ASCO QOPI® Certification Program

Standards Manual

REQUIRED PROCESSES AND DOCUMENTATION TO MEET CERTIFICATION STANDARDS AND ELEMENTS

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Introduction

Use of the Standards Manual for Certification

This Manual is intended to be a tool for use by health care organizations seeking QOPI® Certification and by surveyors who evaluate these organizations. To achieve certification, a health care organization must meet all the certification Standards and elements, as assessed during a site survey. If an organization meets all the elements for a particular Standard, it meets the Standard. This tool aims to provide the information required for each standard.[i]

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The QOPI® Certification Program (QCP™) Standards have four defined domains of responsibility:

Domain 1: Creating a Safe Environment-Staffing and General Policy

Defines staff qualifications, minimum chart documentation requirements, defines relevant patient resources, and policies for patient documentation and follow-up.

Domain 2: Treatment Planning, Patient Consent and Education

Defines requirements for consent and education processes prior to treatment.

Domain 3: Ordering, preparing, dispensing and administering antineoplastic therapy

Defines requirements for antineoplastic therapy order set, order verification, labeling and safe handling, and extravasation management procedures.

Domain 4: Monitoring after antineoplastic therapy is given, including adherence, toxicity and complications

Defines requirements for emergency management, monitoring and care of toxicities, and oral antineoplastic therapy adherence.

Within each domain are **Standards**, and for some Standards there are **elements** that provide more specificity for the Standard. Each Standard and its underlying elements in this manual contain three sections:

1. **Commentary:**
   This section provides an explanation of how to interpret the Standard and its elements.
2. **Required Written Materials/Observations:**
   This section contains the requirements for written materials a health care organization must have in place to meet the Standard and its elements and/or the processes the QOPI® Certification Surveyor must observe during the survey.
3. **Outcomes:**

These are the outcomes that a health care organization will have in place after successful implementation of the Standard and its elements.

The QOPI® Certification Program uses the generic term "policies and procedures" to refer to all types of written materials. Policies and procedures include any written materials that the practice/institution uses to define and communicate its practices, such as standard operating procedures, policy statements, procedure descriptions, checklists, guidelines, educational materials, job descriptions, memoranda, forms, templates, etc. that are used to administer care in the outpatient oncology office.

For some Standards and elements, the QOPI® Certification Program has provided examples of common documents or tools practices have used to meet the Standard requirements. They are not required, and the list is not exhaustive. By designating certain types of written materials that may be used to meet a Standard or its elements, the QOPI® Certification Program does not desire to reduce the flexibility of the certification or limit creativity. The list of common types of materials is intended to be helpful by providing guidance on the types of materials that have generally aided health care organizations in consistently meeting Standards requirements.

If a Standard or element refers to written policies and procedures, it generally means that a written procedure (e.g., formal policy or standard operating procedure) is required. In some cases, an application form or reviewer checklist can serve the same purpose as a written procedure. The QOPI® Certification Program has attempted to identify those elements in this document.

Glossary Definition of Policy: A written course of action (e.g., procedure, guideline, protocol, algorithm). A policy is generally defined as a decision, plans, and actions that are undertaken to achieve specific healthcare goals within a health care organization. A procedure is a method by which a policy can be accomplished. Procedures should describe the operational steps that are followed to meet requirements. A restatement of the Standard for guidance is generally insufficient to provide the necessary specificity. Procedures should include: 1) An explanation of how the Standard is interpreted in the specific practice setting, 2) The actions that are taken, 3) The title of the person, office, or entity responsible for taking the action, and 4) The timing of actions.

No single format is required for policies and procedures, and no specific wording is required to be used in policies and procedures. Practices/institutions have used a range of models for writing policies and procedures. Procedures should provide enough detail to be understandable to individuals within the organization who use them. Procedures should reflect actual practice within the health care organization. An effective date of the policies and procedures communicates the timeline of implementation.

Domain 1: Creating a Safe Environment-Staffing and General Policy

Commentary
This Domain describes the structural foundation of staffing and processes of the entity that assumes responsibility for treating patients who are seen in the outpatient oncology setting. The organizational structure is the means by which the health care organization meets the range of responsibilities needed to create a safe environment for treating oncology patients. The policies for medical record documentation and standardized assessments form the structural foundation of safe, quality oncology care.

Standard 1.1

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.

Commentary
A health care organization should have a policy that describes who is qualified to prescribe and sign treatment plan orders. The policy should define who (physician or other healthcare providers) has prescriptive authority to write the order and differentiate between the types of orders that can be authorized by MDs, NPs, PAs, or PharmDs. Policies should align with regulations, laws, codes, and guidance that the health care organization follows. Verbal orders for antineoplastic agents are NOT permitted under any circumstances and this should be reflected in the policy.

Required Written Materials/Observations
A policy that outlines who is qualified to prescribe and sign orders, including subsequent orders. The policy should align with regulations, laws, codes and guidance that the practice/institution follows.

Outcome
The Practice has a defined process for who can order antineoplastic therapy (initial and ongoing) and how the orders can be transmitted (written and/or electronic).

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.

Commentary
A health care organization is required to have a policy that determines who is qualified to prepare antineoplastic therapy. The policy should define who (physician, pharmacist, pharmacy technician,

or registered nurse) can prepare antineoplastic therapy and how they are determined to be qualified. A comprehensive antineoplastic therapy preparation education program should be included in the policy.

Practices may submit a checklist containing all staff training requirements (e.g. Technician Orientation Checklist). Examples of requirements may include reviewing an American Society of Health-System Pharmacists (ASHP) antineoplastic therapy preparation video, take U.S. Pharmacopeia (USP™) and aseptic technique exams, and demonstrate correct use of your chosen closed system transfer device (CSTD). Pharmacists, pharmacy technicians, or nurses who prepare antineoplastic therapy should have competency evaluations for aspects of sterile compounding which might include:

- performing calculations and preparing dilutions
- compounding base solutions (if necessary)
- preparing medications for complex routes of administration (e.g. intrathecal)
- demonstrating proper use of technology (if available)
- completing competency assessments in compliance with US Pharmacopeia, State Boards of Pharmacy, and other required oversight agencies

A policy should also define the annual education and competency requirements for staff who prepare antineoplastic therapy. Examples of ongoing education may include completing online learning modules and attending in-services or continuing education classes. Additionally, competency assessment is required on an annual basis with defined observable behaviors, skills, and knowledge required for successful performance in the role. Practices may provide a sample competency checklist containing the annual requirements.

Required Written Materials/Observations
A policy that outlines who has the authority to prepare antineoplastic therapy, how these individuals are determined to be qualified, and what preparation education, training and annual competency validation is mandated.

Outcome
The Practice has a defined process for determining who is qualified to prepare antineoplastic therapy, defined requirements for initial and ongoing education, and defined process for initial and annual competency assessment. Staff who prepare antineoplastic therapy have comprehensive education, participate in ongoing education, and demonstrate competency during orientation period and (at least) annually.

Suggested Resource
Hematology/Oncology Pharmacy Association (HOPA) Learn

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.

Commentary

The health care organization that employs the MD, PA, RN or APRN is responsible for determining which staff are competent to deliver treatment and to train them adequately. This decision is made by the health care organization administration in conjunction with the regulations set forth by the state's medical and nursing boards and in observance of any state or federal regulations. Documentation such as a practice or institutional policy should clearly define the process of determining initial and ongoing competency and define the initial and continuing education process. Education and competency assessments should be specific to the oncology setting. Practices are required to have a comprehensive educational program as defined: the comprehensive antineoplastic therapy administration 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. Examples of education programs for staff administering antineoplastic agents include the ONS/ONCC Chemotherapy Immunotherapy Certificate Course, and the APHON Pediatric Chemotherapy & Biotherapy Provider Program. The QOPI® Certification Program requires that all courses developed independently by the health care organization incorporate, at a minimum, similar information and objectives as found in these programs.

Required Written Materials

A policy that defines who may administer all routes of antineoplastic therapy which may be utilized within the health care organization and includes a description of comprehensive initial educational requirements and competencies, annual continuing education requirements, and a description of the (at least) annual competency demonstration and how competency is documented.

Outcome

The Practice has a defined process for who can administer all routes of antineoplastic therapy and defines the initial and ongoing competency requirements for staff. Staff who administer antineoplastic therapy have comprehensive education, participate in ongoing education, and demonstrate competency during orientation period and (at least) annually.

Suggested Resources

ONS/ONCC Chemotherapy Immunotherapy Certificate Course

APHON Pediatric Chemotherapy & Biotherapy Provider Program

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.*

Commentary

Basic Life Support (BLS) is the most basic form of life support, which includes all the methods and techniques necessary to administer CPR. Advanced Cardiovascular Life Support (ACLS) builds upon the tenets of BLS by incorporating advanced tools and methods to facilitate more intensive rescue efforts. The BLS for Healthcare Providers course covers core material such as adult and pediatric CPR including two-rescuer scenarios and use of the bag mask, foreign-body airway obstruction, and automated external defibrillation. The American Red Cross and American Heart Association (AHA) Authorized Training is the most recognized and other trainings must be equivalent.

Required Written Materials/Observations

A policy that defines which (at least one) clinical staff member in the infusion suite maintains current certification in (age appropriate) basic life support. A copy of BLS certifications for selected staff or a list of staff with BLS certification and expiration dates should be submitted. Clinical staff includes staff involved in patient care: RNs, MDs, NPs, etc. The certification must be appropriate to the ages of patients treated in the practice.

Outcome

The practice has a defined policy for staffing in the infusion suite that states at least one clinical staff member who maintains current certification in (age appropriate) basic life support is required to be present during antineoplastic therapy administration. The practice maintains proof of the BLS/ACLS certification.

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

Commentary

Patients are at risk for serious and potentially life-threatening side-effects, toxicities or drug reactions. It is imperative that a licensed practitioner is readily available to staff who administer antineoplastic therapy to direct the management of signs and symptoms of these potential adverse effects and there are protocols in place for this oversight. These life-threatening events, including hypersensitivity reactions or other medical emergencies have heightened awareness due to new immune effector cell therapies, such as bispecific immune cell engager antibodies that may cause cytokine release syndrome (CRS).

Required Written Materials/Observations

A policy that outlines the process ensuring a licensed practitioner is readily available to staff. Specifically, to direct the management of suspected hypersensitivity reaction, or general life-threatening emergencies. A definition for licensed practitioner can be found in the glossary.

Outcome

The practice has a defined policy for a licensed practitioner to be readily available to staff who administer antineoplastic therapy to direct the management of adverse events.

Standard 1.2

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.

1.2.3 Complete medical history and physical examination.

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.

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, 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.

Commentary

Medical records are legal documents whether in written form or as a computer-generated form. Medical Records provide evidence of the care delivered to patients including healthcare providers' documentation and response to care delivered. Standard 1.2 addresses the requirement for documentation of key patient, disease, and antineoplastic therapy details before each new antineoplastic therapy regimen. Safe antineoplastic therapy administration requires a team of professionals (physicians, nurses, pharmacists, support services team members, and others) and, therefore, chart documentation can be performed by the team of professionals and should be available not only to the prescriber but to all members of the treatment team. The nine elements of Standard 1.2 should be completed and documented in the clinical record prior to antineoplastic therapy treatment.

Required Written Materials/Observations

1.2.1 Pathologic confirmation or verification of initial diagnosis. A pathology report should be in the record, which contains the diagnosis and may contain information about the size, shape, and appearance of a

specimen as it looks to the naked eye. Pathology reports play an important role in cancer diagnosis and staging, which helps determine treatment options. If the original pathology report is unobtainable, a note of explanation will be documented.

1.2.2 Initial cancer stage or current cancer status. Cancer stage at diagnosis should be documented in the medical record, or current cancer status including a description of the patient's disease since diagnosis/staging. There are many staging systems. Some, such as the TNM Staging System, are used for many types of cancer. Others are specific to a particular type of cancer. Documentation of staging should include information about cancer stage at diagnosis or prior to administration of a new antineoplastic therapy regimen:

- Where the tumor is located in the body
- The cell type (such as, adenocarcinoma or squamous cell carcinoma)
- The size of the tumor
- Whether the cancer has spread to nearby lymph nodes
- Whether the cancer has spread to a different part of the body
- Tumor grade, which refers to how abnormal the cancer cells look and how likely the tumor is to grow and spread

1.2.3 Complete medical history and physical examination. The medical record should have a documented complete medical history and physical examination including, at minimum, height, weight, 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 pre-treatment assessment of kidney function. Thorough documentation should also include past and present use of cigarettes and alcohol, as well as illicit, prescribed and over-the-counter drugs.

1.2.4 Presence or absence of allergies and history of hypersensitivity and anaphylactoid reactions. Documented presence/absence of allergies or adverse reactions to medications should be prominently noted in the medical record. Absence of allergies (no known allergies – NKA) should also be prominently noted.

1.2.5 Assessment of the patient's and/or caregiver's comprehension of information regarding the disease and the treatment plan. Record should contain a statement of the patient's and/or caregiver's comprehension of information regarding the disease and the treatment plan in a narrative note, on the informed consent form, or a signed decision aid.

1.2.6 Initial psychosocial assessment, with action taken when indicated and agreeable to the patient. ***Psychosocial assessment is defined in the glossary.*** As well as the physical assessment, the medical record should have a documented initial psychosocial assessment, which includes an evaluation of a person's mental health, social status, and functional capacity within the community. This documentation 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. A systematic assessment framework should be used to identify and address these issues over time, and this is the initial assessment. Practices should define when an assessment results in further action to be indicated such as a referral or other intervention. The surveyor will look for a policy or written procedure describing the workflow and referral process if needed to address patient concerns. If using a tool such as the distress thermometer, the policy should have identified parameters of when action is indicated. This could be a distress thermometer score, or change from baseline, require referral to a social worker. Surveyors will observe the medical record documentation of the psychosocial assessment and action taken if indicated.

Suggested Resources
GAD-7 Anxiety Scale

NCCN Distress Thermometer and Problem List for Patients by Clinical Practice Guidelines. Version 1.2025, National Comprehensive Cancer Network
Distress Thermometer Tool Translations

Patient Health Questionnaire (PHQ)-2
PHQ-4
PHQ-9

Depression: Screening and Diagnosis | AAFP

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. The antineoplastic therapy treatment plan should be documented within the medical record and include, at a minimum, the patient diagnosis, drugs, doses, route of administration, anticipated duration of treatment, schedule of treatment, and goals of therapy. The treatment plan should be consistent with diagnoses, have both objective, measurable goals and include continuity and coordination of care activities between the primary clinician, consultants, ancillary providers and healthcare institutions as appropriate. A cancer diagnosis treatment plan can be shared among the patient, family, and care team to facilitate care coordination and provide a detailed explanation to support patients navigating cancer diagnosis and treatment.

Suggested Resource
ACS ASCO Treatment Plan Template

1.2.8 The planned frequency of office visits and patient monitoring that is appropriate for the individual antineoplastic agent(s). With all types of antineoplastic therapy including oral antineoplastics, the medical record must have documentation of the planned frequency of office visits and patient monitoring that is appropriate for the individual antineoplastic therapy agent(s). Examples include weekly for four weeks, bimonthly for two months, then monthly unless

symptomatic. Laboratory visits and pharmacy telephone encounters may also be included for patient monitoring.

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. Health-related social needs (HRSN) are social and economic factors that impact an individual's ability to maintain their health and well-being, including issues like food insecurity, housing instability, transportation barriers, and lack of access to healthcare. An initial assessment of health-related social needs and barriers to care is necessary to identify and mitigate potential risks that may include support service referrals within the health care organization or community resources for the patient and caregivers. The practice may make directed assessments of HRSN and barriers to care through directed interview or validated screening tools (e.g. The Accountable Health Communities Health-Related Social Needs Screening Tool).

Suggested Resources
NCCN Distress Thermometer and Problem List for Patients by Clinical Practice Guidelines. Version 1.2025, National Comprehensive Cancer Network
Distress Thermometer Tool Translations

PRAPARE®: Protocol for Responding to and Assessing Patient Assets, Risks, and Experiences
PRAPARE
PRAPARE-English.pdf
PRAPARE-Portuguese.pdf
PRAPARE-Spanish

The Accountable Health Communities Health-Related Social Needs Screening Tool

American Cancer Society Financial Hardship Resource

Outcome
The practice has a defined process for complete and accurate patient record documentation (including the above nine elements) before the first administration of a new antineoplastic therapy regimen which fosters quality, safety, patient centeredness, and continuity of care.

Standard 1.3

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.

Commentary

Despite opportunities to identify pregnancy earlier in the process, if they are missed, the opportunities before administration of antineoplastic therapy are a key point to prevent the potentially negative sequelae of antineoplastic therapy to patients who are pregnant. Pregnancy status is usually discussed in the context of treatment planning and/or ordering. Clinicians should address fertility preservation for appropriate patients prior to first administration and ensure education is provided on potential long-term and short-term infertility risks. Clinicians should discuss fertility issues in the context of informed consent, through an interdisciplinary approach incorporating risk assessment, patient education, and potential referral to reproductive specialists for fertility preservation. Each health care organization should follow evidence-based guidance to define the details of its specific policies.

Required Written Materials/Observations
A policy that defines the process 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.

Practices will define exclusionary criteria for performing a pregnancy test such as patient is post-menopausal, had a tubal ligation, etc. Pregnancy status or reason why a pregnancy screening was not indicated is in the medical record prior to treatment.

Outcome
The practice has a defined process for pregnancy testing and addressing fertility preservation with appropriate patients prior to initiating antineoplastic therapies. The defined process will include complete and accurate patient record documentation.

Suggested Resources
Pregnancy Screening in Patients with Cancer, *Journal of the National Comprehensive Cancer Network : JNCCN*, 01 Jan 2018

Implementing a Nurse-Driven Pregnancy Screening Protocol in the Radiation Oncology Setting, *Clinical Journal of Oncology Nursing*: *CJON*, October 2024

Standard 1.4

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.

Commentary

Concerns about accuracy of height and weight measurement are well documented in the literature to include clearly mistyped numbers, single-digit errors, decimal misplacement, number transposition, and documentation of pounds rather than kilograms. Findings include errors occurring in measurement, transcription, and documentation were most prevalent. To minimize errors in weight and height–based dosing, the Institute of Safe Medical Practices recommends consistent procedures for height and weight measurement, when measured in metric units only. Additionally, prior to the start of a new treatment plan, consistent methodology and verification of height and weight by two staff members is required.

Required Written Materials/Observations

A policy that defines the process for prior to the start of a new treatment plan, consistent methodology and verification of height and weight independently performed prior to administration of a newly prescribed antineoplastic treatment plan by two staff members approved by the health care organization. The height and weight verification process is required for all patients, regardless of whether these measurements affect the dosing of antineoplastic therapy. The surveyor will confirm the policy through staff interviews.

Outcome

The practice has a defined process for independent verification by two staff members approved by the health care organization of height and weight measurement minimizing errors in weight and height-based dosing of antineoplastic therapies as well as to make assessment of nutritional status and inform estimates of prognosis.

Standard 1.5

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.

Commentary

The purpose of the clinical review before each cycle of antineoplastic therapy is to identify any new or ongoing toxicities experienced, assess the patient's clinical status, and implement any changes in the treatment plan. Antineoplastic therapy has significant and predictable toxicities, which are likely to develop while the patient is at home between treatment cycles. In the clinic setting, the assessment establishes the presence of any toxicities and determines the need for intervention. The patient will be assessed for clinical status to continue the treatment plan. It is essential that systems are in place to record any symptoms the patient reports. General well-being should be recorded using performance status, physical assessment tools, and toxicities are recorded using common toxicity criteria descriptors as defined by the practice/institution (e.g., grading using Common Terminology Criteria for Adverse Events – CTCAE - or mild, moderate, severe). It is advised to use descriptors that are as objective as possible and allow for comparison over time.

Height is performed along with weight prior to administration of newly prescribed antineoplastic therapy plan for accurate treatment plan dosing. Due to the fluidity of pediatric growth and the subsequent impact on chemotherapy antineoplastic dosing, it is critical that variables such as weight and height are measured and documented at least weekly for pediatric patients.

Medication reconciliation occurs with each clinical encounter or day of treatment (or weekly if a patient is seen multiple times in one week) to ensure an accurate list of all medications, herbal products, and supplements that the patient is taking compared to the medical record. A complete list of the patient's medications is communicated to the next provider of service when a patient is referred to or transferred to another setting, service, or practitioner, within (or outside) the practice/institution. Many cancer patients have non-cancer comorbidities and receive care from several doctors. Drug–drug interactions (DDIs) are of major concern in oncology, since cancer patients typically take many concomitant medications. Interactions with other medications can cause

small changes in the pharmacokinetics or pharmacodynamics of an antineoplastic agent that could significantly alter its efficacy or toxicity.

The process can involve staff members interacting with the patient/family but must conclude with a review by a licensed practitioner for changes and action if needed. For instance, the process can involve workflows with clinical assessment and printing patients' medication lists from the electronic medical record and distributing lists to established patients for review. Changes are noted and the lists are then provided to the licensed practitioner for review. The licensed practitioner then documents any medication that the patient was taking or receiving prior to the visit that is to be discontinued, altered, or held pending consultation with the prescriber, as well as follow-up required, such as calling or making appointments with other practitioners and a timeframe for doing so. For patients who may have multiple appointments (with a practitioner and/or infusion visits) in the same week, this does not need to be completed more than once per week.

Required Written Materials/Observations

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. Although not required, a practice may consider having a policy or written process that describes who conducts the assessment, any assessment tools that are used, and where the information can or should be found. Surveyors will review medical record documentation (narrative notes, flowsheets) which should, as indicated, document the nine elements below. Surveyors will review at least the last 2-3 visits to reflect 1-3 months. Unless noted otherwise, each assessment element below is required at each encounter. Clinical encounters include each scheduled or unscheduled licensed practitioner visit, home visits and antineoplastic therapy administration visits, but not laboratory or administrative visits.

1.5.1 Functional status and/or performance status: functional status is defined in glossary as: an individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being and can be documented in a progress note as how well patient is doing, or could be documented using ECOG or Karnofsky scales.

1.5.2 Vital signs are documented in medical record.

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). Medical records will be observed over several visits. Antineoplastic therapy dosing is often based on this.

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). Weight and height are measured and documented at least weekly for pediatric patients. Height should be measured prior to treatment and then as needed for the adult population. Surveyors will observe that this is documented in the medical record.

1.5.5 Age as appropriate to the treatment population will be observed as being documented in the medical record. Patient age is a significant variable in pediatric treatment plans. Some pediatric plans change antineoplastic dosing parameters based on patient age, such as changing from weight-based to body surface area-based dosing at 12 months of age, and intrathecal antineoplastic therapy dosing is often based solely on patient age. Adult date of birth should be recorded at the beginning of treatment and as appropriate to the agent.

1.5.6 Allergies, previous treatment related reactions are documented prominently in each record. If patient has no known allergies this should also be clearly identified.

1.5.7 Treatment toxicities - presence or absence of treatment toxicities are documented in record. Recommend use of toxicity grading scales.

1.5.8 Pain assessment - medical record documentation of pain assessment. This can be descriptive and/or quantified for intensity (e.g., 0-10 scale or mild, moderate, severe). If patient is not experiencing pain this is also documented.

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. Medical record includes indication that medications were updated and reviewed. Required only weekly for patients seen multiple times in one week. Recommend proactively interviewing patients about herbal products and supplements.

Suggested Resource
Memorial Sloan Kettering Cancer Center's "About Herbs" Database

Outcome
The practice has a systematic approach to patient assessments on clinic and treatment days that contain the nine elements above.

Standard 1.6

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.

Commentary
As well as the physical assessment, it is essential that the clinician assess the psychological impact of having a diagnosis of cancer and receiving treatment for it. This includes how well the patient is coping with the impact of receiving antineoplastic therapy on day-to-day life. Cancer and its treatment can significantly impact a patient's psychosocial well-being, leading to issues like anxiety, depression, and difficulty coping, which can affect relationships, work, and overall quality of life. A systematic assessment framework should be used to identify and address these issues. This framework can include tools such as a distress thermometer, which asks a patient to rate their psychological well-being. Given the longevity of treatment plans and the many aspects of a disease

trajectory, this self-assessment is likely to change. Therefore, it is important that assessments of psychosocial well-being are undertaken at regular intervals because this is an important aspect of quality care. Reassessments should be conducted with each treatment cycle or more frequently as indicated, which could include appointments where patients are at an increased risk for distress (e.g., diagnosis, treatment plan changes, completing treatment and re-staging). Referrals to appropriate support should be made if required.

Required Written Materials/Observations
Surveyors will review the medical record documentation of the psychosocial assessment and action taken if indicated. This will be observed over two cycles depending on how often the practice assesses patients. If using a standardized tool such as a distress thermometer or questionnaire, there should be identified parameters for when action is indicated. This could be a parameter (action value) such as a specific score or any change from baseline, requires referral to a social worker. Though not required, a written policy or workflow describing the assessment and referral process if needed to address patient concerns, is useful in assuring assessment and follow-up are performed consistently.

Outcome
The practice has a systematic approach to patient psychosocial assessments during antineoplastic treatment, performed at each cycle or more frequently.

Suggested Resources
GAD-7 Anxiety Scale

NCCN Distress Thermometer and Problem List for Patients by Clinical Practice Guidelines. Version 1.2025, National Comprehensive Cancer Network
Distress Thermometer Tool Translations

Patient Health Questionnaire (PHQ)-2
PHQ-4
PHQ-9

Depression: Screening and Diagnosis | AAFP

Standard 1.7

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

Commentary
A diagnosis of cancer affects the whole person and family. Support communities (online or physical) have programs and services that are available to help people with cancer and their loved ones understand cancer, manage their lives through treatment and recovery, and find the emotional and financial support they need. Cancer-related financial hardship, or "financial toxicity," is a significant

issue, impacting many individuals and families facing the disease, leading to difficulties with treatment, daily living, and overall well-being. The health care organization should identify a member of the healthcare team, such as a nurse navigator, nurse educator, or social worker, to educate and provide access to the many support services available for those who need them.

Required Written Materials/Observations
Surveyors will observe the materials available for patients and interview appropriate staff members regarding the process. A written explanation describing the materials available and referral process needed to address patient concerns could provide complete information to the surveyor.

Common Types of Materials That May Be Used to Support Meeting the Standard:

- Lists of cancer foundations and organizations
- Cancer Facts & Statistics
- Programs & Services lists (support groups, counseling, nutrition, palliative care services) and contact information
- Materials that discuss and refer patients to expertise in:
    - Health Care Insurance Coverage Challenges
    - Emotional & Peer Support
    - Clinical Trials Access
    - Disease-specific education and support groups
    - Hair Loss & Mastectomy Resources and Products
- Lodging for out-of-town cancer care services
- Cancer Care Transportation

Outcome
The practice has a systematic approach to providing patient resources that help patients manage their cancer and participate fully in their treatment.

Standard 1.8

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 QOPI® Certification Program staff if unable to comply with the Standard.*

Commentary
Patients with a diagnosis of cancer will experience symptoms related to their treatment. This Standard requires that patients have 24/7 access to oncology care expertise to reduce unnecessary emergency department and hospitalization admissions.

Required Written Materials/Observations

Practices must submit a policy that identifies a process to provide 24/7 triage to a licensed practitioner. The policy should describe how patient calls are managed during business hours as well as after hours and on holidays. The policy must indicate if the after-hours practitioner is from the practice and, if not, provide a process by which the patient will have access to oncology care.

Practices have policies that state if a patient calls after business hours, the on-call licensed practitioner will be notified and will respond timely or upon arrival at the emergency room, the oncology care team will be contacted. Practices have implemented efficient telephone triage with Standard triage protocols and patient education as to when to call if symptoms arise. Many practices have implemented evidence-based triage for symptom management, same-day sick visits, and extended hours for symptom management.

When the practice relies on the services of another practice or institution, the practice ensures that the services meet the relevant certification Standard. The practice's policy should ensure that if required, the opportunity for transfer of the patient to a facility with dedicated oncology services is met.

Outcome
The health care organization has a structured policy that identifies a process to provide 24/7 triage with oncology care and the opportunity to be treated in a facility with dedicated oncology services.

End of Domain 1

Domain 2: Treatment Planning, Patient Consent and Education

This Domain describes the requirements for obtaining and documenting patient consent or assent for antineoplastic therapy, and patient and family education prior to the initiation of treatment.

Standard 2.1

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.***

Commentary
Informed consent is intended to assure that the patient understands the purpose, benefits, risks, and alternatives to all treatment options before deciding to accept or refuse treatment. There are two components to proper informed consent: content and documentation. The content of informed consent is the discussion with the patient; it is the education and understanding of the patient. The documentation is evidence that the legal obligation of obtaining informed consent has been fulfilled; it is evidence that the discussion occurred, the patient was educated, and the patient understood.

Informed consent for antineoplastic therapy is an essential prerequisite to the administration of an antineoplastic therapy agent by any route in any health care organization. Informed consent needs to be documented. The health care organization may determine if informed consent is obtained and documented as a standardized form or in a licensed practitioner note.

The practice should state in a policy how consent is obtained in their setting, including who may obtain consent, when consent is obtained (before treatment begins), duration of validity of consent (for a specified period of time or as long as treatment continues) and where consent is documented. Best practices dictate that consent/assent conversations should be well documented. One way to document consent is through a written consent/assent form that is reviewed with the patient, signed, and stored in the patient's medical record. Making a detailed note in a patient's medical record to document that all the required elements of a consent/assent conversation took place is equally appropriate. The practice may want to provide a copy of the informed consent form or documentation as a component of written patient education materials.

Legally, children are not able to give true informed consent until they turn 18. Instead, they are asked for their assent. Assent means that they agree to take part. They may also dissent, which means they do not agree. Unlike informed consent, assent is not always required by law, though many pediatric practices require this.

Though consent forms cannot replace direct communication, they can enhance the consent process. Consent forms can serve as a guide for providers during consent conversations to help ensure that they address all required elements and provide a take-home reference for patients about the risks, benefits, and alternatives of their treatment plan.

The health care organization may provide options for consent (e.g., use of chart documentation of patient verbal consent or a signed patient consent form) that allow for variation among practitioners in the practice/institution.

The health care organization will ensure a process and validate that the consent process has been documented, so antineoplastic therapy is not administered without documented consent. A sample consent form can be found in the suggested resources.

Use of the ASCO consent template is entirely voluntary and does not imply ASCO's endorsement of any physician practice, treatment regimen, or product. ASCO assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this template, any changes made to this template by the user, or any errors or omissions.

Required Written Materials/Observations

The health care organization has a policy documenting a standardized process for obtaining and documenting antineoplastic therapy consent or assent. The QOPI® Certification Program will require the practice to have a written policy as to how the practice staff obtain informed consent prior to any antineoplastic therapy regimen/treatment. Health care organization can look equally to either a note in the patient's medical record or use of a consent form as an indication that a consent conversation took place but must have a well-documented comprehensive process. The consent process should follow appropriate professional and legal guidelines. Informed consent (or assent, if in a pediatric practice) for antineoplastic therapy treatment, as appropriate to the treatment population is documented prior to initiation of antineoplastic therapy regimen. Obtaining the patient's informed consent for treatment with antineoplastic agents is the oncologist's responsibility, and all the information the oncologist and patient share and agree to in this process is documented in the patient's medical record in either a form or a detailed note.

The surveyors will observe that documented consent or assent for patients receiving both oral and parenteral therapies is documented in the patient's medical record in either a form or a detailed note. The surveyors will interview staff to determine that the presence of consent documentation is verified by the staff members administering the first antineoplastic therapy treatment.

Outcome
The health care organization has a structured policy that defines a process to obtain informed consent/assent and how it is documented in the medical record. The health care organization has documented informed consent in each patient's medical record prior to the patient receiving antineoplastic therapy by any route, obtained according to the practice's informed consent/assent policy.

Suggested Resource
ASCO Consent to Chemotherapy Template

Standard 2.2

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, 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 and short-term side 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 seek immediate attention.

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

Commentary

Patient education about cancer treatment is crucial for empowering individuals to actively participate in their care, manage side effects, and improve overall outcomes. This education should cover various aspects, including understanding the treatment plan, managing potential side effects, and accessing resources for support. An antineoplastic therapy class or one-on-one education session is an introduction to cancer and its treatment. It covers basic concepts, processes, and side effect management. Increasing numbers of patients are receiving oral antineoplastic therapy at home, and

with oral self-administration, there has been a shift in responsibility of management from the provider to patient. Healthcare professionals should provide patients and caregivers with education and training to ensure their understanding of safe handling procedures as well as thorough knowledge of proper administration of all medications. It is imperative to assess a patient's understanding of the antineoplastic regimen and side effects before treatment. Patients and their families need to understand the signs and symptoms of serious side effects prior to beginning antineoplastic therapy, so that they will be able to recognize at what point to call a healthcare provider. Written information should be used to reinforce antineoplastic therapy teaching. The correct and accurate documentation of education is a key component of the process. Patient literature and other educational materials should be monitored and evaluated to ensure that current and accurate information is delivered.

Individuals have different learning styles and abilities. Compliance is affected by the patient's knowledge and understanding of the specific regimen. The information must be perceived correctly, and to that effect, educational materials must be at an appropriate level of understanding for patient comprehension. Therefore, patient resources, including printed material with relevant illustrations, trustworthy internet sites, computer-assisted learning, audio and video recordings may be utilized. All materials must address the various educational and reading levels of the population. The patient and family should be able to verbalize self-care measures and the appropriate action for common side effects, oncologic emergencies, and problems associated with the disease, treatment and side effects, as well as understand the planned treatment schedule and the instructions provided to them.

Communicating effectively with patients and families means giving them easy access to relevant information. Family caregivers often feel unprepared to provide care or have inadequate knowledge to deliver proper care. This can be improved through caregiver education and support. Symptom management is challenging for both patients and family caregivers. Future treatment plans or expectations is an important area of family concern, as well as information regarding access to the needed care and support due to financial and eligibility barriers involving caregivers, family, and others by providing personalized information, including the strategies for addressing a patient's specific psychosocial and biomedical care needs, as well as the resources to address the specific needs of the patient's family and caregivers resulting in positive patient outcomes.

There should be standardized information for families and the information should be developed in various education formats: written materials, computer and mobile phone applications, Web-based resources, etc., so that information is readily available to different learning styles. Cancer centers can make such guidelines and materials available.

Required Written Materials/Observations

During the site visit, the surveyor will discuss the processes for patient education and review the requested number of medical records selected from all eligible patients to verify compliance with the Standard, including documentation that the patient has received verbal and written education including materials about each element of the Standard.

The surveyor will review policies and procedures that are related to educating patients, as well as interview appropriate personnel regarding the process. The practice may have an overall education policy, or may have an education notebook, folder or booklet that is given to the patient with standardized information. The surveyor will look in the medical record for documentation of the education session and the materials given to the patient (e.g., a template in the EMR for documenting education process). The educational plan should list what is given to each patient. Written requirements per element are below:

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. There will be documentation of family and caregiver attendance at education sessions and patient's and/or caregiver's understanding and engagement for the surveyor to review. A learning assessment will be documented prior to the education session including needs, abilities, preferences and readiness to learn. Patient education materials should be appropriate for the patient's reading level/literacy and patient/caregiver understanding. Ideally, documentation should include patient feedback reflecting understanding and engagement.

2.2.3.1 Patient's diagnosis. The patient must receive written information about their diagnosis. The surveyor will discuss with the staff how this is given to the patient (e.g. diagnosis specific booklet or handout from NCI or ACS).

2.2.3.2 Goals of treatment, that is, cure disease, prolong life, or reduce symptoms. The patient must receive a written document identifying the goal of treatment. The Surveyor will discuss with the staff how this is given to the patient (e.g., specific education document, consent form, treatment plan) and review the record for documentation.

2.3.3.3 Planned duration of treatment and schedule of treatment administration schedule of treatment and planned duration of treatment (such as number of planned cycles, etc.) are identified in written format for the patient. Examples of how this information may be given to the patient could include the consent form, the treatment plan, or a treatment calendar.

2.2.3.4 Drug names and supportive medications, and plan for missed doses. This element of the Standard requires that a written document is given to the patient that identifies drug name(s), including supportive medications and drug interactions. Examples of where this may be documented include the consent form, the treatment plan, or drug information sheets. Surveyors will review information limited to medications that will be administered to the patient in the facility (parenteral), or medications used to treat cancer and support side effects of that treatment if taken at home, such as oral oncolytic therapies.

2.2.3.5 Potential for drug interactions with prescribed drugs, integrative therapies, over the counter drugs, herbal products, supplements, and foods. Drug interactions are a significant concern in cancer therapy, as they can impact the efficacy and safety of treatment, potentially leading

to reduced effectiveness or increased toxicity. When undergoing cancer therapy, caution should be taken about using over-the-counter drugs and herbal supplements, as they can interact with antineoplastic therapy, potentially affecting treatment effectiveness or causing harm. Practices may find drug interaction information and resources included in the intravenous and oral antineoplastic therapy drug education sheets which can be provided to patients. Medication reconciliation, comparing patient's medication orders to all the medications that the patient has been taking, including documenting a list of current medications including prescribed drugs and integrative therapies, over the counter drugs, herbal products, and supplements, and making clinical decisions based on the comparison, communicating the interactions to the licensed practitioners, patient, and caregivers.

2.2.3.6 Potential long and short-term side effects of therapy, including infertility risks for appropriate patients. The surveyor will look for documentation that the patient has received information about side effects, including infertility risks. Examples of documents that may include this information include a consent form or a treatment plan and/or drug information sheets on all drugs to be given, highlighting serious reactions that require contacting the practice and information about all side effects and risks of treatment, including prevention and management.

2.2.3.7 Pregnancy prevention and fertility preservation as defined by health care organization. For cancer patients, pregnancy prevention during treatment and fertility preservation are crucial considerations, with options like sperm banking for men and egg freezing, embryo freezing, or ovarian tissue freezing for women. Patient education materials are available, and the licensed practitioner may consider a referral to a reproductive endocrinologist to discuss cancer-related fertility.

2.2.3.8 Symptoms or adverse effects that require the patient to contact the health care organization or seek immediate attention. Surveyors will review documentation of written information given to patients to ensure that all patients have information needed in recognizing side effects or symptoms that require contacting the health care organization for symptom triage or emergency visit to a hospital. This information may be provided on a handout or an appointment card.

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. Surveyors will look for documentation of oral antineoplastic therapy storage and handling educational materials given to patients. This may include use of a safe handling patient handout or drug sheets.

2.2.3.10 Procedures for handling body secretions and waste in the home. Surveyors will look for documentation of written instruction on handling body waste, medical waste, laundry, safe intimacy, and family interactions following treatment that is given to patients.

2.2.3.11 Follow-up plans, including laboratory and provider visits. Surveyors will look for an appointment card, after visit summary, discharge instructions, patient portal information that

includes subsequent appointments, laboratory and diagnostic test ordering, or other notation given to the patient about their scheduled follow-up over the next several weeks.

2.2.3.12 Contact information for the health care organization, with availability and instructions on when and who to call. Surveyors will look for written documentation that the patient has received specific instructions for health care organization contact information during the practice's office hours, as well as after hours.

2.2.3.13 Expectations for rescheduling or canceling. Surveyors will look for written documentation that the patient that has received specific instructions about how to cancel and reschedule appointments. This information is often provided in a patient letter or on appointment reminder cards.

Outcome

The patient is equipped to take an active role in their care and share in decision making as the practice has a Standardized policy or process to educate patients prior to antineoplastic therapy that provides information to patients about their diagnosis, stage, and treatments, likely outcomes and side effects of treatment, including long-term outcomes. The patient can describe self-care measures and verbalizes the appropriate action for common problems associated with the disease, treatment and side effects, and oncologic emergencies. The patient knows whom to call in the practice and when. Patients understand how to protect themselves and family against antineoplastic therapy exposure. The patient's family or caregiver is equipped to take an active role in supporting the patient's care as the practice has a Standardized policy or process to educate caregivers and others prior to treatment. They understand the planned treatment schedule and the instructions provided to them.

Suggested Resources

American Cancer Society (ACS) Education Materials

Chemotherapy and You: Support for People with Cancer, NIH Publication

How Cancer and Cancer Treatment Can Affect Fertility in Women, American Cancer Society

How Cancer and Cancer Treatment Can Affect Fertility in Men, American Cancer Society

Oral Chemotherapy Education (OCE) Drug-Specific Education Sheets, National Community Oncology Dispensing Association (NCODA) along with HOPA, ACCC, and ONS

ASCO Consent to Chemotherapy Template

ACS ASCO Treatment Plan Template

End of Domain 2

Domain 3: Ordering, Preparing, Dispensing, and Administering Antineoplastic Therapy

Commentary

Because of the complexity of treatment regimens, the narrow therapeutic window of antineoplastic agents, and the potential for serious and fatal consequences of medication errors, it is essential that health care organizations have in place a systematic approach to prescribing and verifying antineoplastic therapy that prevents medication errors when preparing and administering antineoplastic therapy. The goal of cancer therapy is to ensure the delivery of the right drug in the right dose and dosage form at the right time to the right patient. The achievement of this goal requires developing and implementing specific policies and procedures for the process of cancer therapy prescribing, verification, compounding, and administration within a multi-disciplinary team. The entire domain is dedicated to the foundation of quality and safety in antineoplastic therapy preparation and administration.

Standard 3.1

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 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 The variables used to calculate the dose.

3.1.8.3 The frequency that 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 appropriate for the regimen, including pre-medications, hydration, and growth factors, are included in the preprinted or electronic order forms.

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.

Commentary

This Standard describes the required elements for a standard parenteral antineoplastic therapy order using an electronic process and or a handwritten document. The standard antineoplastic therapy order provides the foundation for standardized patient care, reduction of medication errors and the ability to anticipate and manage possible adverse events while enhancing patient safety.

Antineoplastic drugs may be given in combination, using several different medications (regimens), and given at the same time, or subsequent to another for a specific period of time. These regimens may be identified by an acronym, which are formed using the first letter(s) of the chemical name, chemical abbreviation, and/or trade name of the agents used in the regimen. Antineoplastic therapy treatment protocols are prescribed based on the cancer diagnosis and disease staging. Protocols are continually subject to review and revision based upon prevailing evidence in the published literature or upon consensus-derived guidelines for current best practice management. In the adjuvant setting, the majority of treatment protocols, the number of cycles (or the overall duration of the treatment from beginning to end) has been established through research and clinical trials. The duration of the order set, a cycle or specific weeks of therapy, should be standardized, and clear criteria to treat must be documented for the patient to start or continue treatment. In the metastatic setting, patients could be treated until progression or excessive side effects. The order could read, "reevaluate after 4 cycles" or "continue until progression."

When ordering antineoplastic medications, the generic drug name should be used. Brand names are not acceptable unless they aid in identifying combination drug products or a particular drug formulation (e.g., to distinguish between liposomal and nonliposomal product formulations). Drug dosages and calculated doses should be expressed in metric notation. The word units should never be abbreviated in medication orders where drug dosages and administration rates are expressed in biological activity units (e.g., aldesleukin, asparaginase, and bleomycin). Leading zeros (e.g., 0.3 mg) should be used for numbers less than one. Trailing zeros should never be used.

Brand names should be included in orders with the generic only where there are multiple products or when including the brand name otherwise assists in identifying a unique drug formulation. Health care organizations 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.

Methods should be consistent for calculating BSA and ideal body weight, rounding calculated results (e.g., drug dosages and administration rates), and changing dosages and administration rates in response to changes in patient weight and stature. For dosage and administration rates calculated from pharmacokinetic data, the mathematical equations that describe how calculated values were derived should appear in the treatment plans and medication orders. Practices should establish whether drug dosages should be routinely calculated as a function of actual, ideal (lean), or adjusted body weight and develop standard criteria that direct dosage calculation as a function of this weight. Institutions should also define policies for other situations, such as in pediatric or hematopoietic stem cell transplant patients, where adjusted-weight dosing is used, or when cure is not the goal. Investigational protocols may specify treatment parameters different from institutional parameters. In all cases, the treatment plans and medication orders should indicate whether patients' actual or ideal body weight was used in calculating drug dosages and identify the equation from which dosages were calculated. Verification of the Body Surface Area (BSA) formulas include: Mosteller, DuBois and

DuBois, Haycock and Boyd. The most frequently used formula is Mosteller. The Mosteller formula is also applicable to the dosing for children. The practice should have a standardized method used. For AUC, the preferred method of GFR estimation for the Calvert formula is the Cockcroft-Gault equation.

Required Written Materials/Observations
The surveyor will observe the written order or computerized physician order entry (CPOE) and any relevant policies for the following elements:

3.1.1 Patient's name.

3.1.2 A second patient identifier. A second patient identifier may be the patient's date of birth, medical record number or another constant identifier. The surveyor will observe this on the order or CPOE.

3.1.3 Date the order was signed.

3.1.4 Regimen or protocol name and number, when applicable. The surveyor will look for the name and number of active research protocols (e.g., "POG protocol ####), or the name of the standard regimen (e.g., "CHOP"), are indicated on the antineoplastic/immunotherapy order form or CPOE.

3.1.5 Cycle number and day, when applicable. The surveyor will observe if either a single drug or a combination of drugs is used. The treatment may require all the drugs to be administered on a single day, or on successive days, or continuously on an outpatient or inpatient basis. If, for instance, two or more bi-weekly antineoplastic therapy sessions are treated as a single cycle, the day must be noted on the order.

3.1.6 All medications within the order set are listed 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. The surveyor will note that drug dosages and calculated doses are in metric notation. The word units should never be abbreviated for medication orders where drug dosages and administration rates are expressed in biological activity units (e.g., aldesleukin, asparaginase, and bleomycin). Leading zeros (e.g., 0.3 mg) should be used for numbers less than one. Trailing zeros should never be used.

3.1.8 The dose calculation, including:

3.1.8.1 The calculation methodology. The surveyor will be observing if the orders indicate whether patients' actual or ideal body weight was used in calculating drug dosages and identify the equation from which dosages were calculated. These variables and calculations may be defined in a policy and is not required to be in the order itself.

3.1.8.2 The variables used to calculate the dose. The surveyor will be looking for variables such as height (in centimeters), weight (in kilograms), and body surface area (BSA) if used in dose calculations. If targeted area under the curve (AUC) is used to calculate a antineoplastic or immunotherapy dose:
The AUC target value
Patient's estimated or actual creatinine clearance with designation of any cap, if applicable
The name of the formula used to determine the estimated creatinine clearance
The serum creatinine and/or urine creatinine value used to determine the creatinine clearance

3.1.8.3 The frequency that the variables are re-evaluated, such as weight, laboratory values, diagnostic test results, and patient's clinical status. The frequency may be defined in a policy and is not required to be in the order itself.

3.1.8.4 The changes in the values that prompt confirmation or recalculation of dosing. The surveyor will look for dosage modifications as a function of patient-specific variables, e.g., 10% change in BSA would trigger a recalculation or dose adjustment. These variables and calculations may be defined in a policy and is not required to be in the order itself.

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 appropriate for the regimen, including pre-medications, hydration, and growth factors, are included in the preprinted or electronic order forms. The surveyor will note if the prescriber ordered all the medications necessary for the entire treatment regimen, including hydration and supportive care orders, at the same time and prior to administration of any of the medications.

3.1.13 Hypersensitivity, anaphylactoid, and cytokine release syndrome (CRS) (where appropriate) medications are available through site specific workflows. The treatment plan may include supportive medications to be administered when an infusion-related reaction occurs. Medications like epinephrine, diphenhydramine, and hydrocortisone may be included, as well as medications approved by the health care organization may be identified in the emergency treatment policy.

3.1.14 Parameters that would require holding or modifying the dose, for example, laboratory values, diagnostic test results, and patient's clinical status. This may be in the order or defined in a policy.

3.1.15 Sequencing of drug administration, when applicable. Sequencing of drug administration should be indicated in the order. For example, instructions to begin administration time based on

previous medication completion or "Administer 1st" and "Administer 2nd" may be used. If orders list medications in the sequence of administration this should be a consistent practice understood by staff. Sequencing may also be on a chart as a reference or defined in a policy.

3.1.16 Rate of drug administration, when applicable.

3.1.17 An explanation of time limitation, such as number of cycles for which the order is valid. This may be in the order, in a policy, or in the treatment plan. The surveyor will be looking for the number of cycles the order is written, as well as when the order needs to be renewed.

Outcome
The practice has a consistent and systematic, regimen-specific, method for writing antineoplastic therapy orders that either use standard preprinted medication-order forms or forms that are retrievable from a computerized database or oncology specific CPOE system resulting in decreased errors.

Standard 3.2

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 (i.e. SIG – daily, twice a day, schedule/number of days as applicable).

Commentary
This Standard describes the required elements for antineoplastic prescriptions for oral therapy using an electronic process and or a handwritten document. The required elements provide the essential components for standardized patient care, reduction of medication errors, confirmation of prescription with the patient for oral therapies adherence, and the ability to anticipate and manage possible adverse events while enhancing patient safety. Like parenteral antineoplastic therapy treatment protocols, oral therapies are prescribed based on the cancer diagnosis and disease staging. Protocols are continually subject to review and revision based upon prevailing evidence in the published literature or upon consensus-derived guidelines for current best practice management. In

the adjuvant setting, the majority of treatment protocols, the number of cycles (or the overall duration of the treatment from beginning to end) has been established through research and clinical trials. The oral therapies prescription, at a minimum will have the nine standard elements as described.

Required Written Materials/Observations
The surveyor will observe the antineoplastic prescriptions for oral therapy electronic process and or a handwritten document *and any relevant policies for the following elements:*

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

3.2.1 Patient name.

3.2.2 Date of birth. A second patient identifier using the patient's date of birth. The surveyor will observe this on the prescription.

3.2.3 Date the prescription is written.

3.2.4 Drug name, generic name preferred. The surveyor will look for the drug name that may be brand name and preferred generic name.

3.2.5 Drug dose is written following standards for preventing the use of unapproved abbreviations, omitting trailing zeros, and including leading zeros. The surveyor will note that drug dosages and calculated doses are in metric notation. The word units should never be abbreviated for medication orders where drug dosages and administration rates are expressed in biological activity units (e.g., aldesleukin, asparaginase, and bleomycin). Leading zeros (e.g., 0.3 mg) should be used for numbers less than one. Trailing zeros should never be used.

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 (i.e. SIG – daily, twice a day, schedule/number of days as applicable).

Outcome
The practice has a consistent and systematic, regimen-specific, method for writing antineoplastic prescriptions for oral therapy orders that either use standard preprinted medication-order forms or forms that are retrievable from a computerized database or oncology specific CPOE system resulting in decreased errors.

INDEPENDENT VERIFICATIONS

A second person (practitioner or other personnel approved by the health care organization to prepare or administer antineoplastic therapy) performs three independent verifications:

3.3 **Prior to preparation**, (verification of orders and independent variables calculations)
3.4 **During and upon preparation** (verification of calculations, drug vial, drug volume, diluent, administration fluid type, volume, tubing)
3.9 **Prior to administration** (verification of drug(s) products, label, and orders)

Commentary
An independent double-check of antineoplastic therapy agents is a procedure in which two staff members approved by the health care organization independently verify each component of prescribing, compounding, and verifying the antineoplastic therapy agents before administering them to the patient. Best practices in antineoplastic preparation and delivery include verification of the antineoplastic order and preparation as well as independent verification prior to administration of antineoplastic therapy.

Verification and independent double-checking processes should be regulated by specific policies and procedures and supplemented with training and certification programs to maintain accuracy and quality. To reduce process inconsistencies, the practice should establish a standard procedure for performing an independent double check and educate staff about its importance and how to carry it out properly—as an independent intentional verification and not a superficial routine task. Adding a checklist as a reminder of the components of the process or medication that should be checked and when it should be checked is an aid that assists staff. Checklists that include very specific items associated with critical information significantly improve their effectiveness. As appropriate, redesign order forms to facilitate cross-check of information, and ensure the sequence of information on checklists uses the same terminology and follows the logical progression of typical workflow. It is recommended to evaluate the procedures which require a verification, monitor compliance, assess verifications are conducted as required, and then make the necessary revisions to promote effectiveness. It is also recommended to include verification processes in initial and annual competency assessment processes for applicable staff.

Standard 3.3
VERIFICATION 1

A second person (staff member 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.

Commentary

Verifying an antineoplastic therapy order should include a systematic check of all the components of the order and its preparation and dispensing. While technological solutions such as computerized prescriber order entry and bar-coding systems have potential to detect human error, manual redundancies (such as independent verifications) are important in error detection. A potential source of error is the auto-calculation feature of some systems. The system can use the latest height and weight to calculate BSA. However, an incorrect height or weight entry can result in a dosing error and significant data entry errors can have negative results. Some systems may be able to prevent data entry error by displaying an alert when data differ from a previous entry by a certain percentage or final dose amount. Checks are required when CPOE is in place because of the possibility of major variations or deviations in protocol, new protocols not yet built into the CPOE system, or complex calculations involved in antineoplastic therapy preparation. Independent verifications during the antineoplastic therapy preparation process are ideally made by an RN, second pharmacist, or, depending on physical and staffing resources, by a pharmacy technician or by another healthcare professional with appropriate knowledge, skills and training to perform this function.

Required Written Materials/Observations:

The surveyor will ask to observe an independent verification of the antineoplastic therapy order prior to preparation. This person should be qualified and approved by the health care organization to prepare or administer antineoplastic therapy. At a minimum, this should be one person separate from the provider who wrote the order but can include more than one qualified person at the practice (e.g., a nurse or a pharmacist). The independent verification of the provider order shall include:

3.3.1 Two patient identifiers. The identifiers used to confirm the patient's identity are verified and should be consistent throughout the process. The identifiers should include the patient's name and a second data element that is consistently associated with the patient such as the patient's date of birth or medical record number.

3.3.2 Drug name. The full generic drug name is verified.

3.3.3 Drug dose. The dose is confirmed by recalculation using the appropriate formula for the treatment.

3.3.4 Route of administration.

3.3.5 Rate of administration. The desired infusion rate in amount of drug to be infused per unit time is verified. You can then calculate the solution volume to be infused per unit time (e.g., over 30 minutes).

3.3.6 The calculation for dosing including the variables used in this calculation. Variables from which a patient's medication dosage are calculated should be confirmed (e.g., height, weight, BSA, creatinine, AUC). Appropriate laboratory test and physical assessment values should be verified and primary treatment references should be consulted to determine whether they are within acceptable ranges or if treatment modifications are indicated.

3.3.7 Treatment cycle and day of cycle.

Outcome

The antineoplastic therapy order is verified for accuracy before starting antineoplastic compounding with patient safety and drug order accuracy as the primary goal. The use of consistent and systematic methods for reviewing antineoplastic therapy orders reduces the potential for medication errors and confirms the right patient, the right drug, the right dose, the right route, and the right time.

Standard 3.4

VERIFICATION 2

A second person (staff member 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.

Commentary

Between 2004 and 2011, the Institute for Safe Medication Practices (ISMP) has reported serious compounding errors involving 16 patients, nine of whom died, mostly due to wrong concentration/strength, or wrong product or diluent. The second verification, after treatment orders have been verified for preparation, includes all work related to antineoplastic therapy processing and antineoplastic therapy preparation accuracy and should be documented in a Standardized format, either on paper or electronically. Drug products should be verified, after preparation, against both the preparation work sheet and the original order by a staff member approved by the health care organization who was not involved in preparation. To document the process, some practices use drug preparation work sheets to identify the drug products prepared for each patient and the persons who prepared and checked the medications.

A two-person independent verification is required to ensure that the proper ingredients (medications and diluents) are added, including confirmation of the proper amount (volume) of each ingredient prior to its addition to the final container. Records should be confirmed by a second individual (preferably a pharmacist, but other qualified personnel may perform this function.) The calculations should be independently verified. Technology can serve as a surrogate checklist, if practitioners follow procedures in using appropriately developed and applied software. Use technology to assist in the verification process (e.g., barcode scanning verification of ingredients, gravimetric verification, robotics, IV workflow software) to augment the manual processes. It is important that processes are in place to ensure the technology is maintained, the software is updated, and that the technology is always used in a manner that maximizes the medication safety features of these systems.

Required Written Materials/Observations:
The surveyor will observe the verification of the compounded antineoplastic therapy and ask the preparer to verbalize the process, which includes all elements of the Standard (drug vial, concentration, volume, diluent type and volume, administration fluid type and volume and tubing). The surveyor may ask questions related to the process, including the 5 elements above, while in the pharmacy area. The process should be documented, acknowledging that an independent check of prepared antineoplastic therapy is checked against the order, (examples include a worksheet, a record, or initials on the drug label to indicate it was performed).

Approved methods to meet Standard 3.4 verification requirements include (but are not limited to) the following:

1. Second person in pharmacy area performs verification during preparation.
2. Second person in a remote location completes verification during preparation via live camera.
3. Second person in a remote location completes verification using images captured during preparation which are verified and approved prior to drug release.
4. Automated compounding by oncology robot, utilizing barcode scanning, gravimetrics, and digital images which are reviewed by pharmacy staff prior to releasing drug. (ex. KIRO Oncology Robot).
5. Syringe is marked during preparation while drug is still in the syringe; second person verifies drug volume based on marked empty syringe and review of vials used prior to releasing drug.
6. Second person completes double-check following preparation with review of barcode scanning, gravimetrics, photographs which are inclusive of drug vial(s) and bag(s) utilized, and a final visual inspection of the prepared medication.

Outcome
Drug products are verified, upon preparation, against both the preparation work sheet and the original order by a staff member approved by the health care organization who was not involved in preparation. The goal of this verification is to prevent medication errors during sterile compounding of drugs, especially for antineoplastic therapy agents.

Standard 3.5

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/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.

Commentary

Medication label design is frequently a contributing factor to medication errors. The components and formatting of the antineoplastic therapy label provide a systematic method for the complex process of administering antineoplastic therapy. This systematic approach to label design and content is one strategy to provide a consistent method for verifying the compounded antineoplastic agent and elements for safe antineoplastic therapy administration. Labels are applied immediately after manual preparation and the total volume (e.g., bag volume + manufacturers overfill + additive volume) is present on the label. The total volume and amount of drug allows nursing staff to program the system to deliver the correct dose of medication more easily. Labels are applied immediately after manual preparation. The product label does not contain unnecessary information.

Required Written Materials/Observations

The surveyor will observe and compare the label of the compounded antineoplastic therapy to ensure the 10 elements are listed. When dose is divided, the total number of products to be given and the individual product sequence are indicated (e.g., 1 of 2, 2 of 2, etc.). The precautionary label or notice can be on the outer bag or on the prepared drug bag. The prepared medication includes a label denoting "hazardous drug" if applicable. Labels may contain printed or handwritten information when necessary.

Outcome

The practice/institution has a systematic approach to label design and content to provide a consistent method for verifying the compounded antineoplastic agent and elements for safe and accurate antineoplastic therapy administration.

Standard 3.6

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 medication intended for administration into the CNS.

3.6.1.5 Administered immediately after a time out double check procedure involving 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.

Commentary

Administration of antineoplastic therapy via the intrathecal or intraventricular route is necessary for certain treatment regimens. Given the high risk associated with intrathecal and intraventricular administration (e.g., vincristine intrathecal administration is fatal), specific considerations apply to preparation and administration of antineoplastic therapy. Incidents have several common contributing factors:

- Same time - prescription of intravenous vincristine in treatment protocols that require medicines to be administered intrathecally on the same day and, often, at the same time.
- Same place - transport, storage and administration of intravenous vincristine in the same location as medicines required to be administered intrathecally.
- Inadequate checking of medicine labels against treatment orders when selecting medicines from storage locations and immediately prior to administration.
- Staff with insufficient knowledge or experience delegated to manage antineoplastic therapy.

Despite vincristine labeling requirements and increased awareness of harm that occurs when vincristine is accidentally administered intrathecally, wrong-route vincristine errors continue to occur.

ISMP 2024-2025 Targeted Medication Safety Best Practices for Hospitals state that vinca alkaloids (vin**BLAS**tine, vinorelbine, vin**CRIS**tine, and vin**CRIS**tine liposomal) can cause fatal neurological effects if given via the intrathecal route instead of intravenously. Vin**CRIS**tine is particularly problematic, and the most frequently reported with accidental intrathecal administration, because it is often ordered in conjunction with medications that are administered intrathecally (e.g., methotrexate, cytarabine, and/or hydrocortisone). When vinca alkaloids are injected intrathecally, destruction of the central nervous system occurs, radiating out from the injection site. The few survivors of this medication error have experienced devastating neurological damage. Despite repeated warnings by various national and international safety agencies, deaths from this type of error

still occur. The product labeling also carries a special warning ("For Intravenous Use Only—Fatal If Given by Other Routes").

An effective prevention strategy that reduces the risk of inadvertently administering vinca alkaloids via the intrathecal or intraventricular route is to dilute the drug in a minibag that contains a volume that is too large for intrathecal administration (e.g., 25 mL for pediatric patients and 50 mL for adults). Many organizations have successfully transitioned to preparing vinca alkaloids in minibags, including pediatric hospitals, overcoming concerns of extravasation and other complications. There have been no reported cases of accidental administration of a vinca alkaloid by the intrathecal route when dispensed in a minibag.

Required Written Materials/Observations
Through interviews, policy review and observation, the surveyor will confirm how intrathecal and intraventricular medications are prepared, stored, labeled, and administered. The policy must clearly state that intrathecal and intraventricular antineoplastic therapy is prepared and stored separately, labeled uniquely, delivered to patients only with other medications intended for administration into the CNS, and administered immediately after a time out double check. A policy should also specify that vinca alkaloids are administered only by infusion.

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. Intrathecal medications, after preparation, are placed in a location (a clearly labeled bin or separate, clearly labeled shelf) that is separate from storage locations for IV and all other medications. If a process is in place for immediate delivery of the medication instead of storing, this process should also be identified in the policy.
3.6.1.3 Labeled with a uniquely identifiable intrathecal or intraventricular medication label. Drug labels should clearly indicate that the antineoplastic therapy is only intended for intrathecal or intraventricular administration, including ancillary labels. Surveyors will accept a label that says FOR INTRATHECAL or INTRAVENTRICULAR USE ONLY. An added safety mechanism is the use of a label that is large and/or uniquely colored to distinguish intrathecal medication from other medications.
3.6.1.4 Delivered to the patient only with other medication intended for administration into the CNS.
3.6.1.5 Administered immediately after a time-out double check procedure involving two staff members approved by the health care organization to prepare or administer antineoplastic therapy. The policy or written procedure should describe the 'time-out' process and the individuals that will perform the time-out.
3.6.2 Intravenous vinca alkaloids are administered only by infusion. Health care organizations that administer intrathecal antineoplastic therapy have a policy that states intravenous vinca alkaloids are given only by infusion (e.g., minibags).

Outcome
The staff members approved by the health care organization to prepare antineoplastic therapy have a systematic process for the preparation, labeling, storage and delivery of intrathecal and

intraventricular medication. The staff members approved by the health care organization are aware of the process including the use of a time-out process. The goal of this standard is to ensure that intrathecal and intraventricular medications are administered by the correct route of administration. Health care organizations that administer intrathecal and intraventricular antineoplastic therapy have a policy that states intravenous vinca alkaloids are given only by infusion (e.g., minibags) to ensure that intravenous vinca alkaloids are not accidentally administered by the intrathecal or intraventricular route.

Standard 3.7

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.

Commentary

The patient should know information about the drug they will be receiving, has the right to refuse the treatment and is informed about the symptoms they may experience including instructions for reporting them to the clinical staff. Reviewing the medication label with the patient stating the name of the drug, infusion time, route of administration is a workflow process that assures this confirmation is complete with each antineoplastic therapy agent. Regardless of the number of cycles received of the antineoplastic therapy, confirming the treatment and including hypersensitivity symptoms or pain during infusion is performed.

Required Written Materials/Observations:

The surveyor while in the infusion suite will observe this process and may speak with the nursing staff regarding the specific elements reviewed with the patient. The staff member who is administering the antineoplastic therapy 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.

Outcome:

The practice has a well-defined process for how the treatment confirmation process prior to antineoplastic administration is completed with each patient and includes all Standard 3.7 elements. Patient will be informed of the treatment plan and have time to ask questions. The patient will be educated on the potential symptoms that may occur and to report them for clinical intervention as needed.

Standard 3.8

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 using at least two identifiers.

Commentary

All patients expect to receive safe and appropriate care. Safe care includes the right patients receiving the correct treatment plan and all medications. Patients must be identified using two consistent identifiers that are associated with the patient. Examples are the patient's full name, date of birth and the medical record number.

Required Written Materials/Observations:
The surveyor while in the infusion suite will observe two staff members approved by the health care organization to administer or prepare antineoplastic therapy verify patient identity using at least two identifiers prior to antineoplastic therapy administration in the presence of the patient. The staff member should have the patient state their full name and date of birth, while the two staff members verify the information against the prepared drug label and antineoplastic order. Staff members approved by the health care organization to administer or prepare antineoplastic therapy should be defined by practice policy, as described in Standard 1.1.

Outcome:
The practice has a well-defined process for identifying patients prior to receiving antineoplastic treatments, with the goal of ensuring the right drug is delivered to the right patient.

Standard 3.9
Verification 3

A second person (staff member 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/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.

Commentary

The primary goal is to achieve and document safe and appropriate administration of antineoplastic therapy agents. The use of a consistent process to verify antineoplastic agents, dose, rate, route, and current expiration date before administration will provide a high standard for safe and effective patient care. Also included is the visual assessment of the appearance and physical integrity of the prepared drug to see any particulate matter. Sequencing of drug administration should also be verified prior to administration to ensure antineoplastic drugs are administered in the correct order. Staff may reference sequencing instructions in the order, on the antineoplastic labels, or use a reference tool such as a practice policy. Technology may also supplement the verification process such as barcode scanning. The administering RN or chemotherapy-competent staff member should visually inspect the administration set to ensure that it is appropriate for the drug, connected correctly to the patient, and infusing at the prescribed rate. "Tracing the line" immediately prior to administration reduces errors related to unclamped tubing, loose or disconnected lines, ensures multiple lines are infusing at prescribed rate, the right drug is connected to the right pump, and the proper tubing or filters are used.

Required Written Materials/Observations:
The surveyor while in the infusion suite will observe the dual-verification process and may speak with the nursing staff regarding the specific elements reviewed. The surveyor will observe the clinical staff approved to administer antineoplastic therapy verify all ten elements in the Standard in a double-check process and that the double-check process has been documented by at least one of the two independent practitioners. Documentation of the verification must specifically include all ten elements of the verification. A checklist of all ten Standard 3.9 elements may be a helpful tool for staff to reference and could also be used for documentation.

Outcome:
The practice has a well-defined process for how the verification process prior to antineoplastic administration is completed and includes all ten elements and documents that verification.

Standard 3.10

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

Commentary
The purpose of monitoring and documenting the clinical status during and upon the completion of treatment is to identify any symptoms or adverse side effects the patient may be experiencing. The presence of any symptoms or untoward toxicities would initiate further assessment and need for an intervention. It is essential that a process is in place to record the patient's clinical status.

Required Written Materials/Observations:
The surveyor will review medical records for infusion patients to ensure that their clinical status during and upon completion of treatment is documented. Clinical status documentation should include how the patient tolerated treatment, noting if there were any complications or side effects. The documentation may also include how the patient was discharged, for example, in stable condition without assistance etc. Typically this information is in a nursing or discharge note.

Outcome
The practice documents clinical status assessment during and at the completion of treatment within a defined area in the medical record.

Standard 3.11

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.

Commentary
Infiltration and extravasation is the leakage of a non-vesicant or vesicant solution from its intended vascular pathway (vein) into the surrounding tissue. Although many drugs are irritating when they are introduced into extravascular tissues, extravasation of a vesicant drug has the potential to cause tissue damage with severe and/or lasting injury. While rare, antineoplastic extravasation can be a life-threatening medical emergency and requires immediate intervention. The FDA has four approved drugs for the management of antineoplastic extravasation, including: dexrazoxane hydrochloride and/or DMSO for anthracycline antineoplastic therapy; sodium thiosulfate for mechlorethamine; and hyaluronidase for vinca-alkaloids, etoposide and taxanes.

Unfortunately, at this time, there is not a consensus concerning the management of antineoplastic extravasation. Despite a large amount of published literature on this topic, most recommendations are based upon empirical, or anecdotal, evidence. The lack of strength and large variability in management practices in case reports make it difficult to standardize and rank management practice in terms of efficacy. Consequently, the certification program references the extravasation management guidelines within the Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice (Second Edition), 2023. If a practice chooses to cite other guidelines, they must provide the reference and date of the guidelines.

Required Written Materials/Observations
The surveyor will look for a policy, procedure, protocol or guideline for extravasation management. The surveyor will ensure that all antidotes, identified in the practice's written materials, are readily available. A provider is available to write orders for antidotes or the practice has standardized protocols and/or order sets in place that permit the emergency administration of all appropriate antidotes used in the facility. Directions for use/administration are readily available in all clinical areas where extravasation may occur. The surveyor will ask staff and look in your policy to identify:

Antidotes/treatments that are administered in extravasation situations to prevent patient harm.
Timelines for the administration of antidotes in the health care organization policy and staff knowledge. Appropriate protocols or order sets for extravasation antidotes and management.

The surveyor will review the policy and ensure it references current literature and guidelines. The surveyor will verify the pharmacy stocks the antidotes listed in the policy, or if antidotes are not in

stock, the policy states where patients are referred if an antidote is needed. Surveyors will interview nurses and pharmacists about the process. A policy that describes a plan for administration of antidotes required on weekends and holidays is recommended.

Outcome

The goal of this standard is to ensure that when an antidote, or treatment is known for a drug that has a high potential to cause an adverse reaction when extravasation occurs, the agent and treatment is readily available and can be administered without delay.

End of Domain 3

DOMAIN 4: Monitoring After Antineoplastic Therapy is Given, Including Adherence, Toxicity and Complications

Commentary
Standardized documentation of cumulative dose tracking and review of patient adherence are necessary to ensure proper monitoring of dose-limiting toxicities. This domain provides the foundation for patient monitoring and documentation of toxicities.

Standard 4.1

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 emergencies.

Commentary
Following antineoplastic treatment, patients are at risk for serious and potentially life-threatening side-effects, toxicities or drug reactions. It is imperative that licensed practitioners and staff members are aware of the signs and symptoms of these potential adverse effects and there are protocols in place to manage them. Additionally, staff should have clearly defined roles and responsibilities related to other life-threatening events, including hypersensitivity reactions or other medical emergencies for patients and visitors.

Required Written Materials/Observations
The surveyor will look for a written policy, procedure or guideline that states how to manage a suspected hypersensitivity reaction, cytokine-release syndrome, or general life-threatening emergency, that aligns with current literature and guidelines. Recommended guidelines include the Oncology Nursing Society's Chemotherapy and Immunotherapy Guidelines and Recommendations for Practice (Second Edition),or other scholarly journal articles published within the last five years. Policies should include references to emergency protocols, drugs, locations of emergency drugs and non-pharmaceutical interventions (e.g., oxygen, suction, AEDs). Comprehensive policies should also include staff roles and responsibilities and management of outside medical personnel support (e.g., Rapid Response Teams or EMS). The surveyor will ask staff about the procedures and observe emergency equipment and supplies at the practice/institution. It is recommended that emergency protocols are reviewed annually.

Outcome
The practice has a clearly defined policy and procedure for the emergent treatment of suspected hypersensitivity reactions, cytokine-release syndrome, and general life-threatening emergencies that

aligns with current literature and guidelines. Policies should clearly define roles and responsibilities and identify emergency medications and non-pharmaceutical interventions.

Standard 4.2

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. Assessment requires identifying barriers to adherence, including physical, cognitive, and financial constraints. Documentation of assessment is available in the patient record.

Commentary

Prior to the initiation of oral antineoplastic therapy administered outside of the health care organization, practices are required to document an assessment of all patients' ability to adhere to the prescribed regimen. All patients includes those with prescriptions filled from the health care organization or specialty pharmacies. Practitioners should be reviewing any barriers to medication adherence and clearly document any issues identified and prescribed interventions. Documentation should include assessment and identification of any barriers to adherence including but not limited to financial, physical, cognitive, and social support factors that may impact the patient's ability to adhere to oral antineoplastic therapy. Documentation may also include referrals to other practitioners (e.g., financial counselor or social worker), use of adherence tools (i.e., treatment calendar, smartphone applications), and the plan for follow-up and monitoring appropriate to the treatment regimen.

Oral Antineoplastic Therapy: Adherence is the single most important factor in achieving the best possible outcomes. Maximizing adherence to oral antineoplastic agents can have many positive outcomes, but most important is improvement in overall survival and life expectancy. Other outcomes include improved safety and quality of life. Patients risk improper dosing and an increase in disease recurrence when there is non-adherence with medications. Correct dosing, education, and symptom management are all critical to ensuring adherence. Clinician (including pharmacist) interventions that incorporate education, early symptom identification, and reminder prompts can improve outcomes. Adherence is as a dynamic partnership between a provider and a patient – patients are more likely to adhere to a treatment plan if they are engaged in the process and decisions with their provider, and if they are supported by the wider system.

Required Written Materials/Observations

The surveyor will look for a written policy that requires the initial assessment of the patient's ability to adhere to the treatment plan and outlines the procedure for completing the assessment. The policy includes patient education on the importance of oral antineoplastic therapy adherence, identifying barriers to adherence, and documentation of barriers, interventions, or referrals for identified issues. The policy has a description of the assessment process, including who is responsible for the initial adherence assessment. The surveyor will also review patient records for documentation of the initial adherence assessment.

Outcome
The practice has a clearly defined policy that requires the initial assessment of all patients' ability to adhere to an oral antineoplastic therapy administered outside of the health care organization. There is a standardized assessment performed to identify barriers and interventions or referrals to address identified issues. Patients understand the planned treatment schedule and the instructions provided to them and verbalizes the importance of adherence.

Suggested Resource
Oncology Nursing Society (ONS) "Oral Anticancer Medication Toolkit"

Standard 4.3

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.

Commentary
Practices are required to document the patient's adherence to oral antineoplastic therapy agents at each clinically meaningful interval as defined by the practice to address any issues identified. Practitioners should be reviewing any barriers to medication adherence and for any issues identified, clearly document referrals to other practitioners (e.g., financial counselor or social worker), and any follow-up related to previously reported adherence issues. At a minimum, an adherence assessment should include verification of medication scheduling, assessment for missed doses, treatment side effects and toxicities that can lead to adherence issues, and ability for continuation of therapy.

Oral antineoplastic therapy prescriptions may be filled from the health care organization or specialty pharmacies. It is required that all patients self-administering oral antineoplastic therapy agents have consistency in the assessment of adherence and documentation regardless of how the oral therapy is obtained. If a specialty pharmacy is managing the adherence and documentation, the practice needs to be responsible for the quality and accuracy of this patient resource. Ultimately the practice is responsible for monitoring all patients for oral antineoplastic therapy agents prescribed by the health care organizations licensed practitioners. The documentation of adherence assessment needs to be available to the entire oncology care team.

Clinically meaningful intervals are identified in the health care organization's policy which may be with each licensed practitioner visit, clinical support staff contacting the patient directly, patient-reported outcome monitoring, or meeting with the patient for an adherence assessment.

Required Written Materials/Observations
The surveyor will look for a written policy that requires the assessment of patients' adherence to oral antineoplastic therapy at clinically meaningful intervals as defined by the practice. Clinically meaningful intervals should be defined by the practice and should be based on the patient's ability to

adhere to the prescribed regimen, the complexity of the regimen, and any regimen-specific follow-up. The policy includes patient education on the importance of antineoplastic therapy adherence, identifying barriers to adherence, and documentation of interventions or referrals for identified issues. The surveyor will also review patient records for documentation of adherence at clinically meaningful intervals as defined by the practice.

Outcome
The practice has a clearly defined policy that requires the assessment of all patients' adherence to oral antineoplastic therapy at clinically meaningful intervals. Patients understand the planned treatment schedule and the instructions provided to them and verbalizes the importance of adherence.

Standard 4.4

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

Commentary
Specific agents that have dose-limiting toxicities require tracking either electronically through the EHR or on paper. These agents include (but are not limited to) anthracyclines. A significant barrier to monitoring cumulative doses of antineoplastic therapy is that the information about cumulative dose information is not readily available either in paper charts or EHRs. This is especially apparent when patients are treated in multiple facilities and drug administration records are not easily accessed by nurses or pharmacists. While a written policy is not required, it is recommended that a practice have a documented process for tracking cumulative doses, including those administered outside of the practice (e.g., first dose given in the hospital, or previous doses given at another health care organization). The process will include specific individuals who are responsible for gathering and documenting outside doses.

Required Written Materials/Observations
The surveyor will review for a clearly defined process for tracking cumulative doses for agents associated with cumulative toxicity electronically or in the paper medical record. The process includes who is specifically responsible for documenting doses given outside of the practice and who is responsible for cumulative dose monitoring as part of the health care organization's safety check prior to drug administration. For EMR-managed cumulative dose tracking, the process should include the maximum dose notification parameters, and any prescriber override capabilities.

Outcome
The practice has a clearly defined process for tracking electronically or in the paper medical record cumulative doses for agents associated with cumulative toxicity. The process includes who is specifically responsible for documenting doses given outside of the practice, inside the practice, and who monitors cumulative doses during treatment.

End of Domain 4

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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.
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, 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 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.

APPENDIX

LIST OF HYPERLINKED RESOURCES			
	Description	**Hyperlink(s)**	***Language Availability***
1.	Many oncology pharmacy organizations offer pharmacy staff training certifications and/or assessments for initial and ongoing continued education, such as HOPA (Hematology/Oncology Pharmacy Association)	**https://www.hoparx.org/hopa-learn/**	*English*
2.	ONS/ONCC® Chemotherapy Immunotherapy Certificate™ course	**https://www.ons.org/store/courses/onsoncc-chemotherapy-immunotherapy-certificatetm**	*English*
3.	APHON Pediatric Chemotherapy & Biotherapy Provider Program	**https://www.aphon.org/ped-chemo-bio/pediatric-**	*English*

		chemotherapy-biotherapy-provider-program/	
4.	GAD-7 Anxiety Scale	**https://adaa.org/sites/default/files/GAD-7_Anxiety-updated_0.pdf**	*English*
5.	"NCCN Distress Thermometer and Problem List for Patients" by Clinical Practice Guidelines. Version 1.2025, National Comprehensive Cancer Network NCCN Distress Thermometer Tool Translations	**https://www.nccn.org/docs/default-source/patient-resources/nccn_distress_thermometer.pdf** **https://www.nccn.org/global/what-we-do/distress-thermometer-tool-translations**	*Available in over 70 languages*
6.	Patient Health Questionnaire (PHQ)-2 PHQ-4 PHQ-9	**https://med.stanford.edu/content/dam/sm/ppc/documents/Mental_Health/PHQ-2_English.pdf** **https://www.oregonpainguidance.org/app/content/uploads/2016/05/PHQ-4.pdf** **https://med.stanford.edu/fastlab/research/imapp/msrs/_jcr_content/main/accordion/accordion_content3/download_256324296/file.res/PHQ9 id date 08.03.pdf**	*English*
7.	Depression: Screening and Diagnosis. Am Fam Physician. 2018 Oct 15;98(8):508-515.	**https://www.aafp.org/pubs/afp/issues/2018/1015/p508.html#:~:text=The%20PHQ%2D2%20is%20accepted%20as%20an%20initial%20screening%20tool,clinical%20interview%20should%20be%20completed**	*English*
8.	**ACS ASCO Treatment Plan Template**	**https://www.cancer.org/cancer/survivorship/long-term-health-concerns/survivorship-care-plans.html**	*English*
9.	PRAPARE®: Protocol for Responding to and Assessing Patient Assets, Risks, and Experiences	**https://prapare.org/**	*English, Portuguese, Spanish*

	PRAPARE-English PRAPARE-Portuguese PRAPARE-Spanish	**https://prapare.org/wp-content/uploads/2023/01/PRAPARE-English.pdf** **https://prapare.org/wp-content/uploads/2021/10/PRAPARE-Portuguese.pdf** **https://prapare.org/wp-content/uploads/2022/07/PRAPARE-Spanish_revised2022.pdf**	
10.	The Accountable Health Communities Health-Related Social Needs Screening Tool	**https://www.cms.gov/priorities/innovation/files/worksheets/ahcm-screeningtool.pdf**	*English*
11.	American Cancer Society Financial Hardship Resource	**https://www.cancer.org/cancer/financial-insurance-matters/managing-costs/financial-hardship.html**	*English*
12.	ACS provides recommended financial consideration information for patients and caregivers to navigate the costs related to care.	**https://www.cancer.org/cancer/financial-insurance-matters/managing-costs/the-cost-of-cancer-treatment.html**	*English*
13.	ACS provides recommended materials for patients and caregivers to help start a discussion about fertility preservation and raise questions to ask a health care team.	**https://www.cancer.org/cancer/managing-cancer/side-effects/fertility-and-sexual-side-effects.html**	*English*
14.	ACS provides patient education materials for people with cancer and their caregivers.	**https://www.cancer.org/health-care-professionals/patient-education-materials-for-professionals.html**	*English; Several resources in Spanish, Romanian, Portuguese, Greek, and Arabic*
15.	Consent to Chemotherapy Template	**https://cdn.bfldr.com/KOIHB2Q3/as/8gvwnf6kjgj84zgj7nc6khj6/Informed-Consent-for-Chemotherapy-ASCO-Template**	English
16.	ACS recommended patient education materials.	**https://www.cancer.org/cancer.html**	*English*
17.	Chemotherapy and You: Support for People with Cancer, NIH Publication	**https://www.cancer.gov/publications/patient-education/chemo-and-you**	*English*

18.	How Cancer and Cancer Treatment Can Affect Fertility in Women, American Cancer Society	**https://www.cancer.org/cancer/managing-cancer/side-effects/fertility-and-sexual-side-effects/fertility-and-women-with-cancer/how-cancer-treatments-affect-fertility.html**	*English*
19.	How Cancer and Cancer Treatment Can Affect Fertility in Men, American Cancer Society	**https://www.cancer.org/cancer/managing-cancer/side-effects/fertility-and-sexual-side-effects/fertility-and-men-with-cancer/how-cancer-treatments-affect-fertility.html**	*English*
20.	A resource established by National Community Oncology Dispensing Association (NCODA) along with HOPA, ACCC, and ONS provide Oral Chemotherapy Education (OCE) drug-specific sheets. The OCE sheets include drug interactions, safe handling and storage, home care, and possible side effects.	**http://www.oralchemoedsheets.com/**	*English*
21.	NCCN (National Comprehensive Cancer Network) provides a fact sheet for the "Campaign for Safe Vincristine Handling."	**https://www.nccn.org/justbagit/pdf/vincristine_fact_sheet.pdf**	*English*
22.	Oncology Nursing Society (ONS) "Oral Anticancer Medication Toolkit" resource (2022).	**https://www.ons.org/clinical-tools/resources/oral-anticancer-medication-toolkit**	*English*