives that have been developed by ASHP specifically for that practice area (e.g., critical care, drug information, geriatrics, oncology, ambulatory care). RPDs may establish additional program competency areas, educational goals, and educational objectives that reflect the site’s strengths.

For PGY2 residencies in advanced areas of clinical pharmacy practice for which ASHP has not developed a complete set of competency areas, educational goals, and educational objectives, a generic set of program competency areas, educational goals, and educational objectives (*Program Competency Areas, Educational Goals, and Educational Objectives for Postgraduate Year Two (PGY2) Residencies in an Advanced Area of Pharmacy Practice*) is available. This generic set of advanced clinical practice goals and objectives is provided as a required framework for programs that must develop their own Standard-mandated, area-specific, complete set of program competency areas, educational goals, and educational objectives. Also, RPDs for programs in nonclinical practice areas lacking ASHP-developed program competency areas, educational goals, and educational objectives must develop a complete set for their residencies. In both cases, RPDs must provide ASHP’s Accreditation Service Office their complete set of program competency areas, educational goals, and educational objectives at the time of application. These competency areas, educational goals, and educational objectives must be reviewed by the ASHP Commission on Credentialing before the application for accreditation status will be accepted.
Guidance
3.2.b. is a critical factor (see Glossary for definition of “critical factor”).
The program uses all the required educational goals and objectives.
All required goals and objectives are assigned to the program’s learning experiences.
All required goals and objectives are assigned to be taught and evaluated at least once in required
learning experiences. Some goals and objectives may require teaching and evaluation several times
during the residency program year to enable residents to achieve competency.
Programs have a strategy for tracking areas listed in the appendix.

How it will be surveyed
Review of documents that describe the program’s structure and indicate which required objectives
are assigned to each required learning experience to ensure all are taught and evaluated at least
once.
Review or discussion about how Appendix areas are tracked.

3.2.c. Programs may select additional competency areas for all residents to complete. Elective
competency areas may be selected for specific residents only.

Guidance
Elective areas are not required but may be selected by individual programs and included in the
program’s design. If additional competency areas are selected to be included in the program’s design,
each competency area chosen includes a sufficient number of educational goals and objectives to
ensure achievement of the competency area.
Programs may also choose individual educational goals as long as sufficient educational objectives are
included in the program’s design to allow achievement of the goal.
Programs may also choose individual educational objectives to include in the program’s design.
Any additional competency area(s), goal(s), and objective(s) chosen for the program are required for
all residents completing the program.
Elective competency area(s), goal(s), and objective(s) selected for specific residents are documented
and managed through the resident’s development plan.

How it will be surveyed
Review document that describes that the additional competency areas are now a part of the required
program’s design and indicates which additional objectives are assigned to each required learning
experience to ensure all are taught and evaluated at least once.
Review of the specific resident’s development plan for inclusion of elective competency areas, as
applicable.

3.3 Resident Learning
3.3.a. Program Structure
3.3.a.(1) A written description of the structure of the program (the designation of types,
lengths, and sequence of learning experiences) must be documented formally.
3.3.a.(1)(a) The description must include required learning experiences and the
length of time for each experience.
3.3.a.(1)(b) Elective experiences must also be listed in the program’s design.
3.3.a.(2) The educational goals and objectives, including those for residents’ projects, will
be assigned for teaching to a learning experience or a sequence of learning
experiences to allow sufficient practice for their achievement by residents.
3.3.a.(3) The program’s structure must facilitate achievement of the program’s educational
goals and objectives.

Guidance
3.3.a.(3) are critical factors (see Glossary for definition of “critical factor”).
How it will be surveyed
Review of:
bullet the program’s structure and residents’ schedules.
bullet learning experience descriptions.
Discussion with preceptors, residents, and other health care providers.

3.3.b. Orientation
RPDs must orient residents to the residency program.

Guidance
Orientation includes:
bullet the residency’s purpose and practice environment.
bullet the appropriate accreditation standards, competencies, goals and objectives.
bullet design of the residency program including all program requirements.
bullet description of required and, if applicable, elective learning experiences.
bullet evaluation strategy (see standard 3.4).
bullet residency manual (if applicable).
bullet residency policies, terms and conditions, e.g., requirements for completion, moonlighting, duty hours, dismissal.
bullet considering education to the resident during orientation on burnout syndrome, the risks and mitigation strategies. Resources available on the ASHP website can be found here:
https://www.ashp.org/wellbeing
Structure includes orientation as a learning experience.

How it will be surveyed
Review of:
bullet where orientation appears in the residency calendar, if applicable.
bullet learning experience description for orientation.
bullet orientation schedule and materials given to residents.
bullet residency manual, if applicable.
Discussion with residents.

3.3.c. Learning Experiences
3.3.c.(1) Learning experience descriptions must be documented and include the following:
3.3.c.(1)(a) a general description, including the practice area and the roles of pharmacists in the practice area;
3.3.c.(1)(b) expectations of residents;
3.3.c.(1)(c) educational goals and objectives assigned to the learning experience;
3.3.c.(1)(d) for each objective, a list of learning activities that will facilitate achievement; and,
3.3.c.(1)(e) a description of evaluations that must be completed by preceptors and residents.
3.3.c.(2) Preceptors must orient residents to their learning experience using the learning experience description.
3.3.c.(3) During learning experiences, preceptors will use the four preceptor roles as needed based on residents’ needs.

Guidance
3.3.c.(1)(c)-(d) are critical factors (see Glossary for definition of “critical factor”).
Learning experience descriptions are developed by preceptors for all required and elective learning experiences under guidance of the RPD, and/or oversight by the RAC. Learning experience descriptions are documented in PharmAcademic. Learning experience descriptions describe how residents will progress and the expectation for their skill development over time and in any repeated learning experiences. Expectation requirements include progression of the resident over the period of the learning experience (e.g., rotation, longitudinal). Residents should progress over the course of the learning experience to be more efficient, effective, and able to work independently in providing patient care. If a successfully completed learning experience is repeated (e.g., Patient Care 1 and Patient Care 2), the preceptor elevates the expectations for the resident during the repeated experience. Progression timelines are documented in each learning experience. Learning activities are specific, unique to the objective, and developed at the cognitive learning level (Bloom’s Taxonomy) associated with the objective. Learn more at: [http://www.ashpmedia.org](http://www.ashpmedia.org)

Resource: Template for learning experience descriptions and example activities on ASHP website.

### How it will be surveyed
Review of learning experience descriptions in PharmAcademic. Discussion of reasons for second learning experience in an area, if residents have completed the same learning experience a second time.

3.3.c.(2) Preceptors must orient residents to their learning experience using the learning experience description.

### Guidance
Preceptors review learning experience descriptions with residents during the orientation to each learning experience.

### How it will be surveyed
Discussion with residents and preceptors.

3.3.c.(3) During learning experiences, preceptors will use the four preceptor roles as needed based on residents’ needs.

### Guidance
Preceptors assume the appropriate preceptor roles based on the time of the year and residents’ progression.

- Direct instruction appropriate for residents (as opposed to students), when needed.
- Modeling of practice skills described in the educational objectives.
- Coaching skills described in the educational objectives, providing regular, on-going feedback.
- Facilitating by allowing resident to assume increasing levels of responsibility for performance of skills with indirect support of the preceptor as needed.
- Residents function independently in each competency area by the conclusion of the residency program.

### How it will be surveyed
Review of learning experience descriptions. Discussion with residents, preceptors, and RPD.

3.4 Evaluation

3.4.a. The extent of residents’ progression toward achievement of the program’s required educational goals and objectives must be evaluated.

3.4.b. Initial assessment
3.4.b.(1) At the beginning of the residency, the RPD in conjunction with preceptors must assess each resident’s entering knowledge and skills related to the educational goals and objectives.

3.4.b.(2) The results of residents’ initial assessments must be documented by the program director or designee in each resident’s development plan by the end of the orientation period and taken into consideration when determining residents’ learning experiences, learning activities, evaluations, and other changes to the program’s overall plan.

3.4.c. Formative (ongoing, regular) Assessment

3.4.c.(1) Preceptors must provide ongoing feedback to residents about how they are progressing and how they can improve that is frequent, immediate, specific, and constructive.

3.4.c.(2) Preceptors must make appropriate adjustments to residents’ learning activities in response to information obtained through day-to-day informal observations, interactions, and assessments.

Guidance
3.4.b.(2) and 3.4.c(1) are a critical factors (see Glossary for definition of “critical factor”).

Verbal and written feedback is essential for residents’ skill development.

Frequency of ongoing feedback varies based on residents’ progress and time of the year.

Some feedback may be written, such as comments on residents’ SOAP notes or on evaluations of residents’ presentations, projects, monographs, etc.

Residents who are not progressing according to expectations receive more frequent formative feedback.

Oral formative feedback is required by the Standard; to supplement this, documentation of feedback may be necessary for residents who are not progressing satisfactorily.

Specific recommendations for improvement and achievement of objectives are documented for residents who are not progressing satisfactorily.

Preceptors ensure residents’ responsibilities and/or activities align with residents’ progress within each learning experience.

How it will be surveyed

Review of:

- written examples of formative feedback, if applicable.
- assessment strategy as documented in learning experience descriptions.

Discussion with residents and preceptors.

3.4.d. Summative Evaluation

3.4.d.(1) At the end of each learning experience, residents must receive, and discuss with preceptors, verbal and written assessment on the extent of their progress toward achievement of assigned educational goals and objectives, with reference to specific criteria.

Guidance
3.4.d.(1) is a critical factor (see Glossary for definition of “critical factor”).

RPD and preceptors or RAC document and define evaluation ratings (e.g., needs improvement, satisfactory progress, achieved, achieved for residency).

Qualitative written comments:

- are specific and actionable.
- use criteria related to specific educational objectives.
- recognize residents’ skill development.
- focus on how residents’ may improve their performance.

Evaluations are completed by the due date or within 7 days.

**How it will be surveyed**

Determination of timeliness by reviewing summative evaluation dates in PharmAcademic® reports or other reports if PharmAcademic® is not used.

Discussion with preceptors and residents.

Determine quality of summative evaluations by:

- review of explanation of ratings (e.g., achieved, satisfactory, needs improvement).

- review of criteria-based feedback in written summative evaluations.

| 3.4.d.(2) | For learning experiences greater than or equal to 12 weeks in length, a documented summative evaluation must be completed at the 3-, 6-, and 12-month points. |

| 3.4.d.(3) | If more than one preceptor is assigned to a learning experience, all preceptors must provide input into residents’ evaluations. |

**Guidance**

If multiple preceptors, one preceptor should be identified as the primary preceptor.

Programs determine if they will have each preceptor provide input into PharmAcademic® or if all preceptors will provide input to the primary preceptor who will document the joint evaluation.

The primary preceptor seeks consensus of preceptors to determine final ratings and co-sign evaluations.

Co-preceptors are encouraged to provide documentation in residents’ written evaluations.

**How it will be surveyed**

Review of summative evaluations.

Discussion with preceptors and/or residents.

| 3.4.d.(4) | For preceptors-in-training, both the preceptor-in-training and the preceptor advisor/coach must sign evaluations. |

| 3.4.d.(5) | Residents must complete and discuss at least one evaluation of each preceptor at the end of the learning experience. |

**Guidance**

All preceptors with significant exposure to working with residents in a learning experience are evaluated by residents at least once.

Evaluations are completed by the due date or within 7 days.

**How it will be surveyed**

Review of:

- residents’ evaluations of preceptors.

- adherence to the program’s assessment strategy.

Discussion with preceptors and residents.

Timeliness will be surveyed by reviewing learning experience evaluation dates in PharmAcademic® reports or other reports if PharmAcademic® is not used.

| 3.4.d.(6) | Residents must complete and discuss an evaluation of each learning experience at the end of the learning experience. |

**Guidance**

Evaluations are completed by the due date or within 7 days.
Review of:
- residents’ evaluations of learning experiences.
- adherence to the program’s assessment strategy (e.g., timeliness of completion, frequency and content of narrative comments, use of evaluation ratings).

Discussion with preceptors and residents.

3.4.e. Residents’ Development Plans

3.4.e(1) Each resident must have a development plan documented by the RPD or designee.

Guidance

The purpose of resident development plans is to modify the design and conduct of the program to address each resident’s unique learning needs and interests. Development plans also provide a tool for monitoring, tracking, and communicating about residents’ overall progress throughout the residency, and adjustments made to meet their learning needs. The program’s residency advisory committee meets at least quarterly to discuss overall progress by residents and agree to development plan adjustments needed for residents. Adjustments are reflected in the quarterly updates to the plan.

The following is included in the development plan for each resident:

*Initial assessment by the resident, RPD, and/or designee and/or preceptor(s).*

Residents review the design and conduct of the program and complete an initial self-evaluation for use in developing their plan.

The initial self-evaluation includes the following information:
- Short- and long-term career goals *(optional).*
- Incoming strengths *(required).*
  - Professional strengths in terms of knowledge, skills, and abilities related to the educational goals and objectives.
  - Personal strengths related to being a professional.
- Incoming areas for improvements *(required).*
  - Professional areas for improvement in terms of knowledge, skills, and abilities related to the educational goals and objectives.
  - Personal areas for improvement related to being a professional.
- Incoming learning interests related to required or elective learning opportunities *(optional).*

Programs may use their own customized assessment methods such as residents’ self-assessment checklists, case discussions, other checklists, interviews with residents, observation, other methods or combination of methods, or use of tools available in PharmAcademic®.

The initial self-assessment is completed before or during the beginning of the residency, and information is collected and analyzed during orientation.

*An initial development plan is created for each resident (generally within the first 30 days of the residency by the RPD and/or designee), discussed with each resident, and may be reviewed by the RAC.*

Adjustments to initial resident development plans include the following as appropriate:
- Modification of residents’ schedules.
- Preliminary determination of elective learning experiences.
- Educational goals and objectives to be emphasized in required and elective learning experiences.
- Addition of goals and objectives to required or elective learning experiences.
- Changing and/or increasing summative self-evaluations, formative self-evaluations, and preceptors’ feedback related to areas for improvement.
- Modify preceptors’ use of modeling, coaching, and facilitation.
Summaries of initial development plans are shared with residents’ preceptors.

**1st, 2nd, and 3rd quarter updates**

The quarterly updates are completed, discussed with each resident, and documented every 90 days from the start of the residency (e.g. October, January, and April).

Adjustments are made based upon review of residents’ performance (including effectiveness of the previous plan), relevant to the previous quarter’s plan with input from preceptor(s) and residents; the identification of new strengths or areas for improvement and, optionally, changes in residents’ short- or long-term career goals and interests. If there is no need for changes in the development plan, this is documented.

Development plans do not require a separate evaluation of objectives on a quarterly basis.

It is important to note that the assessment information collected about a resident is a component of the development plan, but is not the plan itself.

**Quarterly review of residents’ progress in achieving the competencies, goals and objectives of the program and the resident professional development plans.**

A system is used to track goals and objectives achieved, areas for improvement, and expected progress relative to the time of the year.

A system is used to track adjustments to and the effectiveness of adjustments documented in development plans.

The initial development plan and quarterly updates to the development plan must be uploaded and shared through PharmAcademic.

**How it will be surveyed**

Review of resident development plans in PharmAcademic:

- for initial assessments and plans
- for assessments of/and changes to initial development plans after each quarter
- to determine if adjustments to resident development plans appear appropriate for dates
- Discussion with RPD, preceptors, and residents

**3.4.e.(2)** On a quarterly basis, the RPD or designee must assess residents’ progress and determine if the development plan needs to be adjusted.

**3.4.e.(3)** The development plan and any adjustments must be documented and shared with all preceptors.

**Guidance**

3.4.e.(2) is a critical factors (see Glossary for definition of “critical factor”).

See guidance under 3.4.e.(1)

**3.5 Continuous Residency Program Improvement**

**3.5.a.** The RPD, residency advisory committee (RAC), and pharmacy executive must engage in an on-going process of assessment of the residency program including a formal annual program evaluation.

**3.5.b.** The RPD or designee must develop and implement program improvement activities to respond to the results of the assessment of the residency program.

**3.5.c.** The residency program’s continuous quality improvement process must evaluate whether residents fulfill the purpose of a PGY1 pharmacy residency program through graduate tracking.

**3.5.c.(1)** Information tracked must include initial employment, and may include changes in employment, board certification, surveys of past graduates, or other applicable information.
Programs develop their own process for program quality improvement. Examples:

- residency advisory committee (RAC) meetings at the end of every residency year to discuss areas of strength, opportunities for improvement, and strategies to improve the residency program
- retreats
- focused meetings
- meetings with residents asking their feedback at the end of the residency year
- survey instruments (e.g., preceptor self-assessment, resident evaluations’ of RPD)

For 3.5.c.(1), regarding initial employment, the employment environment may be noted and taken into account. PharmAcademic is used for the tracking of initial employment.

How it will be surveyed
Review of:

- minutes of RAC meetings in which residency program improvements have been discussed, if applicable
- Any documentation of program assessments, instruments, plans for improvement, etc., if available.
- information obtained about graduates
- Graduate tracking report in PharmAcademic

Discussion about the program’s continuous quality improvement efforts.

Standard 4: Requirements of the Residency Program Director and Preceptors

4.1 Program Leadership Requirements

4.1.a. Each residency program must have a single RPD who must be a pharmacist from a practice site involved in the program or from the sponsoring organization.

Guidance
When interim leadership for a residency program is required due to vacancy or leave of absence of the RPD, the director of pharmacy or administrative authority such as the residency advisory committee (RAC), may appoint a pharmacist to serve as Interim RPD.

- The interim appointment is acceptable for a period of no longer than 120 days.
- The organization is not required to notify ASHP, but must change the RPD in PharmAcademic™ to the Interim RPD for continued administration of the residency program.
- By the end of the 120-day period, a new RPD must be appointed if the previous RPD is unable to resume RPD responsibilities.
- Information for a change in RPD must be sent to the Accreditation Services Office (asd@ashp.org) at or before the completion of the 120-day interim appointment. Submitted information must include an updated Academic and Professional Record and an updated Curriculum Vitae.

How it will be surveyed

- Review of RPD’s Academic and Professional Record and PharmAcademic™
- Discussion with RPD
4.1.b. The RPD may delegate, with oversight, the administrative duties/activities for the conduct of the residency program to one or more individuals (e.g., residency program coordinator).

**Guidance**
The terms used (e.g., residency program coordinator) and definition of roles are determined by, and can vary by, program. The term “coordinator” is an example.

4.1.c. For residencies conducted by more than one organization (e.g., two organizations in a partnership) or residencies offered by a sponsoring organization (e.g., a college of pharmacy, hospital) in cooperation with one or more practice sites:

4.1.c.(1) A single RPD must be designated in writing by responsible representatives of each participating organization.

4.1.c.(2) The agreement must include definition of the following:

4.1.c.(2)(a) responsibilities of the RPD; and,

4.1.c.(2)(b) RPD’s accountability to the organizations and/or practice site(s).

4.2 Residency Program Directors’ Eligibility

RPDs must be licensed pharmacists with demonstrated expertise in the chosen area of advanced practice, as substantiated by all of the following: (a.) an ASHP-accredited PGY2 residency in the advanced practice area, followed by a minimum of three years of practice experience, or equivalent experience in the advanced practice area (i.e., five years of practice experience in the advanced area with demonstrated mastery of the knowledge, skills, attitudes, and abilities expected of one who has completed a PGY2 residency); (b.) board certification in the specialty when certification is offered in that specific advanced area of practice; and, (c.) maintenance of an active practice in the respective advanced practice area.

**Guidance**
4.2: is a critical factor (see Glossary for definition of “critical factor”).

4.2.a: The RPD’s PGY2 residency is relevant to the practice setting. The RPD’s pharmacy practice experience is in the same advanced practice area in which the resident is being trained.

4.2.b: Relevant board certifications are obtained by January 1 following three offerings of the exam.

4.2.c: Active practice is defined as maintaining regular and on-going responsibilities for the area where the pharmacist serves as a preceptor (may be part-time but must be actively engaged).

Other aspects of active practice may include:

- contribution to the development of clinical or operational policies/guidelines or protocols in the practice site.
- contribution to the creation/implementation of a new clinical service or service improvement initiative at the practice site.
- active participation on a multi-disciplinary or pharmacy committee or task force responsible for patient care or practice improvement, etc.
- demonstrated leadership within the practice area.

4.3 Residency Program Directors’ Qualifications

**Guidance**
4.3.a-c are critical factors (see Glossary for definition of “critical factor”).

RPDs serve as role models for pharmacy practice, as evidenced by the following:

4.3.a. leadership within the pharmacy department or within the organization, through a documented record of improvements in and contributions to pharmacy practice;
Guidance
Examples of leadership (should have been demonstrated within the last five years):
• contribution to the development of policies/guidelines or protocols.
• implementation of a new service at the practice site.
• demonstrated leadership within the pharmacy department or organization or school of pharmacy such as leading a committee/initiative, team leader, management position, etc.

How it will be surveyed
Review of academic and professional record form or PharmAcademic® review

4.3.b. demonstrating ongoing professionalism and contribution to the profession; and

Guidance
Examples of demonstrating ongoing professionalism and contribution to the profession (should have been demonstrated within the last five years):
• serving as a reviewer (e.g., contributed papers, grants, or manuscripts; reviewing/submitting comments on draft standards/guidelines for professional organizations).
• presentation/poster/publication in professional forums.
• poster/presentation/project co-author for pharmacy students or residents at a professional meeting (local, state, or national).
• active service, beyond membership, in professional organizations at the local, state, and/or national level (e.g., leadership role, committee membership, volunteer work).
• moderator or evaluator at regional residency conferences or other professional meeting.
• faculty or pharmacy student preceptor appointment.
• professional consultation to other health-care facilities or professional organizations.
• contributing to health and wellness in the community and/or organization through active participation in health fairs, public events, employee wellness promotion/disease prevention activities, population-based care management, etc.

How it will be surveyed
Review of academic and professional record form or PharmAcademic® review

4.3.c. representing pharmacy on appropriate drug policy and other committees of the pharmacy department or within the organization.

Guidance
Examples (demonstrated in the last five years):
• active participation on a multi-disciplinary or pharmacy committee or task force responsible for patient care or practice improvement, etc.
• active participation on the pharmacy and therapeutics committee.
• active participation on a drug policy review committee.
• active participation on an IRB or human subjects committee within the organization.
• active participation on a college of pharmacy committee.

How it will be surveyed
Review of academic and professional record form or PharmAcademic® review.

4.4 Residency Program Leadership Responsibilities
RPDs serve as organizationally authorized leaders of residency programs and have responsibility for the following:
4.4.a. activities of a RAC that provides guidance for residency program conduct and related issues;
Guidance:
The RPD determines an appropriate schedule of residency advisory committee meetings to allow for effective oversight of the program. The meetings can be part of another routinely scheduled meeting. The intent of 4.4.a is to ensure that department leadership, program leadership and preceptors are engaged in design and oversight of individual residency programs. In organizations with multiple programs, it may be appropriate to have one organizational RAC. This is an acceptable alternative to having a RAC for each program, if all RPDs are members, there is appropriate representation from department leadership and preceptors, and there is a mechanism to ensure the oversight needs of individual programs are met.

How it will be surveyed
Review of documents relevant to the residency advisory committee (e.g., minutes, agenda, schedule, attendance log, and evidence of programmatic changes).
Discussion with RPD and preceptors.

4.4.b. oversight of the progression of residents within the program and documentation of completed requirements;

Guidance
RPD may delegate responsibility for oversight to a qualified preceptor. Residents’ development plans are used to provide oversight of the progression of residents. Adjustments are made to residents’ development plans, such as to the educational goals and objectives, learning activities, evaluations, opportunities or other aspects of residents’ training, as appropriate.

How it will be surveyed
Review of a system the program has devised to track residents progress, such as review of residents’ development plans:
• for presence of quarterly updates.
• to determine if adjustments to residents’ development plans appear appropriate for residents’ learning needs.
• for dates and signatures on plans.

4.4.c. implementing use of criteria for appointment and reappointment of preceptors;

Guidance
RPD can exercise the authority to apply criteria for preceptor appointment and reappointment. Criteria are documented and used. RPD may delegate this responsibility to an oversight body for sites with multiple programs. Reappointment includes a review of each preceptor’s qualifications and performance on a schedule determined by the RPD.

How it will be surveyed
Review of documentation of criteria for appointment and reappointment. Discussion with RPD about the appointment/reappointment process.

4.4.d. evaluation, skills assessment, and development of preceptors in the program;

Guidance
RPD evaluates preceptors’ competence and uses appropriate methods to evaluate preceptors’ skills (e.g., review of residents’ evaluations of preceptors, peer review, preceptors’ self-assessments, and performance reviews).
How it will be surveyed
Review of processes used for preceptor evaluation, skills assessment, and development.

4.4.e. creating and implementing a preceptor development plan for the residency program;

Guidance
Preceptor development plans are documented and include an assessment of needs, a schedule of activities to address identified needs, and a review of effectiveness of development plan. The preceptor development plan could defer to, or be a part of, an organizational plan. Preceptor development plan may be a group plan or individualized plan or a combination of both. Consider education to the preceptors on burnout syndrome, the risks and mitigation strategies. Resources available on the ASHP website can be found here: https://www.ashp.org/wellbeing

How it will be surveyed
Review of documentation of the program’s preceptor development plan addressing new and established preceptors.
Discussion with preceptors and RPD.

4.4.f. continuous residency program improvement in conjunction with the RAC; and,

How it will be surveyed
Discussion with RPD and review of residency advisory minutes, if applicable.

4.4.g. working with pharmacy administration to ensure ongoing support of the program.

Guidance
The RPD and pharmacy administration work together to ensure the success of the program.

How it will be surveyed
Discussion with RPD and pharmacy administration.

4.5 Appointment or Selection of Residency Program Preceptors

4.5.a. Organizations shall allow RPDs to appoint and develop pharmacists to become preceptors for the program.
4.5.b. RPDs shall develop and apply criteria for preceptors consistent with those required by the Standard.

How it will be surveyed
Review of documentation of criteria for appointment and reappointment.
Discussion with RPD about appointment/reappointment process. (refer to 4.4c)

4.6 Pharmacist Preceptors’ Eligibility

Pharmacist preceptors must be licensed pharmacists who

4.6.a. have completed an ASHP-accredited PGY2 residency followed by a minimum of one year of pharmacy practice in the advanced practice area; or,

4.6.b. without completion of an ASHP-accredited PGY2 residency, have three or more years of practice in the advanced area.

Guidance
4.6.a-b are a critical factors (see Glossary for definition of “critical factor”).

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Preceptor’s pharmacy practice experience is relevant to the practice setting in which the learning experience is conducted. If the preceptor has less than 3 years pharmacy practice experience that is relevant to the practice setting in which the learning experience is conducted, the preceptor must have a PGY2 residency in the same or similar advanced practice.

4.7 Preceptors’ Responsibilities

Preceptors serve as role models for learning experiences. They must:

4.7.a. contribute to the success of residents and the program;
4.7.b. provide learning experiences in accordance with Standard 3;
4.7.c. participate actively in the residency program’s continuous quality improvement processes;
4.7.d. demonstrate practice expertise and preceptor skills and strive to continuously improve;
4.7.e. adhere to residency program and department policies pertaining to residents and services; and,
4.7.f. demonstrate commitment to advancing the residency program and pharmacy services.

How it will be surveyed
Review of relevant documents (e.g., learning experience descriptions, residents’ evaluations of preceptors and learning experiences).
Discussion with preceptors and residents.

4.8 Preceptors’ Qualifications

Preceptors must demonstrate the ability to precept residents’ learning experiences as described in sections 4.8.a-f.

Guidance
4.8.a-f are critical factors (see Glossary for definition of “critical factor”).
When a list of examples is included in the guidance sections for 4.8.a–f, at least one of the examples is demonstrated within the last five years unless otherwise noted.
Duration of accreditation will be impacted only if greater than 2/3rds of preceptors are not fully compliant with 4.8.

4.8.a. ability to precept residents’ learning experiences by use of clinical teaching roles (i.e., instructing, modeling, coaching, facilitating) at the level required by residents;

How it will be surveyed
Review of residents evaluations of preceptors and their learning experiences.
Discussion with preceptors and residents.

4.8.b. the ability to assess residents’ performance;

Guidance
Preceptors provide specific, constructive criteria-based verbal feedback to residents during learning experiences and the end of learning experiences to assist residents in improving their performance. Formative written feedback to residents may be provided, if needed, during learning experiences and written summative feedback is provided at the end of learning experiences.

How it will be surveyed
Review of summative evaluations and other examples of documented feedback provided to the residents.
Discussion with residents and preceptors.
Guidance
Preceptors must have one of the following:
Examples:
- BPS certification
- Fellow at a state or national level organization
- Certificate of Completion from a state or nationally available program that relates to the area of practice in which they precept (e.g., Epic Willow certification, Six Sigma/LEAN Six Sigma certification, ISMP sponsored Medication Safety certificate, ASHP sponsored certificates).

Health-system/local residency site based programs are excluded.
  - Validated certification that results from an exam by the organization providing certification
  - Pharmacy related certification recognized by Council on Credentialing in Pharmacy (CCP) [http://www.pharmacycredentialing.org/Files/CertificationPrograms.pdf](http://www.pharmacycredentialing.org/Files/CertificationPrograms.pdf)
    - Other examples include: Certified Professional in Patient Safety (CPPS), Certified Diabetes Educator (CDE)
  - Exceptions to the list that do not meet this domain are ACLS, PALS and BLS
- Post-Graduate Fellowship in the advanced practice area or an advanced degree beyond entry level pharmacy degree (e.g., MBA, MHA)
- Formal recognition by peers as a model practitioner
  - Pharmacist of the year - recognized at state, city or institutional level where only one individual is recognized
  - Patient care, quality, or teaching excellence – recognition at organization level (not internal to pharmacy department only) for an initiative that resulted in positive outcomes for all patients that either was operational, clinical or educational in nature)
- Credentialing and privileging granted by the organization/practice/health system with ongoing process of evaluation and peer review
- Subject matter expertise as demonstrated by ten or more years of practice experience in the area of practice in which they precept

How it will be surveyed
- Review of academic and professional record form or PharmAcademic® review.
- Review of credentialing and privileging policy as applicable.
- Review of materials used in credentialing and privileging process.

Guidance
Active practice is defined as maintaining regular and on-going responsibilities for the area where the pharmacist serves as a preceptor (may be part-time and/or at a remote location, but must be actively engaged).

Other aspects of active practice may include:
- contribution to the development of clinical or operational policies/guidelines or protocols in the practice site.
- contribution to the creation/implementation of a new clinical service or service improvement initiative at the practice site.
- active participation on a multi-disciplinary or pharmacy committee or task force responsible for patient care or practice improvement, etc.
- demonstrated leadership within the practice area.
How it will be surveyed:
Discussion with preceptors, residents, and other health care practitioners.

4.8.e. maintenance of continuity of practice during the time of residents’ learning experiences; and,

Guidance
Preceptors maintain continuity of practice while residents are in their learning experiences. A learning experience may be precepted by a team of preceptors.

How it will be surveyed
Discussion and review of residents’ evaluations of preceptors and learning experiences.

4.8.f. ongoing professionalism, including a personal commitment to advancing the profession.

Guidance:
Ongoing professionalism is demonstrated by completing at least 3 activities in the last 5 years.
Examples:
• Serving as a reviewer (e.g., contributed papers, grants, or manuscripts; reviewing/submitting comments on draft standards/guidelines for professional organizations)
• Presentation/poster/publication in professional forums
• Poster/presentation/project co-author for pharmacy students or residents at a professional meeting (local, state, or national)
• Active service, beyond membership, in professional organizations at the local, state, and/or national level (e.g., leadership role, committee membership, volunteer work)
• Active community service related to professional practice (e.g., Free Clinic, medical mission trips)
• Evaluator at regional residency conferences or other professional meetings
• Routine in-service presentations to pharmacy staff and other health care professionals
• Primary preceptor for pharmacy students
• Pharmacy technician educator
• Completion of a Teaching and Learning Program \(^1\)
• Providing preceptor development topics at the site
• Professional consultation to other health care facilities or professional organizations (e.g., invited thought leader for an outside organization, mock, or practitioner surveyor)
• Contributing to health and wellness in the community and/or organization through active participation in health fairs, public events, employee wellness promotion/disease prevention activities, consumer education classes, etc.
• Publication of original research or review articles in peer-reviewed journals or chapters in textbooks
• Publication or presentation of case reports or clinical/scientific findings at local, regional, or national professional/scientific meetings or conferences
• Teaching of pharmacy students or other health care professionals (e.g., classroom, laboratory, inservice)
• Active involvement on committees within enterprise (e.g., work impacts more than one site across a health system)

How it will be surveyed
Review of Academic and Professional Record form or PharmAcademic\(^\circ\) review.

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4.9 Preceptors-in-Training

4.9.a. Pharmacists new to precepting who do not meet the qualifications for residency preceptors in sections 4.6, 4.7, and 4.8 above (also known as preceptors-in-training) must:

4.9.a.(1) be assigned an advisor or coach who is a qualified preceptor; and,
4.9.a.(2) have a documented preceptor development plan to meet the qualifications for becoming a residency preceptor within two years.

**Guidance**
The plan developed for preceptors-in-training is documented and provides opportunities for preceptors-in-training to meet preceptor requirement within two years. The plan may be a component of an organizational performance review process.

**How it will be surveyed**
Review of documented plan for preceptor-in-training.
Discussion with preceptors and RPD.

4.10 Non-pharmacist preceptors

When non-pharmacists (e.g., physicians, physician assistants, certified nurse practitioners) are utilized as preceptors:

4.10.a. the learning experience must be scheduled after the RPD and preceptors agree that residents are ready for independent practice; and,
4.10.b. a pharmacist preceptor works closely with the non-pharmacist preceptor to select the educational goals and objectives for the learning experience.

**Guidance**
Utilization of non-pharmacist preceptors may occur when a qualified pharmacist preceptor does not maintain an active practice in the area but the experience adds value to residents’ professional development.

Non-pharmacist preceptors do not need to meet preceptor requirements and don’t have to fill out an Academic and Professional Record form. They do have to participate in the evaluation process (see above). Pharmacist preceptors can enter the information into PharmAcademic® based on input from non-pharmacist preceptors.

Readiness for independent practice in direct patient care learning experiences is reflected by a rating of achieved for the residency (ACHR) for the majority of goals and objectives in Competency Area R1.

**How it will be surveyed**
4.10.a. Review of documentation of residents’ readiness to work independently.

**Standard 5: Requirements of the Sponsoring Organization and Practice Site(s) Conducting the Residency Program**

5.1 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.

**Guidance**
5.1 is a critical factor (see Glossary for definition of “critical factor”).
The sponsoring organization and all practice sites that offer or that participate in offering a pharmacy residency are accredited by applicable organizations [e.g., The Joint Commission (TJC), American Osteopathic Association (AOA)/Healthcare Facilities Accreditation Program (HFAP), National Committee for Quality Assurance (NCQA), Det Norske Veritas (DNV)]. A college or school of pharmacy that participates in offering a pharmacy residency is accredited by the Accreditation Council for Pharmacy Education (ACPE).
5.2 Residency programs must be conducted only in those practice settings where staff are committed to seek excellence in patient care as evidenced by substantial compliance with professionally developed and nationally applied practice and operational standards.

Guidance
Reference: ASHP Best Practices (available at www.ashp.org) and, when necessary, other pharmacy association guides to professional practice and other relevant standards (e.g., NIOSH, OSHA, EPA, ISMP) that apply to specific practice sites.

How it will be surveyed
Observation of instances where professional standards should be followed. Discussion with residents and pharmacy personnel.

5.3 Two or more practice sites, or a sponsoring organization working in cooperation with one or more practice sites (e.g., college of pharmacy, health system), may offer a pharmacy residency.

5.3.a. Sponsoring organizations must maintain authority and responsibility for the quality of their residency programs.

5.3.b. Sponsoring organizations may delegate day-to-day responsibility for the residency program to a practice site; however, the sponsoring organization must ensure that the residency program meets accreditation requirements.

5.3.b.(1) Some method of evaluation must be in place to ensure the purpose of the residency and the terms of the agreement are being met.

5.3.c. A mechanism must be documented that designates and empowers an individual to be responsible for directing the residency program and for achieving consensus on the evaluation and ranking of applicants for the residency.

5.3.d. Sponsoring organizations and practice sites must have signed agreement(s) that define clearly the responsibilities for all aspects of the residency program.

5.3.e. Each of the practice sites that provide residency training must meet the requirements set forth in Standard 5.2 and the pharmacy’s service requirements in Standard 6.

Guidance
Although a residency program may be offered/conducted by more than one organization, there may be only one sponsoring organization designated for a residency program. Sponsorship of a program is determined by the signature of the senior person on the application for accreditation; e.g., if the application is signed by a hospital CEO, the program’s sponsor is a hospital and if it is signed by a Dean, the sponsor is a college of pharmacy.

The sponsoring organization has an appropriate organizational structure for the administration of the residency program (e.g., residency advisory committee) that ensures the organization has final authority for program decisions and program conformance with ASHP standards.

How it will be surveyed
Review of agreements between organizations.

5.4 Multiple-site residency programs must be in compliance with the ASHP Accreditation Policy for Multiple-Site Residency Programs.
Standard 6: Pharmacy 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 and other relevant standards (e.g., NIOSH, OSHA, EPA, ISMP) that apply to specific practices sites will be used to evaluate any patient care sites or other practice operations providing pharmacy residency training.

For hospital settings this Standard is based on the “ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals.”
For ambulatory settings, it is based on “ASHP Guidelines: Minimum Standard for Pharmaceutical Services in Ambulatory Care
Other standards that relate to specific areas may also apply and should be considered by applicable programs (e.g., oncology, pediatrics, solid organ transplant).
These best practice documents should be referenced as the pre-survey self-assessment checklist is being completed.

6.1 Pharmacist Executive
The pharmacy must be led and managed by a professional, legally qualified pharmacist.

Guidance
This pharmacist has assigned responsibility for insuring compliance with requirements for the pharmacy as outlined in this Standard.

From ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals
“Director of Pharmacy. The pharmacy shall be managed by a professionally competent, legally qualified pharmacist. The director of pharmacy should be thoroughly knowledgeable about and have experience in hospital pharmacy practice and management. An advanced management degree (e.g., M.B.A., M.H.A., or M.S.) or an administrative specialty residency is desirable. The director of pharmacy shall be responsible for
• Establishing the mission, vision, goals, and scope of services of the pharmacy based on the needs of the patients served, the needs of the hospital (and any health system of which the hospital may be a component), and developments and trends in health care and hospital pharmacy practice,
• Developing, implementing, evaluating, and updating plans and activities to fulfill the mission, vision, goals, and scope of services of the pharmacy,
Actively working with or as a part of hospital or health-system leadership to develop and implement policies and procedures that provide safe and effective medication use for the patients served by the institution,
• Mobilizing and managing the resources, both human and financial, necessary for the optimal provision of pharmacy services, and
• Ensuring that patient care services provided by pharmacists and other pharmacy personnel are delivered in adherence to applicable state and federal laws and regulations, hospital privileging requirements, and national practice standards.”

How it will be surveyed
Review of:
• pharmacy strategic planning documents.
• survey report of The Joint Commission or other accrediting body.
• pharmacist’s state licensure/registration
• discussion with the pharmacist executive and his/her supervisor.
6.2 The pharmacy must be an integral part of the health-care delivery system at the practice site in which the residency program is offered, as evidenced by the following:

6.2.a. the scope and quality of pharmacy services provided to patients at the practice site is based upon the mission of the pharmacy department and an assessment of pharmacy services needed to provide care to patients served by the practice site;

**Guidance**
An assessment of the pharmacy functions needed to provide care to all patients served by the practice site (as defined by respective national standards for pharmaceutical services) has been conducted.
The assessment results in the development of the scope of the pharmacy’s services.
The assessment is conducted within the context of the whole of the health care delivery system, and the scope identified directly reflects that context.

**How it will be surveyed**
Review of:
- documented mission statement.
- scope of services description applicable to the practice area.
- assessment process and results, if available (e.g., gap analysis) or discussion to determine assessment process and results, including clinical and operational services.
- services grid for ambulatory and acute care.
- strategic plan.
- survey report of The Joint Commission or other accrediting organization.
- written pharmacy policies and procedures.

6.2.b. the practice site includes pharmacy in the planning of patient care services;

**Guidance**
Pharmacy personnel participate in all prospective and concurrent major planning efforts that involve the design and delivery of patient care services and the provision of pharmaceutical care.

**How it will be surveyed**
Review of:
- practice setting organizational chart.
- pharmacy organizational chart.
- list of organization’s committees and identification of pharmacy involvement.
- strategic planning documents for the entire health care delivery system that pertain to the design and delivery of patient care services.
- pharmacy strategic planning documents.
- minutes of Pharmacy and Therapeutics Committee meetings.
- quality dashboard report.
- survey report of The Joint Commission or other accrediting organization.

Discussion with pharmacy leaders about their role in the planning of patient care services.

6.2.c. the scope of pharmacy services is documented and evidenced in practice and quality measures;

**Guidance**
This section refers to depth and breadth of drug distribution, clinical services, drug control, and communication of scope of services to pharmacy, nursing, administration staff, etc.
*From ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals*
“Elements of Care. The mission of pharmacists is to help people make the best use of medications. Therefore, pharmacists shall be concerned with not only the provision but the outcomes of pharmacy services. The elements of pharmacy services that are critical to safe, effective, and cost-conscious
medication use in a hospital include (1) practice management, (2) medication-use policy
development, (3) optimizing medication therapy, (4) drug product procurement and inventory
management, (5) preparing, packaging, and labeling medications, (6) medication delivery, (7)
monitoring medication use, (8) evaluating the effectiveness of the medication-use system, and (9)
research. Although the scope of pharmacy services will vary from site to site, depending upon
the needs of patients and the hospital as well as the resources available, these core elements are
inextricably linked to successful outcomes. Failure to provide any of these services may compromise
the quality of patient care.”

How it will be surveyed
Review of:
• scope of services description applicable to the practice area.
• dashboards and evidence in practice and quality measures [e.g., Practice Advancement Initiative
(PAI) materials].
• pre-survey documents.
• residency survey team’s overall assessment of survey observations.

Discussions with:
• director and RPD regarding practice and quality measures.
• physicians, nurses, and pharmacy staff.

6.2.d. pharmacy services extend to all areas of the practice site in which medications for patients
are prescribed, dispensed, administered, and monitored;

Guidance
6.2.d. is a critical factor (see Glossary for definition of “critical factor”). Pharmacy services extend to all patient care areas (i.e., inpatient, outpatient, diagnostic, emergency
services) in which medications are prescribed, dispensed, administered, and monitored.

How it will be surveyed
Review of:
• services grid for ambulatory and acute care.
• scope of services (what and where).
• on-site tour of patient care areas.
• pharmacy strategic planning documents.
• survey report of The Joint Commission or other accrediting organization.
• pharmacy policies and procedures.

Discussion regarding pharmacy services in prescribing, dispensing, administering, and monitoring.

6.2.e. pharmacists are responsible for the procurement, preparation, distribution, and control of
all medications used; and,

Guidance
The pharmacist executive is responsible for, and accountable for, procurement, preparation,
distribution, and control of all medications used, including investigational drugs.

How it will be surveyed
Review of:
• services grid.
• job descriptions.
• benchmark/outcomes/dashboard.
• survey report of The Joint Commission or other accrediting organization.
• pharmacy personnel work schedules.
• written pharmacy policies and procedures.
• automated dispensing cabinet (ADC) stock list.
• dispensing override documentation.
Discussion regarding pharmacist responsibilities in these areas. On-site tour of patient care areas and other observations.
Reference: ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals
Selecting Sources of Pharmaceutical Products: Medication Acquisition, Pharmaceutical Manufacturers and Suppliers, Pharmaceutical Manufacturers’ Representatives.
Managing Inventory: Medication Storage, drug shortages, samples, patient care area stock, controlled substances, patient’s own medications.

6.2.f. Pharmacists are responsible for collaborating with other health professionals to ensure safe medication-use systems and optimal drug therapy.

Guidance
Pharmacy staff members collaborate and provide information to other providers and staff. Actions are effective.
Reference: ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals
Standard VIII. Evaluating the Effectiveness of the Medication-Use System

How it will be surveyed
Review of:
• outcomes measures and monitoring, benchmarks, performance improvement plans.
• committee involvement.
Discussion with Pharmacy and Therapeutics Committee members, nurses, risk managers, pharmacists.

6.3 The pharmacist executive must provide effective leadership and management for the achievement of short- and long-term goals of the pharmacy and the organization for medication-use and medication-use policies.

Guidance
6.3 is a critical factor (see Glossary for definition of “critical factor”).
Short-term is defined as one year.
Long-term is defined as > two years.

How it will be surveyed
Review of:
• short- and long-term goals for pharmacy
• short- and long-term goals are incorporated into a strategic planning document
• discussion with organization and pharmacy leaders, physicians, nurses and pharmacy staff about the role of pharmacy in strategic planning for the organization and medication use process.

6.4 The pharmacist executive must ensure that the following elements associated with a well-managed pharmacy are in place (as appropriate to the practice setting):

6.4.a. A pharmacy mission statement;

How it will be surveyed
Review of mission statement.
Reference: ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals
“A. Pharmacy and Pharmacist Services
Pharmacy Mission, Goals, and Scope of Services. The pharmacy shall have a written mission statement that reflects both patient care and operational responsibilities. Other aspects of the pharmacy’s mission may require definition as well (e.g., educational and research responsibilities).
The mission statement shall be consistent with the mission of the hospital and, if applicable, aligned with the health system of which the hospital is a component.”

6.4.b. a well-defined pharmacy organizational structure;

**How it will be surveyed**
Review of documented organization structure with titles and reporting structure.

6.4.c. current policies and procedures which are available readily to staff participating in service provision;

**Guidance:**
Reference: *ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals*
“C. Policies and Procedures
Policy and Procedures Manual. ...all pharmacy personnel should be familiar with its contents...”
Policies and procedures are present for all four areas: controlled substance handling, drug distribution and dispensing, clinical services, and chart documentation.

**How it will be surveyed**
Review of policies and procedures.

6.4.d. position descriptions for all categories of pharmacy personnel, including residents;

**Guidance**
Reference: *ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals*
“Position Descriptions. Areas of responsibility within the scope of pharmacy services shall be clearly defined. The responsibilities and related competencies of professional and supportive personnel shall be clearly defined in written position descriptions. These position descriptions shall be reviewed and revised as required by the hospital’s policies. Position descriptions should reflect more general aspects of performance (e.g., communication, motivation, teamwork) in addition to specific responsibilities and competencies.”

**How it will be surveyed**
Review examples of position descriptions including job description for residents.

6.4.e. procedures to document patient care outcomes data;

**Guidance**
This focuses on the presence of procedures, as opposed to the quality of the procedures, which would be reviewed elsewhere.
Reference: *ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals*
“Assessing Pharmacy Services and Practices
Documentation of Pharmacist-Provided Patient Care
Services and Medication Therapy Outcomes
The pharmacy shall have an ongoing process for consistent documentation of the patient care services provided by pharmacists and patient outcomes from medication therapy.30


**How it will be surveyed**
Review of examples of patient care outcomes data.
Discussion (e.g., How do you document patient care outcomes data?).
Examples include medication-use evaluations and core measures for the practice site.
6.4.f. procedures to ensure medication-use systems (ordering, dispensing, administration, and monitoring) are safe and effective;

**Guidance**

6.4.f. is a critical factor (see Glossary for definition of “critical factor”).

Procedures are in place to ensure all aspects of the medication-use system, including clinical and operational, are safe and effective. Quality assurance procedures for each step in the medication-use process are available.

**How it will be surveyed**

Review of:

- policies and procedures.
- benchmarking procedures, if available.
- quality assurance programs for all aspects of the medication-use system.

Examples include procedures such as error rate reporting, adverse drug event reporting, and other examples of metrics used to improve safety, such as BCMA compliance and smart pump compliance.

6.4.g. procedures to ensure clinical pharmacy services are safe and effective; and,

**Guidance**

6.4.g. is a critical factor (see Glossary for definition of “critical factor”).

Policies and procedures include how pharmacists are involved proactively in patient care. This includes procedures for therapeutic regimen design and drug monitoring.

**How it will be surveyed**

Review of:

- scope of services.
- procedures and policies for scope of practice.
- clinical process data that demonstrates that what pharmacists are doing is effective (e.g., antibiotic stewardship program is determined to be safe and effective).

Examples include other benchmarking procedures (e.g., vancomycin monitoring).

Discussion about how clinical pharmacy services are provided proactively.

6.4.h. a staff complement that is competent to perform the duties and responsibilities assigned (e.g., clinical and distributive services).

**Guidance**

Competence can be defined as the condition or quality of being well qualified or capable. One could consider a competent individual to be one who has the essential knowledge and skills necessary to perform a job and actually performs the job according to defined expectations.

Personnel are properly trained to perform duties and responsibilities.

Consider providing education to all staff on burnout syndrome, the risks and mitigation strategies.

Resources available on the ASHP website can be found here: [https://www.ashp.org/wellbeing](https://www.ashp.org/wellbeing)

**How it will be surveyed**

Review of:

- scope of services.
- policies and procedures.
- detail and documentation that there is sufficient specialized staff (e.g., if they serve oncology patients that there are properly trained pharmacists to provide that specialized service).
- review of Academic and Professional Record forms of preceptors.
- review of files that document staff competency.
Discussion with program staff about how they verify competency of pharmacists and technicians for duties and responsibilities assigned to them. Program staff may be asked to describe methods used to ensure competency for all categories of personnel to perform their duties and responsibilities.

### 6.5 Pharmacy leaders ensure pharmacy’s compliance with:

- **6.5.a.** all applicable contemporary federal, state, and local laws, codes, statutes, and regulations governing pharmacy practice unique to the practice site; and,

#### Guidance

6.5.a. is a critical factor (see Glossary for definition of “critical factor”).

Pharmacy leaders meet the regulations of all relevant government agencies and accrediting bodies.

#### How it will be surveyed

Review of:
- rules and regulations.
- policies and procedures.
- survey reports from The Joint Commission and other accrediting organizations.
- inspection reports from the State Board of Pharmacy, as applicable.
- Inspection reports from the State Board of Health, as applicable.

Observation via tour of facilities.

- **6.5.b.** current national practice standards and guidelines.

#### Guidance

Examples may include but are not limited to:
- ASHP Best Practices.
- USP Chapter 797/800 requirements (For USP Chapter 800, based on USP implementation schedule).
- ISMP Targeted Medication Safety Best Practices for Hospitals

Pharmacy leaders meet all applicable practice standards and guidelines, including but not limited to ambulatory care, home care, and long-term care.

#### How it will be surveyed

Review of compliance with:
- ASHP Best Practices.
- USP Chapter 797/800 requirements (For USP Chapter 800, based on USP implementation schedule).
- ISMP Targeted Medication Safety Best Practices for Hospitals checklist
- policies for oncology pharmacy services and high risk populations.

Observation via tour of facilities.

### 6.6 The medication distribution system includes the following components (as applicable to the practice setting): See 6.6a through 6.6k

#### Guidance

Program staff should be familiar with: ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals and, as applicable, Minimum Standard for Pharmaceutical Services in Ambulatory Care.

#### How it will be surveyed

Review of:
- policies and procedures.
- automated drug cabinet override list.
- documentation and logs /audits (e.g., unit dose packaging, investigational drug handling).

Discussion:
• is it part of your performance improvement system?
• describe related training.
• determine if respective personnel are working to the extent that their training and licensure allows them.
• discussion to determine that pharmacists are not routinely or regularly performing technicians’ responsibilities.

Observation of the medication distribution system.

6.6.a. effective use of personnel (e.g., technicians);

**Guidance**
The effective use of support personnel ensures that work schedules, procedures, and assignments optimize the use of personnel and resources.

**How it will be surveyed**
Review of job descriptions.
Discussion to determine:
• if respective personnel are working to the extent that their training and licensure allows them.
• that pharmacists are not routinely or regularly performing technicians’ responsibilities.

6.6.b. a unit-dose drug distribution service;

**Guidance**
6.6.b. is a critical factor (see Glossary for definition of “critical factor”).
Risk assessment completed for any exception to dispensing the dose required by the patient. This item is especially important in NICU and pediatric settings. Best practices are that medications are dispensed in a form ready for administration.

From *ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals*
“Standard V. Preparing, Packaging, and Labeling Medications
B. Packaging Medications
*Unit Dose Packaging.* Whenever possible, medications shall be available for inpatient use in single-unit packages and in a ready-to-administer form. Manipulation of medications before administration (e.g., withdrawal of doses from containers, reconstitution of powdered drug products, labeling of containers, and splitting of tablets) by final users should be minimized.

*Bar-Coding of Unit Dose Packaging and Point of Care Administration.* Unit dose packages should contain a bar code and that code should be used in inventory management, dose preparation and packaging, dispensing, and administration. It is the responsibility of the pharmacy department to ensure the quality of all aspects of bar-code medication administration, including scanability of bar codes and database management.”

**How it will be surveyed**
Review of policies and procedures.
Discussion to determine that there is a unit-dose drug distribution system.
Observation via tour of the facility.

6.6.c. an intravenous admixture and sterile product service;

**Guidance**
6.6.c. is a critical factor (see Glossary for definition of “critical factor”).

References: ASHP Best Practices quoted below, and USP 797 and 800 requirements as published.
“Standard V. Preparing, Packaging, and Labeling Medications”
A. Preparing Medications

**Compounding.** Drug formulations, dosage forms, strengths, and packaging that are not available commercially but are needed for patient care shall be prepared by appropriately trained personnel in accordance with applicable practice standards and regulations. The pharmacy shall provide adequate quality-assurance procedures for these operations. Written master formulas and batch records (including product test results, as appropriate) shall be maintained, and a lot number or other method to identify each finished product with its production and control history shall be assigned to each batch.

**Sterile Preparations.** When possible, manufactured sterile preparations should be preferred to compounding in the pharmacy. All sterile medications shall be prepared and labeled in a suitable environment by appropriately trained personnel in accordance with established quality-assurance and expiration dating procedures. The use of sterile medications compounded outside the pharmacy should be avoided to the extent possible; when they are used, there shall be procedures for aseptic preparation, quality assurance, expiration dating, and ongoing competency evaluations for compounding personnel. Sterile compounding outside the pharmacy or satellite pharmacies (e.g., on nursing units) should be minimized and occur only in emergency situations.

**Hazardous Drug Products.** There shall be policies and procedures that describe special precautions, equipment, and training for preparation, handling, storage, and disposal of hazardous drug products and products used in their preparation. These policies and procedures shall be consistent with applicable laws and regulations and should be adequate to ensure the safety of staff, patients, visitors, the community, and the environment.”

**How it will be surveyed**

Review of:
- compliance with USP Chapter 797/800 requirements, as published.
- quality analysis data for sterile product preparations.

Discussion to determine that, except in emergencies, the pharmacy dispenses IV admixtures and sterile products ready for administration with no manipulation by nursing staff.

Discussion with nurses and pharmacy staff.

Observation by tour of facility.

6.6.d. a research pharmacy including an investigational drug service;

**Guidance**

The pharmacy is responsible for overseeing the procurement, distribution, and control of all investigational drugs.

**How it will be surveyed**

Review of policies and procedures.

6.6.e. an extemporaneous compounding service;

**Guidance**

The pharmacy department maintains the responsibility for ensuring the quality of drug products used in the facility.

**How it will be surveyed**

Review of drug preparation logs and compilation of formulations.

Observation by tour of facility.

6.6.f. a system for handling hazardous drugs;
Guidance
There are policies and procedures that describe special precautions, equipment, and training for preparation, handling, storage, and disposal of hazardous drug products.

How it will be surveyed
Review of policies and procedures.
Observation by tour of facility.

6.6.g. a system for the safe use of all medications, (e.g., drug samples, high alert, look-alike/sound-alike, emergency preparedness programs, medical emergencies);

Guidance
6.6.g. is a critical factor (see Glossary for definition of “critical factor”).
The pharmacy is responsible for the procurement, distribution, and control of all drug products used in the facility.

How it will be surveyed
Review of policies and procedures that ensure a safe medication-use system.
Observation of proper management of (during tour of facility):
• barcoding of unit-dose medications.
• smart pump library use.
• look-alike-sound-alike and high-alert medications.
• drug samples.

6.6.h. a secure system for the use of controlled substances;

Guidance
There are policies and procedures to ensure control of the distribution and use of controlled substances. These policies are consistent with applicable laws and regulations and should include methods for preventing and detecting diversion.

How it will be surveyed
Review of audits and policies.
Discussion to determine how access to controlled substances is regulated and the technology (or manual process) to support regulation.

6.6.i. a controlled floor-stock system for medications administered;

Guidance
6.6.i. is a critical factor (see Glossary for definition of “critical factor”).
The pharmacy is responsible for developing policies and procedures and quality assurance programs regarding drug delivery systems and automated distribution devices that ensure safety, accuracy and patient confidentiality.

How it will be surveyed
Review of:
• policies and procedures.
• overrides.
• anti-diversion measures.
Observation by tour of facility to determine, in part:
• appropriate use of automated drug dispensing machines.
• appropriate segregated storage of medication (e.g., paralytics are not intermixed with other injectables in refrigerators, insulin).
6.6.j. an outpatient drug distribution service including a patient assessment and counseling area; and,

**Guidance**
This applies to outpatient pharmacy drug distribution.

**How it will be surveyed**
Observation of outpatient drug distribution service by tour of facility.

6.6.k. a system ensuring accountability and optimization for the use of safe medication-use system technologies.

**Guidance**
6.6.k. is a critical factor (see Glossary for definition of “critical factor”).
The pharmacy has responsibility for developing policies, procedures, and quality assurance programs for safe drug delivery systems, administration devices, and automated distribution devices and other technologies. Pharmacy personnel supervise the stocking and documentation of medications in automated dispensing devices.

**How it will be surveyed**
Review to ensure:
- optimal use of medication-use system (e.g., use of automated drug cabinets on nursing units is preferable).
- that technology is interfaced appropriately with other information systems.
- analysis of use of technologies (e.g., smart pumps, BCMA).
- optimization of use of alerts [e.g., preconstructed alerts that flag specified lab tests (library with the alerts), clinical alerts].
- optimization of decision support.

6.7 The following patient care services and activities are provided by pharmacists in collaboration with other health-care professionals to optimize medication therapy for patients: See 6.7a through 6.7m(5)

**Guidance**
Pharmacists in collaboration with medical and nursing staff develop policies and procedures based on best practices for ensuring the quality of medication therapy.

**How it will be surveyed**
Review of:
- policies and procedures.
- scope of services.
- competencies.
Discussion with preceptors and facility staff about their practices.
Observation of pharmacist patient care services and activities.

6.7.a. membership on interdisciplinary teams in patient care areas;

**Guidance**
6.7.a. is a critical factor (see Glossary for definition of “critical factor”).
Pharmacists participate with physicians, nurses, and other care givers on teams in the direct care of patients.

**How it will be surveyed**
Discussion about pharmacy staff deployment.
Observation.
6.7.b. prospective participation in the development of individualized medication regimens and treatment plans;

**Guidance**
6.7.b. is a critical factor (see Glossary for definition of “critical factor”). This item focuses on medication regimens and treatment plans that are individualized for specific patients. These do not refer to targeted drugs, but rather refer to patient-focused medication regimens and treatment plans. Examples of prospective participation in development of individualized medication regimens and treatment plans include:
- Pharmacists proactively assess patients using the electronic medical record.
- Patient assessment using laboratory data, interview of patient, patient chart, medication history, being prepared to discuss medication-related problems, with or without patient care rounds.
- Participation in patient care rounds, if applicable.

6.7.c. implementation and monitoring of treatment plans for patients;

**Guidance**
6.7.c. is a critical factor (see Glossary for definition of “critical factor”). Medication therapy monitoring shall be conducted by pharmacists. Medication therapy monitoring includes a proactive assessment of patient problems.

**How it will be surveyed**
Review of policies and procedures.
Discussion with preceptors.
Observation.

6.7.d. identification and responsibility for resolution of medication-related problems;

**Guidance**
6.7.d. is a critical factor (see Glossary for definition of “critical factor”). Pharmacists discover medication-related problems from newly reconciled and admitted patients. Every time a drug is added to the regimen a re-evaluation is completed. Practices adhere to ASHP *Guidelines: Minimum Standard for Pharmacies in Hospitals* “Standard VII. Monitoring Medication Use

**A. Reviewing Patient Responses to Medication Therapy**
Medication therapy monitoring shall be conducted by pharmacists. Medication therapy monitoring includes a proactive assessment of patient problems and an assessment of
- The therapeutic appropriateness of the patient’s medication regimen.
- Therapeutic duplication or omissions in the patient’s medication regimen.
- The appropriateness of the dose of the medication, as well as the route, method, and frequency of administration of the medication.
- Patient adherence to the prescribed medication regimen.
- Adverse drug reactions and other undesired effects.
- Patient medication allergies and sensitivities.
- Clinical and pharmacokinetic laboratory data to evaluate the efficacy and safety of medication therapy and to anticipate toxicity and adverse effects.
- Physical signs and clinical symptoms relevant to the patient’s medication therapy.
j. Assessment of the effectiveness of the patient’s medication therapy."

**How it will be surveyed**
- Review of policies and procedures.
- Discussion with preceptors.
- Observation.

6.7.e. review of the appropriateness and safety of medication prescriptions/orders;

**Guidance**
6.7.e. is a critical factor (see Glossary for definition of “critical factor”).
All patient medication orders shall be prospectively reviewed by pharmacists and assessed in relation to pertinent patient and clinical information before the first dose is administered (except in emergency situations).

**How it will be surveyed**
- Review of policies and procedures.
- Discussion with appropriate facility staff.

6.7.f. development of treatment protocols, care bundles, order sets, and other systematic approaches to therapies involving medications for patients;

**Guidance**
6.7.f. is a critical factor (see Glossary for definition of “critical factor”).
Pharmacists are involved in the process to add their expertise on committees where systematic processes are being discussed. This could be active participation on P&T committees, medical committees, safety committees or any other committee where these issues are discussed.

**How it will be surveyed**
- Review of:
  - minutes of committee meetings (Pharmacy and Therapeutics Committee minutes if these issues are discussed in this committee).
  - rosters or lists reflecting committee involvement.
  - discussion with RPD and others.
- Observation.

6.7.g. participation as a provider of individual and population-based patient care services and disease state management, initiating and modifying drug therapy, based on collaborative practice agreements or other treatment protocols;

**Guidance**
This item is applicable regardless of formal collaborative practice agreements. Examples include critical pathways, treatment protocols, order sets, and therapeutic substitutions. This includes Pharmacy and Therapeutic Committee or medical staff-approved pharmacist to dose protocols and similar responsibilities.

**How it will be surveyed**
- Review of:
  - critical pathways, treatment protocols, order sets, therapeutic substitution.
  - formal consults.
  - informal consult data.

6.7.h. a system to identify appropriately trained and experienced pharmacists and ensure quality care is provided, including when pharmacists are practicing under collaborative practice
agreements (e.g., complete credentialing and privileging for pharmacists providing patient care service);

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<td>A system of training exists to ensure the quality of pharmacists’ actions when practicing collaboratively under physician-approved credentialing, protocols, and similar agreements.</td>
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**How it will be surveyed**

Review of:
- critical pathways, treatment protocols, order sets, therapeutic substitutions.
- formal consults.
- informal consult data.

6.7.i. documentation of significant patient care recommendations and resulting actions, treatment plans, and progress notes in the appropriate section of patients’ permanent medical records;

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<td>6.7.i. is a critical factor (see Glossary for definition of “critical factor”). Pharmacists document all significant patient care recommendations in the appropriate section of the patient’s medical record on a timely basis. Pharmacists aren’t restricted from documenting in the medical record. This item does not refer to intervention documentation.</td>
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**How it will be surveyed**

Review:
- to determine that documentation is in the medical record where other health care providers can see it.
- of policy and procedures statement.

6.7.j. medication administration consistent with laws, regulations, and practice site policy;

**How it will be surveyed**

Discussion with appropriate facility staff.

Observation.

6.7.k. disease prevention and wellness promotion programs (e.g., smoking cessation, immunization);

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<td>Examples of wellness promotion programs include brown bag sessions and discussions with patients about their level of compliance, which can be in any patient care setting. Preceptor qualifications from residency accreditation Standard 4 includes this option for “demonstrating ongoing professionalism and contribution to the profession”: contributing to health and wellness in the community and/or organization through active participation in health fairs, public events, employee wellness promotion/disease prevention activities, population-based care management, etc.</td>
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**How it will be surveyed**

Discussion about disease prevention and wellness promotion programs.

6.7.l. a system to ensure and support continuity-of-care during patient care transitions; and,
**Guidance**
Designated personnel in pharmacy perform this function or work in collaboration with other health care providers.
Examples: bridging anticoagulation and oncology therapy, medication reconciliation, and discharge counseling.
Medication history and an accurate listing of patient-specific medications are included.

**How it will be surveyed**
Discussion to determine points of transition in the setting.
Review of processes to ensure continuity-of-care during these transitions.
Examples: home to acute care, transfers within acute care, acute care to home, critical care to floor, inpatient to outpatient.

6.7.m. drug use policy activities including, but not limited to, the following (as applicable to the practice setting):

**Guidance**
6.7.m. is a critical factor (see Glossary for definition of “critical factor”).
There is participation in the development or modification of policies for: (a) medications; (b) medication-use evaluation; (c) appropriate methods to assess ongoing compliance with such policies. Pharmacists participate in the development and modification of policies for medications, medication-use evaluations, and methods to assess ongoing compliance with these policies.

**How it will be surveyed**
Review of examples of related policies and processes used, how processes are implemented, data, follow-up, how improvements are made.
Discussion of systematic approach used.

6.7.m.(1) developing and maintaining an evidence-based formulary;

6.7.m.(2) educating health care providers on timely medication-related matters and medication policies;

**How it will be surveyed**
Review of:
- department or practice site newsletter or other means used to educate providers/physicians, e.g., inservices.
- policies and procedures.
- P&T committee minutes.

6.7.m.(3) development and monitoring of evidence-based medication-use guidelines, policies, and order sets;

**Guidance**
6.7.m.(3) is a critical factor (see Glossary for definition of “critical factor”).

**How it will be surveyed**
Review examples of medication-use evaluations based on evidence-based sources.

6.7.m.(4) managing adverse drug event monitoring, resolution, reporting, and prevention programs; and,
Guidance
There is participation in the development or modification of policies for: (a) adverse drug event prevention, monitoring, and reporting; and (b) appropriate methods to assess ongoing compliance with such policies.
Pharmacists participate in the development and modification of policies for ADEs, and methods to assess ongoing compliance with these policies.

How it will be surveyed
Review of examples of adverse drug event monitoring, related policies and processes used, how processes are implemented, data, follow-up, how improvements are made.
Discussion of systematic approach used.

6.7.m.(5) managing selection, procurement, storage, and dispensing of medications used within the organization.

Guidance
Refer to ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals, Standard IV. Drug Product Procurement and Inventory Management.

How it will be surveyed
Review of site’s compliance with relevant policies and guidelines.

6.8 The pharmacy practice must have personnel, facilities, and other resources to carry out a broad scope of pharmacy services (as applicable to the practice setting). The pharmacy’s:
   6.8.a.(1) facilities are designed, constructed, organized, and equipped to promote safe and efficient work;

Guidance
6.8.a is a critical factor (see Glossary for definition of “critical factor”).
Examples include adequate air conditioning, clean and neat areas, and adequate space.
Pharmacies are USP Chapter 797 compliant and consider square footage, design, and efficient work flow.

How it will be surveyed
Review of:
- logs and audits in the IV room, cleaning logs, maintenance logs.
- documents related to maintenance of equipment, training on USP Chapter 797 compliance.
Discussion of work flow.
Observation by tour to observe cleanliness and space.

6.8.a.(2) professional, technical, and clerical staff complement is sufficient and diverse enough to ensure that the department can provide the level of service required by all patients served; and,

Guidance
6.8.a is a critical factor (see Glossary for definition of “critical factor”).
There are adequately trained pharmacists in the all areas of medical care at the practice site. Pharmacists and technicians practice at the highest level of their training licensure. Standard 6.8 focuses on sufficient complement of personnel.

How it will be surveyed
Review to determine where there are underserved patient areas (e.g., if there is no pharmacy presence in oncology, antibiotic stewardship, pediatrics, the emergency department, on the night shift, on weekends, or in the NICU).
6.8.a.(3) resources can accommodate the training of the current and future workforce (e.g., residents, students, technicians, and others).

**Guidance**

6.8.a is a critical factor (see Glossary for definition of “critical factor”). Programming and funding is adequate to ensure training of current and future pharmacy staff to ensure competency.

**How it will be surveyed**

Review of education policy, human resources policies, and internal training programs.

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**6.9 Continuous Quality Improvement**

**Guidance**

There is a continuous quality improvement process that is a part of regular and routine pharmacy services and is an ongoing program quality measure. The pharmacy provides leadership and participates with other health professionals in a system to routinely evaluate the quality of direct patient care, procurement, and drug distribution services. Systems help identify priorities for the department (e.g., turn-around times, medication errors, transitions of care, medication reconciliation, drug shortages). Reviews includes financial, quality of care, and distribution services. The resulting plan aligns with the organizational goals. Measures that are important to the department and patient care are measured routinely, documented, and reviewed for action. Evaluation of the results of staff performance and assessment of continuing competency. Use of tracer methodology or peer review methodology could be explored. Reference: *ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals, Standard VIII. Evaluating the Effectiveness of the Medication-Use System.*

**How it will be surveyed**

Review:

- of quality reports, dashboards, etc.
- to determine that there is a “continuous loop” or quality improvement process, not just isolated medication-use evaluation, for example.

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6.9.a. Pharmacy department personnel must engage in an on-going process to assess the quality of pharmacy services.

**Guidance**

6.9.a. is a critical factor (see Glossary for definition of “critical factor”). This includes drug distribution, clinical services, and notation in the medical record.

**How it will be surveyed**

Discussion with appropriate practice site staff.

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6.9.b. Pharmacy department personnel must develop and implement pharmacy services improvement initiatives to respond to assessment results.

**Guidance**

6.9.b. is a critical factor (see Glossary for definition of “critical factor”).

**How it will be surveyed**

Review of documentation of improvement initiatives and resulting changes implemented, where necessary.
6.9.c. The pharmacy department’s assessment and improvement process must include assessing and developing skills of the pharmacy department’s staff.

**How it will be surveyed**

Review of documentation of improvement initiatives for pharmacy staff skill improvement and resulting changes implemented, where necessary.

Discussion with pharmacy staff.

6.10 Pharmacy services must be provided to all patients of the organization (or practice) that are in the PGY2 residency’s practice area. Additional considerations are (as applicable to the practice setting):

6.10.a. A sufficient patient population (both in terms of the number of patients and the variety of disease states) must be available in all areas required for instruction in the PGY2 residency program.

6.10.b. Pharmacists providing advanced practice services must be essential members of interdisciplinary teams in the patient care areas associated with the residency program.

6.10.c. Pharmacists providing advanced practice pharmacy services must participate in the development of treatment protocols, critical pathways, order sets, and other systems approaches involving medications for patients on involved services.

6.10.d. For patients of involved advanced practice services, pharmacists must engage in collaborative practice agreements with other providers and should be authorized to manage patients following collaborative practice agreements, treatment protocols, critical pathways; and,

6.10.e. Pharmacists providing advanced practice pharmacy services must participate prospectively in the development of individualized treatment plans for patients of involved services.

**Guidance**

6.10.a, b, c, and e are critical factors (see Glossary for definition of “critical factor”).

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**Glossary**

*Critical factors.* Elements of accreditation standards that the ASHP Commission on Credentialing has determined to be more important and, therefore, carry more weight than others when they are assessed as being less than fully compliant and used to determine length of accreditation.

**Note:** The reader is referred to the Glossary of Definitions at the conclusion of the *ASHP Accreditation Standard for Postgraduate Year One (PGY2) Pharmacy Residency Programs* for a complete list.