QOPI® CERTIFICATION PROGRAM STANDARDS

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

1.1 The health care organization has policies to define the qualifications of clinical staff who order, prepare, and administer antineoplastic therapy and documents:

1.1.1 Orders for antineoplastic therapy are signed manually or by using electronic approval by licensed independent practitioners who are determined to be qualified by the health care organization.

1.1.2 Antineoplastic therapy is prepared by a licensed pharmacist, pharmacy technician, physician, or registered nurse with documented comprehensive antineoplastic therapy preparation education, initial training, and (at least) annual continuing education and competency validation.

1.1.3 Antineoplastic therapy is administered by a qualified physician, physician assistant, registered nurse or advanced practice nurse with documented comprehensive antineoplastic therapy 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 antineoplastic therapy administration. *Certification should be from a nationally accredited course. Clinical staff includes staff involved in patient care, RNs, MDs, NPs, etc.*

1.1.5 A licensed practitioner is readily available to staff who administer antineoplastic therapy in the health care organization.

1.2 Before the first administration of a new antineoplastic therapy regimen, regardless of route of treatment, 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 Presence or absence of allergies and history of hypersensitivity and anaphylactoid reactions.

1.2.5 Assessment of the patient's and/or caregiver's comprehension of information regarding the disease and the treatment plan.

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1.2.6 Initial psychosocial assessment, with action taken when indicated and agreeable to the patient. *Psychosocial assessment is defined in the glossary*.

1.2.7 The plan for antineoplastic therapy, including, at minimum, the patient diagnosis, drugs, doses, route of administration, anticipated duration of treatment, schedule of treatment, and goals of therapy.

1.2.8 The planned frequency of office visits and patient monitoring that is appropriate for the individual antineoplastic agent(s).

1.2.9 Initial assessment of health-related social needs and barriers to care including financial and logistical constraints that could impact access to treatment.

1.3 The health care organization has a policy for pregnancy testing and addressing fertility preservation with appropriate patients regardless of route of treatment at a minimum of prior to initiating antineoplastic therapies. Before the first administration of each new antineoplastic therapy regimen, pregnancy status is documented when applicable.

1.4 The health care organization has a policy requiring that weight and height are measured and documented in metric units (e.g., kg and cm) and the measurement and documentation are independently performed prior to administration of a newly prescribed antineoplastic treatment plan by two staff members approved by the health care organization.

1.5 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:

1.5.1 Functional status and/or performance status.

1.5.2 Vital signs.

1.5.3 Weight is measured at least weekly when present in the health care organization and is documented in metric units (e.g., kg).

1.5.4 Height is measured at least weekly when present in the health care organization and when appropriate to the treatment population. Height is documented in metric units (e.g., cm).

1.5.5 Age as appropriate to the treatment population.

1.5.6 Allergies, previous treatment related reactions.

1.5.7 Treatment toxicities.

1.5.8 Pain assessment.

1.5.9 Patient’s medications including prescribed and over-the-counter medications, herbal products, and supplements are documented in the medical record and reviewed by a licensed practitioner when a change occurs.

1.6 Staff assesses and documents psychosocial concerns and need for support with each cycle or more frequently, with action taken when indicated and agreeable to the patient.

1.7 The health care organization provides information about financial resources and/or refers patients to psychosocial and other cancer support services.

1.8 The health care organization has a policy that identifies a process to provide 24/7 triage to a licensed 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 licensed practitioner from the treating health care organization, 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 organization has a policy that documents a standardized process for obtaining and documenting informed consent or assent (if applicable) for antineoplastic therapy regardless of route of administration. Informed consent and assent (if applicable) is documented prior to initiation of each antineoplastic therapy 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, and plan for missed doses.

2.2.3.5 Potential for drug interactions with prescribed drugs, integrative therapies, over the counter drugs, herbal products, supplements, and foods.

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

2.2.3.7 Pregnancy prevention and fertility preservation as defined by health care organization.

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

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2.2.3.9 Procedures for handling medications in the home, including storage, safe handling, management of unused medication, and clean-up of drug spills when applicable.

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

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

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

2.2.3.13 Expectations for rescheduling or cancelling appointments.

DOMAIN 3: ORDERING, PREPARING, DISPENSING AND ADMINISTERING ANTINEOPLASTIC THERAPY

3.1 Antineoplastic orders for parenteral therapy 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 was signed.

3.1.4 Regimen or protocol name and number, when applicable.

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 preventing the use of unapproved abbreviations, omitting trailing zeros, and including 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, such as weight, laboratory values, diagnostic test results, and patient's clinical status.

3.1.8.4 The changes in the values that prompt confirmation or recalculation of dosing.

3.1.9 Date of administration.

3.1.10 Route of administration.

3.1.11 Allergies, reviewed at the time of ordering.

3.1.12 Supportive care treatments that are appropriate for the regimen, including premedication, hydration, and growth factors, are included in the preprinted or electronic order forms.

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3.1.13 Hypersensitivity, anaphylactoid, and cytokine release syndrome (CRS) (where appropriate) medications are available through site specific workflows.

3.1.14 Parameters that would require holding or modifying the dose, for example, laboratory values, diagnostic test results, and patient's clinical status.

3.1.15 Sequencing of drug administration, when applicable.

3.1.16 Rate of drug administration, when applicable.

3.1.17 An explanation of time limitation, such as the number of cycles for which the order is valid.

3.2 Antineoplastic prescriptions for oral therapy include at least the following elements:

3.2.1 Patient's name.
3.2.2 Date of birth.
3.2.3 Date the prescription is written.
3.2.4 Drug name, generic name preferred.
3.2.5 Drug dose is written following standards for preventing the use of unapproved abbreviations, omitting trailing zeros, and including leading zeros.
3.2.6 Route of administration.
3.2.7 Drug quantity or volume to be dispensed.
3.2.8 Number of refills or cycles as appropriate.
3.2.9 Directions for administration (ie SIG – daily, twice a day, schedule/number of days as applicable).

VERIFICATION 1

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

3.3 Before preparation of the antineoplastic therapy, a second person – a staff member approved by the health care organization to prepare or administer antineoplastic therapy - independently verifies:

3.3.1 Two patient identifiers.

3.3.2 Drug name.

3.3.3 Drug dose.

3.3.4 Route of administration.

3.3.5 Rate of administration.

3.3.6 The calculation for dosing, including the variables used in this calculation.

3.3.7 Treatment cycle and day of cycle.

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

3.4 Upon preparation of the antineoplastic medication, a second staff member approved by the health care organization to prepare parenteral antineoplastic therapy verifies:

3.4.1 The drug vial(s).

3.4.2 Concentration.

3.4.3 Drug volume or weight.

3.4.4 Diluent type and volume, when applicable.

3.4.5 Administration fluid type and volume.

3.5 Antineoplastic drugs are labeled immediately upon preparation and labels include the following 11 elements:

3.5.1 Patient's name.

3.5.2 A second patient identifier.

3.5.3 Full generic drug name.

3.5.4 Drug dose.

3.5.5 Drug administration route.

3.5.6 Total volume required to administer the drug.

3.5.7 Date the medication is to be administered.

3.5.8 Expiration dates and/or times.

3.5.9 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.).

3.5.10 A warning or precautionary label or sticker, as applicable, to storage and handling; may be included within the label or on an auxiliary label.

3.5.11 A label denoting HAZARDOUS DRUG, if applicable.

3.6 The health care organization that administers intrathecal or intraventricular medication maintains a policy that specifies:

3.6.1 Intrathecal medications are:

3.6.1.1 Prepared separately.

3.6.1.2 Stored in an isolated container or location after preparation.

3.6.1.3 Labeled with a uniquely identifiable intrathecal or intraventricular medication label.

3.6.1.4 Delivered to the patient only with other medications intended for administration into the CNS.

3.6.1.5 Administered immediately after a time-out, double-check procedure that involves two staff members approved by the health care organization to prepare or administer antineoplastic therapy.

3.6.2 Intravenous vinca alkaloids are administered only by infusion.

3.7 Before initiation of each antineoplastic therapy administration cycle, the staff member who is administering the antineoplastic(s) 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.

3.8 Before antineoplastic therapy administration: At least two staff members approved by the health care organization to administer or prepare antineoplastic therapy, 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 antineoplastic therapy) performs the following independent verification:

3.9 Before each antineoplastic therapy administration, at least two staff members approved by the health care organization to administer or prepare antineoplastic therapy verify and document the accuracy of the following elements:

3.9.1 Drug name.

3.9.2 Drug dose

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

3.9.4 Rate of administration.

3.9.5 Route of administration.

3.9.6 Expiration dates and/or times.

3.9.7 Appearance and physical integrity of the drugs.

3.9.8 Infusion pump (if applicable) settings, including rate.

3.9.9 Sequencing of drug administration.

3.9.10: Administration set (as applicable) e.g., filters, specialized tubing, and tracing the lines for accuracies.

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

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3.11 Infiltration and extravasation management policy is present and aligns with current literature and guidelines; antidote order sets and antidotes are accessible within the appropriate timeframe.

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

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

4.1.1 Availability of appropriate emergency equipment, rescue agents, and antidotes.

4.1.2 Procedures to follow and a plan for escalation of care, when required, for life threatening emergencies. Emergencies may include suspected hypersensitivity reactions including cytokine release syndrome reactions, or general life-threatening emergency.

4.2 The health care organization has a policy that outlines the procedure to assess patients' ability to adhere to antineoplastic therapy that is administered outside of the heath care setting prior to the start of treatment. Assessment requires identifying barriers to adherence, including physical, cognitive, and financial constraints. Documentation of assessment is available in the patient record.

4.3 The health care organization has a policy that outlines the procedures to assess patients' adherence to antineoplastic therapy that is administered outside of the health care organization at defined clinically meaningful intervals to address any issues identified. Documentation of assessment is available in the patient record.

4.4 Cumulative doses of antineoplastic therapy are tracked for agents associated with cumulative toxicity.

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GLOSSARY

COMMON DEFINITIONS FOR ASCO/ONS ANTINEOPLASTIC THERAPY ADMINISTRATION SAFETY STANDARDS	
Term	**Definition**
Adherence	The degree or extent of conformity to the provider's recommendations about day-to-day treatment with respect to timing, dosing, and frequency.
Antineoplastic Prescription	A written communication from a licensed practitioner that defines a particular antineoplastic drug, dose, and schedule to be administered to a particular patient.
Antineoplastic therapy Preparation Verification: Use of technology	Preparation of antineoplastic therapy should be independently verified by a second healthcare provider who did not prepare the antineoplastic therapy. 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.
Antineoplastic therapy/Antineoplastic regimen	All antineoplastic agents used to treat cancer, regardless of the route and hazardous drug status. Types include targeted agents (eg, small-molecule inhibitors), chemotherapy, and immunotherapy (eg, monoclonal antibodies, checkpoint inhibitors, biologics, cellular therapies). Hormonal therapies are not included in the definition of antineoplastic agents for these standards.
Antineoplastic Treatment Plan	A treatment plan specific to the patient developed before the initiation of antineoplastic therapy.
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 can be obtained and is time limited. (eg, American Heart Association) *Basic life support is a term used to describe maintenance of a clear airway and support of breathing and the circulation in cases of cardiac arrest.*
Cancer Stage	A formal, standardized categorization of the extent to which a cancer has spread at diagnosis. Systems vary by tumor type and staging but 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 services	A list of informational, psychosocial, and financial resources that is available for cancer support.

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Clinical Encounter	Clinical encounters include each inpatient day, scheduled or unscheduled practitioner visits, home visits and antineoplastic therapy administration visits, but not laboratory or administrative visits.
Combination of Antineoplastic Therapy/Regimen	One or more antineoplastic agents used alone or in combination in a well-defined protocol or course of treatment, generally administered cyclically.
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 antineoplastic therapy administration used in the health care organization and concludes in clinical competency assessment. Example of education programs for staff administering antineoplastic therapy 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	A request for antineoplastics or doses of antineoplastics that differs from the standardly available institutional treatments for a given condition. Examples include using an order set for a disease not assigned, adding a medication not included in the standard regimen, and escalation of dose or schedule beyond that defined in a standard regimen
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.
Health Care Organization	Entity responsible for antineoplastic therapy ordering, preparation, and administration regardless of the setting including but not limited to a medical office or practice, clinic, agency, company, hospital, or the patient or caregiver’s home
Health-Related Social Need	Adverse social conditions that impact a person’s health or health care such as transportation, food insecurity, housing instability, and financial toxicity.
Hypersensitivity/Anaphylactoid 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. Anaphylaxis reactions range from severe to life-threatening immune reactions.
Identifier (patient identification)	A set of parameters which, when taken, are unique to the individual. These can include but are not limited to: Last name,

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	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 and/or from interpreter services (if language barrier) at the bedside. This must exactly match the information on the identity band, order, drug label (or equivalent). All paperwork that relates to the patient must include and be identical in every detail to the minimum patient identifiers on the identity band.
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.
Independent Verification	Independent verification is the act of verifying or checking the status or quality of a component or product independent of the person who established its present state. Independent verification has a higher probability of catching an error than does peer-checking or concurrent verification as the second person is not influenced by the first person and has freedom of thought. Independent verification catches errors after they have been made. The individual performing the independent verification must physically check the condition without relying on observation or verbal confirmation by the initial performer. True independence requires separation in time and space between the individuals involved to ensure freedom of thought Independent verification of antineoplastic therapy preparation 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 during the preparation (ie, mixing, compounding) process based on ample evidence showing equivalent safety outcomes and 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
Label	A descriptor which is tightly affixed to an antineoplastic agent which identifies its contents, dose, and parameters of administration. The required components of the label and their verification are detailed in the standards.
Licensed Practitioner	Any individual permitted by law and by the medical staff and board to provide care and services without direction or supervision within the scope of the individual’s license and consistent with individually granted clinical privileges, e.g., MD, DO, NP, PA, PharmD, CNS, etc.
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.
Medical Record	Document containing specifics of patient care in either electronic or written form
Orders: Written and Verbal	Patient care communications that are written or sent electronically can be on paper, emailed from a secure encrypted

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	computer system, written, or faxed; and includes the licensed independent practitioner'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.
Parenteral	Introduction of substances by intravenous, intra-arterial, subcutaneous, intramuscular, intrathecal, intravesical, or intra-cavitary routes.
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).
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.
Readily available	Interruptible and able to rapidly respond and furnish on-site assistance and direction throughout the performance of the procedure.

Additional Notes:

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