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

1.1 The healthcare setting has policy to document the qualifications of clinical staff who order, prepare, and administer chemotherapy and documents: \( \text{(Replaces standards 1A, 1D, 1E)} \)
   
   1.1.1 Description of initial educational requirements and competencies
   
   1.1.2 Description of ongoing continuing education requirements
   
   1.1.3 Description of competency demonstration and how competency is documented

1.2 The healthcare setting uses a comprehensive education program for initial and ongoing educational requirements for all staff who prepare and administer chemotherapy. \( \text{(Replaces 1D, 1E)} \)

1.3 At least one clinical staff member who maintains current certification in (age appropriate) basic life support is present during chemotherapy administration \( \text{(replaces 1F)} \)

1.4 A licensed independent practitioner is on-site and immediately available to staff administering chemotherapy in the healthcare setting \( \text{(replaces 23)} \)

1.5 Before the first administration of a new chemotherapy regimen chart documentation is available including at least the following eight elements. \( \text{(Replaces 2 A-I)} \)
   
   1.5.1 Pathologic confirmation or verification of initial diagnosis
   
   1.5.2 Initial cancer stage, or current cancer status
   
   1.5.3 Complete medical history and physical examination including pregnancy status, as applicable
   
   1.5.4 Presence or absence of allergies and history of hypersensitivity reactions
   
   1.5.5 Assessment of the patient’s and/or caregiver’s comprehension of information regarding the disease and the treatment plan
   
   1.5.6 Initial psychosocial assessment, with action taken when indicated.
   
   1.5.7 The chemotherapy treatment plan, including at a minimum, the patient diagnosis, drugs, doses, duration of treatment, and goals of therapy
   
   1.5.8 The planned frequency of office visits and patient monitoring that is appropriate for the individual antineoplastic agent(s)

1.6 On each clinical encounter, staff performs and documents a patient assessment that includes at least the following 5 elements, and takes appropriate action. \( \text{(replaces 26)} \)
   
   1.6.1 Functional status and/or performance status
   
   1.6.2 Vital signs and weight for all patients, performed at least weekly, and height as well as age when appropriate to the treatment population.
   
   1.6.3 Allergies, previous treatment related reactions
2.1 The healthcare setting has a policy documenting a standardized process for obtaining and documenting chemotherapy consent or assent (Replaces 6)

2.2 Informed consent or assent for chemotherapy treatment, as appropriate to the treatment population, is documented prior to initiation of a chemotherapy regimen. (Replaces 19)

2.3 Patients are provided with verbal and written or electronic information as part of an education process prior to the first administration of treatment of each treatment plan. The content of this educational material will be documented. Educational information includes the following at a minimum: (Replaces 18, 20, 14)

2.3.1 Patient’s diagnosis
2.3.2 Goals of treatment [i.e. cure disease, prolong life, or reduce symptoms]

2.3.3 Planned duration of treatment, schedule of treatment administration, drug names and supportive medications, drug-drug and drug-food interactions, plan for missed doses

2.3.4 Potential long and short term side effects of therapy, including infertility risks

2.3.5 Symptoms or side effects that require the patient to contact the healthcare setting or seek immediate attention

2.3.6 Symptoms or events that require immediate discontinuation of oral or other self-administered treatments

2.3.7 Procedures for handling medications in the home, including storage, safe handling, and management of unused medication (replace 14).

2.3.8 Procedures for handling body secretions and waste in the home (new)

2.3.9 Follow-up plans including laboratory and provider visits

2.3.10 The healthcare setting’s contact information with availability and instructions on when and whom to call

2.3.11 The healthcare setting’s missed appointment policy and expectations for rescheduling or cancelling

2.4 Education includes family, caregivers, or others based on the patient’s ability to assume responsibility for managing therapy. Educational activities will be performed based on the patient’s learning needs, abilities, preferences, and readiness to learn. (replaces 20B)

Domain 3: Ordering, preparing, dispensing and administering chemotherapy

3.1 The healthcare setting defines standard chemotherapy regimens by diagnosis with references. (replaces 3A)

3.2 The healthcare setting verifies Institutional Review Board approval of research regimens (replaces 3B)

3.3 Orders for chemotherapy are signed manually or using electronic approval by licensed independent practitioners who are determined to be qualified by the healthcare setting. (replaces 1A)

3.4 The healthcare setting has policy for managing chemotherapy orders that vary from standard regimens. The policy requires a supporting reference and/or authorization by a second licensed independent practitioner (Replaces 4)

   3.4.1 The rationale for an exception order is documented in the medical record.

3.5 The healthcare setting has a policy for chemotherapy orders that ensure: (Replaces 9)

   3.5.1 Verbal orders are not allowed except to hold or stop chemotherapy administration. (9)

   3.5.2 New orders or changes to orders, including changes to oral chemotherapy regimens (e.g., dose adjustments communicated directly to patients), are documented in the medical record. (9)
3.6 The healthcare setting uses standardized, regimen-level, preprinted or electronic forms for parental chemotherapy. (Replaces 10)

3.7 Chemotherapy orders include at least the following elements: (Replaces 11)

   3.7.1 The patient’s name
   3.7.2 A second patient identifier
   3.7.3 Date the order is written
   3.7.4 Regimen or protocol name and number
   3.7.5 Cycle number and day when applicable
   3.7.6 All medications within the order set are listed using full generic names
   3.7.7 Drug dose is written following standards for abbreviations, trailing zeros, and leading zeros
   3.7.8 The dose calculation, including:
     3.7.8.1 The calculation methodology
     3.7.8.2 The variables used to calculate the dose
     3.7.8.3 The frequency that the variables are re-evaluated
     3.7.8.4 The changes in the values that prompt confirmation of dosing
   3.7.9 Date of administration
   3.7.10 Route of administration
   3.7.11 Allergies
   3.7.12 Supportive care treatments appropriate for the regimen (including pre-medications, hydration, growth factors, and hypersensitivity medications)
   3.7.13 Parameters that would require holding or modifying the dose (e.g. lab values, diagnostic test results, patient’s clinical status)
   3.7.14 Sequencing of drug administration when applicable
   3.7.15 Rate of drug administration when applicable
   3.7.16 An explanation of time limitation, such as number of cycles that the order is valid for. (Replace 13)

3.8 Prescriptions for oral chemotherapy whether to be dispensed by the healthcare setting or another facility include the following elements: (Replaces 12)

   3.8.1 The patient’s name
   3.8.2 A second patient identifier
3.8.3 Full generic drug name
3.8.4 Date of order
3.8.5 Drug dose, following standards for abbreviations, symbols and dose designations
3.8.6 Includes calculation methodology
3.8.7 Route of administration, special instructions (if applicable)
3.8.8 Drug quantity to be dispensed
3.8.9 Schedule of administration
3.8.10 Duration of therapy, and an explanation of time limitation, such as number of cycles
3.8.11 Number of refills, with zero being the acceptable default value

3.9 Chemotherapy is prepared by a pharmacist, pharmacy technician, physician or registered nurse with documented chemotherapy preparation education, training and annual competency validation (Replace 1b)

3.10 A licensed pharmacist verifies all orders prior to administration/dispensing of chemotherapy in healthcare setting that treat pediatric patients under the age of 18. (new addition)

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

3.11.1 Prior to preparation, a second person (a practitioner or other personnel approved by the practice/institution to prepare or administer chemotherapy) independently verifies: (Replace 15)

3.11.1.1 Two patient identifiers
3.11.1.2 Drug name
3.11.1.3 Drug dose
3.11.1.4 Route of administration
3.11.1.5 Rate of administration
3.11.1.6 The calculation for dosing (including the variables used in this calculation)
3.11.1.7 Treatment cycle and day of cycle

3.11.2 Upon preparation, a second person approved by the healthcare setting to prepare parenteral chemotherapy verifies: (New addition)

3.11.2.1 The drug vial(s)
3.11.2.2 Concentration
3.11.2.3 Drug volume or weight
3.11.2.4 Diluent type and volume (when applicable)
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3.11.2.5 Administration fluid type, volume, and tubing

3.11.3 Before each chemotherapy administration, at least two practitioners approved by the practice to administer or prepare chemotherapy verify and document the accuracy of the following elements: (Replaces 21B)
   3.11.3.1 Drug name
   3.11.3.2 Drug dose
   3.11.3.3 Infusion volume or drug volume when prepared in a syringe
   3.11.3.4 Rate of administration
   3.11.3.5 Route of administration
   3.11.3.6 Expiration dates/times
   3.11.3.7 Appearance and physical integrity of the drugs
   3.11.3.8 Rate set on infusion pump, when utilized

3.12 Chemotherapy drugs are labeled immediately upon preparation and labels include the following 10 elements at a minimum (Replace 16)
   3.12.1 Patient’s name
   3.12.2 A second patient identifier
   3.12.3 Full generic drug name
   3.12.4 Drug dose
   3.12.5 Drug administration route
   3.12.6 Total volume required to administer the drug
   3.12.7 Date the medication is to be administered
   3.12.8 Expiration dates/times
   3.12.9 Sequencing of drug administration when applicable and total number of products to be given when medication is provided in divided doses (each product should be labeled with the total number of products to be administered and the individual products sequence within that total grouping, e.g. 1 of 5, 2 of 2, etc.)
   3.12.10 A warning or precautionary label/sticker as applicable to storage and handling (may be included within the label or on an auxiliary label)

3.13: Labels for medications dispensed from healthcare setting to be taken at home include: (new)
   3.13.1 Patient’s name
   3.13.2 A second patient identifier
3.13.3 Date of preparation and expiration
3.13.4 Full generic drug name
3.13.5 **Dosage** form and strength
3.13.6 Quantity dispensed within each container
3.13.7 Number of pills per dose when the container holds more than one dose
3.13.8 Administration schedule, including number of times per day and days on and off treatment when applicable
3.13.9 Administration instructions related to food ingestion and other medications
3.13.10 A warning or precaution statement as applicable to storage and handling
3.13.11 Caution statement label attached to the prepared product (e.g., “caution: chemotherapy” or HAZARDOUS DRUG)
3.13.12 Storage conditions
3.13.13 Prescriber name

3.14 The healthcare setting that administers intrathecal medication maintain policy specifying that intrathecal medication is: *(Replaces 17)*

3.14.1 Prepared separately
3.14.2 Stored in an isolated container or location after preparation
3.14.3 Labeled with a uniquely identifiable intrathecal medication label.
3.14.4 Delivered to the patient only with other medication intended for administration into the central nervous system.
3.14.5 Administered immediately after a time out double check procedure involving two licensed individuals

3.15 The healthcare setting that administers intrathecal chemotherapy has a policy that specifies that intravenous vinca alkaloids are given only by infusion (e.g., mini-bags) in healthcare settings in which intrathecal medications are administered. *(new)*

3.16 If the healthcare setting administers chemotherapy that is prepared (mixed) off site, the healthcare setting maintains a policy for quality control of that chemotherapy including documentation certifying that the offsite pharmacy complies with all applicable regulatory requirements. *(Replaces 7)*

3.17 If a healthcare setting maintains its own pharmacy, there is a policy regarding the safe storage of chemotherapy (including separation of look-alike products, sound-a-like products, and agents available in multiple strengths). *(Replaces 8)*
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3.18 Chemotherapy is administered by a physician, physician assistant, registered nurse or advanced practice nurse with documented chemotherapy preparation education, training and (at least) annual competency validation. (Replace 1C)

3.19 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). (Replace 21A)

3.20 At least two individuals, in the presence of the patient, verify the patient identification using at least two identifiers (Replace 21D)

3.20.1 When chemotherapy is administered in a non-healthcare setting by a healthcare provider, a second identifier, such as a driver’s license, is used to verify the patient’s or parent’s identify. (New addition)

3.21 Documentation of chemotherapy administration confirms the verification of the 8 elements of standard 3.11.3 and also includes the patient’s clinical status during and upon completion of treatment. (Replace 21C)

3.22 Extravasation management procedures are defined and align with current literature and guidelines; antidote order sets and antidotes are accessible within the appropriate timeframe. (Replace 22)

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

4.1 The healthcare setting uses standard, disease-specific processes to monitor treatment response has policy that determines the appropriate time interval for regimen-specific laboratory and organ function tests that are based on evidence and national guidelines when available (Replaces 5, 36)

4.2 The healthcare setting has a policy for emergent treatment of patients which aligns with current literature and guidelines and addresses: (Replaces 24)

4.2.1 Availability of appropriate treatment agents

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

4.3 The healthcare setting policy outlines the procedure to complete an initial assessment of patients’ adherence to chemotherapy that is administered outside of the healthcare setting. (Replaces 25)

4.4 The healthcare setting has a policy that requires assessment of each patient’s chemotherapy adherence and toxicity at each clinical encounter to address any issues identified. (Replaces 35 & 33)

4.5 The healthcare setting has a policy that requires evaluation and documentation of treatment-related toxicities, dose modification related to toxicities, and how these are communicated prior to subsequent administration (Replaces 35)

4.6 Cumulative doses of chemotherapy are tracked for agents associated with cumulative toxicity. (Replaces 34)