**DATA SUPPLEMENT**

**TITLE: 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for Pediatric Oncology**

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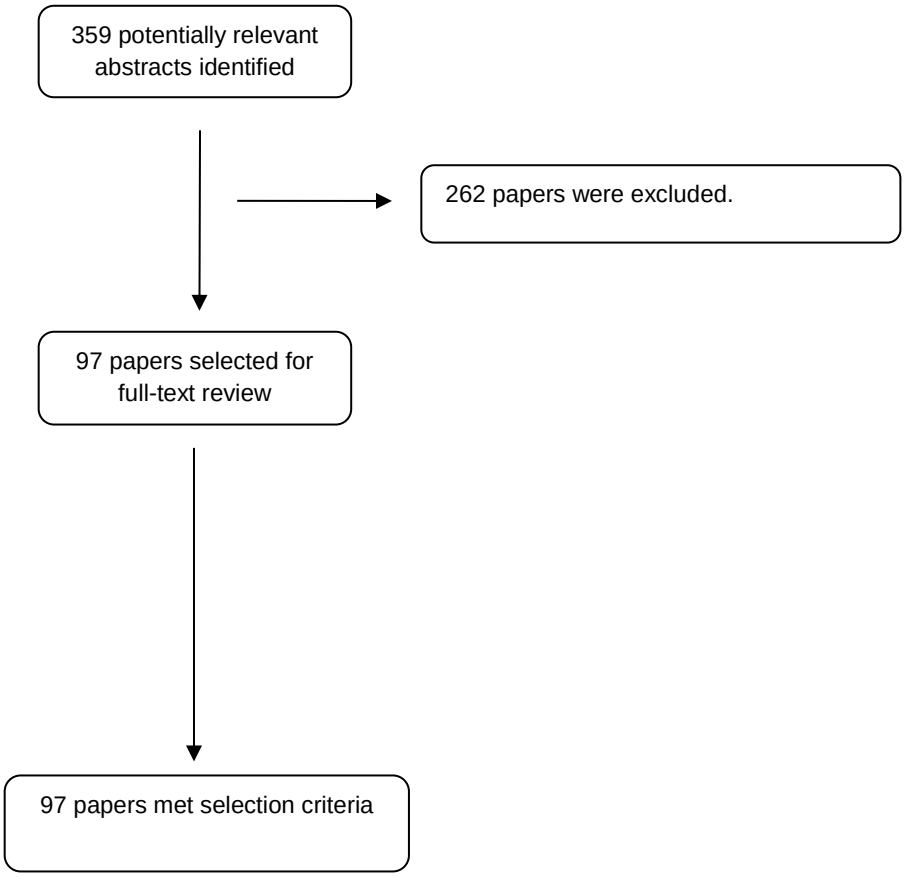
**Data Supplement 1: Search Strategy String and Dates**

A computerized literature search of MEDLINE was performed. The searches of the English-language literature published from March 1, 2013 to March 1, 2016 combined chemotherapy terms with safety and organization and administration terms and MeSH headings.

("neoplasms"[MeSH Terms] OR "neoplasms"[All Fields] OR "cancer"[All Fields]) AND ("drug therapy"[Subheading] OR ("drug"[All Fields] AND "therapy"[All Fields]) OR "drug therapy"[All Fields] OR "chemotherapy"[All Fields] OR "drug therapy"[MeSH Terms] OR ("drug"[All Fields] AND "therapy"[All Fields]) OR "chemotherapy"[All Fields]) AND (("mouth"[MeSH Terms] OR "mouth"[All Fields] OR "oral"[All Fields]) AND intravenous[All Fields]) AND (("safety"[MeSH Terms] OR "safety"[All Fields]) AND ("organization and administration"[MeSH Terms] OR ("organization"[All Fields] AND "administration"[All Fields]) OR "organization and administration"[All Fields] OR "administration"[All Fields]))

**Data Supplement 2: QUORUM Diagram**



**Data Supplement 3: 2016 Update to the ASCO/ONS Standards with 2013 Standard Reference Crosswalk**

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| **Domain 1: Creating a Safe Environment: Staffing and General Policy** | 1. The practice/institution has policies, procedures, and/or guidelines for verification of training and continuing education for clinical staff.<br>1A. Orders for parenteral and oral chemotherapy are written and signed by licensed independent practitioners who are determined to be qualified by the practice/institution according to the practice's/institution's policies, procedures, and/or guidelines<br>1D. The practice/institution has a comprehensive educational program for new staff administering chemotherapy, including a competency assessment, or the practice/institution uses an established educational program regarding chemotherapy administration that ends in competency assessment. Education and competency assessment regarding chemotherapy administration includes all routes of administration used in the practice/institution site (eg, parenteral, oral, intrathecal, intraperitoneal, intravesicular), and safe handling of hazardous chemotherapy agents. An example of an established educational program is the ONS Chemotherapy and Biotherapy Course.<br>1E. The practice/institution has a standard mechanism for monitoring chemotherapy administration competency at specified intervals. | 1 The healthcare setting has policy to document the qualifications of clinical staff who order, prepare, and administer chemotherapy and documents: (Replaces standards 1A, 1D, 1E)<br>1 Description of initial educational requirements and competencies<br>1.1.2 Description of (at least) annual ongoing continuing education requirements<br>3 Description of credentialing processes (licensed independent practitioners (LIPs)) and how credentialing is documented.<br>4 Description of competency demonstration and how competency is documented.<br>1.2 The healthcare setting uses a comprehensive education program for initial and ongoing educational requirements for all staff who prepare and administer chemotherapy. (Replaces 1D, 1E) |
| | 1F. There must be at least one clinical staff member who maintains current certification in basic life support on site during chemotherapy administration in the health care setting. Certification should be from a nationally accredited course. Clinical staff includes staff involved in patient care; RNs, MDs, NPs, etc. | 1. 3 At least one clinical staff member who maintains current certification in (age appropriate) basic life support is present during chemotherapy administration (Replaces 1F) |
| | 23. A licensed independent practitioner is on site and immediately available during all chemotherapy administration in licensed infusion centers and acute care settings. A licensed practitioner must be on site for the initiation of first doses of parenteral chemotherapy and should remain available throughout the administration unless the patient is transitioned | 1.4 A licensed independent practitioner is on-site and immediately available to staff administering chemotherapy in the healthcare setting (Replaces 23) |

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| | to a home care or nonacute facility. Patients/caregivers are educated in procedures for unplanned events and circumstances when subsequent doses are administered in either a home care or nonacute facility | |
| | . Before the first administration of a new chemotherapy regimen, chart documentation available to the practice/institution includes:<br>A. Pathologic confirmation or verification of initial diagnosis. If original pathology report is unobtainable, note of explanation is in chart or a reference to primary source pathology. This standard does not imply the need to re-biopsy if not clinically necessary.<br>. Initial cancer stage or current cancer status. Cancer stage is defined at diagnosis. Cancer status includes a current description of the patient's disease since diagnosis/staging, if relevant (e.g., recurrence, metastases).<br>C. Complete medical history and physical examination that includes, at minimum, height, weight, pregnancy screening (when applicable), 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.<br>D. Presence or absence of allergies and history of other hypersensitivity reactions.<br>. Documentation of patient's comprehension regarding chemotherapy regimens (and associated medications), including information regarding disease.<br>. Assessment regarding psychosocial concerns and need for support, with action taken when indicated.<br>Documentation of psychosocial concerns may include copy of distress, depression, or anxiety screening form in the chart; patient self-report of distress, depression, or anxiety; or chart documentation regarding patient coping, adjustment, depression, distress, anxiety, emotional status, family support | 5 Before the first administration of a new chemotherapy regimen, chart documentation is available including at least the following eight elements. (Replaces 2 A-I)<br>1 Pathologic confirmation or verification of initial diagnosis<br>1.5.2 Initial cancer stage, or current cancer status<br>3 Complete medical history and physical examination including pregnancy status, as applicable<br>4 Presence or absence of allergies and history of hypersensitivity reactions<br>1.5.5 Assessment of the patient's and/or caregiver's comprehension of information regarding the disease and the treatment plan<br>6 Initial psychosocial assessment, with action taken when indicated.<br>7 The chemotherapy treatment plan, including at a minimum, the patient diagnosis, drugs, doses, duration of treatment, and goals of therapy<br>8 The planned frequency of office visits and patient monitoring that is appropriate for the individual antineoplastic agent(s) |

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| | and care giving, coping style, cultural background, and socioeconomic status.<br>. The chemotherapy treatment plan, including, at minimum, chemotherapy drugs, doses, anticipated duration, and goals of therapy.<br>. For oral chemotherapy, the frequency of office visits and monitoring that is appropriate for the individual and the antineoplastic agent and is defined in the treatment plan.<br>I. Before initiation of an oral chemotherapy regimen, assessment of the patient's ability to obtain the drug and administer it according to the treatment plan is documented, along with a plan to address any identified issues. Assessment includes socioeconomic, psychosocial, financial, administrative and regulatory factors that may influence initiation and/or adherence to prescribed regimen. | |
| | 26. On each clinical visit or day of treatment during chemotherapy administration, staff:<br>. Assess and document clinical status and/or performance status<br>B. Document vital signs and weight<br>. Verify allergies, previous reactions, and treatment-related toxicities | 6 On each clinical encounter, staff performs and documents a patient assessment that includes at least the following 8 elements, and takes appropriate action. (Replaces 26)<br>1.6.1 Functional status and/or performance status<br>1.6.2 Vital signs<br>1.6.3 Weight is measured, at least weekly, when present in the healthcare setting.<br>1.6.4 Height is measured at least weekly, when present in the healthcare setting, when appropriate to the treatment population.<br>1.6.5 Age as appropriate to the treatment population.<br>1.6.6 Allergies, previous treatment related reactions<br>1.6.7 Treatment toxicities<br>1.6.8 Pain assessment |
| | 26D. Assess and document psychosocial concerns and need for support, taking action when indicated<br>This standard applies to all clinical encounters (including each inpatient day, practitioner visits, and chemotherapy administration visits, but not laboratory or administrative visits). | 1.7 Staff assesses and document psychosocial concerns and need for support with each cycle or more frequently as indicated, with action taken when indicated. (replaces 26D) |
| | 28. The practice/institution maintains referral resources for psychosocial and other supportive care services | 1.8 The healthcare setting provides information and financial resources and/or refers patients to psychosocial and other cancer support services. (Replaces 28) |

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| | 27. At each clinical encounter, staff review and document the patient's current medications, including over-the-counter medications and complementary and alternative therapies. Any change in the patient's medications prompts a review for drug-drug interactions. This standard applies to all clinical encounters (including each inpatient day, practitioner visits, and chemotherapy administration visits, but not laboratory or administrative visits) | 1.9 The patient's medications are updated at every visit and reviewed by a practitioner when a change occurs. (Replaces 27) |
| | 29. The practice/institution has a procedure for documentation and follow-up for patients who miss or cancel scheduled visits and/or chemotherapy treatments. | 1.10 The healthcare setting has policy for documentation and follow-up for patients who miss or cancel scheduled visits and/or chemotherapy treatments. (Replaces 29)<br>1.10.1 The healthcare setting has policy addressing mandates and processes for pediatric patients which account for legal requirements. (New addition) |
| | 31. The practice/institution has policies and procedures that identify:<br>A. A process to provide 24/7 triage to a practitioner (eg, on-call practitioner, emergency department) for care of toxicities | 1.11 The healthcare setting has policy that identifies a process to provide 24/7 triage to a practitioner (e.g., on-call practitioner, 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 provider and the opportunity for transfer of the patient to a facility with dedicated oncology services. (Replaces 31). |
| | B. Consistent documentation and communication of toxicities, modifications in dose or schedule, or discontinuation of treatment, within the practice/institution | 1.12 The healthcare setting has a policy for standardized documentation and communication of toxicities, modifications in dose or schedule, or discontinuation of treatment. (Replaces 31B) |
| | 32. The practice/institution has a system in place to promote a safe handoff between all sites of care, including evaluating and communicating appropriateness of, and schedule for, chemotherapy administration in another setting. | 1.13 The healthcare setting has standardized and clearly defined systems in place to promote a safe handoff between all sites of care, including provide timely, accurate information about a patient's care plan, treatment including schedule for chemotherapy administration, safety concerns including critical lab values, current condition and any recent or anticipated changes. (Replaces 32) |

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| | *Standard 37 was published in a journal correction to the Journal of Oncology Practice in September, 2013, http://jop.ascopubs.org/content/9/5/265.full:*<br>37. The practice/institution encourages the reporting of errors and near misses and has a formal process in place for evaluating the data. Error and near-miss reports are reviewed and evaluated at least semiannually. | 1.14 The healthcare setting has a policy for reporting of adverse events and near misses and has a formal process for collecting and evaluating the data at a defined frequency. (Replaces 37) |
| **Domain 2: Treatment Planning, Patient Consent and Education** | 6. The practice/institution maintains a policy for how informed consent is obtained and documented for chemotherapy. The practice/institution may provide options for consent (eg, use of chart documentation of patient consent or a signed patient consent form) that allow for variation among practitioners in the practice/institution. | 2.1 The healthcare setting has a policy documenting a standardized process for obtaining and documenting chemotherapy consent or assent (Replaces 6) |
| | 19. Informed consent for chemotherapy must be documented prior to initiation of a chemotherapy regimen. The consent process should follow appropriate professional and legal guidelines. For more information and sample forms, see http://www.asco.org/consent. | 2.2 Informed consent and assent (optional) for chemotherapy treatment, as appropriate to the treatment population, is documented prior to initiation of a chemotherapy regimen. (Replaces 19) |
| | 18. Before initiation of a chemotherapy regimen, each patient is given written documentation, including, at minimum:<br>A. Information regarding his or her diagnosis<br>B. Goals of therapy<br>C. Planned duration of chemotherapy, drugs, and schedule<br>. Information on possible short- and long-term adverse effects, including infertility risks<br>E. Regimen- or drug-specific risks or symptoms that require notification and emergency contact information, including:<br>• How to contact the practice or organization<br>• Symptoms that should trigger a call<br>• Who should be called in specific circumstances (oncologist or other provider)<br>F. Plan for monitoring and follow-up, including appointments with practitioners or laboratory testing<br>Patient education materials should be appropriate for the patient's reading level/literacy and patient-caregiver | 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)<br>1 Patient's diagnosis<br>2 Goals of treatment [i.e. cure disease, prolong life, or reduce symptoms]<br>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<br>4 Potential long and short term side effects of therapy, including infertility risks<br>5 Symptoms or side effects that require the patient to contact the healthcare setting or seek immediate attention |

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| | understanding. Documentation should include patient feedback reflecting understanding and engagement.<br>20. All patients who are prescribed oral chemotherapy are provided written or electronic patient education materials about the oral chemotherapy before or at the time of prescription.<br>A. Patient education includes:<br>•The storage, handling, preparation, administration, and disposal of oral chemotherapy<br>• Concurrent cancer treatment and supportive care medications/measures (when applicable)<br>•Possible drug/drug and drug/food interactions 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. Documentation should include patient feedback reflecting understanding and engagement.<br>•The plan for missed doses<br>14. The practice/institution maintains procedures for communicating discontinuation of oral chemotherapy, including patient education regarding time to stop treatment, and patient education regarding disposal of remaining medication. In certain circumstances, it may be appropriate to alert the dispensing pharmacy when the oral chemotherapy is discontinued. | 2.3.6 Symptoms or events that require immediate discontinuation of oral or other self-administered treatments<br>7 Procedures for handling medications in the home, including storage, safe handling, and management of unused medication (replaces 14).<br>2.3.8Procedures for handling body secretions and waste in the home (new additions)<br>9 Follow-up plans including laboratory and provider visits<br>10 The healthcare setting's contact information with availability and instructions on when and whom to call<br>11 The healthcare setting's missed appointment policy and expectations for rescheduling or cancelling |
| | 20B. The education plan 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. Documentation should include patient feedback reflecting understanding and engagement. | 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. The practice/institution:<br>. Defines standard chemotherapy regimens by diagnosis with references readily available, and/or | 3.1 The healthcare setting defines standard chemotherapy regimens by diagnosis with references. (Replaces 3A) |

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| | B. Identifies source(s) for chemotherapy regimens, including local or centralized institutional review board–approved clinical research protocols or guidelines. | 3.2 The healthcare setting verifies Institutional Review Board approval of research regimens (Replaces 3B) |
| | . The practice/institution has policies, procedures, and/or guidelines for verification of training and continuing education for clinical staff.<br>. Orders for parenteral and oral chemotherapy are written and signed by licensed independent practitioners who are determined to be qualified by the practice/institution according to the practice's/institution's policies, procedures, and/or guidelines. | 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) |
| | 4. For orders that vary from standard chemotherapy regimens, practitioners provide a supporting reference. Reasons for dose modification or exception orders are documented. Exception orders may include notation that standard treatment is contraindicated as a result of pre-existing comorbidity, organ dysfunction, or prior therapy | 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)<br>3.4.1 The rationale for an exception order is documented in the medical record. |
| | 9. The practice/institution does not allow verbal orders except to hold or stop chemotherapy administration. New orders or changes to orders, including changes to oral chemotherapy regimens (eg, dose adjustments communicated directly to patients), are documented in the medical record. Fax and e-mail orders are considered written orders. | 3.5 The healthcare setting has a policy for chemotherapy orders that ensure: (Replaces 9)<br>1 Verbal orders are not allowed except to hold or stop chemotherapy administration. (9)<br>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) |
| | 10. The practice/institution maintains and uses standardized, regimen-level, preprinted or electronic forms for parental chemotherapy prescription writing.<br>Standardized forms may be incorporated into e-prescribing software or electronic health records. | 3.6 The healthcare setting uses standardized, regimen-level, preprinted or electronic forms for parenteral chemotherapy. (Replaces 10) |
| | 11. Order forms inclusively list all chemotherapy agents in the regimen and their individual dosing parameters. All medications within the order set are listed using full generic names and follow Joint Commission standards regarding abbreviations. Brand names should be included in orders only where there are | 3.7 Chemotherapy orders include at least the following elements: (Replaces 11)<br>3.7.1 The patient's name<br>3.7.2 A second patient identifier<br>3.7.3 Date the order is written |

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| | multiple products or when including the brand name otherwise assists in identifying a unique drug formulation.<br>Complete orders must include:<br>. Patient's full name and a second patient identifier (eg, medical record number, DOB)<br>B. Date<br>C. Diagnosis<br>D. Regimen name and cycle number<br>E. Protocol name and number (if applicable)<br>Appropriate criteria to treat (eg, based on relevant laboratory results and toxicities)<br>G. Allergies<br>. Reference to the methodology of the dose calculation or standard practice equations (eg, calculation of creatinine clearance)<br>. Height, weight, and any other variables used to calculate the dose<br>J. Dosage<br>K. Doses do not include trailing zeros; use a leading zero for doses < 1 mg.<br>L. Route and rate (if applicable) of administration<br>M. Length of infusion (if applicable)<br>N. Supportive care treatments appropriate for the regimen (including premedications, hydration, growth factors, and hypersensitivity medications)<br>O. Sequence of drug administration (if applicable)<br>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.<br>13. Orders for parenteral/oral chemotherapy should be written with a time limitation to ensure appropriate evaluation at predetermined intervals. | 4 Regimen or protocol name and number<br>3.7.5 Cycle number and day when applicable<br>3.7.6 All medications within the order set are listed using full generic names<br>7 Drug dose is written following standards for abbreviations, trailing zeros, and leading zeros<br>3.7.8 The dose calculation, including:<br>1 The calculation methodology<br>3.7.8.2 The variables used to calculate the dose<br>3.7.8.3 The frequency that the variables are re-evaluated<br>3.7.8.4 The changes in the values that prompt confirmation of dosing<br>9 Date of administration<br>3.7.10 Route of administration<br>3.7.11 Allergies<br>12 Supportive care treatments appropriate for the regimen (including pre-medications, hydration, growth factors, and hypersensitivity medications)<br>13 Parameters that would require holding or modifying the dose (e.g. lab values, diagnostic test results, patient's clinical status)<br>3.7.14 Sequencing of drug administration when applicable<br>3.7.15 Rate of drug administration when applicable<br>16 An explanation of time limitation, such as number of cycles that the order is valid for. (Replaces 13) |

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| | 12. Complete prescriptions for oral chemotherapy include:<br>. Patient's full name and a second patient identifier (eg, medical record number, DOB<br>B. Drug name<br>C. Date<br>. Reference to methodology of dose calculation, height, weight and other variables (as applicable)<br>E. Dosage<br>F. Quantity to be dispensed<br>G. Doses may be rounded to the nearest tablet size or specify alternating doses each day to obtain the correct overall dosage. Doses do not include trailing zeros; use a leading zero for doses < 1 mg<br>H. Route and frequency of administration<br>I. Duration of therapy number of days of treatment (if the medication is not to be taken continuously)<br>J. Number of refills (including none)<br>Practices/institutions are not expected to be in full compliance with this standard if they currently have electronic ordering systems or electronic prescribing systems that prevent compliance. Appropriate changes should be implemented as soon as possible to ensure that electronic ordering or prescribing systems integrate all of these elements. If the information cannot be captured in the electronic system, it should be documented within the patient record. | 3.8 Prescriptions for oral chemotherapy whether to be dispensed by the healthcare setting or another facility include the following elements: (Replaces 12)<br>1 The patient's name<br>3.8.2 A second patient identifier<br>3.8.3 Full generic drug name<br>3.8.4 Date of order<br>5 Drug dose, following standards for abbreviations, symbols and dose designations<br>3.8.6 Includes calculation methodology<br>7 Route of administration, special instructions (if applicable)<br>3.8.8 Drug quantity to be dispensed<br>3.8.9 Schedule of administration<br>10 Duration of therapy, and an explanation of time limitation, such as number of cycles<br>11 Number of refills, with zero being the acceptable default value |
| | 1B. Chemotherapy drugs (oral or parenteral) are prepared by a pharmacist, pharmacy technician, or nurse determined to be qualified according to the practice's policies, procedures, and/or guidelines. | 3.9 Chemotherapy is prepared by a licensed 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 treats pediatric patients under the age of 18. (new addition) |
| | 15. A second person (a practitioner or other personnel approved by the practice/institution to prepare or administer | 3.11 A second person (a practitioner or other personnel approved by the practice/institution to prepare or |

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| | chemotherapy) independently verifies each order for chemotherapy before preparation, including confirming:<br>A. Two patient identifiers<br>B. Drug names<br>C. Drug dose<br>D. Drug volume<br>E. Route of administration<br>F. Rate of administration<br>G. The calculation for dosing (including the variables used in this calculation)<br>H. Treatment cycle and day of cycle<br><br>21 Before chemotherapy administration:<br>B. At least two practitioners or personnel approved by the practice/institution to prepare or administer chemotherapy, verify the accuracy of:<br>• Drug name<br>• Drug dose<br>• Drug volume<br>• Rate of administration<br>• Expiration dates/times, if applicable; expiration date/time is not required if for immediate use (Immediate use must be defined by institutional policy, state, federal regulations, eg, use within 2 h)<br>• Appearance and physical integrity of the drugs<br>• Rate set on infusion pump, when utilized | administer chemotherapy) performs three independent verifications:<br>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)<br>1 Two patient identifiers<br>3.11.1.2 Drug name<br>3.11.1.3 Drug dose<br>3.11.1.4 Route of administration<br>3.11.1.5 Rate of administration<br>6 The calculation for dosing (including the variables used in this calculation)<br>3.11.1.7 Treatment cycle and day of cycle<br>3.11.2 Upon preparation, a second person approved by the healthcare setting to prepare parenteral chemotherapy verifies: (New addition)<br>3.11.2.1 The drug vial(s) 3.11.2.2 Concentration 3.11.2.3 Drug volume or weight<br>3.11.2.4 Diluent type and volume , when applicable<br>3.11.2.5 Administration fluid type, volume, and tubing<br>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)<br>3.11.3.1 Drug name<br>3.11.3.2 Drug dose<br>3 Infusion volume or drug volume when prepared in a syringe<br>3.11.3.4 Rate of administration<br>3.11.3.5 Route of administration<br>3.11.3.6 Expiration dates/times<br>3.11.3.7 Appearance and physical integrity of the drugs<br>3.11.3.8 Rate set on infusion pump, when utilized |

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| | 16. Chemotherapy drugs are labeled immediately upon preparation, including, at minimum:<br>. Patient's full name and a second patient identifier (eg, medical record number, DOB)<br>B. Full generic drug name<br>C. Drug administration route<br>D. Total dose to be given<br>E. Total volume required to administer this dosage<br>F. Date of administration<br>G. Date and time of preparation<br>. Date and time of expiration when not for immediate use Immediate use must be defined by institutional policy, state, and federal regulations (eg, use within 2 h)<br>I. Special handling instructions as appropriate<br>J. Administration instructions (oral agents)<br>K. Number of refills (oral agents)<br>L. Prescriber name (oral agents)<br>Practices/institutions are not expected to be in full compliance with this standard if they currently have electronic systems that are unable to meet these labeling requirements. Appropriate changes should be implemented as soon as possible to ensure that electronic labels integrate all of these elements. | 2 Chemotherapy drugs are labeled immediately upon preparation and labels include the following 10 elements at a minimum (Replaces 16)<br>1 Patient's name<br>3.12.2 A second patient identifier<br>3.12.3 Full generic drug name<br>3.12.4 Drug dose<br>3.12.5 Drug administration route<br>3.12.6 Total volume required to administer the drug<br>3.12.7 Date the medication is to be administered<br>3.12.8 Expiration dates/times<br>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.)<br>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 addition)<br>3.13.1 Patient's name<br>3.13.2 A second patient identifier 3.13.3 Date of preparation and expiration 3.13.4 Full generic drug name<br>5 Dosage form and strength<br>3.13.6 Quantity dispensed within each container<br>7 Number of pills per dose when the container holds more than one dose<br>8 Administration schedule, including number of times per day and days on and off treatment when applicable |

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| | | 9 Administration instructions related to food ingestion and other medications<br>10 A warning or precaution statement as applicable to storage and handling<br>11 Caution statement label attached to the prepared product (e.g. “caution: chemotherapy” or HAZARDOUS DRUG)<br>12 Storage conditions<br>3.13.13 Prescriber name |
| | 17. Practices/institutions that administer intrathecal medication maintain policies specifying that intrathecal medication will:<br>A. Not be prepared during preparation of any other agents<br>B. Be stored, once prepared, in an isolated container or location with a uniquely identifiable intrathecal medication label<br>C. Be delivered to the patient only with other medication intended for administration into the CNS | 4 The healthcare setting that administer intrathecal medication maintain policy specifying that intrathecal medication is: (Replaces 17)<br>3.14.1 Prepared separately<br>3.14.2 Stored in an isolated container or location after preparation<br>3 Labeled with a uniquely identifiable intrathecal medication label.<br>3.14.3 Delivered to the patient only with other medication intended for administration into the central nervous system.<br>3.14.5 Administered immediately after a time out double check procedure involving two licensed practitioners or other personnel approved by the practice/institution to prepare or administer chemotherapy. |
| | | 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 addition) |
| | 7. If the practice/institution administers chemotherapy that is prepared (mixed) off site, the practice/institution maintains a policy for quality control of that chemotherapy. | 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 that the offsite pharmacy complies with all applicable regulatory requirements. (Replaces 7) |

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| | 8. If practice/institution manages its own pharmacy, the practice/institution has a policy regarding the storage of chemotherapy (including separation of look-alike products, sound-a-like products, and agents available in multiple strengths). Chemotherapy is stored in a designated area according to regulatory guidelines. | 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) |
| | 1C. Only qualified physicians, physician assistants, advanced practice nurses, or registered nurses administer chemotherapy | 3.18 Chemotherapy is administered by a qualified physician, physician assistant, registered nurse or advanced practice nurse as defined in standard 1.1. (Replace 1C) |
| | 21. Before chemotherapy administration:<br>A. A practitioner who is administering the chemotherapy confirms with the patient his/her planned treatment prior to each cycle | 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) |
| | 21D. At least two individuals, in the presence of patient, verify the patient identification using at least two identifiers (eg, medical record number, DOB) | 3.20 At least two individuals, in the presence of the patient, verify the patient identification using at least two identifiers (Replace 21D)<br>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) |
| | C. A practitioner who is administering the chemotherapy documents that the verification in B was done. | 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) |
| | 22. Extravasation management procedures are defined and align with current literature and guidelines; antidote order sets and antidotes are accessible. | 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. (Replaces 22) |

| Standard | 2013 | 2016 |
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| **Domain 4: Monitoring after chemotherapy is given, including adherence, toxicity and complications** | 5. The practice/institution maintains written statements that determine the appropriate time interval for regimen-specific laboratory tests that are:<br>A. Evidence based when national guidelines exist (eg, American Society of Clinical Oncology or National Comprehensive Cancer Network guidelines), or<br>B. Determined by practitioners at the site.<br>Documentation of regimen-specific laboratory tests may be part of standardized regimen orders.<br>36. The practice/institution uses standard, disease-specific processes to monitor treatment response (eg., use of evaluations, laboratory results, or scans/imaging) that are based on published literature/guidelines or are determined by the practice/institution. | 4.1 The healthcare setting uses standard, disease-specific processes to monitor treatment response and 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) |
| | 24. The practice/institution maintains protocols for response to life-threatening emergencies, including escalation of patient support beyond basic life support.<br>It is recommended that emergency protocols be reviewed annually. | 4.2 The healthcare setting has a policy for emergent treatment of patients which aligns with current literature and guidelines and addresses: (Replaces 24)<br>4.2.1 Availability of appropriate treatment agents<br>4.2.2 Procedures to follow and a plan for escalation of care when required for life threatening emergencies |
| | 25. The practice/institution maintains a written policy and/or procedure to complete an initial assessment of patients' adherence to oral chemotherapy. The policy must include a plan for clinical staff to address any issues identified within a time frame appropriate to the patient and regimen. Examples of assessment for adherence to an oral chemotherapy treatment plan include:<br>•Confirmation that the patient filled the prescription as written<br>• Inquiry regarding concerns about treatment costs •<br>Verification that the patient understands how to take the prescribed oral chemotherapy (eg, frequency, with/without food, whole or crushed, etc)<br>•Verification that the patient understands what to do in case of missed doses<br>• Assessment for potential toxicity | 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) |

| Standard | 2013 | 2016 |
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| | 33. Toxicity assessment documentation is available for planning subsequent treatment cycles.<br>35. The practice/institution maintains a plan for ongoing and regimen-specific assessment of each patient's oral chemotherapy adherence and toxicity. The policy includes, at minimum, patient assessment for adherence and toxicity at each clinical encounter at the practice/institution, as well as a plan for clinical staff to address any issues identified. | 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 33 & 35) |
| | 35. The practice/institution maintains a plan for ongoing and regimen-specific assessment of each patient's oral chemotherapy adherence and toxicity. The policy includes, at minimum, patient assessment for adherence and toxicity at each clinical encounter at the practice/institution, as well as a plan for clinical staff to address any issues identified | 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) |
| | 34. The practice/institution has a process to track cumulative doses of chemotherapy agents associated with a risk of cumulative toxicity. | 4.6 Cumulative doses of chemotherapy are tracked for agents associated with cumulative toxicity. (Replaces 34) |
| | 30. The practice/institution evaluates and documents treatment-related toxicities using standard definitions or criteria selected by that practice/institution. Examples include NCI Common Toxicity Criteria and WHO Toxicity Criteria. | (Standard deleted and incorporated into 4.4) |
| *Table courtesy of Michelle L. Kopp, MSN, RN, AOCNS, NE-BC, Penn State Hershey Medical Center, Hershey, PA, with edits by K. LeFebvre, ONS staff.* | | |

**Data Supplement 4: Glossary**

| COMMON DEFINITIONS FOR ASCO/ONS CHEMOTHERAPY ADMINISTRATION SAFETY STANDARDS | |
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| **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 Services** | A list of informational, psychosocial and financial resources that is available for cancer support. |
| **Chemotherapy** | All antineoplastic 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. |

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| **Chemotherapy Regimen** | One or more chemotherapeutic agents used alone or in combination in a well-defined protocol or 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:<br><br>1. Diagnosis, including the cancer site, histology and stage<br>2. Goals of therapy (may be specified by the type of template; e.g., adjuvant chemotherapy plan)<br>3. Patient health status and co-morbidities<br>4. Surgical history and notable pathology findings<br>5. Chemotherapy regimen and starting dosages<br>6. Duration of treatment and number of planned cycles<br>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. Education and competency assessment regarding Chemotherapy administration includes all routes of administration used in the practice/institution or home site (e.g., parenteral, oral, intrathecal, intraperitoneal, intravesicular), and safe handling of hazardous chemotherapy agents* 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- |

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| | 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:<br><br>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). All paperwork relating to the patient must include, and be identical in every detail, to the minimum patient identifiers on the identity band. |
| **Immediate Use:** | For the purposes of these Standards, immediate use is defined as “use within 2 hours” in accordance with drug stability, state and federal regulations. |
| **Independent Verification** | Independent verification (IV) is the act of verifying or checking a component's or product’s status or quality independent of the person that established its present state. IV has a higher probability of catching an error than peer-checking or concurrent verification, since the second person is not influenced by the first person and has freedom of thought. IV catches errors after they have been made. The individual performing the IV must physically check the condition without relying on observation or verbal confirmation by the initial performer. True independence requires separation in time and space between the individuals involved to ensure ‘freedom of thought.’<br><br>*Independent verification of Chemotherapy Preparation should include checking the preparation for completeness and accuracy of content, with particular attention given to special preparation instructions. Technology can serve as a surrogate; if practitioners follow procedures in using appropriately developed and applied procedures. Verification may include* |

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| | *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.* |
| **Labels** | The standards (3.12, 3.13) require the labels to include identified elements at a minimum. 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. |
| **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.<br><br>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:<br>• Chronicity<br>• Severity<br>• Quality<br>• Contributing/associated factors<br>• Location/distribution or etiology of pain, if identifiable<br>• Barriers to pain assessment |
| **Parenteral** | Introduction of substances by intravenous, intra-arterial, subcutaneous, intramuscular, intrathecal, or intra-cavitary routes. |

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| **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. |