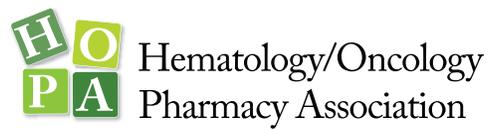

Scope of Hematology/ Oncology Pharmacy Practice



Hematology/Oncology
Pharmacy Association



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Notes and Acknowledgments

This document was written to define the scope of practice of hematology/oncology pharmacy within the United States, using U.S. laws and regulations governing pharmacy. However, regional or international laws and regulations could be applied as appropriate to define the scope of practice outside the United States. The authors and HOPA Board members thank peer reviewers Lily Leu, PharmD, Janet L. Espirito, PharmD BCOP, Virginia Spadoni, PharmD BCOP, and Amy Hatfield Seung, PharmD BCOP, for their thoughtful review and comments; the HOPA members for their comments and contributions to the profession; and the HOPA staff for their editorial, project management, and publication contributions.

Introduction and Foundation

The purpose of a healthcare scope of practice document should be to unify and establish a setting for demonstrating the value of a profession in improving patient outcomes. Without a unified definition or scope of practice document to support a profession, it is very difficult to demonstrate consistent value and justify resources. Hematology/oncology pharmacy is a diverse specialty within health care, positively affecting patients across the cancer care continuum. The practice of hematology/oncology pharmacy varies across different healthcare systems and practices, and a need to identify commonalities between divergent practice settings, cultures, and patient populations remains. Although certification for oncology pharmacy exists (e.g., board certified oncology pharmacist [BCOP]), it largely reflects direct patient care activities. Many oncology pharmacists, however, perform activities or functions that fall outside of the board certification domains. The purpose of this scope of practice document is to describe the evolution of hematology/oncology pharmacy and address the knowledge, skills, and functions of a hematology/oncology pharmacist (primarily related to direct patient care) to promote a better understanding of the profession. For the purposes of this document, hematology/oncology pharmacists will be referred to as oncology pharmacists.

History of Oncology Pharmacy

Specialty training in oncology pharmacy has been available since the 1980s through residency or fellowship training programs. Residency programs offer an organized, directed postgraduate training in a defined area of pharmacy practice, whereas fellowships focus on preparing the participant to become an independent researcher.¹ Residency training has evolved since its inception, including establishment and refining of accreditation standards, expansion of program offerings from sites other than colleges of pharmacy, and transition from multiple residency types to a two-tier approach that requires a fundamental development program before specialization.²

One way to unify a profession is to define criteria for certification. Since 1998, the Board of Pharmacy Specialties (BPS) has defined criteria for board certification in oncology pharmacy. Prior to the availability of board certification, some pharmacists functioned in a specialized capacity within cancer care; however, no consistent training or established duties to dictate daily activities existed. In the 1990s, a small group of oncology specialty pharmacists representing the American Society of Health System Pharmacists (ASHP) proposed certification based on the premise that as a member of the cancer care team, oncology pharmacists possess specialized knowledge and training, ensuring optimal drug therapy, and bring a unique

ability and perspective to the patient care team (Board of Pharmacy Specialties, written communication, September 1992). Based on this proposal, the BPS acknowledged oncology pharmacy as a specialty, and the first certification examination was offered in 1998. Continual efforts are used by BPS to ensure that certification examination remains relevant and reflects current practice through peer-based recognition and exam content. A council of experts in each area of specialization works with BPS and psychometric consultants to develop the bank of test items. The content of these items is developed by practitioners working in the field and is vetted for psychometric validity, ensuring a democratic examination with real-life relevance. At least every 5 years, BPS conducts a role delineation survey to identify any changes in practice that may require modification of the exam content. To date, the content domains for BCOP remain largely related to direct patient care, reflecting current practice patterns, but do not include all activities that oncology pharmacists may perform (**Appendix 1**).³ As of February 2013, the number of BCOPs worldwide is 1,289, includes people from 17 countries, and continues to grow.⁴ Thirty-three percent of pharmacists who have self-identified with a hematology/oncology interest have indicated they are BCOPs.⁵ These data suggest that a large proportion of oncology pharmacists are not certified. BPS, in a white paper outlining their 5-year vision for pharmacy specialties, envisions a future model where board certification will be the expectation for pharmacists engaged in direct patient care by 2017.⁶ The reasons for not obtaining board certification may be multifactorial (e.g., not recognized or required by employer, not able to meet the requirements for examination, does not reflect current job responsibilities, expense). Although board certification represents an advanced level of oncology pharmacy practice, many oncology pharmacists perform similar functions as a BCOP. The Hematology/Oncology Pharmacy Association (HOPA) encourages certification but does not wish to minimize the experience, knowledge, and skills of those who are not board certified. Therefore, this document was developed to identify commonalities among oncology pharmacists in an effort to unify practice.

History of the Hematology/Oncology Pharmacy Association

HOPA, a professional society for hematology/oncology pharmacists and associates, was launched in 2004. The goal of HOPA is to have an oncology pharmacist as an integral member of the care team for all individuals affected by cancer. HOPA supports pharmacy practitioners and promotes and advances oncology pharmacy through (1) educational efforts, (2) development and endorsement of practice standards to support roles and responsibilities of oncology pharmacists, (3) research, and (4) advocacy efforts. The

association comprises not only hematology/oncology pharmacists (regardless of board certification) but also pharmacy interns, residents, fellows, nurses, technicians, researchers, administrators specializing in hematology/oncology practice, students and other trainees, and other healthcare professionals with an interest in hematology/oncology. HOPA membership is primarily based in the United States, but it does include members from around the world. In 2010, the HOPA Foundation was created to support research efforts of oncology pharmacists to further optimize the care of individuals affected by cancer.

Also in 2010, HOPA updated its strategic plan, which included a priority focused on developing HOPA as the source for practice standards to support roles and responsibilities of oncology pharmacists.⁷ One objective of that goal area was to increase the understanding of oncology pharmacists' scope of practice across the cancer care continuum. Therefore, the HOPA Board identified and invited 10 HOPA members with varying backgrounds, practice sites, and geographical locations to form a task force to develop the scope of practice document, representing the wide spectrum of practices within oncology pharmacy (see **Appendix 2**). This document was vetted for veracity on several levels and may be used in many different aspects (see **Table 1**).

Table 1. Uses for the HOPA Scope of Oncology Pharmacy Practice Document

Define or create job descriptions and responsibilities
Define educational offerings
Define institutional competencies, standards, and certification
Define quality improvement activities
Develop and evaluate pharmacy service delivery systems and organizational structures
Educate other healthcare professionals
Provide roles, challenges, and future directions of profession
Support certification activities
Support health policy advocacy

Definitions and Goals

Oncology pharmacy practice is a specialty practice area within the domain of pharmacy practice. To understand the specialty of oncology pharmacy, it is important to first understand the roles of individuals involved in pharmacy practice.

Definitions

Pharmacist

Pharmacists represent a broad range of expertise and levels of practice, skill, and responsibilities. Following graduation from a school of pharmacy, a pharmacist is licensed after meeting the requirements of the state or jurisdiction in which the pharmacist wishes to practice. Usually this involves passing a national board exam that assesses the knowledge gained in pharmacy school and experiential training, a drug law exam, and at least 1,740 hours of practice experience (see **Pharmacy Trainee** below). Some states also require additional laboratory or practice exams.⁸

Once licensed, pharmacists may practice in a variety of settings and perform various tasks, including interpretation, evaluation, and implementation of medication orders; dispensing of prescription drugs; administration of drugs (e.g., immunizations); participation in drug and device selection, drug utilization review, or drug-related research; and provision of patient counseling and medication therapy management.⁸ In addition, pharmacists are responsible for compounding and labeling of drugs and devices, proper and safe storage of drugs and devices, and maintenance of required records. Pharmacists may also provide patient care services through collaborative pharmacy practice agreements, whereby pharmacists have joined to work in conjunction with physicians under protocol to provide optimal medication therapy and desired patient outcomes.⁹⁻¹⁵ This allows pharmacists to order medications under a physician's supervision. Pharmacists are also continually optimizing patient safety and quality of services through effective use of emerging technologies (e.g., robotics, bar-code technology), competency-based training, and continual participation in accredited educational activities to gain additional knowledge and skills.¹⁶

Pharmacists may further specialize in an area of pharmacy practice beyond that which is required for licensure.¹⁷ For a pharmacist to gain the knowledge, skills, and competencies needed to perform a specialty pharmacy job, several paths may be taken. A pharmacist may receive on-the-job training, complete a postgraduate residency (1 or 2 years), complete a postgraduate fellowship, or obtain advanced specialty board certification. Current specialties recognized by BPS include ambulatory care pharmacy, critical care pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, and psychiatric therapy.¹⁸

Pharmacy Trainee

An internship in the United States, consisting of at least 1,740 hours of experience gained during and/or after pharmacy school completion and before licensure, is required by all state boards of pharmacy.⁸ During an internship, the pharmacist intern practices directly under a licensed pharmacist. Additional on-the-job training may occur at the site where the intern practices.

Pharmacy residents are also considered “trainees,” and standards exist for these training programs as well. ASHP has established an accreditation program for residencies in the United States. Accreditation is currently optional but highly recommended. Accreditation establishes standards by which all programs are measured and held accountable. It also allows for a unified understanding of what activities graduates from accredited programs are competent to perform.

Residency training is designed to formalize and condense on-the-job training experiences. Currently, the postgraduate year-1 (PGY-1) pharmacy residency training enhances general competencies in managing medication therapy outcomes for a broad range of disease states, managing pharmacy operations, and fostering leadership skills.¹⁹ Postgraduate year-2 (PGY-2) residency training is designed to build upon the competencies developed in the PGY-1 residency; increase the trainee’s depth of knowledge, skills, and medication management abilities in a focused area of practice (e.g., oncology, nutrition support, ambulatory care); and, when available, prepare the pharmacist for board certification.²⁰ Pharmacy fellowships are highly individualized postgraduate training programs designed to develop competency and expertise in the scientific research process and practice skills relevant to conducting research related to a particular knowledge area.²¹

Oncology Pharmacists

The specialty of oncology pharmacy incorporates all of the knowledge, skills, and expertise of pharmacy practice, with a focus and skill set that are specific to the area of oncology. Like pharmacists in general, oncology pharmacists represent a broad range of expertise and levels of practice, skills, and responsibilities. The standard path to gain the knowledge, skills, and expertise required in oncology pharmacy is through specialty residency training (described in the next paragraph). The only available formal method to assess an oncology pharmacist’s knowledge, as it relates to the four content domains, is through the BCOP examination (Appendix 1).³ A BCOP, per BPS, recommends, designs, implements, monitors, and modifies pharmacotherapeutic plans to optimize outcomes in patients with malignant diseases.²² This represents a high level of expertise and is primarily focused on direct patient care activities, while incorporating other important aspects of practice (e.g., medication safety, formulary management, and guideline and policy develop-

ment/implementation).²² Although “competence” includes knowledge, skills, and abilities to perform tasks, not all of these aspects are tested by the BPS process. The BCOP designation signifies that the person has met a rigorous standard above and beyond the usual training. Currently, certification is largely optional and not required in many settings.

To become an oncology pharmacist, two general paths may be taken (see **Figure 1**).²² One path represents a formalized progression through a PGY-1 residency program, then a PGY-2 oncology specialty residency, then 1 year of experience with more than 50% time spent in oncology pharmacy activities, followed by successful completion of the BCOP examination. Once these steps are completed, the pharmacist is then recognized as a BCOP. The other general path to practice in oncology pharmacy may consist of a combination of traditional, nontraditional, formal, informal, validated, and invalidated steps. This path may lead to board certification if all of the eligibility criteria are met to sit for the exam (see below), or it may not lead to board certification at all. Because these steps are not standardized, there is no way to easily ascertain the knowledge of an individual taking this path unless he or she becomes board certified. Whether to become board certified is an individual decision that is often driven by both professional and personal reasons.

Common practice settings for oncology pharmacists include, but are not limited to, a cancer center, academic medical center, outpatient oncology center or infusion center, medical oncology community practice, community retail pharmacy, managed care organization, home health-care company, specialty or mail-order pharmacy, palliative care or hospice setting, professional/regulatory/advocacy organization, and the pharmaceutical industry.

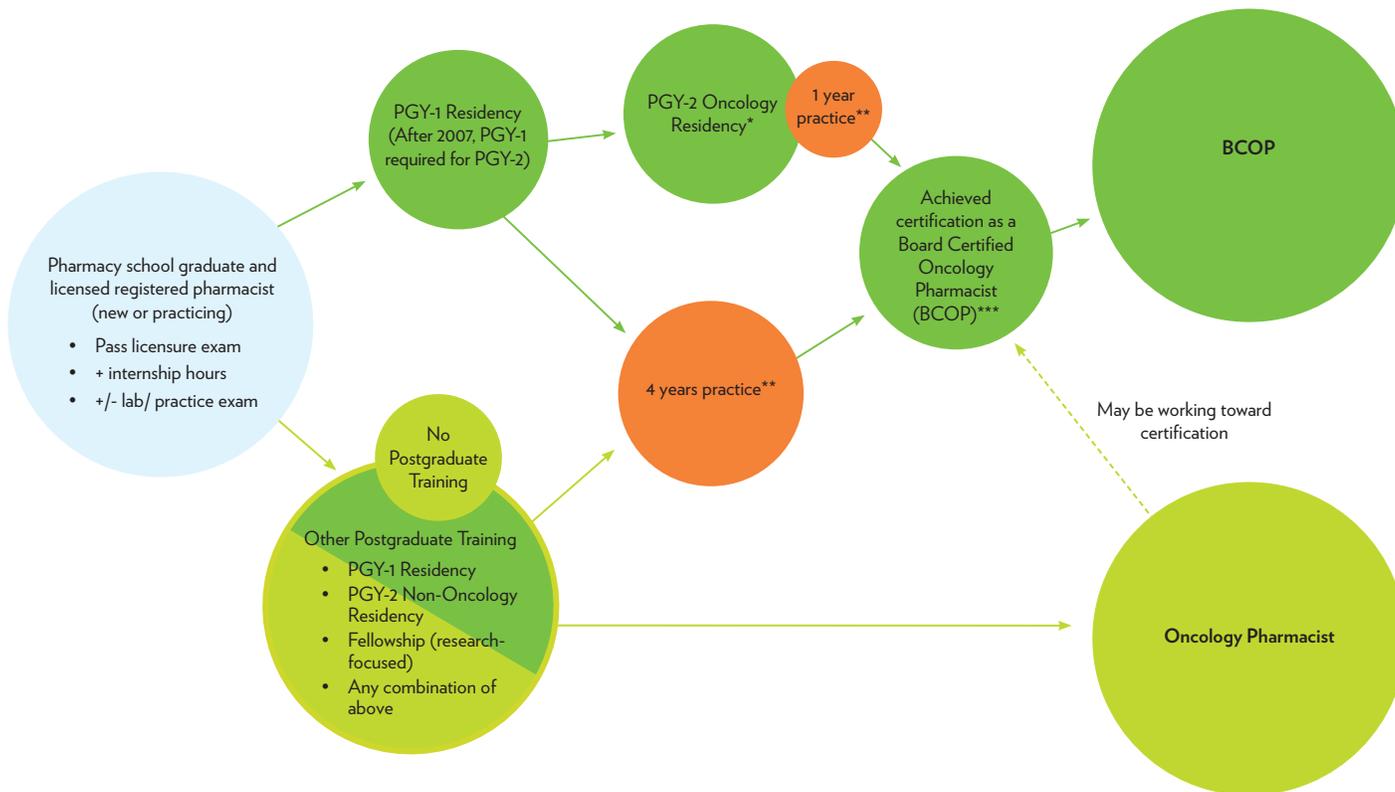
Knowledge, Skills, and Functions of an Oncology Pharmacist

The role of the oncology pharmacist is strikingly broad and increasingly complex. Attempting to define the oncology pharmacist is a challenge because roles vary at the international, national, local, institutional, and even individual level. The scope of the position and the functions that define it may be as varied as the individuals who practice it. The only available formalized standards of practice are the PGY-2 residency standards for oncology pharmacy and the BCOP examination content domains. **Table 2** provides a general summary of select core functions that contribute to the role of the oncology pharmacist; however, many oncology pharmacists perform additional functions.^{3,23}

PGY-2 residencies in oncology are available, many of which are accredited by ASHP. ASHP-accredited programs are designed to meet the needs of the specialty. Each

Figure 1. Pathways to Specialization in Oncology Pharmacy²²

- Green circles depict formal steps toward certification and practicing as an Oncology Pharmacist.
- Light green circles depict other (informal) steps toward certification and practicing as an Oncology Pharmacist.
- Orange circles depict requirements to sit for the BCOP exam (as defined by BPS); these are individually reviewed upon application for examination.



Abbreviations: PGY-1, postgraduate year 1 residency; PGY-2, postgraduate year 2 residency; BCOP, board-certified oncology pharmacist; BPS, Board of Pharmacy Specialties.

* Effective January 1, 2013, only residencies accredited by the American Society of Health-System Pharmacists (ASHP) or residency programs that are under active consideration for accreditation by ASHP are creditable for this purpose.

** At least this amount of years as a practicing pharmacist with at least 50% of time spent in oncology pharmacy activities (as defined by the BPS oncology-pharmacy content outline).

*** Certification currently not required but preferred for an oncology pharmacist position.

ASHP-accredited oncology residency program is designed to prepare the graduate to (1) serve as an authoritative resource on the optimal use of medications used to treat individuals with cancer; (2) optimize the outcomes of the care of individuals with cancer by providing evidence-based, patient-centered medication therapy as an integral part of an interdisciplinary team; (3) manage and improve the medication-use process in oncology patient care areas; (4) demonstrate excellence in the provision of training or educational activities for healthcare professionals and healthcare professionals in training; (5) promote health improvement, wellness, and cancer prevention; (6) sustain the ongoing development of expertise and professionalism in the practice of oncology pharmacy; (7) conduct oncology pharmacy practice research; and (8) function effectively in oncology settings participating in clinical investigations.²³

Recognizing the value of on-the-job training, the qualifications for BCOP include emphasis on oncology pharmacy experience, including either 4 years of practice with at

least 50% of time spent in oncology pharmacy activities or a graduate of a PGY-2 oncology residency plus 1 additional year of practice with at least 50% of time spent in oncology pharmacy activities (see Figure 1).²² The definition of oncology pharmacy activities includes the four content domains of the BPS Oncology Pharmacy Exam: (1) clinical skills and therapeutic management (60%); (2) generation, interpretation, and dissemination of information (20%); (3) guidelines, policies, and standards (15%); and (4) public health and advocacy (5%) (Appendix 1).³

Direct Patient Care

Traditionally, the pharmacist has worked in an inpatient or outpatient pharmacy to provide necessary safety checks and dispense medication in an accurate and timely fashion. A growing number of pharmacists have been freed up from dispensing functions (due to robotics, technology [computerized prescriber order entry, patient-assistance program software, hand-held electronic devices to assist with clin-

Table 2. Select Core Functions of the Oncology Pharmacist^{3,23}

Oncology Pharmacy Activities ³	Specialty Practice Outcomes ²³	Examples of Tasks, Skills, and Knowledge
Apply clinical skills and knowledge of therapeutic drug management in cancer patients.	<ul style="list-style-type: none"> • Optimize outcomes by providing evidence-based, patient-centered medication therapy as part of an interdisciplinary team. • Function effectively in oncology settings by participating in clinical investigations. 	<ul style="list-style-type: none"> • Drug ordering (provider role) • Therapy monitoring (including TDM/PK) • Chemotherapy verification and dispensing • Symptom management and supportive care • Drug shortage management (patient-focused and supply/management decisions) • Medication adherence strategies
Generate, interpret, and disseminate cancer-related information.	<ul style="list-style-type: none"> • Optimize outcomes by providing evidence-based, patient-centered medication therapy as part of an interdisciplinary team. • Serve as an authoritative resource on the optimal use of medications to treat cancer patients. • Provide training or educational activities for healthcare professionals and healthcare professionals in training. • Conduct oncology pharmacy practice research. 	<ul style="list-style-type: none"> • Patient/family education • Provider education (MD, RN, pharmacist) • Precepting (students, residents) • Didactic training/lectures related to drug therapy • Training and competencies
<p>Develop, implement, and maintain oncology-related guidelines, policies, and standards.</p> <p>Provide public health awareness and serve as a public health advocate for the oncology population.</p>	<ul style="list-style-type: none"> • Serve as an authoritative resource on the optimal use of medications to treat cancer patients. • Manage and improve the medication use process in oncology. • Promote health improvement, wellness, and cancer prevention. 	<ul style="list-style-type: none"> • Protocol development and support • Policy development • Medication reconciliation • Formulary management • Cost-savings initiatives • Drug utilization • Guideline and order set development (clinical and technical content) • Medication safety • Drug use standards • Development/maintenance of oncology medication-related EHR systems • Cancer prevention and screening • Community teaching and outreach • Payer regulations and advocacy (public and commercial)
Other pharmacy functions specific to an oncology patient population.	<ul style="list-style-type: none"> • Sustain the ongoing development of expertise and professionalism in the practice of oncology pharmacy. 	<ul style="list-style-type: none"> • Oncology-focused metrics (quality, clinical, productivity, financial) • Accreditation and “accountable care organization” standards for oncology • Professional standards • Ethics

Note. TDM, therapeutic drug monitoring; PK, pharmacokinetics; EHR, electronic health record.

ical activities], use of technicians, etc.) to provide direct patient care at the bedside or in the clinic where treatment decisions are being made.²⁴⁻³¹ Oncology pharmacists have the training and expertise that places them in an optimal position to provide medication management services across the care continuum (from assessment and diagnosis to treatment decisions, medication management, symptom management and supportive care, and survivorship programs). They are viewed as the “cancer medication experts” and work with other healthcare professionals to develop institutional guidelines and make evidence-based decisions designed to improve patient care.

Depending on institutional policies and state laws, facilitation of patient assessment and therapeutic management occurs through a collaborative practice agreement. A collaborative practice agreement typically is between one or more physicians and pharmacists and permits the pharmacist to assume professional responsibility for performing patient assessments; ordering drug therapy-related laboratory tests; administering drugs; and/or selecting, initiating, monitoring, continuing, and adjusting drug regimens under a defined protocol.^{9-15,32} Both the state Board of Pharmacy and the institution may set criteria for the extent of services allowed through collaborative practice agreements, and in some states, pharmacists are allowed to prescribe specified drugs.³³ Drugs included in these collaborative practice agreements are typically for the management of symptoms or comorbidities (but can include any drug) and require patient referral to the physician if the symptoms are not resolved or become worse. Regulatory agencies may also allow institutions to develop policies for pharmacists to prescribe and manage therapy under institutionally approved and monitored guidelines, such as a protocol for supportive care therapy (e.g., pain management, antiemetic prophylaxis or therapy, colony-stimulating factor dosing) or management of complex therapy that requires frequent dose adjustments (e.g., anticoagulation, aminoglycoside therapy).^{9,10,12,13,15,33} In collaborative practice agreements, the responsibility of the pharmacist is clearly defined in the protocol and typically requires a patient assessment, followed by a complete medical order and documentation in the patient medical record.

Oncology pharmacists facilitate transfers of patients and their medications between levels of care, ensure a current and accurate medication list is maintained (i.e., medication reconciliation), recommend or select the most appropriate therapies, monitor the effects of medications prescribed (therapeutic or pharmacokinetic drug monitoring), and manage the adverse effects that often accompany cancer treatment. Additional job functions for pharmacists continue to be implemented, such as the introduction of medication therapy management (MTM) programs instituted by Medicare and later approved as part of healthcare reform.

MTM programs include many components, such as medication therapy review, pharmacotherapy management, disease management, pharmacogenomics, medication safety, and other clinical support that may lead to improved clinical outcomes for the patient.³⁴

During a time when increasing demands are being made on all healthcare disciplines and the care of cancer patients continues to be challenged with high cost therapies, medication shortages, regulatory requirements, and dwindling reimbursement, the oncology pharmacist is heavily relied upon to provide support for the clinical team for both symptoms and comorbid diseases, with the goal of improving overall care and quality of life. With their knowledge of therapeutics, pharmacology, and drug interactions, oncology pharmacists are in an optimal position to provide the acute and longitudinal support for management of pain, nausea, vomiting, diarrhea, anemia, depression, and other symptoms frequently experienced by these complex patients.

Education

Due to the integral involvement of the oncology pharmacist in the overall care of the patient with cancer, the pharmacist is a key educator for both patients and providers. For the patient with cancer, the pharmacist is in an optimal position to provide patient-directed education and tools to improve medication adherence with complicated regimens. The pharmacist alerts the patient to potential drug interactions and anticipated toxicities or manages symptoms that the patient may already be experiencing. The pharmacist educates patients and family members on how to handle chemotherapy in the home and limit exposure to family members, children, or pets.

In addition to their role as patient educators, oncology pharmacists are recognized as an essential component of medication education for other pharmacists and healthcare providers. The experienced oncology pharmacist may share his or her knowledge with clinicians in training via hands-on teaching during a rotation-site experience or through a didactic lecture at a college of pharmacy, medicine, or nursing; in-services at practice sites; and continuing education programs at professional society meetings. The oncology pharmacist may also assist with the development of core competencies related to drug therapy for other staff members who do not routinely work in oncology but need to maintain a high skill level.

Oncology pharmacists are not only involved in the communication of education to patients and healthcare providers but also in the development of educational tools (e.g., patient education sheets) and implementation of educational programs (e.g., risk evaluation and mitigation strategies [REMS], formulary management). Evaluation of the literature and integration of new information into

an existing knowledge base is essential for the oncology pharmacist to establish recommendations for clinical use of oncology therapeutics. As a component of that, oncology pharmacists often play an integral role in different aspects of the drug development process and clinical research. Some examples include independent or collaborative protocol development and conduct of clinical trials, reporting important observations from practice, participation in institutional review boards or scientific review committees, and provision of investigational pharmacy services.

Guidelines, Policies, and Standards

Many oncology pharmacists are called on to use their clinical knowledge to provide policy and procedure development and support for other oncology- and medication-related issues. A strong knowledge of oncology therapeutics; safe preparation, administration, and disposal of cancer therapies; and supply, cost, and reimbursement for cancer therapies is crucial in developing collaborative institutional guidelines and practice-based decisions.

Oncology pharmacists are involved not only in the development of clinical guidelines, such as the prevention and treatment of nausea and vomiting, but also in other aspects of safe medication use and oncology practice. Many oncology pharmacists are members of their institutional Pharmacy and Therapeutics Committees and make formulary recommendations on the efficacious, safe, and cost-effective use of oncology drugs. As government and private insurers develop disease management programs and initiatives to address both quality and cost of care, oncology pharmacists have the drug therapy knowledge and experience to help determine safe and effective ways to meet the goals of these initiatives.

Standards related to patient safety for chemotherapy administration have been developed by the Oncology Nursing Society, the American Society of Clinical Oncology, ASHP, and other related organizations.³⁵⁻³⁸ Oncology pharmacists are often involved in the development of these types of standards, and the individual oncology pharmacist is involved in the application of those standards to the practice setting, establishing written policies and procedures for the training of staff, ensuring chemotherapy orders are safe and accurate, and the preparation of hazardous medications. The oncology pharmacist may also be responsible for updating these policies and procedures as needed according to current literature.

Oncology pharmacists assess drug inventory, ensure that drug waste is minimized, maintain an adequate but not excessive supply of drugs, and minimize exposure to cytotoxic drugs. With the ongoing crisis of drug shortages, oncology pharmacists have become a critical component of drug management strategies and are relied on for their abil-

ity to optimize dosing and alternate therapies. Additionally, knowledge of USP 797 standards is necessary for institutional pharmacies to maintain compliance with pharmacy regulations that protect patient and staff safety.³⁹

Advocacy

The oncology pharmacist is perfectly suited and positioned to be an advocate for the patient (optimal and safe care), the institution (financial responsibility), healthcare colleagues (education and standards), and the community. Oncology pharmacists are often active in advocacy programs that reach into the community and provide education related to prevention and early detection education and screening resources. Further promotion of public health and patient care needs are accomplished by active participation in multidisciplinary public and professional organizations. Additionally, oncology pharmacists are active in advocating for and helping to create regulations and payer rules that affect such things as the development and testing of new drugs, reimbursement, patient education, provision of care, safety, evidence-based appropriate use of drugs, and disposal of unused product. They often educate those who develop regulations and ensure ensuing regulations are fair, just, and affordable and do not detract from high-quality, patient-centric care.

Other Functions

Depending on the practice setting, oncology pharmacists may also be involved in other indirect patient care responsibilities related to product and service offerings, which also have important implications in the care of individuals affected by cancer. As technology is increasingly used in routine dispensing functions, pharmacists are seeking additional training opportunities to prepare them for a more global clinical role in addition to direct patient care. For example, because of the high-risk nature of the drugs used in cancer care, pharmacists play an instrumental role in medication safety initiatives, oncology clinical decision support (e.g., informatics), and electronic health record and order set development. Oncology pharmacy administrators within a cancer center or institution bring the pharmacy's needs to the forefront in addition to being a vital partner in helping the facility meet its overall goals and overcome challenges.

Some pharmacists function more in a research capacity, carrying out basic, clinical, or translational science, often in either an academic or pharmaceutical industry-related setting. Oncology pharmacists may also work for the pharmaceutical industry, pharmacy benefit managers (PBMs), or medical communications organizations, using the skills and knowledge of cancer therapeutics to improve access to and development of cancer medications.

Roles That Support the Oncology Pharmacist

Pharmacy Technician

A pharmacy technician works under the supervision of a pharmacist to assist with pharmacy practice by performing a variety of functions, such as assisting with dispensing drugs, processing medical coverage claims, and stocking medications.⁸ Technicians may receive on-the-job training or attend a certification training program and take a certification exam that assesses competency of pharmacy technician-related tasks, including assisting the pharmacist in serving patients, maintaining medication and inventory control systems, and participating in administration and management of pharmacy practice.⁴⁰

The pharmacy technician provides support to the oncology pharmacist by fulfilling several basic functions, such as preparing medications (including chemotherapy drugs) for dispensing, performing pharmaceutical calculations, managing inventory, and ordering stock. In addition, experienced technicians may take on expanded roles unique to oncology pharmacy. Expanded roles may include reviewing orders for accuracy and completeness, confirming lab results according to a hospital or office protocol, participating in sterile preparation of cytotoxic drugs following technical guidelines from authoritative entities (e.g., ASHP, Occupational Safety and Health Administration [OSHA], National Institute for Occupational Safety and Health [NIOSH]), participating in the checking process as the initial or double-check, assisting with managing investigational drug documents, and participating in obtaining medication access for patients with limited or no insurance. To perform basic functions, pharmacy technicians should complete a training program, preferably one that is ASHP accredited; meet state licensure requirements; and pass a national certification examination (PTCB or ExCPT); however, these are not mandatory in every state or country.⁴⁰⁻⁴² To enable technicians to achieve expanded roles in oncology, the oncology pharmacist should provide opportunities for technician-appropriate oncology continuing education. Demonstration of competency is a critical part of using technicians in expanded roles; competency should be assessed after initial training and at least annually thereafter.

Other Pharmacists

In small institutions, the oncology pharmacist may function more globally to address all medication issues for a patient or a patient population. In some practice settings (such as large institutions), the oncology pharmacist may also receive support from clinical pharmacists in other specialties (e.g., anticoagulation services, nutrition support, hospice/palliative care, or home health).

Other support services available to the oncology pharmacist may be provided by other pharmacists or by nonpharmacist personnel, or may be part of the oncology pharmacists' functions. For example, investigational drug services that manage drug inventory and ordering, coordinate accountability logs and paperwork, and participate in protocol review and approval processes may be provided by multiple healthcare providers, an investigational drug specialist, or the oncology pharmacist or technician. Similarly, all or some of the components of reimbursement services, such as verification of coding and billing, audit patient medical records for accurate billing, identifying patients requiring assistance, and applying for assistance and tracking benefits may be performed by an oncology pharmacist or may be coordinated through the general pharmacy department or nonpharmacy personnel.

Conclusion

The knowledge base and skill sets of an oncology pharmacist support a wide variety of functions in the global aspects of cancer patient care, from the bedside to implementing policies and influencing cancer management as it relates to drug therapy, as illustrated in the preceding discussion. This in-depth knowledge and skill set provide the healthcare team with a unique perspective on disease management that encompasses not only individual patient care but also includes the broader scope of the institution and healthcare system. The oncology pharmacist is often a clinician who understands both the clinical and financial components related to the care of a cancer patient.

Oncology pharmacist positions have existed in hospital settings for many years, and their importance and value have been well-established. Areas for growth include establishing a greater presence and a consistent role in outpatient clinics, infusion centers, and other settings (e.g., hospice, community pharmacies, specialty pharmacies); expanding MTM billing and independent prescribing protocols; and developing a role in cancer prevention and survivorship issues as they relate to drug therapy. The changing landscape of health care and evolving therapeutic approaches to cancer care (e.g., oral therapies, targeted therapies, personalized medicine) will emphasize the need for a multidisciplinary healthcare team that includes an oncology pharmacist. The impact of an oncology pharmacist extends beyond individual patient care to indirectly affecting patient outcomes through activities such as involvement with drug development, medication safety, implementation of guidelines and policies, and formulary management.

As the population of patients with cancer increases and the therapies become more complex, the need for individuals who are dedicated to oncology pharmacy practice continues to grow. Historically, the profession has not

consistently documented the value of oncology pharmacy services, such as improvements to patient outcomes or reduction of healthcare costs, although this has been accomplished within other pharmacy practice disciplines.⁴³⁻⁴⁸ To generate interest in oncology pharmacy as a valued and sustainable profession, documenting outcomes related to individual care and the healthcare system in the medical literature and widely disseminated formal publications is essential, whether it is research or quality based. Additionally, the profession needs to advocate for itself by educating other healthcare professionals and the public about the benefits of having an oncology pharmacist as part of routine cancer care. This document serves to support the current practice and begin the discussion on how to better define and shape the future profession of oncology pharmacists who are functioning in all domains of the profession. It also serves to support oncology pharmacists who desire to expand their role or improve quality of cancer care in their practice.

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Appendix 1. Content Outline Domains, Tasks, and Knowledge Statements for Board Certification in Oncology Pharmacy³

DOMAIN 1—CLINICAL SKILLS AND THERAPEUTIC MANAGEMENT: Optimize drug therapy for patients with cancer through the design, recommendation, implementation, monitoring, and modification of individualized pharmacotherapeutic plans in collaboration with the healthcare team.

Tasks	Knowledge Statements
<ol style="list-style-type: none"> 1. Collect and assess comprehensive patient information necessary to design a pharmacotherapeutic plan. 2. Establish therapeutic goals in collaboration with the patient/caregivers and the healthcare team. 3. Design, communicate/document, implement, and modify a pharmacotherapeutic plan for patient-specific problem(s) through the integration of pathophysiological, pharmacogenomic, pharmacokinetic, pharmacodynamic, age-related, socioeconomic, ethical/legal, and cultural considerations. 4. Design, communicate/document, implement, and modify a monitoring plan to assess patient-specific outcomes to the therapeutic plan, including outcomes related to concomitant disease states (e.g., symptom evaluation, adverse-effect evaluation, physical and laboratory assessment, and frequency and duration of follow-up). 5. Assess outcomes relative to therapeutic goals (e.g., effectiveness, drug-related issues, adherence). 6. Predict, prevent, identify, and resolve treatment- or disease-related problems. 7. Provide education and counseling to patients/caregivers regarding the pharmacotherapeutic plan, concurrent drug therapies, and outcomes. 	<ol style="list-style-type: none"> 1. Pathology 2. Anatomy and physiology 3. Molecular biology 4. Etiology and pathophysiology of cancer and cancer treatment–related complications 5. Cancer pharmacotherapies including chemotherapies, biologic therapies, hormonal therapies, labeled uses, and off-label uses 6. Nonpharmacological treatments (e.g., radiation therapy, surgery, observation, radiopharmaceuticals) 7. Hematopoietic stem cell transplants 8. Alternative/complementary therapies (e.g., herbals, vitamins, acupuncture) and nonprescription medications 9. Drug interactions 10. Use of clinical trials as a treatment option 11. Cancers, including staging, diagnosis, prognosis, and treatment outcomes by stage 12. Expected response rates based on patient-specific factors 13. Complications of cancer or cancer treatment, including both early and late effects 14. Toxicity assessment and grading 15. Factors that may influence treatment and outcomes, including age, organ function, biology of the disease, genetics, and comorbidities 16. Pharmacology/pharmacokinetics, pharmacodynamics, and pharmacogenetics of anticancer and supportive care agents 17. Drug-delivery technology 18. Drug administration and routes of delivery 19. Diagnostic and monitoring tests 20. Social and cultural factors impacting treatment and outcomes 21. Pain/palliative care and end-of-life care 22. Issues related to supportive care, including growth factors, chemoprotectants, antiemetics, antiinfectives, etc.

Appendix 1. Content Outline Domains, Tasks, and Knowledge Statements for Board Certification in Oncology Pharmacy³ (continued)

DOMAIN 2—GENERATION, INTERPRETATION, AND DISSEMINATION OF INFORMATION: Contribute to the care of patients with cancer through research, the application of research results, and education.

Tasks	Knowledge Statements
<ol style="list-style-type: none"> 1. Evaluate the literature with regard to study design, methodology, and significance of findings. 2. Integrate new information with existing information to establish recommendations for clinical use. 3. Develop, modify, and evaluate patient and public educational materials for approved and investigational therapies. 4. Provide education and consultation to the healthcare team. 5. Participate in the drug development process and clinical research activities (e.g., research protocol development, data collection and analysis, recruitment and monitoring of patients, investigational drug management, ensure adherence to the research protocol). 6. Contribute new knowledge to the profession (e.g., case reports, adverse drug event reports, medication safety, review articles, abstracts). 	<ol style="list-style-type: none"> 1. Literature and information retrieval systems 2. Study design and methodology, including strengths and limitations 3. Common study endpoints (e.g., response, adverse events, economics, quality of life, pharmacokinetics, pharmacodynamics, pharmacogenomics) 4. Generalizability (application) of research results 5. Statistical methods 6. Educational and counseling methods 7. Information resources for education and counseling 8. Regulatory and ethical issues related to research (including confidentiality, informed consent, and patient rights) 9. Drug development process

DOMAIN 3—GUIDELINES, POLICIES, AND STANDARDS: Ensure the safe, effective, and appropriate use of medications in patients with cancer through the implementation of guidelines and the development and modification of pharmacy policies and systems.

Tasks	Knowledge Statements
<ol style="list-style-type: none"> 1. Design, implement, evaluate, and modify pharmacy services appropriate to the needs of patients across the continuum of care. 2. Establish and modify systems to ensure the safe use of medications. 3. Ensure that oncology-related pharmacy services comply with established regulations and standards. 4. Ensure that care is consistent with appropriate clinical practice guidelines. 5. Incorporate patient rights and ethical standards into pharmacy policies and procedures (e.g., confidentiality/HIPAA, age-appropriate informed consent, right of refusal). 6. Develop appropriate drug use policies in collaboration with other providers or agencies. 	<ol style="list-style-type: none"> 1. Clinical practice guidelines (e.g., ASCO, ASHP, NCCN) 2. Methods for developing and evaluating clinical practice guidelines 3. Professional practice standards (e.g., ASHP, USP, ASCO) 4. National accreditation and regulatory standards (e.g., TJC, CMS, HIPAA, NIOSH, USP 797, OSHA, OBRA, DEA, ASHP Oncology Pharmacy Practice Residency Standards) and their impact on the care of patients 5. Reimbursement policies of federal and private agencies 6. Quality improvement strategies to avoid medication misadventures (e.g., processing of chemotherapy orders, protocol reviews) 7. Methods for handling cytotoxic drugs and related materials (administration, compounding, and disposal) 8. Investigational drug management

Appendix 1. Content Outline Domains, Tasks, and Knowledge Statements for Board Certification in Oncology Pharmacy³ (continued)

DOMAIN 4—PUBLIC HEALTH AND ADVOCACY: Raise awareness among the public and healthcare providers regarding cancer-related issues.

Tasks	Knowledge Statements
<ol style="list-style-type: none"> 1. Provide information to the public regarding cancer-related issues, including cancer risk factors, prevention, screening, and treatment. 2. Serve as a public advocate regarding treatment-related issues that pertain to the prevention, treatment, and palliation of cancer. 3. Refer the public to appropriate sources of information, cancer-support organizations, and agencies. 	<ol style="list-style-type: none"> 1. Resources available through groups, organizations, agencies, and the pharmaceutical industry (e.g., American Cancer Society, National Cancer Institute, Leukemia and Lymphoma Society, National Coalition of Cancer Survivors) 2. Cancer risk factors 3. Cancer prevention strategies 4. Cancer screening guidelines 5. Cancer treatment strategies 6. Clinical trial options

Note. ASCO, American Society for Clinical Oncology; ASHP, American Society of Health-Systems Pharmacists; CMS, Centers for Medicare & Medicaid Services; DEA, Drug Enforcement Administration; HIPAA, Health Information Portability and Accountability Act; NCCN, National Comprehensive Cancer Network; NIOSH, National Institute for Occupational Safety and Health; OBRA, Omnibus Budget Reconciliation Act of 1990; OSHA, Occupational Safety and Health Administration; TJC, The Joint Commission; USP, U.S. Pharmacopeial Convention.

Appendix 2

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