



Assess & Improve

Cancer Care in your Hematology-Oncology Practice

QOPI THE QUALITY ONCOLOGY PRACTICE INITIATIVE | CERTIFICATION PROGRAM



QOPI Certification Site Assessment Standards

All standards are from JO Jacobson, MJ Polovich, KK McNiff, et al: *American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards*. J Clin Oncol, 2009

Explanatory notes or examples are provided in italics, when applicable.

❖ Implementation exceptions are noted using this bullet.

Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards

Term	Definition
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.
Chemotherapy regimen	One or more chemotherapeutic agents used alone or in combination in a well-defined protocol, generally administered cyclically
Practitioner	Licensed independent practitioner, including physicians, advanced practice nurses (nurse practitioner or clinical nurse specialist), and/or physician assistants, as determined by state law
Outpatient chemotherapy setting (site)	Any non-inpatient treatment setting, with the exclusion of home infusion services

Staffing-Related Standards

1. 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.

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.

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 practices nurses, or registered nurses administer chemotherapy.

D. 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 (e.g. parenteral, oral, intrathecal, intraperitoneal, intravesicular).

An example of an offsite educational program is the ONS Chemotherapy and Biotherapy Course.

E. Practice has a standard mechanism for monitoring chemotherapy administration competency at specified intervals.

Annual competency re-assessment is recommended.

F. All clinical staff maintains current certification in basic life support.

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 re-biopsy 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 (e.g., 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

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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; chart documentation regarding patient coping, adjustment, depression, distress, anxiety, emotional status, family support and care-giving, coping style, cultural background, 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.

General Chemotherapy Practice Standards

3. The practice maintains a policy for how informed consent is obtained and documented for chemotherapy.

Practice may provide options for consent (e.g., use of chart documentation of patient consent or a signed patient consent form) that allow for variation among practitioners in the practice.

Chemotherapy Order Standards

4. 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.

Complete orders must include:

A. patient full name and a second patient identifier (e.g. 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 (e.g., based on relevant labs and toxicities)

G. allergies

H. reference to the methodology of the dose calculation or standard practice equations (e.g., 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 less than one milligram

K. route and rate (if applicable) of administration

L. schedule

M. duration

N. cumulative lifetime dose (if applicable)

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- O. supportive care treatments appropriate for the regimen (including pre-medications, hydration, growth factors, and hypersensitivity medications)
- P. sequence of drug administration (if applicable)

❖ 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 can not be captured in the electronic system, it should be documented within the patient record.

Drug Preparation

5. A second person (a practitioner or other personnel approved by the practice to prepare or administer chemotherapy) independently verifies each order for chemotherapy prior to 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).

6. Chemotherapy drugs are labeled immediately upon preparation, including at minimum:

- A. patient full name and a second patient identifier (e.g., 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.

❖ 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.

7. 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 central nervous system.

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Chemotherapy Administration

8. Prior to 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 (e.g. 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.

9. Extravasation management procedures are defined; antidote order sets and antidotes are accessible.

Monitoring and Assessment

10. Practice maintains protocols for response to life-threatening emergencies, including escalation of patient support beyond basic life support.

It is recommended that emergency protocols are reviewed annually.

11. 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.

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

12. On 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.

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

13. The practice maintains a referral list for psychosocial and other supportive care services.

14. The practice establishes a procedure for documentation and follow-up for patients who miss office visits and treatments.

15. The practice has policies and procedures that identify:

A. a process to provide 24/7 triage to a practitioner (e.g., on call practitioner, emergency department) for care of toxicities

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| B. consistent documentation and communication of toxicity across sites of care within the practice (if applicable). |
| 16. Toxicity assessment documentation is available for planning subsequent treatment cycles. |
| 17. The practice has a process to track cumulative doses of chemotherapy agents associated with a risk of cumulative toxicity. |

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