

# American Society of Clinical Oncology / Oncology Nursing Society Chemotherapy Administration Safety Standards

| <b>Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards</b>              |   |
|--|---|
| <b>Term</b>  | <b>Definition</b>   |
| <b>Chemotherapy</b>  | All antineoplastic agents used to treat cancer, given through oral and paraneural 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 |
| <b>Chemotherapy regimen</b>  | One or more chemotherapeutic agents used alone or in combination in a well-defined protocol, generally administered cyclically  |
| <b>Practitioner</b>  | Licensed independent practitioner, including physicians, advanced practice nurses (nurse practitioner or clinical nurse specialist), and/or physician assistants, as determined by state law  |
| <b>Outpatient chemotherapy setting (site)</b>  | Any non-inpatient treatment setting, with the exclusion of home infusion services   |
| <b>Abbreviations: ASCO, American Society of Clinical Oncology; ONS, Oncology Nursing Society</b> |   |

# ASCO/ONS Chemotherapy Administration Safety Standards

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### Standards

#### Staffing-Related Standards

1. The practice has policies, procedures, and/or guidelines for verification of training and continuing education for clinical staff.
  - A. Orders for parenteral and oral chemotherapy are written and signed by licensed independent practitioners who are determined to be qualified by the practice according to the practice's policies, procedures, and/or guidelines.
  - B. 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.
  - C. Only qualified physicians, physician assistants, advanced practice nurses, or registered nurses administer chemotherapy.
  - D. The practice has a comprehensive educational program for new staff administering chemotherapy, including a competency assessment, or the practice uses an off-site educational program regarding chemotherapy administration that ends in competency assessment.

Chemotherapy administration education must include all routes of administration used in the practice site (eg, parenteral, oral, intrathecal, intraperitoneal, intravesicular).

*An example of an off-site educational program is the ONS Chemotherapy and Biotherapy Course.*
  - E. The practice has a standard mechanism for monitoring chemotherapy administration competency at specified intervals.

*Annual competency reassessment is recommended.*
  - F. All clinical staff maintains current certification in basic life support.<sup>1,2,4,22-27</sup>

#### Chemotherapy Planning: Chart Documentation Standards

2. Prior to prescribing a new chemotherapy regimen, chart documentation available to the prescriber includes:
  - A. Pathologic confirmation or verification of initial diagnosis

If original pathology report is unobtainable, note of explanation is in chart.  
*This standard does not imply the need to rebiopsy if not clinically necessary.*
  - B. 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 (eg, recurrence, metastases).*
  - C. Complete medical history and physician examination that includes, at minimum, height, weight, 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*
  - D. Presence or absence of allergies and history of other hypersensitivity reactions
  - E. Documentation of patient's comprehension regarding medication regimens, including information regarding disease and self-care
  - F. Assessment regarding psychosocial concerns and need for support

*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 and care giving, coping style, cultural background, and socioeconomic status.*
  - G. The chemotherapy treatment plan, including, at minimum, chemotherapy drugs, doses, duration, and goals of therapy
  - H. For oral chemotherapy, the frequency of office visits and monitoring that is appropriate to the agent and is defined in the treatment plan<sup>1-3,5,6,8,22-24,27-30</sup>

#### General Chemotherapy Practice Standards

3. The practice:
  - A. Defines standard chemotherapy regimens by diagnosis with references readily available, and/or
  - B. Identifies source(s) for chemotherapy regimens, including local or centralized IRB-approved clinical research protocols or guidelines<sup>2,29,31,32</sup>
4. For orders that vary from standard regimens, practitioners provide a supporting reference. Reasons for dose modification or exception orders are documented.<sup>29</sup>

*Exception orders may include notation that standard treatment is contraindicated as a result of pre-existing comorbidity, organ dysfunction, or prior therapy.*
5. The practice maintains written statements that determine the appropriate time interval for regimen-specific laboratory tests that are:
  - A. Evidence-based when national guidelines exist (eg, ASCO or NCCN guidelines), or
  - B. Determined by practitioners at the site<sup>31</sup>

*Documentation of regimen-specific laboratory tests may be part of standardized regimen orders.*
6. The practice maintains a policy for how informed consent is obtained and documented for chemotherapy.<sup>33</sup>

*The practice 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.*
7. If the practice site administers chemotherapy that is prepared (mixed) off-site, the practice site maintains a policy for quality control of that chemotherapy.<sup>1,34</sup>

#### Chemotherapy Order Standards

8. The practice does not allow verbal orders except to hold or stop chemotherapy administration. New orders or changes to orders must be made in writing.<sup>3,27</sup>

*Fax and e-mail orders are considered written orders.*
9. The practice maintains and uses standardized, regimen-level, preprinted or electronic forms for chemotherapy prescription writing (oral and parenteral).<sup>14,15</sup>

*Standardized forms may be incorporated into e-prescribing software or electronic health records.*
10. 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 multiple products or when including the brand name otherwise assists in identifying a unique drug formulation.

# ASCO/ONS Chemotherapy Administration Safety Standards

## ASCO/ONS Chemotherapy Administration Safety Standards (continued)

### Standards

#### Complete orders must include:

- A. Patient's full name and a second patient identifier (eg, medical record number, DOB)
- B. Date
- C. Diagnosis
- D. Regimen name and cycle number
- E. Protocol name and number (if applicable)
- F. Appropriate criteria to treat (eg, based on relevant laboratory results and toxicities)
- G. Allergies
- H. Reference to the methodology of the dose calculation or standard practice equations (eg, calculation of creatinine clearance)
- I. Height, weight, and any other variables used to calculate the dose
- J. Dosage  
Doses do not include trailing zeros; use a leading zero for doses 1 mg.
- K. Route and rate (if applicable) of administration
- L. Schedule
- M. Duration
- N. Cumulative lifetime dose (if applicable)
- O. Supportive care treatments appropriate for the regimen (including premedications, hydration, growth factors, and hypersensitivity medications)
- P. Sequence of drug administration (if applicable)<sup>2,3,14,15,27,29</sup>

Practices 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.

11. Orders for parenteral/oral chemotherapy should be written with a time limitation to ensure appropriate evaluation at predetermined intervals.<sup>8,13</sup> Drug

#### Preparation

12. A second person (a practitioner or other personnel approved by the practice to prepare or administer chemotherapy) independently verifies each order for chemotherapy before preparation, including confirming:
  - A. Two patient identifiers
  - B. Drug names
  - C. Drug dose
  - D. Drug volume
  - E. Rate of administration
  - F. Route of administration
  - G. The calculation for dosing (including the variables used in this calculation)<sup>2,3,10,28,29</sup>
13. Chemotherapy drugs are labeled immediately upon preparation, including, at minimum:
  - A. Patient's full name and a second patient identifier (eg, medical record number, DOB)
  - B. Full generic drug name
  - C. Drug administration route
  - D. Total dose to be given
  - E. Total volume required to administer this dosage
  - F. Date of administration
  - G. Date and time of preparation and expiration<sup>3,35</sup>Practices 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.
14. Practices that administer intrathecal medication maintain policies specifying that intrathecal medication will:
  - A. Not be prepared during preparation of any other agents
  - B. Be stored, once prepared, in an isolated container or location with a uniquely identifiable intrathecal medication label
  - C. Be delivered to the patient only with other medication intended for administration into the CNS<sup>9</sup>

#### Patient Consent and Education

15. Before initiation of chemotherapy, each patient is given written documentation, including, at minimum:
  - A. Information regarding his/her diagnosis
  - B. Goals of therapy
  - C. Planned duration of chemotherapy, drugs, and schedule
  - D. Information on possible short- and long-term adverse effects
  - E. Regimen- or drug-specific risks or symptoms that require notification and emergency contact information, including:
    - How to use practice call system
    - Symptoms that should trigger a call
    - Who should be called in specific circumstances (oncologist or other provider)
  - F. Plan for monitoring and follow-up<sup>1,3,18,19,28</sup>*Patient education materials should be appropriate for the patient's reading level/literacy and patient/caregiver understanding.*
16. Informed consent for chemotherapy must be documented by a physician in the practice prior to chemotherapy administration.<sup>2,3</sup>  
*The consent process should follow appropriate professional and legal guidelines. (For more information and sample forms, see <http://www.asco.org/consent>.)*
17. 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.
  - A. Patient education includes the preparation, administration, and disposal of oral chemotherapy.
  - B. The education plan includes family, caregivers, or others based on the patient's ability to assume responsibility for managing therapy.<sup>1-3,18,23,24,28</sup>*Patient education materials should be appropriate for the patient's reading level/literacy and patient/caregiver understanding.*

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##### Chemotherapy Administration

18. Before administration, at least two practitioners or personnel approved by the practice to prepare or administer chemotherapy:

- A. Verify patient identification using at least two identifiers (eg, medical record number, DOB)
- B. Confirm with the patient his/her planned treatment, drug route, and symptom management
- C. Verify the accuracy of:

- Drug name
- Drug dose
- Drug volume
- Rate of administration
- Route of administration
- Expiration dates/times
- Appearance and physical integrity of the drugs

D. Sign (in record or electronically) to indicate verification was done<sup>2,8,27</sup>

19. Extravasation management procedures are defined; antidote order sets and antidotes are accessible.<sup>2,28</sup>

20. A licensed independent practitioner is on site and immediately available during all chemotherapy administration.<sup>1-3</sup>

##### Monitoring and Assessment

21. Practice maintains protocols for response to life-threatening emergencies, including escalation of patient support beyond basic life support.<sup>1,29</sup> *It is recommended that emergency protocols are reviewed annually.*

22. On each clinical visit during chemotherapy administration, practice staff assess and document in the medical record:

- A. Changes in clinical status, weight
- B. Changes in performance status
- C. Allergies, previous reactions, and treatment-related toxicities
- D. Patient psychosocial concerns and need for support<sup>29</sup>

*This standard applies to all clinical encounters (practitioner visits and chemotherapy administration visits, but not laboratory or administrative visits).*

23. At each clinical visit during chemotherapy administration, practice staff assess and document the patient's current medications, including over-the-counter medications and complementary and alternative therapies. Any changes in the patient's medications are reviewed by a practitioner during the same visit.<sup>29</sup>

*This standard applies to all clinical encounters (practitioner visits and chemotherapy administration visits, but not laboratory or administrative visits).*

24. The practice maintains a referral list for psychosocial and other supportive care services.<sup>2,30</sup>

25. The practice establishes a procedure for documentation and follow-up for patients who miss office visits and treatments.<sup>17,36</sup>

26. The practice evaluates and documents treatment-related toxicities using standard definitions or criteria selected by that practice.<sup>28,31</sup>

*Examples include NCI Common Toxicity Criteria and WHO Toxicity Criteria.*

27. The practice has policies and procedures that identify:

- A. A process to provide 24/7 triage to a practitioner (eg, on-call practitioner, emergency department) for care of toxicities
- B. Consistent documentation and communication of toxicity across sites of care within the practice (if applicable)<sup>16,27</sup>

28. Toxicity assessment documentation is available for planning subsequent treatment cycles.<sup>10</sup>

29. The practice has a process to track cumulative doses of chemotherapy agents associated with a risk of cumulative toxicity.<sup>13</sup>

30. The practice 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.<sup>1,16</sup>

31. The practice has a process for risk-free reporting of errors or near misses. Error and near-miss reports are reviewed and evaluated at least semiannually.<sup>27,29</sup>

NOTE. Explanatory notes or examples are provided in italics, when applicable. **Disclaimer:** These standards related to patient safety for chemotherapy administration in the ambulatory/outpatient setting were developed jointly by ONS and ASCO using a consensus process. The standards are intended to reflect current thinking on best practices but are not comprehensive and do not account for individual patient variation. It is the responsibility of each administering agent to determine the best methods for chemotherapy administration for each patient. The standards are not medical advice or legal advice. To the extent that the standards conflict with applicable federal, state, or local legal requirements, practitioners should comply with those requirements. The administering agent is solely responsible for, and assumes all risks of, administering chemotherapy drugs notwithstanding any adherence to the standards herein. ASCO and ONS disclaim any and all liability with respect to the standards and the execution of the standards by any party.

Abbreviations: ASCO, American Society of Clinical Oncology; ONS, Oncology Nursing Society; IRB, institutional review board; NCCN, National Comprehensive Cancer Network; DOB, date of birth; NCI, National Cancer Institute.

\*Implementation exception.