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 practices and institutions seeking QOPI® Certification and by surveyors who evaluate these organizations. To achieve certification, a practice/institution must meet all the certification Standards and elements, as assessed during an on-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 chemotherapy

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

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

Defines requirements for emergency management, monitoring and care of toxicities, and oral chemotherapy 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 practice/institution must have in place in order to meet the Standard and its elements and/or the processes the QOPI® Certification Surveyor must observe during the on-site survey.
3. **Outcomes:**

These are the outcomes that a practice/institution 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 practices/institutions 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 strategy, goal, or objective. It defines an expectation regarding a behavior or course of action. 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 practice/institution.

Domain I: 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 practice or institution meets the range of responsibilities needed to create a safe environment for treating oncology patients. The policies for chart documentation and routine assessments form the structural foundation of safe, quality oncology care.

Standard 1.1

1.1 The healthcare setting has policies to define the qualifications of clinical staff who order, prepare, and administer chemotherapy and documents:

1.1.1 Orders for chemotherapy are signed manually or by using electronic approval by licensed independent practitioners who are determined to be qualified by the healthcare setting.

Commentary
A practice/institution should have a policy that describes who is qualified to write and sign orders. The policy should define who (physician or other providers) has prescriptive authority to write the order and differentiate between the types of orders that can be authorized by MDs, NPs, or PAs. Policies should align with regulations, laws, codes, and guidance that the practice/institution 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 write 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 chemotherapy (initial and ongoing) and how the orders can be transmitted (written and/or electronic).

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

Commentary
A practice/institution is required to have a policy that determines who is qualified to prepare chemotherapy. The policy should define who (physician, pharmacist, pharmacy technician, or

registered nurse) can prepare chemotherapy and how they are determined to be qualified. A comprehensive chemotherapy preparation education program should be included in the policy. Documentation for verifying staff competence is also required[1]. 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) chemotherapy 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 chemotherapy 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 USP, State Boards of Pharmacy, and other required oversight agencies

A policy should also define the annual education and competency requirements for staff who prepare chemotherapy. Examples of ongoing education may include completing online learning modules and attending in-services or classes. Additionally, competency assessment is required on an annual basis with defined metrics. Practices may submit a checklist containing the annual competency requirements.

Required Written Materials/Observations

A policy that outlines who has the authority to prepare chemotherapy, 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 chemotherapy, defined requirements for initial and ongoing education, and defined process for initial and annual competency assessment. Staff who prepare chemotherapy have comprehensive education, participate in ongoing education, and demonstrate competency during orientation period and (at least) annually.

[1] Many oncology pharmacy organizations offer pharmacy staff training certifications and/or assessments for initial and ongoing continued education. For recommended resources, please see the Appendix, "*List of Hyperlinked Resources*" found at the end of this manual.

1.1.3 Chemotherapy is administered by a qualified physician, physician assistant, registered nurse or advanced practice nurse with documented comprehensive chemotherapy administration education, initial training, and (at least) annual continuing education and competency validation.

Commentary

The healthcare setting 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 healthcare setting 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 chemotherapy administration program is current, evidence-based, and age appropriate. It may be internally developed or use an established educational curriculum, includes all routes of chemotherapy administration used in the healthcare setting and concludes in clinical competency assessment. Example of education programs for staff administering chemotherapy agents includes the ONS/ONCC Chemotherapy Biotherapy Certificate Course, and the APHON Pediatric Chemotherapy & Biotherapy Provider Program. The QOPI® Certification Program requires that all courses developed independently by the practice/institution 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 chemotherapy 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 chemotherapy and defines the initial and ongoing competency requirements for staff. Staff who administer chemotherapy have comprehensive education, participate in ongoing education, and demonstrate competency during orientation period and (at least) annually.

1.1.4 At least one clinical staff member who maintains current certification in (age appropriate) basic life support is present during chemotherapy administration. *Certification should be from a nationally accredited course. Clinical staff includes staff involved in patient care, RNs, MDs, NPs, etc.*

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. 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 chemotherapy 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 chemotherapy 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 chemotherapy administration. The practice maintains proof of the BLS/ACLS certification.

Standard 1.2

1.2 Before the first administration of a new chemotherapy regimen chart documentation is available that includes at least the following nine elements:

1.2.1. Pathologic confirmation or verification of initial diagnosis.

1.2.2. Initial cancer stage or current cancer status.

1.2.3. Complete medical history and physical examination.

1.2.4. Pregnancy status for women of childbearing age.

1.2.5. Presence or absence of allergies and history of other hypersensitivity reactions.

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

1.2.7. Initial psychosocial assessment, with action taken when indicated.

1.2.8. The chemotherapy treatment plan, including, at minimum, the patient diagnosis, drugs, doses, anticipated duration, and goals of therapy.

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

Commentary

Medical records are legal documents, whether in written form or as a computer-generated form. Medical Records provide proof of the care patients receive including the response to that care. The Medical Record consists of all the contributions from each healthcare provider providing care to that patient. Standard 1.2 addresses the requirement for documentation of key patient, disease, and chemotherapy details before each new chemotherapy regimen. Safe chemotherapy administration

requires a team of professionals (physicians, nurses, pharmacists, others) and, therefore, chart documentation 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 complete and documented in the clinical record prior to chemotherapy 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 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 chemotherapy 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 Pregnancy status for women of childbearing age. A documented pregnancy screening is required on fertile women of childbearing age. Practices may 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.

1.2.5 Presence or absence of allergies and history of other hypersensitivity 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.

1.2.6 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 consent form, or a signed decision aid.

1.2.7 Initial psychosocial assessment, with action taken when indicated. 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[2]; 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. 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 parameter such as three or above, 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.

1.2.8 The chemotherapy treatment plan, including, at minimum, the patient diagnosis, drugs, doses, anticipated duration, and goals of therapy. The chemotherapy treatment plan[3] should be documented within the medical record and include, at a minimum, the patient diagnosis, drugs, doses, anticipated duration, 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 treatment plan can be shared among the patient, family, and care team in order to facilitate care coordination and provide a roadmap to help patients navigate the path of cancer treatment.

[2] NCCN Distress Thermometer and Problem List for Patients" by Clinical Practice Guidelines. Version 2.2018, National Comprehensive Cancer Network, For more information, visit https://www.nccn.org/patients/resources/life_with_cancer/distress.aspx and https://www.nccn.org/patients/resources/life_with_cancer/pdf/nccn_distress_thermometer.pdf.

[3] Cancer.Net recommended ASCO treatment plan template. For more information, visit: https://www.cancer.net/survivorship/follow-care-after-cancer-treatment/asco-cancer-treatment-and-survivorship-care-plans.

1.2.9. The planned frequency of office visits and patient monitoring that is appropriate for the individual chemotherapy agent(s). With all types of chemotherapy but especially oral chemotherapy, the medical record must have documentation of the planned frequency of office visits and patient monitoring that is appropriate for the individual chemotherapy 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.

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 chemotherapy regimen which fosters quality, safety, patient centeredness, and continuity of care.

Standard 1.3

1.3 On each clinical encounter or day of treatment, staff performs and documents a patient assessment that includes at least the following nine elements, and takes appropriate action:

1.3.1 Functional status and/or performance status.

1.3.2 Vital signs.

1.3.3 Weight is measured at least weekly when present in the healthcare setting.

1.3.4 Height is measured at least weekly when present in the healthcare setting and when appropriate to the treatment population.

1.3.5 Age as appropriate to the treatment population.

1.3.6 Allergies, previous treatment related reactions.

1.3.7 Treatment toxicities.

1.3.8 Pain assessment.

1.3.9 Patient medications are updated and reviewed by a practitioner when a change occurs.

Commentary
The purpose of the clinical review before each cycle of chemotherapy is to identify any toxicities experienced previously, assess the individual's fitness to continue, and implement any planned changes in the treatment pathway. Chemotherapy has significant and predictable toxicities, the most serious of which are likely to develop while the patient is at home between treatment cycles. Usually these resolve with time. In the clinic setting, the assessment establishes the presence of any toxicities and determines the need for intervention. If the patient is fit, chemotherapy can continue. It is essential that systems are in place to record any symptoms the patient might develop. General well-being should be recorded using performance status and needs 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.

Medication reconciliation occurs when a complete list of the patient's medications is communicated to the next provider of service when a patient is referred 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 a chemotherapy agent that could significantly alter its efficacy or toxicity.

The process can involve any clinical staff interacting with the patient/family but must conclude with a review by a practitioner for changes and action if needed. For instance, the process can involve workflows with clinic assistants 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 practitioner for review. The 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

1.3 On each clinical encounter or day of treatment, staff performs and documents a patient assessment that includes at least the following nine elements and takes appropriate action. 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 inpatient day, scheduled or unscheduled practitioner visits, home visits and chemotherapy administration visits, but not laboratory or administrative visits.

1.3.1 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.

1.3.2 Vital signs are documented in medical record.

1.3.3 Weight is measured at least weekly when present in the healthcare setting. Medical records will be observed over several visits. Chemotherapy dosing is often based on this.

1.3.4 Height is measured at least weekly, when present in the healthcare setting, <u>when appropriate to the treatment population.</u> Due to the fluidity of pediatric growth and the subsequent impact on chemotherapy dosing, it is critical that variables such as 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.

1.3.5 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 chemotherapy 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.

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

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

1.3.8 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.

1.3.9 Patient medications are updated and reviewed by a 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.

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

Standard 1.4

1.4 Staff assesses and documents psychosocial concerns and need for support with each cycle or more frequently, with action taken when indicated.

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 chemotherapy on day-to-day life. The presence of physical symptoms can often have a detrimental effect on an individual's psychological well-being. Body image changes due to weight loss/gain, hair loss, skin texture and nail changes, potential for fatigue,

stoma management, and limb loss can confound the problems of psychological distress. A systematic assessment framework should be used to identify and address these issues. This framework can include tools such a distress thermometer, which asks a patient to rate their psychological well-being. Given the longevity of treatment pathways and the many aspects of a disease trajectory, this self-assessment is likely to change. Therefore, it is extremely important that assessments of 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 score of three or above 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 chemotherapy treatment, performed at each cycle or more frequently.

Standard 1.5

1.5 The healthcare setting provides information about financial resources and/or refers patients to psychosocial and other cancer support services.

Commentary

Cancer afflicts not only the body, but also the whole person and the whole 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[4] they need. The practice or institution 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.

[4] Cancer.Net provides financial consideration recommendations for patients and caregivers to navigate the costs related to care. For more information, visit: https://www.cancer.net/navigating-cancer-care/financial-considerations.

Required Written Materials/Observations

Surveyors will observe the materials available for patients and interview appropriate personnel 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 Meet 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:
  - Fertility Preservation[5]
  - Insurance Challenges
  - Emotional & Peer Support
  - Clinical Trials Matching
  - Breast or other specific disease Cancer Support
  - Hair Loss & Mastectomy Products
- Lodging
- Rides to Treatment

Outcome

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

Standard 1.6

1.6 The healthcare setting has a policy that identifies a process to provide 24/7 triage to a practitioner, for example, on-call practitioners or emergency department, to manage treatment-related toxicities and emergencies. If the patient's initial contact is not a practitioner from the treating healthcare setting, the person having initial patient contact must have continuous access to consultation from an experienced oncology practitioner and the opportunity for transfer of the patient to a facility with dedicated oncology services. ***Practices in rural low population areas should consult with QOPI® Certification Program staff in unable to comply with the Standard.***

Commentary

Many oncology patients will suffer severe symptoms at some point during their treatment after business hours. In many cases, they turn to the emergency department (ED) for care. Unfortunately, the ED is not the ideal place to manage cancer patients' symptoms. Many EDs struggle with overcrowding resulting in long waits for patients. They may be exposed to pathogens in the process,

[5] Cancer.Net provides dating, sex, and reproduction materials for patients and caregivers to help start a discussion about fertility preservation and raise questions to ask a health care team. For a 1-page factsheet on fertility and cancer treatment, visit: https://www.cancer.net/navigating-cancer-care/dating-sex-and-reproduction.

which is a particular concern for immunocompromised cancer patients and few ED clinicians have oncology-specific training. This Standard requires that the patients have access 24/7 to oncology expertise to reduce unnecessary hospitalizations, inappropriate utilization of services, and lower quality care. After-hours access to oncology expert care is linked with lower emergency department use and less unmet medical need.

Required Written Materials/Observations
Practices must submit a policy that identifies a process to provide 24/7 triage to a 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 expertise.

Practices have policies that state if a patient calls after business hours, the on-call physician will be paged and will respond quickly or upon arrival at the emergency room, the patient will ask the staff to call the cancer center physician. Practices have implemented efficient telephone triage with Standard triage protocols and patient education[6] as to when to call if symptoms arise. Many practices have implemented flexible scheduling systems 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 healthcare setting has a structured policy that identifies a process to provide 24/7 triage with oncology expertise 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 chemotherapy, and patient and family education prior to the initiation of treatment.

Standard 2.1

[6] Cancer.Net provides *ASCO Answer* Fact Sheets. *ASCO Answers* is a collection of oncologist-approved patient education materials developed by the American Society of Clinical Oncology (ASCO) for people with cancer and their caregivers.

2.1 The healthcare setting has a policy that documents a standardized process for obtaining and documenting chemotherapy consent or assent. Informed consent and assent (optional) is documented prior to initiation of each chemotherapy regimen. The consent process should follow appropriate professional and legal guidelines.

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 chemotherapy is an essential prerequisite to the administration of a chemotherapeutic agent by any route in any healthcare setting. Informed consent needs to be documented. Legally, it makes no difference whether the documentation is a Standardized form, or a clinic 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 of the required elements of a consent/assent conversation took place is equally appropriate because written consent/assent forms are not required by law in most states.

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 practice/institution 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.

Find a process to ensure and validate that the consent process has been documented, so no chemotherapy is given without documented consent. Sample consent forms and discussion guides can be found on the ASCO.org website:

Consent to Chemotherapy template (modifiable Microsoft Word document)
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 healthcare setting has a policy documenting a standardized process for obtaining and documenting chemotherapy 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 chemotherapy regimen/treatment. Practice 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 chemotherapy treatment, as appropriate to the treatment population is documented prior to initiation of chemotherapy 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 both oral and parenteral treatment patients 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 clinical staff administering the first chemotherapy treatment.

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

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.**

[7] Consent to Chemotherapy Template: https://practice.asco.org/sites/default/files/drupalfiles/ASCO Informed Consent Form.pdf

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. ***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.***

2.2.2 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, drug-drug and drug-food interactions, and plan for missed doses.

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

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

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

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

2.2.3.9 Follow-up plans including laboratory and provider visits.

2.2.3.10 The healthcare setting's contact information with availability and instructions on when and who to call.

2.2.3.11 Expectations for rescheduling or cancelling appointments

Commentary

Patients who receive chemotherapy education experience more successful outcomes compared to patients who have not been educated. Education is essential for patients to understand how to take care of themselves by managing side effects and knowing when to call healthcare providers for assistance. Understanding what chemotherapy is, how it works, and what to expect during administration can lessen patient fear and anxiety. The literature supports the idea that patients want as much information as possible about their illness and treatment plans. A chemotherapy class or one-on-one education session is an introduction to cancer and its treatment with chemotherapy. It covers basic concepts, processes, and side effect management. Increasing numbers of patients are receiving oral chemotherapy at home, and with this move to oral self-administration, there has been

a critical shift in responsibility of management from the provider to patient [8]. 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 chemotherapy regimen and side effects before treatment. Patients and their families need to understand the signs and symptoms of serious side effects prior to beginning chemotherapy, so that they will be able to recognize at what point to call a healthcare provider. Written information should be used to reinforce chemotherapy 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 being 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, a variety of resources must be available to meet the learning needs of each individual [9], including printed material with relevant pictures, trustworthy internet sites, computer-assisted learning, audiotapes and videotapes. All materials must be culturally sensitive and 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 [10]. 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: hard copy, smart phone apps, Web-based, DVDs, etc., so that information

[8] Cancer.Net Mobile Applications to provide patients the tools to manage their care through their smartphone functionalities such as appointments history, medication log, symptoms tracking, etc. ASCO 2019. All rights reserved worldwide.

[9] Cancer.Net recommended patient education materials. For more information, visit: https://www.cancer.net/patient-education-resources

[10] An example is provided by Cancer.Net oncology health care professionals with comprehensive patient education materials that are reviewed and approved by an ASCO Editorial Board.

is readily available to different learning styles. Cancer centers can make such guidelines and materials available via Webinars, smart phone apps, and Websites, as part of their routine care.

Required Written Materials/Observations
During the on-site visit, the surveyor will discuss the processes for patient education and review the requested number of charts selected from all eligible patients to verify compliance with the Standard, including documentation that the patient has received written materials about each element of the Standard.

The surveyor will review any 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 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 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, ACS, or ASCO Answers[11]).

2.2.3.2 Goals of treatment, that is, cure disease, prolong life, or reduce symptoms. The patient must receive a written document identifying their 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

[11] Cancer.Net recommended patient education materials. For more related information, visit https://www.cancer.net/about-us/asco-answers-patient-education-materials

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[12], or a treatment calendar.

2.2.3.4 Drug names and supportive medications, drug-drug and drug-food interactions, 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 be looking for both information limited to medications that will be administered to the patient in the facility (IV), or medications used to treat cancer and support side effects of that treatment if taken at home (oral).

2.2.3.5 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.

2.2.3.6 Symptoms or side effects that require the patient to contact the healthcare setting or seek immediate attention. Surveyors will look for documentation of written information given to patients to ensure that all patients have a clear understanding of which side effects or symptoms should trigger a call to the practice or a visit to a hospital emergency room. This information may be provided on a handout or an appointment card.

2.2.3.7 Procedures for handling medications in the home, including storage, safe handling, and management of unused medication. Surveyors will look for documentation of oral chemotherapy storage and handling educational materials[13] given to patients. This may include use of a safe handling patient handout or drug sheets[14].

2.2.3.8 Procedures for handling body secretions and waste in the home. Surveyors will look for documentation of written instruction on handling body waste, trash, laundry, spills, and family interactions that is given to patients.

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[12] Cancer.Net recommended ASCO treatment plan template. For more related information on ASCO Treatment Plan, visit https://www.cancer.net/survivorship/follow-care-after-cancer-treatment/asco-cancer-treatment-and-survivorship-care-plans

[13] Cancer.Net recommended oral chemotherapy storage and handling educational materials. For more related information, visit https://www.cancer.net/about-us/health-care-professionals. .

[14] 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. Visit http://www.oralchemoedsheets.com/.

2.2.3.9 Follow-up plans including laboratory and provider visits. Surveyors will look for an appointment card, after visit summary, patient portal page with next appointment/labs or other notation given to the patient about their scheduled follow-up over the next several weeks.

2.2.3.10 The healthcare setting's contact information with availability and instructions on when and who to call. Surveyors will look for written documentation that the patient has received specific instructions about what number to call during the practice's office hours, as well as after hours.

2.2.3.11 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 chemotherapy 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 outcomes, oncologic emergencies, and problems associated with the disease, treatment and side effects. The patient knows whom to call in the practice and when. Patients understand how to protect themselves and family against chemotherapy 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 chemotherapy. They understand the planned treatment schedule and the instructions provided to them and verbalizes the appropriate action for common oncologic emergencies, and problems associated with the disease, treatment and side effects.

End of Domain 2

Domain 3: Ordering, Preparing, Dispensing, and Administering Chemotherapy

Commentary

Because of the complexity of treatment regimens, the narrow therapeutic window of anti-cancer agents, and the potential for serious and fatal consequences of medication errors, it is essential that oncology practices have in place a systematic approach to prescribing and verifying anti-cancer therapy that prevents medication errors when providing treatment to cancer patient. 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 establishing and implementing specific policies and procedures for the process of cancer therapy prescribing, verification, dispensing, and administration within a multi-disciplinary team. The entire domain provides the foundation for safe patient care.

Standard 3.1

3.1 Chemotherapy orders include at least the following elements:

3.1.1 The patient's name.

3.1.2 A second patient identifier.

3.1.3 Date the order is written.

3.1.4 Regimen or protocol name and number.

3.1.5 Cycle number and day, when applicable.

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

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

3.1.8 The dose calculation, including:

3.1.8.1 The calculation methodology.

3.1.8.2 The variables used to calculate the dose.

3.1.8.3 The frequency that the variables are re-evaluated.

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

3.1.9 Date of administration.

3.1.10 Route of administration.

3.1.11 Allergies.

3.1.12 Supportive care treatments appropriate for the regimen (including pre-medications, hydration, growth factors, and hypersensitivity medications).

3.1.13 Parameters that would require holding or modifying the dose (e.g., lab values, diagnostic test results, and patient's clinical status).

3.1.14 Sequencing of drug administration when applicable.

3.1.15 Rate of drug administration, when applicable.

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

Commentary

This Standard describes the required elements for a standard chemotherapy order using an electronic process and or a handwritten document. The standard chemotherapy 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.

Chemotherapy drugs may be given in combination, using several different medications (regimens), and given at the same time, or one after 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. Chemotherapy treatment protocols are grouped according to the condition that they are used to treat. 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 chemotherapy 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. Healthcare settings 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. ASCO has produced guidelines for dosing chemotherapy in obese patients that suggest using actual body weight if the intent is cure. 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, which combines both an accurate BSA calculation and is easy to use. 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 The 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 is written.

3.1.4 Regimen or protocol name and number. 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 chemotherapy/ 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 chemotherapy 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 abbreviations, trailing zeros, and 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 chemotherapy 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. 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 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

3.1.12 Supportive care treatments appropriate for the regimen, including pre-medications, hydration, growth factors, and hypersensitivity medications. 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 Parameters that would require holding or modifying the dose (e.g., lab values, diagnostic test results, and patient's clinical status). This may be in the order or defined in a policy.

3.1.14 Sequencing of drug administration when applicable. Sequencing of drug administration should be indicated in the order. For example, instructions such as "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.

3.1.15 Rate of drug administration, when applicable.

3.1.16 An explanation of time limitation, such as number of cycles that the order is valid for. 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 chemotherapy 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 practice/institution to prepare or administer chemotherapy) performs three independent verifications:

3.2 **Prior to preparation**, (check of orders and independent variables calculations)
3.3 **During and upon preparation** (calculations, right drug, right dose, right volume, right label)
3.8 **Prior to administration** (check of the 5 Rights, verification of drug(s) and orders)

Commentary
An independent double-check of a high-alert medication is a procedure in which two clinicians separately check (alone and apart from each other, then compare results) each component of prescribing, dispensing, and verifying the high-alert medication before administering it to the patient. Except for urgently required treatments, chemotherapy medication preparation and administration should be scheduled when staffing is adequate to ensure that appropriate safety checks are performed during ordering, compounding, and administration. Best practices in chemotherapy preparation and delivery include verification of the chemotherapy order and preparation as well as independent verification prior to administration of chemotherapy.

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 carrying out an independent double check and educate staff about its importance and how to carry it out properly—as an independent cognitive task 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 with memory errors. Checklists that include very specific items associated with critical information significantly improve their effectiveness. As appropriate, redesign order forms to facilitate crosschecking of information, and make sure the sequence of information on checklists uses the same terminology and follows the logical progression of typical workflow. Take the time to evaluate the procedures for which you require a double check, monitor compliance, assess how often the checks are conducted as designed, and then make the necessary revisions to promote effectiveness.

Standard 3.2
VERIFICATION 1

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

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

3.2.1 Two patient identifiers.

3.2.2 Drug name.

3.2.3 Drug dose.

3.2.4 Route of administration.

3.2.5 Rate of administration.

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

3.2.7 Treatment cycle and day of cycle.

Commentary

Verifying a chemotherapy order should include a systematic check of all the components of the chemotherapy order and its preparation and dispensing. While technological solutions such as computerized prescriber order entry and bar-coding systems have great potential to detect human error, manual redundancies (such as independent double checks) still play an important role 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 small but 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 chemotherapy preparation. Independent double checking during the chemotherapy preparation process is ideally made by a 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 check of the chemotherapy order prior to preparation. This person should be qualified and approved by the practice/institution to prepare or administer chemotherapy. 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 check of the provider order shall include:

3.2.1 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.

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

3.2.3 Drug dose. The dose is confirmed by recalculation using the appropriate formula for the treatment.
3.2.4 Route of administration.
3.2.5 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).
3.2.6 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.
3.2.7 Treatment cycle and day of cycle.

Outcome
The chemotherapy order is verified for accuracy before starting chemotherapy compounding with patient safety the primary goal. The use of consistent and systematic methods for reviewing chemotherapy 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 3.3
VERIFICATION 2

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

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

3.3.1 The drug vial(s).

3.3.2 Concentration.

3.3.3 Drug volume or weight.

3.3.4 Diluent type and volume, when applicable.

3.3.5 Administration fluid type, volume, and tubing.

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 chemotherapy processing and chemotherapy preparation accuracy and should be documented in a Standardized format, either on paper or electronically. Drug products should be checked, after preparation, against both the preparation work sheet and the original order by an individual who was not involved in preparation. To document the process, some practices use drug preparation work sheets (sometimes referred to

as work cards or admixture or compounding logs, sheets, and cards) 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 chemotherapy 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 chemotherapy is checked against the order, (examples include a worksheet, a record, or initials on the drug label to indicate it was performed).

Outcome
Drug products are checked, upon preparation, against both the preparation work sheet and the original order by an individual who was not involved in preparation. The goal of this best practice is to prevent medication errors during sterile compounding of drugs, especially for high-alert medications.

Standard 3.4

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

3.4.1 Patient's name.

3.4.2 A second patient identifier.

3.4.3 Full generic drug name.

3.4.4 Drug dose.

3.4.5 Drug administration route.

3.4.6 Total volume required to administer the drug.

3.4.7 Date the medication is to be administered.

3.4.8 Expiration dates/times.

3.4.9 When dose is divided, the total number of products to be given and the individual product sequence (e.g., 1 of 2, 2 of 2, etc.).

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

Commentary

Medication label design is frequently a contributing factor to medication errors. The components and formatting of the chemotherapy label provide a systematic method for the complex process of administering chemotherapy. This systematic approach to label design and content is one strategy to provide a consistent method for verifying the compounded chemotherapy agent and elements for safe chemotherapy 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. The use of bar coding continues to grow as more research is done. 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 chemotherapy 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. 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 chemotherapy agent and elements for safe chemotherapy administration.

Standard 3.5

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

3.5.1 Intrathecal medications are:

3.5.1.1 Prepared separately.

3.5.1.2 Stored in an isolated container or location after preparation.

3.5.1.3 Labeled with a uniquely identifiable intrathecal medication label.

3.5.1.4 Delivered to the patient only with other medication intended for administration into the CNS.

3.5.1.5 Administered immediately after a time out double check procedure involving two licensed practitioners or other personnel approved by the healthcare setting to prepare or administer chemotherapy.

3.5.2 Intravenous vinca alkaloids are administered only by infusion.

Commentary

Administration of chemotherapy via the intrathecal route is necessary for certain treatment regimens. Given the high risk associated with intrathecal administration (e.g., vincristine intrathecal administration is fatal), specific considerations apply to intrathecal preparation and administration of chemotherapy. 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 chemotherapy.

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 2016-2017 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[15], 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

[15] National Comprehensive Cancer Network (NCCN) Fact sheet for the "Campaign for Safe Vincristine Handling" For more information, visit https://www.nccn.org/justbagit/pdf/vincristine_fact_sheet.pdf.

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 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 switched 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 medications are prepared, stored, labeled, and administered. The policy must clearly state that intrathecal chemotherapy 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.

3.5.1.1 **Prepared separately.**

3.5.1.2 **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.

3.5.1.3 **Labeled with a uniquely identifiable intrathecal medication label.** Drug labels should clearly indicate that the chemotherapy is only intended for intrathecal administration, including ancillary labels. Surveyors will accept a label that says FOR INTRATHECAL 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.

3.5.1.4 **Delivered to the patient only with other medication intended for administration into the CNS.**

3.5.1.5 **Administered immediately after a time-out double check procedure involving two licensed practitioners or other personnel approved by the healthcare setting to prepare or administer chemotherapy.** The policy or written procedure should describe the 'time-out' process and the individuals that will perform the time-out.

3.5.2 **Healthcare settings that administer intrathecal chemotherapy have a policy that states intravenous vinca alkaloids are given only by infusion (e.g., minibags).**

Outcome

The pharmacy staff have a systematic process for the preparation, labeling, storage and delivery of intrathecal medication. The pharmacy staff and the clinical staff are aware of the process including the use of a time-out process. The goal of this best practice is to ensure that intrathecal medications are administered by the intrathecal route only. Healthcare settings that administer intrathecal chemotherapy have a policy that states intravenous vinca alkaloids are given only by infusion (e.g., minibags) to ensure that intravenous vinca alkaloids are not accidently administered by the intrathecal route.

Standard 3.6

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

Commentary

The patient has the right to 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.

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 chemotherapy confirms the treatment with the patient including, at a minimum, the name of the drug, infusion time, route of administration, and infusion-related symptoms to report.

Outcome:

The practice has a well-defined process for how the treatment confirmation process prior to chemotherapy administration is completed with each patient and includes all Standard 3.6 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 3.7

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

Commentary

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

Required Written Materials/Observations:

The surveyor while in the infusion suite will observe two clinical staff members verify patient identity using at least two identifiers prior to chemotherapy administration in the presence of the patient. A best practice is to 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 chemotherapy order.

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

Standard 3.8
Verification 3

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

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

3.8.1 Drug name.

3.8.2 Drug dose.

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

3.8.4 Rate of administration.

3.8.5 Route of administration.

3.8.6 Expiration dates/times.

3.8.7 Appearance and physical integrity of the drugs.

3.8.8 Rate set on infusion pump, when used.

3.8.9 Sequencing of drug administration

Commentary
The primary goal is to achieve and document safe and appropriate administration of chemotherapy agents. The use of a consistent process to verify chemotherapy 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 while gently rotating the bag to see any particulate matter. Sequencing of drug administration should also be double-checked prior to administration to ensure chemotherapy drugs are administered in the correct order. Staff may reference sequencing instructions in the order, on the chemotherapy labels, or use a reference tool such as a practice policy. Technology may also supplement the verification process such as barcode scanning.

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 chemotherapy verify all nine 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 double-check must specifically include all nine elements of the verification. A checklist of all nine Standard 3.8 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 chemotherapy administration is completed and includes all nine elements and documents that verification.

Standard 3.9

3.9 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 3.10

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

Commentary
Extravasation is the leakage of a 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, chemotherapy extravasation can be a life-threatening medical emergency

and requires immediate intervention. The FDA has four approved drugs for the management of chemotherapy extravasation, including: dexrazoxane hydrochloride and/or DMSO for anthracycline chemotherapy; 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 chemotherapy 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 ONS Chemotherapy and Biotherapy Guidelines and Recommendations for Practice (Fifth Edition), 2019. 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 your policy and staff knowledge. Appropriate protocols or coupled order sets to ensure that the above best practice is met.

The surveyor will look at the policy and ensure it references current literature and guidelines. The surveyor will make sure 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 best practice 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 that the agent and treatment is readily available and can be administered without delay.

End of Domain 3

DOMAIN 4: Monitoring After Chemotherapy 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 healthcare setting has a policy for emergent treatment of patients, that aligns with current literature and guidelines and addresses:

4.1.1 Availability of appropriate treatment agents.

4.1.2 Procedures to follow and a plan for escalation of care when required for life threatening emergencies.

Commentary
Following chemotherapy treatment, patients are at risk for serious and potentially life-threatening side-effects, toxicities or drug reactions. It is imperative that practitioners 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, or general life-threatening emergency, that aligns with current literature and guidelines. Recommended guidelines include the Oncology Nursing Society's Chemotherapy and Biotherapy Guidelines and Recommendations for Practice (Fifth Edition), or other scholarly journal articles published within the last five years. Policies should include references to emergency 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 (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 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 healthcare setting has a policy that outlines the procedure to assess patients' ability to adhere to chemotherapy that is administered outside of the heath care setting. Documentation of assessment is available in the patient record.

Commentary

Prior to the initiation of chemotherapy administered outside of the healthcare setting, practices are required to document an assessment of the patient's ability to adhere to the prescribed regimen. Practitioners should be reviewing any barriers to medication adherence and clearly document any issues identified and prescribed interventions. Documentation should include but is not limited to referrals to other practitioners (e.g., financial counselor or social worker), use of adherence tools (i.e., chemo calendar, smartphone applications) and the plan for follow-up and monitoring appropriate to the treatment regimen.

Oral Chemotherapy: Adherence is the single most important factor in achieving the best possible outcomes. Maximizing adherence to oral chemotherapy agents[16] 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. The policy includes patient education on the importance of chemotherapy 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 it. The surveyor will also review patient records for documentation of the adherence assessment.

Outcome

The practice has a clearly defined policy that requires the initial assessment of patient's adherence for chemotherapy administered outside of the healthcare setting. Patients understand the planned treatment schedule and the instructions provided to them and verbalizes the important of adherence.

Standard 4.3

[16] Oncology Nursing Society (ONS) recommended "Oral Adherence Toolkit" resource (2016). For more information, visit: https://www.ons.org/sites/default/files/ONS_Toolkit_ONLINE.pdf

4.3 The healthcare setting has a policy that requires assessment of each patient's chemotherapy adherence at defined clinically meaningful intervals to address any issues identified when chemotherapy is administered outside of the health care setting. Documentation of assessment is available in the patient record.

Commentary

Practices are required to document the patient's adherence 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, practitioners should clearly document referrals to other practitioners (e.g., financial counselor or social worker), and any follow-up related to previously reported adherence issues.

Required Written Materials/Observations

The surveyor will look for a written policy that requires the assessment of patient's adherence (oral) 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 chemotherapy 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 patient's adherence 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 chemotherapy 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 chemotherapy is that the information about cumulative dose information is not readily available either in paper charts or EHRs. This is especially true 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 physician office). The process will include specific individuals who are responsible for gathering and documenting outside doses.

Required Written Materials/Observations

The surveyor will look 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 your 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

GLOSSARY

COMMON DEFINITIONS FOR ASCO/ONS CHEMOTHERAPY ADMINISTRATION SAFETY STANDARDS	
Term	**Definition**
Acronyms	ASCO, American Society of Clinical Oncology; APHON, Association of Pediatric Hematology/Oncology Nurses; ASPHO, American Society of Pediatric Hematology/Oncology; ONCC, Oncology Nursing Certification Corporation; ONS, Oncology Nursing Society
Adherence	The degree or extent of conformity to the provider's recommendations about day-to-day treatment with respect to timing, dosing, and frequency.
Assent	Assent expresses a willingness to participate in a proposed treatment by persons, who are by definition, too young to give informed consent, but who are old enough to understand the diagnosis and proposed treatment in general, its expected risks and possible benefits. Assent, by itself, is not sufficient, however. If assent is given, informed consent must still be obtained from the subject's parents or guardian, both which must be done according to all applicable state and federal laws. (see Consent below)
Basic Life Support	Certification through an accredited class in provisioning resuscitation, and management and assessment of life-threatening conditions, including CPR, controlling bleeding, treating shock and poisoning, stabilizing injuries and/or wounds, and basic first aid. An example would be the American Heart Association's BLS. Higher medical functions use some or all of the Advanced Cardiac Life Support (ACLS) protocols, in addition to BLS protocols.
Cancer Stage	A formal, standardized categorization of the extent to which a cancer has spread at diagnosis. Systems vary by tumor type and staging should be specific to the tissue of tumor origin. Stage should be distinguished from Cancer Status. Cancer status does change over time.
Cancer Status	Description of the patient's disease since diagnosis, if relevant (e.g. recurrence, metastases).
Cancer Support, Information and Financial Resources	A list of resources that is available for cancer support.

Chemotherapy	All chemotherapy agents used to treat cancer, given through oral and parenteral routes or other routes as specified in the standard. Types include targeted agents, alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, antitumor antibiotics, monoclonal antibodies, and biologics and related agents. Hormonal therapies are not included in the definition of chemotherapy for the Standards.
Chemotherapy Preparation Verification: Use of technology	Preparation of chemotherapy should be independently verified by a second healthcare provider who did not prepare the chemotherapy. Independent verification should include checking the preparation for completeness and accuracy of content, with particular attention given to special preparation instructions. Technology can serve as a surrogate; if practitioners follow procedures in using appropriately developed and applied procedures. Verification may include bar code and/or gravimetric verification and may be performed on site or remotely via digital images or video as allowed by state law or other regulations.
COMMON DEFINITIONS FOR ASCO/ONS CHEMOTHERAPY ADMINISTRATION SAFETY STANDARDS	
Term	**Definition**
Chemotherapy Regimen	One or more chemotherapeutic agents used alone or in combination in a well- defined course of treatment, generally administered cyclically.
Chemotherapy Treatment Plan	A plan of treatment specific to the patient that is developed prior to the initiation of chemotherapy. The core elements of a chemotherapy treatment plan are: 1. Diagnosis, including the cancer site, histology and stage 2. Goals of therapy (may be specified by the type of template; e.g., adjuvant chemotherapy plan) 3. Patient health status and co-morbidities 4. Surgical history and notable pathology findings 5. Chemotherapy regimen and starting dosages 6. Duration of treatment and number of planned cycles 7. Major side effects of chemotherapy
Clinical encounter	Clinical encounters include each inpatient day, scheduled or unscheduled practitioner visits, home visits and chemotherapy administration visits, but not laboratory or administrative visits.
Clinical Staff	Staff involved in patient care (e.g. practitioners, registered nurses, etc.)
Comprehensive Education Program	A comprehensive educational program is current, evidence-based, and age appropriate. It may be internally developed or use an established educational curriculum, includes all routes

	of chemotherapy administration used in the health care setting and concludes in clinical competency assessment. Example of education programs for staff administering chemotherapy agents includes the ONS/ONCC Chemotherapy Biotherapy Certificate Course, and APHON Pediatric Chemotherapy & Biotherapy Provider Program.
Consent	Consent to treatment is an important part of delivering quality cancer care. Consent is the process by which a patient is provided with sufficient information about the disease diagnosis and treatment options so that the individual can make a reasonable decision about treatment, based on an understanding of the potential risks and anticipated benefits of the treatment. Informed consent is not a waiver of rights.
Dosage	Includes the amount or quantity of medicine to be taken or administered and implies the duration or the frequency of the dose to be administered (e.g., daily, every 21 days, etc.).
Dose	The amount or quantity of medicine to be taken or administered to the patient each time in a day.
Exception Order	Notation that the standard treatment is contraindicated as a result of pre- existing comorbidity, organ dysfunction or prior therapy.
Functional Status	An individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being.
Handoff	The transfer of patient information and knowledge, along with authority and responsibility, from one clinician or team of clinicians to another clinician or team of clinicians during transitions of care across the continuum.
Healthcare Setting	A medical office or practice, clinic, agency, company, hospital or institution that provides healthcare, and home environment where healthcare is provided.
Hypersensitivity Reaction	A symptomatic interaction between antibodies and allergens that causes an exaggerated and harmful response in the body. Hypersensitivity reactions range from mild to life threatening in severity and symptoms.
Identifier (patient identification)	Minimum patient identifiers for positive patient identification are: Last name, first name, date of birth, unique identification number such as medical record number. Whenever possible, ask patients to state their full name and date of birth. For patients who are unable to identify themselves (pediatric, unconscious, confused or language barrier) seek verification of identity from a parent or caregiver at the bedside. This must exactly match the information on the identity band, order, drug label (or equivalent).

Immediate Use	For the purposes of these Standards, immediate use is defined as "use within 2 hours" in accordance with drug stability, state and federal regulations.
Label	A small piece of material attached to the medication or a container for the medication giving information about it
Labeling	Practices/institutions are not expected to be in full compliance with this standard if they currently have electronic ordering systems that prevent compliance. Appropriate changes should be implemented as soon as possible to ensure that electronic ordering systems integrate all of these elements. If the information cannot be captured in the electronic system, it should be documented within the patient record. (If their machines have not caught up)
Medical History and Physical	Includes, at minimum, height, weight, pregnancy screening (when applicable), treatment history, and assessment of organ-specific function as appropriate for the planned regimen. Example of assessment of organ-specific function as appropriate for the planned regimen: patient plan for cisplatin requires pretreatment assessment of kidney function.
On-site and immediately available	Physically present, interruptible and able to furnish assistance and direction throughout the performance of the procedure
Orders: Written and Verbal	Orders that are written or sent electronically can be on paper, emailed from a secure encrypted computer system, written, or faxed; and includes the prescriber's signature, and in some instances, an identifying number. Verbal Orders are those that are spoken aloud in person or by telephone and offer more room for error than orders that are written or sent electronically.
Pain Assessment	Assessment of pain in the oncology patient using a multidimensional approach, with determination of the following: • Chronicity • Severity • Quality • Contributing/associated factors • Location/distribution or etiology of pain, if identifiable • Barriers to pain assessment
Parenteral	Introduction of substances by intravenous, intra-arterial, subcutaneous, intramuscular, intrathecal, intravesical, or intra-cavitary routes.
Patient	The recipient of health care, and when applicable, includes parents, family members, significant others, lay caregivers,

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

APPENDIX

LIST OF HYPERLINKED RESOURCES			
Footnote #	**Footnote 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),	http://www.hoparx.org/education	*English*
2.	"NCCN Distress Thermometer and Problem List for Patients" by Clinical Practice Guidelines. Version 2.2018, National Comprehensive Cancer Network,	https://www.nccn.org/patients/resources/life_with_cancer/distress.aspx https://www.nccn.org/patients/resources/life_with_cancer/pdf/nccn_distress_thermometer.pdf.	*English*
3.	**Cancer.Net**** recommended ASCO treatment plan template.	https://www.cancer.net/survivorship/follow-care-after-cancer-treatment/asco-cancer-treatment-and-survivorship-care-plans	*English*
4.	Cancer.Net provides recommended financial consideration information for patients and caregivers to navigate the costs related to care.	https://www.cancer.net/navigating-cancer-care/financial-considerations	*English, Spanish*
5.	Cancer.Net provides recommended materials, such as ASCO Answers on Fertility, for patients and caregivers to help start a discussion about fertility preservation and raise questions to ask a health care team.	https://www.cancer.net/navigating-cancer-care/dating-sex-and-reproduction	*English, Spanish*
6.	Cancer.Net provides recommended *ASCO Answer* Fact Sheets. *ASCO Answers* is a collection of oncologist-approved patient education materials developed by the American Society of Clinical	https://www.cancer.net/about-us/asco-answers-patient-education-materials/asco-answers-fact-sheets	*English; Several fact sheets in Spanish, Romanian, Portuguese,*

	Oncology (ASCO) for people with cancer and their caregivers.		*Greek, and Arabic*

Footnote #	Footnote Description	Hyperlink(s)	***Language Availability***
7.	Consent to Chemotherapy Template	https://practice.asco.org/sites/default/files/drupalfiles/ASCO Informed Consent Form.pdf	English
8.	Cancer.Net recommended Mobile Applications to provide patients the tools to manage their care through their smartphone functionalities such as appointments history, medication log, symptoms tracking, etc. ASCO 2019. All rights reserved worldwide.	https://www.cancer.net/navigating-cancer-care/managing-your-care/mobile-applications	*English; Spanish enabled*
9.	Cancer.Net recommended patient education materials.	https://www.cancer.net/patient-education-resources	*English*
10.	A recommended example is provided by Cancer.Net oncology health care professionals with comprehensive patient education materials that are reviewed and approved by an ASCO Editorial Board.	https://www.cancer.net/about-us/health-care-professionals	*English*
11.	Cancer.Net recommended patient education materials.	https://www.cancer.net/about-us/asco-answers-patient-education-materials	*English; Spanish*
12.	Cancer.Net recommended ASCO treatment plan template.	https://www.cancer.net/survivorship/follow-care-after-cancer-treatment/asco-cancer-treatment-and-survivorship-care-plans	*English*
13.	Cancer.Net recommended oral chemotherapy educational material for patients and caregivers found on ASCO Answers Fact Sheets under "Diagnosis, Treatment, and Coping."	https://www.cancer.net/about-us/asco-answers-patient-education-materials/asco-answers-fact-sheets https://www.cancer.net/sites/cancer.net/files/asco_answers_oral_chemotherapy.pdf	*English*
14.	A resource established by National Community Oncology Dispensing Association (NCODA) along with HOPA, ACCC, and ONS provide Oral Chemotherapy Education (OCE)	http://www.oralchemoedsheets.com/	*English*

	drug-specific sheets. The OCE sheets include drug interactions, safe handling and storage, home care, and possible side effects.		
15.	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*

Footnote #	**Footnote Description**	**Hyperlink(s)**	***Language Availability***
16.	Oncology Nursing Society (ONS) recommended "Oral Adherence Toolkit" resource (2016).	https://www.ons.org/sites/default/files/ONS_Toolkit_ONLINE.pdf	*English*
**	**Cancer.net en Español** Sitio de web traducido en Español/ Translated content for visitors in Spanish	**https://www.cancer.net/es**	**Español / *Spanish***