

GUIDANCE DOCUMENT FOR THE ASHP ACCREDITATION STANDARD FOR INTERNATIONAL PHARMACY PRACTICE RESIDENCY PROGRAMS NOVEMBER 2017

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.

In general, throughout the survey process, survey teams will be sensitive to local and cultural regulations and standards that influence the design and conduct of the residency program and pharmacy practice, and the survey team assessment of compliance with established criteria and standards.

Preamble:

The need for pharmacy postgraduate training opportunities throughout the world to foster pharmacy practice development and patient care services has led ASHP to develop a new accreditation standard and survey process for use in countries or areas of world that cannot meet the intent of the ASHP pharmacy residency standards that are used in the United States and in some other countries. This international pharmacy practice accreditation standard is structurally similar to the PGY1 and PGY2 accreditation standards, but differs substantially in the requirements of the hospital offering the residency program and the pharmacy services provided within the hospital offering the residency program. In this regard, this accreditation standard embodies the processes of continuous quality improvement. This accreditation standard also utilizes a different set of competencies, educational goals and objectives than the PGY1 pharmacy residency accreditation standard.

The international pharmacy practice residency accreditation standard requires a departure from the survey process utilized for PGY1 and PGY2 residency programs, and will utilize a structured continuous quality improvement process. For decades, PGY1 programs and PGY2 programs have been deemed to be fully, partially, or non-compliant with elements of the accreditation standards. Those terms will not be utilized for this Standard. Rather, for this Standard, survey teams will measure the current state of each element of the

standards (as explained below) and will work with pharmacy leaders and program directors to establish goals to reach the intent of these elements and appropriate timeframes for achievement. Accreditation decisions for the international pharmacy practice residency programs will be "Accredited", "Not Accredited", or "Conditional Accreditation". Survey response and subsequent progress reports to the ASHP International Accreditation Commission will be required at appropriate intervals to measure progress.

Introduction

Purpose of this Standard: the ASHP Accreditation Standard for International Pharmacy Practice Residency Programs (hereinafter the Standard) establishes criteria for training pharmacists to achieve professional competence in the delivery of patient-centered care and pharmacy services.

Residency Program Purpose: International pharmacy practice residency programs build on pharmacy education and outcomes to contribute to the development of clinical pharmacists responsible for medication-related care of patients with a wide range of conditions and to have a leadership role in advancing pharmacy practice in their country.

Application of the Standard: the requirements serve as the basis for evaluating an international pharmacy practice residency program 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 hospitals that apply for accreditation of their residency program. 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 Standard for International Pharmacy Practice Residency Programs

The following explains the rationale and importance of the areas selected for inclusion in the standards.

Standard 1: Requirements of the Sponsoring Organization and Hospital(s) Conducting the Residency Program

It is important that residents learn in a high quality learning environment. Therefore, the hospital conducting the residency should be accredited or working toward accreditation, regulatory requirements, and other nationally applicable standards, and will have sufficient resources to achieve the purposes of the residency program.

Standard 2: Requirements of Pharmacy Services

Since pharmacy facilities and services provide the learning environment where residents are trained, it is important that they train in exemplary environments. After completion of a residency program, residents' should strive to provide for exemplary pharmacy services that improve patient care outcomes. The pharmacy department's role in providing effective leadership, quality improvement efforts, appropriate organization, staffing, and collaboration with others to provide safe and effective medication-use systems are reviewed in this section. This section sets the expectation that sites should continue to improve and advance pharmacy services and should motivate the profession to continually improve patient care outcomes.

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Standard 3: 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 residency program director 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 4: 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 5: Requirements and Selection of Residents

This Standard is intended to help ensure success of residents and that exemplary pharmacists are identified for further development for the benefit of the profession and contributions to patient care. Therefore, residents must be pharmacists committed to attaining professional competence beyond entry-level practice, committed to attaining the program's educational goals and objectives, and supportive of the organization's mission and values.

Standard 6: 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 and become more mature, clinically competent practitioners, enabling them to address patients' needs. Proper design and implementation of programs helps ensure successful residency programs.

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Standard 1: Requirements of the Sponsoring Organization and Hospital(s) Conducting the Residency Program

1.1 As appropriate, residency programs should be conducted in hospitals 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 hospital.

Guidance:

The sponsoring organization and all practice sites that offer or that participate in offering a pharmacy residency are accredited by applicable organizations [e.g., in the United States: The Joint Commission (TJC), American Osteopathic Association (AOA)/Healthcare Facilities Accreditation Program (HFAP), National Committee for Quality Assurance (NCQA), Det Norske Veritas (DNV). In other countries, The Joint Commission International (JCI) or other organizations, as required by state or national law]. A college or school of pharmacy that participates in offering a pharmacy residency is accredited by the Accreditation Council for Pharmacy Education (ACPE) or other pharmacy education accrediting body.

How it will be surveyed:

Review of the most recent documentation of recognition.

- 1.2 Residency programs must be conducted only in those hospitals where staff and leaders are committed to seek excellence in patient care as evidenced by substantial compliance with professionally developed and internationally applied practice and operational standards.
 - 1.2.a. The hospital offering the residency program should comply with currently published medication-related international patient safety goals (e.g., JCI, WHO, or others);
 - 1.2.b. Medication use in the hospital is organized and delivered to meet patient needs, complies with applicable laws and regulations, and is under the direction and supervision of a licensed pharmacist who practices at that site;
 - 1.2.c. Pharmacy and Therapeutics Committee/Medication Management Committee provides oversight over medication use throughout the hospital;
 - 1.2.c.(1) Medication prescribing, ordering, and transcribing processes are guided by policies and procedures;
 - 1.2.c.(2) All medications that are administered to patients are prescribed and documented in the patient's record;
 - 1.2.d. Quality and patient safety programs use current evidence to support safe medication use in the hospital.
 - 1.2.d.(1) Data measures selected reflect patient needs and best practices and are selected by an interprofessional group that includes a pharmacist.
 - 1.2.d.(2) Data collected is analyzed, aggregated, and reported to appropriate committees.
 - 1.2.d.(3) The hospital uses a defined process for identifying and managing sentinel events; specifically, pharmacists are involved in medication-related sentinel event management.
 - 1.2.d.(4) The organization uses a defined process for the identification, analysis and management of near-miss events.;
 - 1.2.e. The hospital maintains a standardized medical record for every patient. Pharmacists should have access to the medical record and should document significant patient care activities;
 - 1.2.f. The hospital offering the residency program must develop and use uniform processes for prescribing patient medications;

- 1.2.g. All medication orders or prescriptions are reviewed, interpreted, and validated by pharmacists for appropriateness prior to medicine administration. If a pharmacist is not available for this function, prior review must be done by someone who has been trained according to a written policy;
- 1.2.h. All medications used in the hospital are properly and safely stored;
- 1.2.i. All medications used in the hospital are prepared and dispensed in a safe and clean environment. If medications are prepared outside of the pharmacy, staff who perform compounding (sterile or non-sterile), should be properly trained;
- 1.2.j. Human subjects research conducted in the hospital is guided by laws, regulations, and hospital leadership.
 - 1.2.j.(1) The hospital has a committee or another way to oversee all medication-related research in the hospital involving human subjects.
 - 1.2.j.(2)All medications involved with investigational studies should be controlled, stored, and dispensed by the pharmacy department, where possible. Where not possible, the pharmacy department must still maintain control via oversight and audit.
- 1.2.k. As a part of the hospital's emergency management program (emergencies, epidemics, and disasters), all medications involved in emergency management programs should be appropriately selected and controlled, stored, and dispensed by the pharmacy department;
- 1.2.l. Laboratory services required to support safe and appropriate medication use are available to meet patient needs, and all such services should meet applicable local and national standards, laws, and regulations;
- 1.2.m. The hospital offering the residency program should design and carry out processes to provide continuity of care of medication-related information to patients in the hospital and at discharge to home or other health care facilities;
- 1.2.n. The hospital offering the residency program should provide patient and family education and instruction for all medications used by the patient during the hospitalization and at discharge from the hospital;
- 1.2.o. Pharmacy leaders define the desired education, skills, knowledge, and other requirements of all staff members. Each staff member's responsibilities are defined in current job descriptions; and,
- 1.2.p. The hospital uses a defined process to ensure that clinical and non-clinical staff knowledge and skills are consistent with patient needs.

Guidance:

Hospitals that offer or collaborate with colleges of pharmacy to offer pharmacy residency programs are expected to comply with established best practices, standards of care, applicable regulations and laws. 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, WHO, CDC, and others) that apply to specific practice sites..

Select ASHP Best Practice Documents may be of particular value for the development of or optimization of corresponding pharmacy services, including the following ASHP Guidelines:

Minimum Standard for Pharmacies in Hospitals; Compounding Sterile Preparations; Pharmacy and Therapeutics Committees and the Formulary System; Adverse Drug Reaction Monitoring and Reporting; Preventing Medication Errors in Hospitals; Standardized Method of Pharmaceutical Care; Documenting Pharmaceutical Care in Patient Medical Records; Clinical Drug Research; Recruitment, Selection, and Retention of Pharmacy Personnel.

Additionally, select ASHP Technical Assistance Bulletins may be of particular value for the development

of or optimization of pharmacy services, including the following:

Hospital Drug Distribution and Control; Repackaging Oral Solids and Liquids in Single Unit and Unit Dose Packages; and, Single Unit and Unit Dose Packages of Drugs.

How it will be surveyed:

Discussion with hospital leaders, medical staff members, nursing staff members, and pharmacy staff members.

Tour of the facilities

- 1.3. Two or more hospitals, or a sponsoring organization (e.g., college of pharmacy, ministry of health) working in cooperation with one or more hospitals, may offer a pharmacy residency.
 - 1.3.a Sponsoring organizations must maintain authority and responsibility for the quality of their residency programs.
 - 1.3.b. Sponsoring organizations may delegate day-to-day responsibility for the residency program to a hospital; however, the sponsoring organization must ensure that the residency program meets accreditation requirements.
 - 1.3.b.(1) the sponsoring organization must ensure that the purpose of the residency and the terms of the agreement are being met.
 - 1.3.c. The sponsoring organization must designate and empower an individual to be responsible for directing the residency program and for achieving consensus on the evaluation and ranking of applicants for the residency.
 - 1.3.d. Sponsoring organizations and hospitals must have signed agreement(s) that defines clearly the responsibilities for all aspects of the residency program.
 - 1.3.e. Each of the hospitals that provide residency training must meet the requirements set forth in Standard 1.2 and the pharmacy's service requirements in Standard 2.

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.

1.4 Multiple-site residency programs must be in compliance with the ASHP Accreditation Policy for Multiple-Site Residency Programs⁵.

Standard 2: Requirements of 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) 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."

See Section 1.2 for additional guidance. 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.

2.1 Pharmacy Services Integration Within the Hospital

2.1.a. 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."

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How it will be surveyed:

- 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.

- 2.1.b. Current professional practice standards and guidelines should be followed, such as: ASHP Best Practices for Health-System Pharmacy and FIP Basal Statements on the Future of Hospital Pharmacy and, when necessary, other standards that apply to specific practices or sites will be used to evaluate any patient care sites or other practice operations providing pharmacy residency training.
- 2.1.c. The pharmacy department is integrated into planning and provision of patient care services. This includes pharmacy representation on key hospital committees and developing goals for the hospital and the pharmacy department regarding medication use;

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 pertains 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.
 - 2.1.d. The scope of pharmacy services is documented and is based upon the mission of the pharmacy department and an assessment of needs of the patients served by the hospital. These may include but are not limited to hours of service, types of pharmacy services provided, such as clinical pharmacy programs, formulary management programs, medication reconciliation, IV admixture, unit dose drug distribution service, pharmacokinetic service, and others.

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. This includes inpatient services, outpatient clinics, satellite clinics/facilities, procedures areas, perioperative services areas, and the emergency department.

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:

- 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.
 - 2.1.e. Clinical pharmacy services are provided by pharmacy department employees for all areas of the hospital, including diagnostic and treatment areas, (and clinics, if applicable). Policies and procedures are used to manage employees who provide clinical pharmacy services who are not members of the pharmacy department, if applicable.

Guidance:

Policies and procedures include how pharmacists provide patient care services, such as therapeutic regimen design, education, and drug monitoring; and for how such services are provided by pharmacists who are not members of the pharmacy staff.

How it will be surveyed:

Review of:

- 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).
- scope of services.
- 2.1.f. All medications used in all areas of the hospital, including diagnostic and treatment areas, (and clinics, if applicable) should be provided by the pharmacy department. Where medications are not provided by the pharmacy, there is pharmacy oversight.

Guidance:

Pharmacy services extend to all patient care areas (i.e., inpatient, outpatient, diagnostic, emergency services) in which medications are prescribed, dispensed, administered, and monitored. The director of pharmacy is responsible for, and accountable for, procurement, preparation, distribution, and control of all medications used, including investigational drugs. Accordingly, all medications used in the organization should be provided by the pharmacy department. If the pharmacy is not open 24 hours daily, seven days per week, systems must be in place to provide medications using processes that ensure patient safety. Such processes should involve reviews of and double checks of medication dose, route, and dosage form, at minimum. Pharmacy services should have a process to retrospectively review all orders for medications provided outside of the pharmacy department. The pharmacy department should review requests for and oversee the processes of stocking all medications stocked anywhere outside of the pharmacy department.

How it will be surveyed:

- Policies and procedures for review of medication orders, preparation and dispensing, including retrospective review processes
- processes for determining medications stocked outside of the pharmacy department
- medication stock lists
- medication event reporting and trending to identify opportunities to improve the processes
- services grids for ambulatory and acute care.
- scope of services document (what services and medications are provided and where).

- pharmacy strategic planning documents.
- survey report of The Joint Commission International or other accrediting organization.

Observational tour of the hospital.

Discussion of pharmacist's responsibilities in patient care areas.

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

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, and patient's own medications.

On-site tour of patient care areas.

2.1.g. Policies and procedures are used to ensure the medication-use processes (ordering, preparation, dispensing, storage, administration, and monitoring) are safe and effective for all drugs (up to the point of administration) to all patients in all areas of the health care organization.

Guidance:

Policies and 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 developed and implemented with measures guiding planning and CQI processes in the pharmacy department.

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.

- 2.2 Pharmacy Services Administration/Management
 - 2.2.a. A pharmacy mission statement and strategic plan or pharmacy goals are developed and used to guide the pharmacy service;

How it will be surveyed:

Review of pharmacy department strategic plan and/or goals

Discussion with hospital and pharmacy leaders, physicians, nurses, and pharmacy staff about the role of pharmacy in strategic planning for the hospital and the pharmacy department concerning the medication use process.

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."

2.2.b. A well-defined pharmacy organizational structure is developed and implemented;

How it will be surveyed:

Review of documented organization structure with titles and reporting structure.

2.2.c. Current policies and procedures for all pharmacy operations and services are readily available to staff;

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. Discussion with pharmacy managers.

2.2.d. Current position descriptions are used for all categories of pharmacy personnel, including residents. Position descriptions include the desired education, skills, knowledge, and other requirements.

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 reviewed 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.

2.2.e. A staffing strategy for the hospital is maintained by leaders of the pharmacy department, and identifies the number, types, and desired qualifications of staff based on patient need. Such strategy is reviewed and revised on an ongoing basis, and is updated as necessary

Guidance:

The pharmacy scope of services document, master staffing plan or a similar document should outline the numbers and qualifications of staff needed at all times to provide the services to which the pharmacy department is committed.

How it will be surveyed:

Review of scope of services document

Discussion with organizational leaders, medical staff members, nursing leaders, and pharmacy department leaders and staff members.

2.2.f. Each staff member receives ongoing education and training to maintain or to advance his/her knowledge and skills.

Guidance:

Competence can be defined as the condition or quality of being well qualified or capable. A competent individual is considered to have 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.

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.

2.2.g. The hospital has a uniform process to gather, verify, and evaluate staff members' credentials (license, education, training, and experience).

How it will be surveyed:

Review of the process utilized to verify and evaluate credentials of all applicable staff members

2.2.h. The pharmacy department measures and demonstrates the value and quality of pharmacy services (e.g., patient satisfaction surveys, operational and clinical measures)

Guidance:

The pharmacy department develops and uses indicators to measure all aspects of performance.

How it will be surveyed:

Review of the pharmacy department strategic plan and goals, and quality measures/indicators used Review of surveys conducted

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Review of data collected from strategic plans, goals, and quality measures/indicators

Discussions with medical staff and nursing staff

Discussion with pharmacy staff

2.2.i. Pharmacy services comply with all applicable laws, codes, statutes, and regulations governing pharmacy practice unique to the hospital;

Guidance:

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 International (JCI) and other accrediting organizations.
- inspection reports from the Board of Pharmacy and/or Board of Health, as applicable. Discussion with appropriate pharmacy and facility staff.

Observation via tour of facilities.

2.2.j. Systems are used to assess financial performance of the pharmacy department;

How it will be surveyed:

Review of the pharmacy budget, procurement records, and financial indicators from strategic plans Discussion with pharmacy department leaders

2.2.k. Financial, personnel, and facilities resources support the training of current and future workforce (e.g., residents, students, technicians, and others).

Guidance:

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.

- 2.3 Drug Information, Medication Use Policy and Safety
 - 2.3.a. Pharmacists respond to inquiries for medication information using appropriate drug information references and literature sources;
 - 2.3.b. Medication use and safety programs are adequately supported by current drug information sources, including journals, periodicals, textbooks, and/or electronic systems in all areas of the hospital where medications are prepared, dispensed and administered to patients;
 - 2.3.c. A pharmacy and therapeutics committee, or similar group, provides oversight of medication use in the organization
 - 2.3.c.(1) committee membership is interdisciplinary (e.g., physicians, nurses, pharmacists) and represents patient care needs;
 - 2.3.c.(2) frequency of meetings is based on patient care and organizational needs;
 - 2.3.c.(3) meeting discussions and decisions are evidence-based, unbiased and independent from political influences; and,
 - 2.3.c.(4) Committee reports to the medical executive committee or other appropriate organizational committee;
 - 2.3.d. The pharmacy department maintains a drug formulary approved by the Pharmacy &

Therapeutics Committee, based on criteria, safety and efficacy;

- 2.3e. Drug formulary decisions are based on defined criteria that include the indication for use, effectiveness, risks, and costs;
- 2.3.f. Evidence-based medication-use guidelines, policies, and order sets are developed, utilized and evaluated at appropriate intervals;
- 2.3.g. Medication-use (including compliance with clinical guidelines, protocols and order sets, and the appropriateness of ward-stock medications) is evaluated for safety, clinical effectiveness, and cost effectiveness;

Guidance:

Pharmacy department staff should utilize the following documents to develop policies and procedures: ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals, Pharmacist's Role in Providing Drug Information, Pharmacy and Therapeutics Committee and the Formulary System, Medication-Use Evaluation, Pharmacist's Role in the Development, Implementation and Assessment of Critical Pathways.

- 2.3.h. The hospital has developed and implemented a medication safety plan that addresses all aspects of the medication-use process;
- 2.3.i. Hospital and pharmacy systems report and review adverse events and medication errors, including individual report analysis, aggregation, and trend analysis to evaluate medication use. Systems such as root-cause analysis and failure mode effect analysis and other appropriate tools are used when appropriate;

Guidance:

Pharmacy department staff should utilize the following documents to develop policies and procedures: ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals, Adverse Drug Reaction Monitoring and Reporting, Preventing Medication Errors in Hospitals, Preventing Medication Errors with Chemotherapy and Biotherapy.

- 2.3.j. Policies define which medications are permitted to be stocked in all areas of the hospital, including outside of the pharmacy;
- 2.3.k. Policies are developed and used when the pharmacy is closed, including medication order review, interpretation and verification, medication selection, and access to medications within the pharmacy or pharmacy satellite(s);
- 2.3.l. Policies are developed and used for the identification, control, and use of patient's own medications (not provided by the hospital);

Guidance:

See Elements 2.5a, 2.5e, 2.5i, and 2.5j for additional guidance and information about how the standard will be surveyed.

- 2.3.m. Policies are developed and used for complementary and alternative medications used for patients or self-administered by patients (natural, herbal, tribal, traditional);
- 2.3.n. The pharmacy department provides education and information to health care professionals on timely medication-related matters and medication policies (in-services, newsletters, meetings, intranet use);

- 2.3.o. Processes are used by the hospital and by the hospital pharmacy department to evaluate the safety of the medication-use system, including manual and automated systems:
 - 2.3.o.(1) Use of information systems;
 - 2.3.o.(2) Use of automation in pharmacy and in patient care areas;
 - 2.3.o.(3) Use of smart infusion devices and their libraries and guardrails;
 - 2.3.o.(4) 24 hour access to pharmacy and medications.

2.4 Procurement

- 2.4.a. The pharmacy department is responsible for and manages the selection, procurement, storage, and dispensing of medications used within the organization. Pharmacists should ensure transparent procurement processes are in place in line with best practice and national legislation, are free from conflict of interest, and are based on principles of safety, quality, and efficacy.
- 2.4.b. Processes are utilized for the approval of all vendors and suppliers of medications used in the organization;
- 2.4.c. Appropriate packaging procedures are used to prepare medications;
- 2.4.d. The hospital and/or pharmacy department procures and dispenses ready-to-administer medications as much as possible; and,
- 2.4.e. The pharmacy department manages processes for drug that are in short supply;
- 2.4.f. The pharmacy department manages process for recalled, expired and defective medications; and,
- 2.4.g. Appropriate personal protective equipment for medication preparation, dispensing, and administration is purchased and used for hazardous materials handling by all staff.

Guidance:

Pharmacy department staff should utilize the following documents to develop policies and procedures: ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals, Selecting Pharmaceutical Manufacturers and Suppliers, Managing Drug Product Shortages in Hospitals and Health Systems.

ASHP Statements on Unit Dose Drug Distribution, Pharmacists' Responsibility for Distribution and Control of Drug Products

ASHP Technical Assistance Bulletins: Hospital Drug Distribution and Control, Repackaging Oral Solids and Liquids in Single Unit and Unit Dose Packages, and Single Unit and Unit Dose Packages of Drugs. Pharmacy department staff should work with medical, nursing, and environmental services department staff to assess hazardous medication use and needs for personal protective equipment for staff involved in the administration, waste management, and clean up processes.

2.5 Medication Distribution Systems

Guidance: Program staff should utilize the ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals and, as applicable, Minimum Standard for Pharmaceutical Services in Ambulatory Care to develop policies and procedures

How it will be surveyed:

- policies and procedures.
- automated drug cabinet override list, if applicable.

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.

2.5.a. Pharmacists are responsible for the preparation, distribution, and control of all medications used;

2.5.a.(1) If pharmacy services are not provided 24 hours daily, pharmacy policies and procedures, training, and reconciliation processes are used to ensure medication safety and appropriate medication therapies;

2.5.a.(2) Access to medications is appropriately controlled when the pharmacy department is closed.

How it will be surveyed:

Review of pharmacy, medical staff, and nursing (as applicable) policies and procedures

Review of medication dispensing logs when pharmacy does not do dispensing

Review of medications stocked outside of the pharmacy department

Tour of the facilities

Discussion with pharmacy, nursing and other staff members for areas where medications are stored

2.5.b. Medication storage, labeling, and packaging in the pharmacy and in the hospital complies with high risk, high alert and sound alike-look alike medication safe practices;

How it will be surveyed:

Review of pharmacy, medical staff, and nursing (as applicable) policies and procedures Review of high risk, high alert medications lists

Tour of the facilities

Discussion with pharmacy, nursing and other staff members

2.5.c. All oral medication dosage forms are packaged and dispensed from the pharmacy in the most ready-to-administer to patients form;

Guidance:

Best practices are that medications are dispensed in a form ready for administration to the patient. A risk assessment (by the pharmacy and nursing staff) is completed for any exception to dispensing the ready-toadminister dose required by the patient. This practice is especially important in oncology, NICU and pediatric settings. Refer to ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals "Standard V. Preparing, Packaging, and Labeling Medications"

Guidance: 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. (if applicable)

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 scan-ability of bar codes and database management.

How it will be surveyed:

Review of policies and procedures.

Discussion with pharmacy leaders, managers and staff. Discussion with nursing representatives. Observation during the tour of the facility to observe how the drug distribution system works.

2.5.d. All intravenous admixtures, including all small and large volume parenteral solutions, chemotherapy, TPN (IV nutrition), concentrated electrolyte supplements and infusions, dialysis solutions and all others are provided for all patients in the most ready-to-administer form;

Guidance:

References: ASHP Best Practices quoted below, and USP Chapter <797> requirements "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. The pharmacy department should procure manufactured sterile preparations, and should prepare and label all sterile medications 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 policies and 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 and USP Chapter <800> requirements, or other similar requirements of the country offering the residency program. 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 minimal or no manipulation needed by nursing staff to administer the medication.

Discussion with nurses and pharmacy staff.

Observation during the tour of facilities.

2.5.e. All medications are packaged and labeled to ensure identification of the medicine and to maintain integrity until immediately prior to administration to individual patients;

Guidance:

The pharmacy department maintains the responsibility for ensuring the quality of drug products used in the facility. See 2.5c Guidance.

How it will be surveyed:

Review of policies and procedures.

Discussion with pharmacy leaders, managers and staff. Discussion with nursing representatives. Observational tour of facilities to observe how the drug distribution system works.

2.5.f. The pharmacy follows applicable quality standards when compounding non-sterile products;

Guidance:

The pharmacy department maintains the responsibility for ensuring the quality of drug products used in the facility. See 2.5d Guidance.

How it will be surveyed:

Review of drug preparation logs and compilation of formulations. Observation by tour of facility.

2.5.g. The pharmacy establishes procedures for dispensing, handling and administering institutionally-identified high-risk medications.

Guidance:

The pharmacy department is responsible for the procurement, distribution, and control of all drug products used in the facility, and has established, through a multidisciplinary process, a list of medications that are identified as high-risk. Such determination may be made at the organizational level, or may refer to or defer to other professionally developed an accepted lists.

How it will be surveyed:

Review of high-risk medication lists. Observational tour of the facilities.

Discussion with pharmacists and the Chair, P & T Committee.

2.5.h. The pharmacy ensures the development and implementation of policies and procedures for the safe handling of hazardous drugs.

Guidance:

Policies and procedures that describe special precautions, equipment, and training for the handling, storage, and disposal of hazardous drug products. Refer to USP Chapter <800>.

How it will be surveyed:

Review of policies and procedures Observational tour of the facility.

2.5.i. A secured ward-stock system is used for a minimal amount of medications and access is limited;

Guidance:

The pharmacy department is responsible for developing policies and procedures and quality assurance programs regarding medication storage within the hospital. With respect to ward-stock systems, pharmacy staff should work with medical and nursing staff representatives to ensure that appropriate medications are available to meet patient care needs while maintaining appropriate control. Ward stock medications should be stored in secure areas to limit access to authorized personnel only.

How it will be surveyed:

Review of policies and procedures and ward stock lists.

Discussion with pharmacy staff.

Observational tour of facilities to determine appropriate storage and segregation of medications (as appropriate).

2.5.j. A secure system for the safe storage, control, use and disposal of controlled substances and narcotics is used for all medications in all hospital areas

Guidance:

There are policies and procedures to ensure control of the distribution and use of controlled substances and narcotics. 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.

Observational tour of the facility to review how technology or manual processes support a safe system.

2.5.k. The pharmacy department ensures that systems are in place for medications and supplies used for emergencies;

Guidance:

The pharmacy department maintains responsibility for ensuring the quality of drug products used in the facility, including ward stock, emergency cart/crash cart, and other medication storage locations.

How it will be surveyed:

Review of drug preparation logs and compilation of formulations.

Observation by tour of facility.

2.5.l. Appropriate pharmacy facilities for medications used for research should be provided, including an investigational drug service, if applicable;

Guidance:

The pharmacy is responsible for overseeing the procurement, distribution, and control of all investigational drugs, including any unique storage, distribution or dispensing requirements.

How it will be surveyed:

Review of policies and procedures. Tour of the facilities.

2.5.m. The pharmacy department ensures that systems are used for the safe storage, control, and use of medication kits through the organization, if applicable;

Guidance:

The pharmacy department is responsible for the control of all drug products used in the facility. "Kits" refer to collections of medications, generally contained within a box that should be locked, that are used in emergent or urgent situations. (e.g., rapid sequence intubation (RSI), etc.). The pharmacy department should maintain control of assembling kits, recording lot and expiration dates, and for maintaining a list of where kits are located.

How it will be surveyed:

Review of lot sheets/logs

Observational tour of the facilities

2.5.n. The pharmacy department ensures the development and implementation of policies and procedures for the safe storage, control, use and disposal of medication samples, if applicable; and,

Guidance:

A policy and procedure outlines how samples enter into the organization, how and where lot numbers and expiration dates are recorded and maintained, a recording system for patient name, lot number and expiration date upon dispensing, and a method to record where samples are securely located.

How it will be surveyed:

Review of policies and procedures

Review of sample dispensing logs

Observational tour of the facilities

- 2.5.o. If an outpatient dispensing service is provided, it should include a patient assessment and counseling area.
- 2.6 Patient Care Services
 - 2.6.a. Clinical pharmacy services are based on an assessment of patient care needs;

Guidance:

An assessment of the clinical pharmacy services needed by patients served in the organization should be conducted, with input from patients, physicians, nurses, and other caregivers.

How it will be surveyed:

Review of scope of services document.

Interviews with pharmacy, nursing, and medical staff members.

2.6.b. Pharmacists are members on interdisciplinary teams in patient care areas;

Guidance:

Pharmacists should participate with physicians, nurses, and other care givers on teams in the direct care of patients. This may include participating on interdisciplinary rounding, or through direct contact with physicians, nurses and other members of the health care team.

How it will be surveyed:

Interviews with pharmacy, nursing, and medical staff members.

Observation.

2.6.c. Pharmacists are responsible and accountable for pursuing optimal medication-related patient care outcomes;

Guidance:

Pharmacy staff members collaborate with and provide information to other providers and staff. Actions are effective and are measured on an ongoing basis.

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.

2.6.d. Pharmacists are responsible for identification of patient specific medication-related problems, including but not limited to those related to therapeutic failures, adverse drug reactions, medication errors, inappropriate prescribing;

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Guidance:

Pharmacists identify medication-related problems for all 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

- a. The therapeutic appropriateness of the patient's medication regimen.
- b. Therapeutic duplication or omissions in the patient's medication regimen.
- c. The appropriateness of the dose of the medication, as well as the route, method, and frequency of administration of the medication.
- d. Patient adherence to the prescribed medication regimen.
- e. Medication–medication, medication–food, medication–dietary supplement, medication–laboratory test, and medication–disease interactions.
- f. Adverse drug reactions and other undesired effects.
- g. Patient medication allergies and sensitivities.
- h. Clinical and pharmacokinetic laboratory data to evaluate the efficacy and safety of medication therapy and to anticipate toxicity and adverse effects.
- i. 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 pharmacists, residents, physicians Observation.

2.6.e. In collaboration with the healthcare team, pharmacists contribute to prospective development of patient-specific medication therapy and treatment plans;

Guidance:

Pharmacists identify goals of therapy for each patient, and prospectively develop patient-specific treatment plans using evidence-based guidelines and best practices, and patient-specific information. These treatment plans may include to targeted drugs, but should 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.
- 2.6.f. Pharmacists are responsible for the monitoring of patient response to medication therapy;

Guidance:

Medication therapy monitoring shall be conducted and/or coordinated by pharmacists. Medication therapy monitoring includes a proactive assessment of patient problems and collaboration with the healthcare team to achieve desired outcomes.

How it will be surveyed:

Review of policies and procedures.

Discussion with pharmacists.

Observation.

2.6.g. Pharmacists participate in disease prevention and wellness promotion programs within the hospital, and community, if possible (e.g., smoking cessation, weight reduction, immunization, etc.);

Guidance:

Examples of wellness promotion programs may include immunization programs, smoking cessation programs, weight loss programs, medication regimen reviews and discussions with patients about their level of medication adherence, 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.

How it will be surveyed:

Discussion about disease prevention and wellness promotion programs.

2.6.h. Pharmacists participate in continuity-of-care processes utilized during patient care transitions;

Guidance:

Pharmacists, pharmacy residents, and pharmacy students perform this function or work in collaboration with other health care providers who do so.

Examples: Conducting a medication history and acquiring an accurate listing of patient-specific medications; bridging anticoagulation and oncology therapy; medication reconciliation, patient education; and discharge counseling.

How it will be surveyed:

Discussion to determine points of transitions of care in the hospital.

Review of processes to ensure continuity-of-care during these transitions.

Examples: home to admission to the hospital, transfer from floor care to the ICU, discharge to home

2.6.i. Pharmacists and residents document in the patient record clinically-relevant activities which significantly impact individual patient care.

Guidance:

By policy, pharmacists aren't restricted from documenting in the medical record. Pharmacists document all significant patient care recommendations in the appropriate section of the patient's medical record on a timely basis. This item does **not** refer to documentation of interventions.

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.

2.7 Quality Assurance

Guidance:

The pharmacy department utilizes an ongoing continuous quality improvement process to regularly and routinely evaluate pharmacy services. Indicators and quality measures assist in directing pharmacy service enhancements and development or new programs.

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 include 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.
 - 2.7.a. Pharmacy department personnel engage in an on-going process to assess and improve the quality of pharmacy services, including evaluation and implementation of new practice standards and guidelines;

Guidance:

This includes reviews of all aspects of pharmacy services, including procurement, storage, preparation, distribution, clinical services, reviews of intervention data, reviews of outcomes and chart documentation.

How it will be surveyed:

Discussion with appropriate practice site staff.

2.7.b. The pharmacy department's assessment and improvement process include assessing and developing skills of the of 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.

2.7.c. A system ensuring accountability and optimization for the use of safe medication-use system technologies, including devices used for medication preparation, distribution, and administration is used and monitoring for continuous improvement;

Guidance 2.7.c-e:

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 include:

- 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.
 - 2.7.d. A process is used to ensure safe and effective medication use while the pharmacy is closed (if applicable);

Guidance:

The pharmacy department must ensure safe and effective medication use at all times. If the pharmacy department is not open 24 hours per day, 7 days per week, then policies and procedures must be developed and implemented to guide who has access to the pharmacy department when it is closed. A pharmacist should be available on call while the pharmacy is closed. Access to a limited supply of medications for urgent and emergent needs should be available to an authorized, licensed health care professional (this is generally a nursing supervisor). When new orders are received, policies and procedures should be written and implemented to support an immediate review of new orders by licensed personnel (generally, this involves a staff nurse or unit charge nurse review of a new order with subsequent review by a second nurse, such as a nursing supervisor). Medications removed from the pharmacy when it is closed should be monitored and documented, and double checked by a second licensed health care professional before administration to a patient. These medication orders should be reviewed retrospectively by a pharmacist to ensure appropriate use. The list of available medications should be accessible to all pharmacy, medical and nursing staff members, and should be approved by the pharmacy and therapeutics committee or its equivalent. Reference: ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals

How it will be surveyed:

Review of policies and procedures and list of medications available while the pharmacy is closed. Review of dispensing logs.

Discussion with pharmacy staff and nursing staff

Observational tour of the pharmacy department

- 2.7.e. Pharmacy personnel conduct routine inspections of ward-stock, procedure areas, and any other locations where medications are stored. The results of inspections are reported to pharmacy and nursing leaders/managers, and reported to the appropriate medication policy committee; and,
- 2.7.f. Pharmacy department inspections by external organizations are conducted and results are reported and used for process improvement.

How it will be surveyed:

Review of inspection documents and related data

Review of programs implement in response to inspection requirements or recommendations

- 2.8 Personnel/Human Resources:
 - 2.8.a. The professional, technical, and clerical staff complement is sufficient to ensure that the department can provide the level of service required by all patients served;

Guidance:

An appropriate complement of competent pharmacists practice routinely in the all areas of the practice site. Pharmacists and technicians practice at the highest level of their training licensure. Standard 2.8 focuses on sufficient complement of personnel.

How it will be surveyed:

Review to determine where there are underserved patient care 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, etc.).

2.8.b. The staff complement 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.

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.

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2.9 Pharmacy Facilities:

- 2.9.a. Inpatient pharmacy and satellite (if applicable) pharmacy facilities are designed, constructed, organized, and equipped to promote safe and efficient work and to meet patient care needs;
- 2.9.b. Sterile product facilities are appropriate to meet patient care needs and are compliant with appropriate guidelines;
- 2.9.c. Outpatient pharmacy facilities are designed to promote safe and efficient work;
- 2.9.d. Adequate office space for managers, supervisors, staff and learners is provided;
- 2.9.e. Adequate workspace for pharmacists in patient care areas is provided;
- 2.9.f. Adequate office space for residents is provided;
- 2.9.g. Adequate meeting space is provided;
- 2.9.h. Space is adequate for patient education in pharmacy areas;
- 2.9.i. Space is adequate for security and control of controlled substances and narcotics in all pharmacy and patient care areas;
- 2.9.j. Space and facilities are adequate for storage, handling and dispensing of investigational drugs; and,
- 2.9.k. Space and facilities are adequate for safe preparation, handling and storage of hazardous drugs.

Guidance:

Examples include adequate space and air conditioning, and clean and neat areas. Pharmacies are compliant with USP Chapter <797> and Chapter <800> requirements, or other similar requirements of the country offering the residency program, and have adequate 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, or compliance with other similar requirements of the country offering the residency program. Discussion of work flow and observation by tour to observe cleanliness and space.

2.10 IT Systems

Guidance:

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.
 - 2.10.a. If utilized, electronic health information technology systems support a safe medication-use system;
 - 2.10.b. If utilized, automated medication-related technologies support safe medication-use in patient care areas.

Standard 3: Requirements of the Residency Program Director and Preceptors

- 3.1 Program Leadership Requirements
 - 3.1.a. Each residency program must have a single residency program director (RPD) who must be a pharmacist from the hospital involved in the program or from the sponsoring organization.
 - 3.1.b. The RPD must establish and chair a residency advisory committee (RAC) specific to that residency program.

Guidance:

The intent of 3.1b 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 that there is a mechanism to ensure the oversight needs of individual programs are met.

The RAC is composed of a cross section of clinical, operational, and administrative preceptors. The program director establishes a process to choose members.

How it will be surveyed:

Review of preceptor roster.

RAC roster.

Review of meeting agendas and meeting minutes if available.

- 3.1.c. The RPD may delegate, with oversight, to one or more individuals [(e.g., residency program coordinator(s)] administrative duties/activities for the conduct of the residency program.
- 3.1.d. 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 hospitals:
 - 3.1.d.(1) A single RPD must be designated in writing by responsible representatives of each participating organization.
 - 3.1.d.(2) The agreement must include the definition of:
 - 3.1.d.(2)(a) responsibilities of the RPD (oversight of preceptors); and,
 - 3.1.d.(2)(b) RPD's accountability to the organizations and/or hospital(s) (e.g. patient care responsibilities, participation on hospital committees).

3.2 Residency Program Directors' Eligibility

RPD must be licensed (or equivalent designation for the country conducting the residency, e.g., OPA 1/2018 28

- registered) pharmacists who
- has not completed a residency but have five or more years of hospital pharmacy practice experience; or,
- has completed an ASHP accredited international Pharmacy Practice Residency, s/he
 must have a minimum of two years of hospital pharmacy practice experience; or,
- has completed an ASHP-accredited PGY1 residency, s/he must have one year of hospital pharmacy practice experience; or,
- has completed an ASHP-accredited PGY2 residency. (No additional pharmacy practice experience is required.)

3.3 Residency Program Directors' Qualifications

RPD serves as role models for pharmacy practice, as evidenced by:

3.3.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

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

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 for or PharmAcademic review

3.3.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.

3.4 Residency Program Leadership Responsibilities

RPD serves as organizationally authorized leaders of residency programs and have responsibility for:

3.4.a. organization and leadership of a residency advisory committee 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 a part of another routinely scheduled meeting.

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.

3.4.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.

3.4.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

How it will be surveyed:

Review of documentation of criteria for appointment and reappointment.

Discussion with RPD about the appointment/reappointment process.

3.4.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.

3.4.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.

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.

3.4.f. continuous residency program improvement in conjunction with the residency advisory committee; and,

How it will be surveyed:

Discussion with RPD and review of residency advisory minutes, if applicable.

3.4.g. working with pharmacy administration.

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.

- 3.5 Appointment or Selection of Residency Program Preceptors
 - 3.5.a. Organizations shall allow residency program directors to appoint and develop pharmacy staff to become preceptors for the program.
 - 3.5.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 3.4c)

3.6 Pharmacist Preceptors' Eligibility

Pharmacist preceptors must be licensed (or equivalent designation for the country conducting the residency, e.g., registered) pharmacists who,

- have three or more years of hospital pharmacy practice experience; or,
- have completed an ASHP-accredited International Pharmacy Practice Residency followed by a minimum of one year of hospital pharmacy practice experience; **or**,
- have completed an ASHP-accredited PGY1 residency; or,
- have completed an ASHP-accredited PGY1 residency followed by an ASHP-accredited PGY2 residency.

Guidance:

Preceptor's pharmacy practice experience is relevant to the practice setting in which the learning experience is conducted.

3.7 Preceptors' Responsibilities

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

- 3.7.a. contribute to the success of residents and the program;
- 3.7.b. provide learning experiences in accordance with Standard 6;
- 3.7. c. participate actively in the residency program's continuous quality improvement processes;
- 3.7.d. demonstrate practice expertise, preceptor skills, and strive to continuously improve;
- 3.7.e. adhere to residency program and department policies pertaining to residents and services; and,
- 3.7.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.

3.8 Preceptors' Qualifications

Guidance

When a list of examples is included in the guidance sections for 3.8.a-f, at least one of the examples is

demonstrated within the last five years unless otherwise noted.

Preceptors must demonstrate the ability to precept residents' learning experiences by meeting one or more qualifying characteristics in all of the following six areas:

3.8.a. demonstrating the 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:

Discussion with preceptors

Discussion with residents.

3.8.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.

3.8.c. recognition in the area of pharmacy practice for which they serve as preceptors (e.g., Board certification, recognition by their college faculty or professional pharmacy organizations);

Guidance:

Examples:

- active BPS certification (ASHP is committed to board certification for pharmacists and expects that most will be board certified over time, when applicable).
 - (See http://www.pharmacycredentialing.org/Files/CertificationPrograms.pdf for current listing.)
- competency in a practice area as determined by credentialing by the institution if applicable, or
- multi-disciplinary certification in disease or patient care management recognized by the Council on Credentialing in Pharmacy.
 - (See http://www.pharmacycredentialing.org/Files/CertificationPrograms.pdf for current listing.)
- formal recognition by peers as a model practitioner (e.g., professional fellow, recognition as pharmacists of the year, institutional service award winner); or multidisciplinary certification in disease or patient care management within the past seven years.
- degrees or other structured training related to practice area precepted
- other recognition for service excellence within the institution

How it will be surveyed:

Review of Academic and Professional Records

Discussion with RPD and preceptors

3.8.d. an established, active practice in the area for which they serve as preceptor;

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 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:

Review of Academic and Professional Records

Discussion with RPD and preceptors

3.8.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.

3.8.f. on-going professionalism, including a personal commitment to advancing the profession.

Guidance:

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).
- moderator or evaluator at regional residency conferences or other professional meetings.
- routine in-service presentations to pharmacy staff and other health care professionals.
- faculty appointment or pharmacy student preceptor.
- pharmacy technician educator.
- completion of, enrollment in, or teaching in, a teaching certificate program.
- providing preceptor development topics at the site.
- 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, consumer education classes, etc.
- participates in research.
- 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.

How it will be surveyed:

Review of Academic and Professional Records

Discussion with RPD and preceptors

3.9 Preceptors-in-Training

- 3.9.a. Pharmacists new to precepting roles who do not meet the qualifications for residency preceptors in sections 3.6, 3.7, and 3.8 above (also known as preceptors-in-training) must:
 - (1) be assigned an advisor or coach who is a qualified preceptor; and,
 - (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.

PGY1 residents may not be preceptors-in-training.

How it will be surveyed:

Review of documented plan for preceptor-in-training.

Discussion with preceptors and RPD.

3.10 Non-pharmacist preceptors

When non-pharmacists (e.g., physicians,) are utilized as preceptors:

- 3.10.a. the learning experience must be scheduled following the RPD and preceptors agreement that residents are ready for independent practice; and,
- 3.10.b. a pharmacist preceptor works closely with the non-pharmacist preceptor to select the educational goals and objectives for the learning experience and to provide formative feedback and written summative evaluations.

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.

In general, two-thirds (2/3) of the required and elective learning experiences, and overall residency program time, must be precepted by a qualified pharmacist preceptor, or a pharmacist preceptor-intraining who is supervised by a qualified pharmacist preceptor.

How it will be surveyed:

Review of documentation of residents' readiness to work independently. Review of resident schedules.

Standard 4: Responsibilities of the Program to the Resident

4.1 Programs must be a minimum of twelve months and a full-time practice commitment.

Guidance:

If a resident takes a leave of absence, time away is not counted towards the 12 months.

How it will be surveyed:

Review of:

- residents' schedules.
- extended leave policy.

Discussion with residents.

4.2 Programs must comply with the ASHP duty hour standards². (https://www.ashp.org/professional-development/residency-information/international-pharmacy-residency-accreditation)

Guidance:

Programs provide a link or documentation to residents of the ASHP policy on duty hours and must document in program materials whether or not moonlighting is allowed. Programs must have a process for monitoring compliance with the ASHP duty hour standard.

If the country offering the residency program also has a duty hours policy, requirement, or standard, that policy, requirement, or standard may supersede the ASHP policy. However, the more rigorous policy should apply. Survey teams will review other duty hours policies, requirements or standards in effort to ensure that the intent of ASHP duty hours standard is preserved and that no significant variances exist.

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.

- 4.3 The RPD must provide residents who are accepted into the program with a letter outlining their acceptance to the program.
 - 4.3.a. Information on the pre-employment requirements for their organization (e.g., licensure and human resources requirements,) and other relevant information (e.g., benefits, stipend) must be provided.
 - 4.3.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, and shared with the resident applicant during the interview process, as well as with residents who enroll in the program during orientation.

Guidance:

Programs have a list of requirements and expectations for completion of the residency program. Transmittal and execution of a contract constitutes acceptance, and would be acceptable in place of a letter of acceptance.

How it will be surveyed:

Review of acceptance letter and attachments or review of executed contract.

4.4 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:

There is a sufficient number of preceptors <u>available</u> 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.

4.5 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), 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.

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

Guidance:

The residency program director and preceptors must have documented a list of all program requirements and expectations, including learning experience, projects, staffing, evaluations and all other requirements

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.
- 4.7 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 Residencies¹, and signed by the RPD and the chief executive officer of the organization or an appropriate executive with ultimate authority over the residency.
 - 4.7.a. Reference must be made on the residency certificate that the program is accredited by ASHP as an International Postgraduate Year One Pharmacy Residency Program.

Guidance:

For programs in candidate status, certificates to residents indicate that 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 as published by ASHP on the accreditation website.

How it will be surveyed:

Review of certificate for signatures and wording.

4.8 The RPD must maintain the program's compliance with the provisions of the current version of the ASHP Regulations on International Accreditation of Pharmacy Residencies throughout the accreditation cycle.

How it will be surveyed:

The survey team may elect to review records of past residents to determine if they have been maintained for the appropriate length of time as specified in the regulations.

https://www.ashp.org/professional-development/residency-information/international-pharmacy-residency-accreditation 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 5: Requirements and Selection of Residents

5.1 The residency program director or designee must evaluate the qualifications of applicants to pharmacy residencies through a documented, formal, procedure based on predetermined criteria.

Guidance:

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.

How it will be surveyed:

Review of:

- formal, documented procedure.
- predetermined criteria used to select applicants to interview and rank.
- 5.2 The predetermined criteria and procedure used to evaluate applicants' qualifications must be used by all involved in the evaluation and ranking of applicants.

How it will be surveyed:

Review of procedure and criteria Discussion with preceptors/RAC

5.3 Applicants to pharmacy residencies should be graduates or candidates for graduation of an accredited, or certified by an appropriate body for the country, pharmacy degree program (or one in process of pursuing accreditation or certification. At a minimum, the graduate must have completed a 5-year collegiate program with at least 4 years devoted to pharmacy curriculum or 4-year collegiate program of pharmacy curriculum plus at least one year of pharmacy practice experience, or be a graduate of a Pharm.D. program.

Guidance:

See guidance for 5.1. RPDs must evaluate the academic curricula and the accreditation status of all applicants' schools of pharmacy if such school is unfamiliar.

How it will be surveyed:

Review of residents' Academic and Professional Records and the documented procedure described above in Standard 1.1.

- 5.4 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.
- 5.5 Consequences of residents' failure to obtain appropriate licensure (or equivalent process) either prior to or within 90 days of the start date of the residency must be addressed in written policy of the residency program.

Guidance:

- 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.

- 5.6 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 leaves and the consequences of any such leave on residents' ability to complete the residency program, and for dismissal from the residency program.
 - 5.6.a. These policies must be reviewed with residents and be consistent with the organization's human resources policies for pharmacists.

Guidance:

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

It can be provided to applicants before, or at, the interview.

Organization's dismissal policy is shared with residents as well as residency policy addressing consequences of failure to progress.

How it will be surveyed:

Review of documents given to applicants invited to interview to determine inclusion of items listed in the Standard.

Standard 6: Design and Conduct of the Residency Program

6.1 Residency Purpose and Description

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 standard.

Residency Program Purpose: *International* pharmacy practice residency programs build on pharmacy education and outcomes to contribute to the development of clinical pharmacists responsible for medication- related care of patients with a wide range of conditions and to have a leadership role in advancing pharmacy practice in their country.

Guidance:

The program documents the required PGY1 purpose statement in program materials.

The program's design is consistent with the program purpose statement.

The program may develop a brief description of their program that aligns with the purpose statement of a PGY1 residency and elaborates on any unique aspects of their program.

How it will be surveyed:

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

- 6.2 Competency Areas, Educational Goals and Objectives
 - 6.2.a. The program's educational goals and objectives must support achievement of the residency's purpose.
 - 6.2.b. Programs may select additional competency areas that are required for their program. If so, they must be required for all residents in the program.

Guidance:

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, particularly those in R1, may require teaching and evaluation several times during the residency program year to enable residents to achieve competency.

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.

Guidance for Competencies, Educational Goals and Objectives:

DEFINITIONS:

Competency Areas: Categories of the residency graduates' capabilities. Competency areas fall into one of three categories:

Required: Six competency areas are required (all programs must include them and all their associated educational goals and objectives in their program design).

Additional: Competency area(s) other than the six areas required for all programs that may be selected to add as required competencies for their specific residency program.

Elective: Competency area(s) selected optionally for specific resident(s).

Educational Goals (Goal): Broad statement of abilities.

Educational Objectives: Observable, measurable statement describing what residents will be able to do as a result of participating in the residency program.

Criteria: Examples intended to help preceptors and residents identify specific areas of successful skill development or needed improvement in residents' work.

Criteria are examples that describe competent performance of educational objectives. They are intended to be used to give feedback to residents on the how well they are doing on the skill described in educational objectives while they engage in an activity, as well as how they can improve.

<u>Activities</u>: The Standard requires that learning activities be specified for each educational objective in learning experience descriptions. Activities are what residents will do, and how they will do it, to learn and practice the skills described in objectives. Activities are the answer to the question "What can residents do in the context of this learning experience that will provide the kind of experiences necessary to achieve the educational objective?" Specified activities should match the Bloom's Taxonomy learning level stated in parentheses before each objective. Link to program on Bloom's Taxonomy learning levels:

http://www.ashpmedia.org/softchalknewbloomlearningtaxonomiesandlevels-2015-Jan/index.html Example:

Objective R1.1.2 (Applying) Interact effectively with patients, family members, and caregivers. Learning activity: Provide education to patients regarding proper medication use and administration, adherence, and possible adverse drug effects for all new medications initiated during clinic appointments.

Criteria:

- Interactions are respectful and collaborative.
- Uses effective communication skills.
- Shows empathy.
- Empowers patients to take responsibility for their health.

• Demonstrates cultural competence.

If/when residents produce documents, they are maintained for possible review during a survey; this includes feedback on the document residents received, if applicable.

How it will be surveyed

The competency areas, goals, and objectives are surveyed as part of the survey of Standard 3, most commonly in the following areas:

- 3.2.—c: Surveyors review the program's teach/evaluate grid, descriptions of required and elective learning experiences, residents' schedules, and residents' evaluations. Surveyors have discussions with preceptors and residents to determine that the required competency areas, goals, and objectives are included in the program's design. Also, residents' written work products (electronic or paper) are reviewed for applicable objectives.
- 3.3.2: Surveyors review the teach/evaluate grid and residents' schedules and have discussions with the program director, preceptors, and residents to determine the structure of the program and how the goals and objectives are assigned to be evaluated in the learning experiences provided in the program.
- 3.3.a.3-4: Surveyors review the teach/evaluate grid, residents' schedules, and learning experience descriptions and have discussions with residents and preceptors to determine if residents are given experience in an adequate diversity of issues.
- 3.3.c and 3.3.c.1.d: Surveyors review learning experience descriptions to determine that residents' learning activities teach the objectives.
- 3.4.c.1: Surveyors review residents' evaluations and interview preceptors and residents to determine that specific feedback is provided to residents about how they can improve.

Documentation to be requested pre-survey*:

- Teach/evaluate grid*
- Description of the program's structure that indicates required and elective learning experiences
- Residents' schedules for current and past year*
- Examples of residents' evaluations for current and past year*

*Access to PharmAcademic® will be requested prior to the survey. Program using PharmAcademic® do not need to include these items with the documents to be supplied to ASHP prior to the survey

Information regarding specific objectives required by the Accreditation Standard:

Guidance for Objective 1.1.4:

The residency program creates a strategy describing what residents will do, and how they will do it that will help residents develop the skills to effectively self-evaluate. Residents compare their self-evaluation with the preceptor for feedback during formative and summative evaluations, if applicable, to determine the degree of accuracy of their self-evaluation. An example for formative might include asking the resident what they thought they did well and how they can improve on specified objectives.

Residents are able to identify their strengths and areas for improvement and define a plan for improving, where indicated. This objective is included in at least three learning experiences or one learning experience and two times in a longitudinal learning experience or required 3 times in a longitudinal learning experience.

Beyond the requirements, programs are encouraged to use other methods

Resources: Motycka CA, Rose RL, Reid DL, Brazeau G. Self-Assessment in Pharmacy and Health Science Education and Professional Practice. Am J Pharmaceutical Ed 2010;74(5):article 85.

Formative Feedback in PharmAcademic. Help Documentation, <u>www.pharmacademic.com</u>, accessed 8/30/2015.

How it will be surveyed:

Review of:

- Strategy for self-evaluation, if written, or verbal description of strategy in discussions with RPD, preceptors, and residents.
- Evidence that preceptors track resident progress toward achievement of this objective.

Guidance for Objectives R6.1.1-7:

Objectives R6.1.1—R6.1.7 may be addressed through residents working on one practice-related project or research project; however, if this is not possible, all objectives must be addressed by the end of the residency year and can be addressed through work on more than one initiative.

For example, residents might participate in a medication use evaluation to accomplish some of the objectives and assist in developing a clinical pathway to fulfill other objectives. However they should have sole responsibility for, present, and prepare a manuscript for one major project to be completed during the residency. The major project could address quality improvement, a practice problem, or a research question.

Objective R6.1.7 (the presentation and preparation of the manuscript) refers to the major project.

6.3 Resident Learning

6.3.a. Program Structure

- 6.3.a.(1) A written description of the structure of the program must be documented formally.
 - 6.3.a.(1)(a) The description must include required learning experiences and the length of time for each experience.
 - 6.3.a.(1)(b) Elective experiences must also be listed in the program's design.
 - 6.3.a.(2) The program's structure must facilitate achievement of the program's educational goals and objectives.
 - 6.3.a.(3) The structure must permit residents to gain experience and sufficient practice with diverse patient populations, a variety of disease states, and a range of patient problems.
 - 6.3.a.(4) No more than one-third of the twelve-month pharmacy residency program may deal with a specific patient disease state and population (e.g., critical care, oncology, and cardiology).
 - 6.3.a.(5) Residents must spend two thirds or more of the program in direct patient care activities.

Guidance:

The residency program structure is designed so that at least 2/3 of residents' time being spent in direct patient care.

Direct Patient Care by Pharmacists:

Activities performed by pharmacists with the intent of contributing to positive pharmacotherapeutic and health outcomes of individual patients. Care is in collaboration and communication with other members of the health care team with responsibilities for the individual patient, and is achieved directly with patients and caregivers face-to-face, telephonically, virtually, or in writing. (See Glossary for related references.)

Examples of direct patient care activities (but are not limited to this list):

- Completing comprehensive medication reviews (i.e., thorough review of medication profiles).
- Performing drug therapy management (e.g., anticoagulation management, renal dosing, and pharmacokinetics) and participating in disease state management services.
- Collecting and organizing patient-specific information needed by the pharmacist to prevent, detect, and resolve medication-related problems and to make appropriate evidence-based, patient- centered medication therapy recommendations as part of the interdisciplinary team.
- Specifying therapeutic goals for patients incorporating the principles of evidence-based medicine
 that integrate patient-specific data, disease and medication-specific information, ethics, and qualityof-life considerations.
- Designing patient-centered regimens and monitoring plans that meet the evidence-based therapeutic goals established for patients, which integrates patient-specific information, disease and drug information, ethical issues and quality-of-life issues, and considers pharmacoeconomic principles.
- Recommending or communicating patient-centered, evidence-based therapeutic regimens and corresponding monitoring plans to other members of the interdisciplinary team and patients in a way that is systematic, logical, accurate, timely, and secures consensus from the team and patient.
- Initiating, when appropriate, the patient-centered, evidence-based therapeutic regimen and monitoring plan for patients according to the organization's policies and procedures.
- Assessing patients' progress toward therapeutic goal(s) and, when necessary, redesigning a patientcentered, evidence-based therapeutic plan as necessary based on evaluation of monitoring data and therapeutic outcomes.
- Performing or participating in medication reconciliation.
- Using effective patient education techniques to provide education and counseling to patients and caregivers, including information on medication therapy, adverse effects, compliance, appropriate use, handling, and medication administration.
- Patient-centered preparation and dispensing of medications for individual patients.

How it will be surveyed:

Review of:

- the program's structure and residents' schedules.
- learning experience descriptions.

Discussion with preceptors, residents, and other health care providers.

6.3.b Orientation

Residency program directors must orient residents to the residency program. The orientation to the residency program must be considered a learning experience that includes the assignment of a preceptor, educational goals and objectives, and appropriate activities assigned to the objectives.

Guidance:

Orientation includes:

- the residency's purpose and practice environment.
- the appropriate accreditation standards, competencies, goals and objectives.
- design of the residency program including all program requirements.
- description of required and, if applicable, elective learning experiences.
- evaluation strategy (see standard 3.4).
- residency manual (if applicable).
- residency policies, terms and conditions, e.g., requirements for completion, moonlighting, duty hours, dismissal.

Structure includes orientation as a learning experience.

How it will be surveyed:

Review of Learning experience description for orientation and orientation schedule and materials given to residents.

Review of Residency Manual

Discussion with residents.

6.3.c Learning Experiences

6.3.c.(1) Learning experience descriptions must be documented and include:

6.3.c.(1)(a) a general description, including the practice area and the roles of pharmacists in the practice area

6.3.c.(1)(b) expectations of residents;

6.3.c.(1)(c) educational goals and objectives assigned to the learning experience;

6.3.c.(1)(d) for each objective, a list of learning activities that will facilitate its achievement; and,

6.3.c.(1)(e) a description of evaluations that must be completed by preceptors and residents.

Guidance:

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 describe how residents will progress and the expectation for their skill development over time and in any repeated learning experiences. If a successfully completed learning experience is repeated, the preceptor differentiates them.

Learning activities are developed at the cognitive learning level (Bloom's Taxonomy) associated with the objective. Learn more at: http://www.ashpmedia.org/softchalknewbloomlearningtaxonomiesandlevels-2015-Jan/index.html Resource: template for learning experience descriptions on ASHP website

How it will be surveyed:

Review of learning experience descriptions.

Discussion of reasons for second learning experience in an area, if residents have completed the same learning experience a second time.

6.3.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.

6.3.c.(3) During learning experiences, preceptors must use the four preceptor roles (direct instruction, modeling, coaching, facilitating) 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.

6.3.c.(4) Learning experiences must be designed and appropriately sequenced to facilitate residents' progress over the course of the residency to be more efficient, effective, and able to work independently in providing direct patient care.

6.4 Evaluation

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

6.4. a. Initial assessment

- 6.4.a.(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.
- 6.4.a.(2) By the end of the orientation period, the results of residents' initial assessments must be documented by the program director or designee in each resident's development plan and taken into consideration when determining residents' learning experiences, learning activities, evaluations, and other changes to the program's overall plan.
- 6.4.b. Formative (on-going, regular) assessment
 - 6.4.b.(1) Preceptors must provide on-going feedback to residents about how they are progressing and how they can improve. The feedback must be frequent, immediate, specific, and constructive.

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6.4.b.(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:

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.

6.4.c. Summative evaluation

6.4.c.(1) At the end of each learning experience, preceptors must discuss with residents their verbal and written assessment on the extent of the resident's progress toward achievement of assigned educational goals and objectives, using specific criteria for performance.

Guidance:

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 quality of criteria-based feedback in written summative evaluations.

6.4.c.(2) For learning experiences greater than or equal to 12 weeks in length, a documented summative evaluation must be completed by the preceptor at the end of 12 weeks or if a longer learning experience, at least every three months.

6.4.c.(3) If more than one preceptor is assigned to a learning experience, all preceptors must provide input into residents' evaluations. A lead or primary preceptor must collect and aggregate this information.

Guidance:

If multiple preceptors are assigned to precept a learning experience, 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.

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

6.4.c.(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.

How it will be surveyed:

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.

6.4d Residents' development plans

6.4.d.(1) Each resident must have a resident development plan documented by the RPD or OPA 1/2018 48

designee by the end of the resident orientation period.

General 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 approximately every 90 days from the start of the residency (e.g. October, January, and April).

Adjustments are made based upon review of residents' performance 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.

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.

How it will be surveyed:

Review of resident development plans:

- 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

- 6.4.d.(2) On a quarterly basis, the RPD or designee must assess residents' progress and determine if the development plan needs to be adjusted.
- 6.4.d.(3) The development plan and any initial and quarterly adjustments must be documented and shared with all preceptors.

Guidance:

See guidance under 3.4.d. (1)

6.5 Continuous Residency Program Improvement

- 6.5.a. The RPD, residency advisory committee (RAC), and director or chief of pharmacy must engage in an on-going process of assessment of the residency program including a formal annual program evaluation.
- 6.5.b. The RPD or designee must develop and implement program improvement activities to respond to the results of the assessment of the residency program.
- 6.5.c. The residency program's continuous quality improvement process must evaluate whether residents fulfill the purpose of an international pharmacy practice residency program through graduate tracking.
 - 6.5.c.(1) Information tracked must include initial employment, and may include changes in employment, , surveys of past graduates, or other applicable information.

Guidance:

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. May be tracked in PharmAcademic®.

How it will be surveyed:

Review of:

- minutes of RAC meetings in which residency program improvements have been discussed
- information about graduates

Discussion about the programs continuous quality improvement efforts and results

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Glossary

Assessment: Measurement of progress on achievement of educational objectives.

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

Clinical pharmacist: Clinical pharmacists work directly with physicians, other health professionals, and patients to ensure that the medications prescribed for patients contribute to the best possible health outcomes. Clinical pharmacists practice in health care settings where they have frequent and regular interactions with physicians and other health professionals, contributing to better coordination of care. (American College of Clinical Pharmacy)

Competency area: Category of residency graduates' capabilities.

Complex condition: Patients with complex conditions are those who are being treated with high-risk medications, high numbers of medications, and/or have multiple disease states.

Criteria: Examples intended to help preceptors and residents identify specific areas of successful skill development or needed improvement in residents' work.

Educational Goal: Broad statement of abilities.

Educational Objective: Observable, measurable statement describing what residents will be able to do as a result of participating in the residency program.

Evaluation: Judgment regarding quality of learning.

Formative assessment: On-going feedback to residents regarding their progress on achievement of educational objectives for the purpose of improving learning.

Formulary: A formulary includes, but is not limited to, a list of medications and medication-associated products or devices, medication-use policies, important ancillary drug information, decision-support tools, and organizational guidelines. The formulary system is the ongoing process through which a health care organization establishes policies on the use of drugs, therapies, and drug-related products and identifies those that are most medically appropriate and cost-effective to best serve the health interests of a given patient population.

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

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

- 1. To run a multiple-site residency there must be a compelling reason for offering the training in a multiple-site format (that is, the program is improved substantially in some manner). For example:
 - a. RPD has expertise, however the site needs development (for example, site has a good variety of patients, and potentially good preceptors, however the preceptors may need some oversight related to the residency program; or services need to be more fully developed);
 - b. quality of preceptorship is enhanced by adding multiple sites;
 - c. increased variety of patients/disease states to allow wider scope of patient interactions for residents;
 - d. increased administrative efficiency to develop more sites to handle more residents across multiple sites/geographic areas;
 - e. synergy of the multiple sites increases the quality of the overall program;
 - f. allows the program to meet all of the requirements (that could not be done in a single site alone); and,
 - g. ability to increase the number of residents in a quality program.
- 2. In a multiple-site residency program, a sponsoring organization must be identified to assume ultimate responsibility for coordinating and administering the program. This includes:
 - a. designating a single residency program director (RPD);
 - b. establishing a common residency purpose statement to which all residents at all sites are trained;
 - c. ensuring a program structure and consistent required learning experiences;
 - d. ensuring the required learning experiences are comparable in scope, depth, and complexity for all residents, if home based at separate sites;
 - e. ensuring a uniform evaluation process and common evaluation tools are used across all sites;
 - f. ensuring there are consistent requirements for successful completion of the program;
 - g. designating a site coordinator to oversee and coordinate the program's implementation at each site that is used for more than 25% of the learning experiences in the program (for one or more residents); and,
 - h. ensuring the program has an established, formalized approach to communication that includes at a minimum the RPD and site coordinators to coordinate the conduct of the program across all sites.

Non-traditional residency: Residency program that meets requirements of a 12-month residency program in a different timeframe.

Pharmacist Executive: The person who has ultimate responsibility for the residency hospital/pharmacy in which the residency program is conducted. (In some settings this person is referred to, for example, as the *director of pharmacy*, the *pharmacist-in-charge*, the *chief of pharmacy services*) In a multiple-site residency, a sponsoring organization must be identified to assume ultimate responsibility for coordinating and administering the program.

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

Preceptor-in-training: Pharmacists who are new to precepting residents who have not yet met the OPA 1/2018 53

qualification for a preceptor in an accredited program. Through coaching and a development plan, they may be a preceptor for a learning experience and become full preceptors within two years.

Residency Advisory Committee (RAC): The residency Advisory Committee (RAC) is commonly a standing committee within the pharmacy department. It may also be a subcommittee of a pharmacy department education committee. Its members include the residency program director (RPD) and preceptors that represent different components of the residency program (e.g., clinical rotations, administrative, medication policy, the project, orientation and staffing learning experiences and more). The RAC generally meets monthly and has a general purpose to oversee all aspects of the program design and conduct, and for continuous quality improvement efforts of the residency program. The RAC may also assume roles for resident recruitment and selection, monitoring resident progress during the program, preceptor development, and managing residency program policies.

Residency program director (RPD): The pharmacist responsible for direction, conduct, and oversight of the residency program. In a multiple-site residency, the residency program director is a pharmacist designated in a written agreement between the sponsoring organization and all of the program sites.

Resident's Development Plan: Record of modifications to residents' program based on their learning needs.

Self-evaluation: A process of reflecting on one's progress on learning and/or performance to determine strengths, weaknesses, and actions to address them.

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

Single-site residency: A residency site structure in which the hospital assumes total responsibility for the residency program. In a single-site residency, the majority of the resident's training program occurs at the site; however, the resident may spend assigned time in short elective learning experiences off-site.

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

Site Coordinator: A preceptor in a multiple-site residency program who is designated to oversee and coordinate the program's implementation at an individual site that is used for more than 25% of the learning experiences. This individual may also serve as a preceptor in the program. A site coordinator must:

- 1. be a licensed pharmacist who meets the minimum requirements to serve as a preceptor (meets the criteria identified in Principle 3.6 of the appropriate pharmacy residency accreditation standard);
- 2. practice at the site at least ten hours per week;
- 3. have the ability to teach effectively in a clinical practice environment; and,
- 4. have the ability to direct and monitor residents' and preceptors' activities at the site (with the RPD's direction).

Sponsoring organization: The organization assuming ultimate responsibility for the coordination and administration of the residency program. The sponsoring organization is charged with ensuring that residents' experiences are educationally sound and are conducted in a quality practice environment. The sponsoring organization is also responsible for submitting the accreditation application and ensuring

periodic evaluations are conducted. If several organizations share responsibility for the financial and management aspects of the residency (e.g., school of pharmacy, health-system, and individual site), the organizations must mutually designate one organization as the sponsoring organization.

Staffing: See "Service commitments."

Summative evaluation: Final judgment and determination regarding quality of learning.

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References

- ASHP regulations on accreditation of pharmacy residencies; American Society of Health-System Pharmacists; 2010. American Society of Health-System Pharmacists Home Page [resource on World Wide Web]. URL: http://www.ashp.org. Available from Internet. Accessed 2015 February 12.
- Pharmacy specific duty hour requirements for the ASHP accreditation standards for pharmacy residencies; American Society of Health-System Pharmacists; 2012. American Society of Health- System Pharmacists Home Page [resource on World Wide Web]. URL: http://www.ashp.org. Available from Internet. Accessed 2015 February 12.
- Rules for the ASHP pharmacy resident matching program; American Society of Health-System Pharmacists; 2006. American Society of Health-System Pharmacists Home Page [resource on World Wide Web]. URL: http://www.ashp.org. Available from Internet. Accessed 2015 February 12.
- 4. Required and elective educational competency areas, goals, and objectives for the postgraduate year one (PGY1) pharmacy residency standard. American Society of Health-System Pharmacists Home Page [resource on World Wide Web]. URL: http://www.ashp.org. Available from Internet. Accessed 2015 February 12.
- 5. ASHP accreditation policy for multiple-site residency programs. American Society of Health-System Pharmacists Home Page [resource on World Wide Web]. URL: http://www.ashp.org. Available from Internet. Accessed 2015 February 12.

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