

QOPI® CERTIFICATION PROGRAM STANDARDS

DOMAIN 1: CREATING A SAFE ENVIRONMENT - STAFFING AND GENERAL POLICY

- 1.1 The healthcare setting has policies to define the qualifications of clinical staff who order, prepare, and administer chemotherapy and documents:**
- 1.1.1 Orders for chemotherapy are signed manually or by using electronic approval by licensed independent practitioners who are determined to be qualified by the health care setting.
 - 1.1.2 Chemotherapy is prepared by a licensed pharmacist, pharmacy technician, physician, or registered nurse with documented comprehensive chemotherapy preparation education, initial training, and (at least) annual continuing education and competency validation.
 - 1.1.3 Chemotherapy is administered by a qualified physician, physician assistant, registered nurse or advanced practice nurse with documented comprehensive chemotherapy administration education, initial training, and (at least) annual continuing education and competency validation.
 - 1.1.4 At least one clinical staff member who maintains current certification in (age appropriate) basic life support is present during chemotherapy administration. *Certification should be from a nationally accredited course. Clinical staff includes staff involved in patient care, RNs, MDs, NPs, etc.*
- 1.2 Before the first administration of a new chemotherapy regimen chart documentation is available that includes at least the following nine elements:**
- 1.2.1 Pathologic confirmation or verification of initial diagnosis.
 - 1.2.2 Initial cancer stage or current cancer status. *Cancer stage/Cancer status is defined in the glossary.*
 - 1.2.3 Complete medical history and physical examination. *Medical history and physical examination is defined in the glossary.*
 - 1.2.4 Pregnancy status for women of childbearing age.
 - 1.2.5 Presence or absence of allergies and history of other hypersensitivity reactions.
 - 1.2.6 Assessment of the patient's and/or caregiver's comprehension of information regarding the disease and the treatment plan.
 - 1.2.7 Initial psychosocial assessment, with action taken when indicated. *Psychosocial assessment is defined in the glossary.*
 - 1.2.8 The chemotherapy treatment plan, including, at minimum, the patient diagnosis, drugs, doses, anticipated duration of treatment, and goals of therapy.

- 1.2.9 The planned frequency of office visits and patient monitoring that is appropriate for the individual chemotherapy agent(s).
- 1.3 On each clinical encounter or day of treatment, staff performs and documents a patient assessment that includes at least the following nine elements, and takes appropriate action:**
- 1.3.1 Functional status and/or performance status.
 - 1.3.2 Vital signs.
 - 1.3.3 Weight is measured at least weekly when present in the health care setting.
 - 1.3.4 Height is measured at least weekly when present in the health care setting and when appropriate to the treatment population.
 - 1.3.5 Age as appropriate to the treatment population.
 - 1.3.6 Allergies, previous treatment related reactions.
 - 1.3.7 Treatment toxicities.
 - 1.3.8 Pain assessment.
 - 1.3.9 Patient's medications are updated and reviewed by a practitioner when a change occurs.
- 1.4 Staff assesses and documents psychosocial concerns and need for support with each cycle or more frequently, with action taken when indicated.**
- 1.5 The health care setting provides information about financial resources and/or refers patients to psychosocial and other cancer support services.**
- 1.6 The health care setting has a policy that identifies a process to provide 24/7 triage to a practitioner, for example, on-call practitioners or emergency department, to manage treatment-related toxicities and emergencies. If the patient's initial contact is not a practitioner from the treating health care setting, the person having initial patient contact must have continuous access to consultation from an experienced oncology practitioner and the opportunity for transfer of the patient to a facility with dedicated oncology services. *Practices in rural low population areas should consult with QCP staff if unable to comply with the standard.***

DOMAIN 2: TREATMENT PLANNING, PATIENT CONSENT AND EDUCATION

- 2.1 The health care setting has a policy that documents a standardized process for obtaining and documenting chemotherapy consent or assent. Informed consent and assent (optional) is documented prior to initiation of each chemotherapy regimen. *The consent process should follow appropriate professional and legal guidelines.***
- 2.2 Patients are provided with comprehensive verbal and written or electronic information as part of an education process before starting each treatment plan.**
- 2.2.1 The education process will be tailored to the patient's learning needs, abilities, preferences, and readiness to learn as assessed and documented prior to treatment. Education

includes family, caregivers, or others based on the patient's ability to assume responsibility for managing therapy.

2.2.2 Documentation that written or electronic educational materials were given to patients.

2.2.3 Educational information includes the following at a minimum:

2.2.3.1 Patient's diagnosis.

2.2.3.2 Goals of treatment, that is, cure disease, prolong life, or reduce symptoms.

2.2.3.3 Planned duration of treatment and schedule of treatment administration.

2.2.3.4 Drug names and supportive medications, drug-drug and drug-food interactions, and plan for missed doses.

2.2.3.5 Potential long-term and short-term adverse effects of therapy, including infertility risks for appropriate patients.

2.2.3.6 Symptoms or adverse effects that require the patient to contact the health care setting or to seek immediate attention.

2.2.3.7 Procedures for handling medications in the home, including storage, safe handling, and management of unused medication.

2.2.3.8 Procedures for handling body secretions and waste in the home.

2.2.3.9 Follow-up plans, including laboratory and provider visits.

2.2.3.10 Contact information for the health care setting, with availability and instructions on when and who to call.

2.2.3.11 Expectations for rescheduling or cancelling appointments.

DOMAIN 3: ORDERING, PREPARING, DISPENSING AND ADMINISTERING CHEMOTHERAPY

3.1 Chemotherapy orders include at least the following elements:

3.1.1 Patient's name.

3.1.2 A second patient identifier.

3.1.3 Date the order is written.

3.1.4 Regimen or protocol name and number.

3.1.5 Cycle number and day, when applicable.

3.1.6 All medications within the order set are listed by using full generic names.

3.1.7 Drug dose is written following standards for abbreviations, trailing zeros, and leading zeros.

- 3.1.8 The dose calculation, including:
 - 3.1.8.1 The calculation methodology.
 - 3.1.8.2 Variables used to calculate the dose.
 - 3.1.8.3 The frequency at which the variables are re-evaluated.
 - 3.1.8.4 The changes in the values that prompt confirmation of dosing.
- 3.1.9 Date of administration.
- 3.1.10 Route of administration.
- 3.1.11 Allergies.
- 3.1.12 Supportive care treatments that are appropriate for the regimen, including premedication, hydration, growth factors, and hypersensitivity medications.
- 3.1.13 Parameters that would require holding or modifying the dose, for example, laboratory values, diagnostic test results, and patient's clinical status.
- 3.1.14 Sequencing of drug administration, when applicable.
- 3.1.15 Rate of drug administration, when applicable.
- 3.1.16 An explanation of time limitation, such as the number of cycles for which the order is valid.

VERIFICATION 1

A second person (a practitioner or other personnel approved by the practice/institution to prepare or administer chemotherapy) performs the following independent verification:

3.2 Before preparation, a second person – a practitioner or other personnel approved by the health care setting to prepare or administer chemotherapy - independently verifies:

- 3.2.1 Two patient identifiers.
- 3.2.2 Drug name.
- 3.2.3 Drug dose.
- 3.2.4 Route of administration.
- 3.2.5 Rate of administration.
- 3.2.6 The calculation for dosing, including the variables used in this calculation.
- 3.2.7 Treatment cycle and day of cycle.

VERIFICATION 2

A second person (a practitioner or other personnel approved by the practice/institution to prepare or administer chemotherapy) performs the following independent verification:

3.3 Upon preparation, a second person approved by the health care setting to prepare parenteral chemotherapy verifies:

- 3.3.1 The drug vial(s).
- 3.3.2 Concentration.
- 3.3.3 Drug volume or weight.
- 3.3.4 Diluent type and volume, when applicable.
- 3.3.5 Administration fluid type, volume, and tubing.

3.4 Chemotherapy drugs are labeled immediately upon preparation and labels include the following 10 elements:

- 3.4.1 Patient's name.
- 3.4.2 A second patient identifier.
- 3.4.3 Full generic drug name.
- 3.4.4 Drug dose.
- 3.4.5 Drug administration route.
- 3.4.6 Total volume required to administer the drug.
- 3.4.7 Date the medication is to be administered.
- 3.4.8 Expiration dates and/or times.
- 3.4.9 When dose is divided, the total number of products to be given and the individual product sequence (e.g., 1 of 2, 2 of 2, etc.).
- 3.4.10 A warning or precautionary label or sticker, as applicable, to storage and handling; may be included within the label or on an auxiliary label.

3.5 The health care setting that administers intrathecal medication maintains a policy that specifies:

- 3.5.1 Intrathecal medications are:
 - 3.5.1.1 Prepared separately.
 - 3.5.1.2 Stored in an isolated container or location after preparation.
 - 3.5.1.3 Labeled with a uniquely identifiable intrathecal medication label.
 - 3.5.1.4 Delivered to the patient only with other medications intended for administration into the CNS.

3.5.1.5 Administered immediately after a time-out, double-check procedure that involves two licensed practitioners or other personnel approved by the health care setting to prepare or administer chemotherapy.

3.5.2 Intravenous vinca alkaloids are administered only by infusion.

3.6 Before initiation of each chemotherapy administration cycle, the practitioner who is administering the chemotherapy confirms the treatment with the patient, including, at a minimum, the name of the drug, infusion time, route of administration, and infusion-related symptoms to report—for example, but not limited to, hypersensitivity symptoms or pain during infusion.

3.7 Before chemotherapy administration: At least two individuals, in the presence of the patient, verify the patient identification by using at least two identifiers.

VERIFICATION 3

A second person (a practitioner or other personnel approved by the practice/institution to prepare or administer chemotherapy) performs the following independent verification:

3.8 Before each chemotherapy administration, at least two practitioners approved by the health care setting to administer or prepare chemotherapy verify and document the accuracy of the following elements:

3.8.1 Drug name.

3.8.2 Drug dose

3.8.3 Infusion volume or drug volume when prepared in a syringe.

3.8.4 Rate of administration.

3.8.5 Route of administration.

3.8.6 Expiration dates and/or times.

3.8.7 Appearance and physical integrity of the drugs.

3.8.8 Rate set on infusion pump, when used.

3.8.9 Sequencing of drug administration.

3.9 Documentation of the patient's clinical status during and upon completion of treatment.

3.10 Extravasation management procedures are defined and align with current literature and guidelines; antidote order sets and antidotes are accessible within the appropriate timeframe.

DOMAIN 4: MONITORING AFTER CHEMOTHERAPY IS GIVEN, INCLUDING ADHERENCE, TOXICITY AND COMPLICATIONS

4.1 The health care setting has a policy for emergent treatment of patients, that aligns with current literature and guidelines and addresses:

- 4.1.1 Availability of appropriate treatment agents.
- 4.1.2 Procedures to follow and a plan for escalation of care, when required, for life threatening emergencies.
- 4.2 The health care setting has a policy that outlines the procedure to assess patients' ability to adhere to chemotherapy that is administered outside of the health care setting prior to the start of treatment. Documentation of assessment is available in the patient record.**
- 4.3 The health care setting has a policy that requires assessment of each patient's chemotherapy adherence at defined clinically meaningful intervals to address any issues identified when chemotherapy is administered outside of the health care setting. Documentation of assessment is available in the patient record.**
- 4.4 Cumulative doses of chemotherapy are tracked for agents associated with cumulative toxicity.**

The standards are not deemed comprehensive and do not account for individual patient variation. It is the responsibility of each administering agent to determine the best methods for chemotherapy administration for each patient. The standards are not medical advice or legal advice. To the extent that the standards conflict with applicable federal, state, or local legal requirements, practitioners should comply with those requirements. The administering agent is solely responsible for, and assumes all risks of, administering chemotherapy drugs notwithstanding any adherence to the standards herein. ASCO and ONS disclaim any and all liability with respect to the standards and the execution of the standards by any party.

GLOSSARY

COMMON DEFINITIONS FOR ASCO/ONS CHEMOTHERAPY ADMINISTRATION SAFETY STANDARDS	
Term	Definition
Acronyms	ASCO, American Society of Clinical Oncology; APHON, Association of Pediatric Hematology/Oncology Nurses; ASPHO, American Society of Pediatric Hematology/Oncology; ONCC, Oncology Nursing Certification Corporation; ONS, Oncology Nursing Society
Adherence	The degree or extent of conformity to the provider's recommendations about day-to-day treatment with respect to timing, dosing, and frequency.
Assent	Assent expresses a willingness to participate in a proposed treatment by persons, who are by definition, too young to give informed consent, but who are old enough to understand the diagnosis and proposed treatment in general, its expected risks and possible benefits. Assent, by itself, is not sufficient, however. If assent is given, informed consent must still be obtained from the subject's parents or guardian, both which must be done according to all applicable state and federal laws. (see Consent below)
Basic Life Support	Certification through an accredited class in provisioning resuscitation, and management and assessment of life-threatening conditions, including CPR, controlling bleeding, treating shock and poisoning, stabilizing injuries and/or wounds, and basic first aid. An example would be the American Heart Association's BLS. Higher medical functions use some or all of the Advanced Cardiac Life Support (ACLS) protocols, in addition to BLS protocols.
Cancer Stage	A formal, standardized categorization of the extent to which a cancer has spread at diagnosis. Systems vary by tumor type and staging should be specific to the tissue of tumor origin. Stage should be distinguished from Cancer Status. Cancer status does change over time.
Cancer Status	Description of the patient's disease since diagnosis, if relevant (e.g. recurrence, metastases).
Cancer Support, Information and Financial Resources	A list of resources that is available for cancer support.
Chemotherapy	All chemotherapy agents used to treat cancer, given through oral and parenteral routes or other routes as specified in the standard. Types include targeted agents, alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, antitumor antibiotics, monoclonal antibodies, and biologics and related agents. Hormonal therapies are not included in the definition of chemotherapy for the Standards.
Chemotherapy Preparation Verification: Use of technology	Preparation of chemotherapy should be independently verified by a second healthcare provider who did not prepare the chemotherapy. Independent verification should include checking the preparation for completeness and accuracy of content, with particular attention given to special preparation instructions. Technology can serve as a surrogate; if practitioners follow procedures in using appropriately developed and applied procedures. Verification may include bar code and/or gravimetric verification and may be performed on site or remotely via digital images or video as allowed by state law or other regulations.

COMMON DEFINITIONS FOR ASCO/ONS CHEMOTHERAPY ADMINISTRATION SAFETY STANDARDS	
Term	Definition
Chemotherapy Regimen	One or more chemotherapeutic agents used alone or in combination in a well- defined course of treatment, generally administered cyclically.
Chemotherapy Treatment Plan	A plan of treatment specific to the patient that is developed prior to the initiation of chemotherapy. The core elements of a chemotherapy treatment plan are: <ol style="list-style-type: none"> 1. Diagnosis, including the cancer site, histology and stage 2. Goals of therapy (may be specified by the type of template; e.g., adjuvant chemotherapy plan) 3. Patient health status and co-morbidities 4. Surgical history and notable pathology findings 5. Chemotherapy regimen and starting dosages 6. Duration of treatment and number of planned cycles 7. Major side effects of chemotherapy
Clinical encounter	Clinical encounters include each inpatient day, scheduled or unscheduled practitioner visits, home visits and chemotherapy administration visits, but not laboratory or administrative visits.
Clinical Staff	Staff involved in patient care (e.g. practitioners, registered nurses, etc.)
Comprehensive Education Program	A comprehensive educational program is current, evidence-based, and age appropriate. It may be internally developed or use an established educational curriculum, includes all routes of chemotherapy administration used in the health care setting and concludes in clinical competency assessment. Example of education programs for staff administering chemotherapy agents includes the ONS/ONCC Chemotherapy Biotherapy Certificate Course, and APHON Pediatric Chemotherapy & Biotherapy Provider Program.
Consent	Consent to treatment is an important part of delivering quality cancer care. Consent is the process by which a patient is provided with sufficient information about the disease diagnosis and treatment options so that the individual can make a reasonable decision about treatment, based on an understanding of the potential risks and anticipated benefits of the treatment. Informed consent is not a waiver of rights.
Dosage	Includes the amount or quantity of medicine to be taken or administered and implies the duration or the frequency of the dose to be administered (e.g., daily, every 21 days, etc.).
Dose	The amount or quantity of medicine to be taken or administered to the patient each time in a day.
Exception Order	Notation that the standard treatment is contraindicated as a result of pre- existing comorbidity, organ dysfunction or prior therapy.
Functional Status	An individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being.
Handoff	The transfer of patient information and knowledge, along with authority and responsibility, from one clinician or team of clinicians to another clinician or team of clinicians during transitions of care across the continuum.
Healthcare Setting	A medical office or practice, clinic, agency, company, hospital or institution that provides healthcare, and home environment where healthcare is provided.

COMMON DEFINITIONS FOR ASCO/ONS CHEMOTHERAPY ADMINISTRATION SAFETY STANDARDS	
Term	Definition
Hypersensitivity Reaction	A symptomatic interaction between antibodies and allergens that causes an exaggerated and harmful response in the body. Hypersensitivity reactions range from mild to life threatening in severity and symptoms.
Identifier (patient identification)	Minimum patient identifiers for positive patient identification are: Last name, first name, date of birth, unique identification number such as medical record number. Whenever possible, ask patients to state their full name and date of birth. For patients who are unable to identify themselves (pediatric, unconscious, confused or language barrier) seek verification of identity from a parent or caregiver at the bedside. This must exactly match the information on the identity band, order, drug label (or equivalent).
Immediate Use:	For the purposes of these Standards, immediate use is defined as “use within 2 hours” in accordance with drug stability, state and federal regulations.
Label	A small piece of material attached to the medication or a container for the medication giving information about it
Labeling:	Practices/institutions are not expected to be in full compliance with this standard if they currently have electronic ordering systems that prevent compliance. Appropriate changes should be implemented as soon as possible to ensure that electronic ordering systems integrate all of these elements. If the information cannot be captured in the electronic system, it should be documented within the patient record. (If their machines have not caught up)
Medical History and Physical	Includes, at minimum, height, weight, pregnancy screening (when applicable), treatment history, and assessment of organ-specific function as appropriate for the planned regimen. Example of assessment of organ-specific function as appropriate for the planned regimen: patient plan for cisplatin requires pretreatment assessment of kidney function.
On-site and immediately available	Physically present, interruptible and able to furnish assistance and direction throughout the performance of the procedure
Orders: Written and Verbal	Orders that are written or sent electronically can be on paper, emailed from a secure encrypted computer system, written, or faxed; and includes the prescriber's signature, and in some instances, an identifying number. Verbal Orders are those that are spoken aloud in person or by telephone and offer more room for error than orders that are written or sent electronically.
Pain Assessment	Assessment of pain in the oncology patient using a multidimensional approach, with determination of the following: <ul style="list-style-type: none"> • Chronicity • Severity • Quality • Contributing/associated factors • Location/distribution or etiology of pain, if identifiable • Barriers to pain assessment
Parenteral	Introduction of substances by intravenous, intra-arterial, subcutaneous, intramuscular, intrathecal, intravesical, or intra-cavitary routes.

COMMON DEFINITIONS FOR ASCO/ONS CHEMOTHERAPY ADMINISTRATION SAFETY STANDARDS	
Term	Definition
Patient	The recipient of health care, and when applicable, includes parents, family members, significant others, lay caregivers, and healthcare proxies (e.g. legal surrogates, guardians/conservators, healthcare agents).
Performance Status	The use of standard criteria for measuring how the disease impacts the patient's daily living abilities.
Policy	A written course of action (e.g. procedure, guideline, protocol, algorithm).
Practitioner	Licensed independent practitioner, including physicians, advanced practice nurses (nurse practitioner or clinical nurse specialist), and/or physician assistants, as determined by state law.
Provider	Anyone who administers care to a patient including, for example, therapists, nurses, and physicians
Psychosocial Assessment	An evaluation of a person's mental health, social status, and functional capacity within the community. May include the use of a distress, depression, or anxiety screening form, patient self-report of distress, depression, or anxiety, or medical record documentation regarding patient coping, adjustment, depression, distress, anxiety, emotional status, family support and caregiving, coping style, cultural background and socioeconomic status.

Additional Notes:

The ASCO/Oncology Nursing Society (ONS) Chemotherapy Administration Safety Standards are intended to reflect current thinking on best practices and, as such, are intended to be a living document; future modifications are expected.

Although the standards were not developed to address this issue, ASCO and ONS endorse the safe handling of chemotherapy agents. Published guidelines define the expectations for organizations and health care workers related to the use of safe handling precautions (American Society of Health-System Pharmacists: Am J Health Syst Pharm 63:1172-1193, 2006; National Institute for Occupational Safety and Health: DHHS publication No. 2004-165, 2004; Occupational Safety and Health Administration: OSHA technical manual, 1995; Polovich M: Pittsburgh, PA, Oncology Nursing Society, 2011; US Pharmacopeial Convention, Rockville, MD, 2016). Education, training, and competency validation for chemotherapy administration must necessarily include this aspect of practice. Organizations should focus on a culture of safety because of the relationship between patient and health care worker safety (Friese CR et al: BMJ Qual Saf 21:753-759, 2012; Polovich M, Clark PC: Oncology Nursing Forum, 2012). The standards are not deemed comprehensive and do not account for individual patient variation. It is the responsibility of each administering agent to determine the best methods for chemotherapy administration for each patient.

The standards are not medical advice or legal advice. To the extent that the standards conflict with applicable federal, state, or local legal requirements, practitioners should comply with those requirements. The administering agent is solely responsible for, and assumes all risks of, administering chemotherapy drugs, notwithstanding any adherence to the standards herein. ASCO and ONS disclaim any and all liability with respect to the standards and the execution of the standards by any party.