2020 QOPI® Certification Standards Comparison

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Certification Standards Overview

- Standards Categorized into Four Domains:
  - Domain 1: Creating A Safe Environment – Staffing and General Policy
    - Defines staff qualifications, minimum chart documentation requirements, defines relevant patient resources, and policies for patient documentation and follow-up.
  - Domain 2: Treatment Planning, Patient Consent and Education
    - Defines requirements for consent and education processes prior to treatment.
  - Domain 3: Ordering, Preparing, Dispensing and Administering Chemotherapy
    - Defines requirements for chemotherapy order set, order verification, labeling and safe handling, and extravasation management procedures.
  - Domain 4: Monitoring After Chemotherapy is Given, Including Adherence, Toxicity and Complications
    - Defines requirements for emergency management, monitoring and care of toxicities, and oral chemotherapy adherence.

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Certification Standards Overview

- Domain → Standard → Element(s)
- 22 Total Standards
  - Policy
  - Process
  - Patient Documentation
- Standards Manual
  - https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program/about-qopi-certification

Standards Comparison

2018-2019 Standards (28 Certification Standards)	New 2020 Standards (22 Certification Standards)
Standard 1.1: Clinical Staff Qualifications Policy	Standard 1.1: Clinical Staff Qualifications Policy
Standard 1.2: Initial Chart Documentation	Standard 1.2: Initial Chart Documentation
Standard 1.3: Documentation at Each Clinical Visit	Standard 1.3: Documentation at Each Clinical Visit
Standard 1.4: Psychosocial Concerns Documentation	Standard 1.4: Psychosocial Concerns Documentation
Standard 1.5: Ancillary Support Services	Standard 1.5: Ancillary Support Services
Standard 1.6: Medication Assessment	Standard 1.6: 24/7 Triage Policy
Standard 1.7: Missed Appointment Follow-Up Policy	Standard 2.1: Patient Consent Policy
Standard 1.8: 24/7 Triage Policy	Standard 2.2: Patient Education Documentation
Standard 2.1: Patient Consent Policy	Standard 3.1: Chemotherapy Orders
Standard 2.2: Informed Consent Documentation	Standard 3.2: Chemotherapy Orders Verification
Standard 2.3: Patient Education Documentation	Standard 3.3: Chemotherapy Preparation Verification
Standard 2.4: Patients' Support Education	Standard 3.4: Drug Labeling
Standard 3.1: Chemotherapy Orders	Standard 3.5: Intrathecal Chemotherapy Preparation Policy
Standard 3.2: Chemotherapy Orders Verification	Standard 3.6: Treatment Plan Confirmation
Standard 3.3: Chemotherapy Preparation Verification	Standard 3.7: Patient Identification Verification
Standard 3.4: Drug Labeling	Standard 3.8: Chemotherapy Administration Verification
Standard 3.5: Intrathecal Chemotherapy Preparation Policy	Standard 3.9: Chemotherapy Administration Documentation
Standard 3.6: Intrathecal Chemotherapy Administration Policy	Standard 3.10: Extravasation Management
Standard 3.7: Treatment Plan Confirmation	Standard 4.1: Emergent Treatment Policy
Standard 3.8: Patient Identification Verification	Standard 4.2: Initial Oral Adherence Assessment Policy
Standard 3.9: Chemotherapy Administration Verification	Standard 4.3: Ongoing Oral Adherence Assessment
Standard 3.10: Chemotherapy Administration Documentation	Standard 4.4: Cumulative Dose Tracking
Standard 3.11: Extravasation Management	
Standard 4.1: Emergent Treatment Policy	
Standard 4.2: Initial Oral Adherence Assessment Policy	
Standard 4.3: Ongoing Oral Adherence Assessment Policy	
Standard 4.4: Toxicity Monitoring Policy	
Standard 4.5: Cumulative Dose Tracking	

Summary of Changes - Domain 1

Standard	Requirement
1.1	The healthcare setting has policies to define the qualifications of clinical staff who order, prepare, and administer chemotherapy.
1.1.2	Chemotherapy is prepared by a licensed pharmacist, pharmacy technician, physician, or registered nurse with documented comprehensive chemotherapy preparation education, initial training, and (at least) annual continuing education and competency validation.
1.1.3	Chemotherapy is administered by a qualified physician, physician assistant, registered nurse or advanced practice nurse with documented comprehensive chemotherapy administration education, initial training, and (at least) annual continuing education and competency validation.
1.2.4	Pregnancy status for women of childbearing age.
1.3.9	Patient's medications are updated and reviewed by a practitioner when a change occurs.

Summary of Changes - Domain 2

Standard	Requirement
2.1	The health care setting has a policy that documents a standardized process for obtaining and documenting chemotherapy consent or assent. Informed consent and assent (optional) is documented prior to initiation of each chemotherapy regimen. The consent process should follow appropriate professional and legal guidelines.
2.2	Patients are provided with comprehensive verbal and written or electronic information as part of an education process before starting each treatment plan.
2.2.1	The education process will be tailored to the patient's learning needs, abilities, preferences, and readiness to learn as assessed and documented prior to treatment. Education includes family, caregivers, or others based on the patient's ability to assume responsibility for managing therapy.
2.2.2	Documentation that written or electronic educational materials were given to patients.

Summary of Changes - Domain 3

Standard	Requirement
3.4.9	When dose is divided, the total number of products to be given and individual product sequence (e.g., 1 of 2, 2 of 2, etc.).
3.5.2	Intravenous vinca alkaloids are administered only by infusion.
3.8.9	Sequencing of drug administration. **Sequencing is now a part of the pre-administration checks when applicable for multi-agent regimens (previously was a requirement on chemo labels).*
3.9	Documentation of the patient's clinical status during and upon completion of treatment.

Summary of Changes - Domain 4

Standard	Requirement
4.2	The health care setting has a policy that outlines the procedure to assess patients' ability to adhere to chemotherapy that is administered outside of the heath care setting prior to the start of treatment. Documentation of assessment is available in the patient record
4.3	The health care setting has a policy that requires assessment of each patient's chemotherapy adherence at defined clinically meaningful intervals to address any issues identified when chemotherapy is administered outside of the health care setting. Documentation of assessment is available in the patient record.

Overview of updated 2020 Standards

Note: Only standards which have been modified are in the following slides

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Patient Population Key

Patient Population:	Pediatric Only Patients	Pediatric & Adult Patients	IV Patients	Oral Patients	Intrathecal Patients	All Patients: Staffing & Setting
Symbol:						

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

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

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

- 1.2.1 Pathologic confirmation or verification of initial diagnosis.
- 1.2.2 Initial cancer stage or current cancer status. *Cancer stage/Cancer status is defined in the glossary.*
- 1.2.3 Complete medical history and physical examination. *Medical history and physical examination is defined in the glossary.*
- 1.2.4 Pregnancy status for women of childbearing age.
- 1.2.5 Presence or absence of allergies and history of other hypersensitivity reactions.
- 1.2.6 Assessment of the patient's and/or caregiver's comprehension of information regarding the disease and the treatment plan.
- 1.2.7 Initial psychosocial assessment, with action taken when indicated. *Psychosocial assessment is defined in the glossary.*
- 1.2.8 The chemotherapy treatment plan, including, at minimum, the patient diagnosis, drugs, doses, anticipated duration of treatment, and goals of therapy.
- 1.2.9 The planned frequency of office visits and patient monitoring that is appropriate for the individual chemotherapy agent(s).

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

- 1.3.6 Allergies, previous treatment related reactions.
- 1.3.7 Treatment toxicities.
- 1.3.8 Pain assessment.
- 1.3.9 Patient's medications are updated and reviewed by a practitioner when a change occurs.

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

2.2 Patients are provided with comprehensive verbal and written or electronic information as part of an education process before starting each treatment plan.

2.2.1 The education process will be tailored to the patient's learning needs, abilities, preferences, and readiness to learn as assessed and documented prior to treatment. Education includes family, caregivers, or others based on the patient's ability to assume responsibility for managing therapy.

2.2.2 Documentation that written or electronic educational materials were given to patients.

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

- 3.4.1 Patient's name.
- 3.4.2 A second patient identifier.
- 3.4.3 Full generic drug name.
- 3.4.4 Drug dose.
- 3.4.5 Drug administration route.
- 3.4.6 Total volume required to administer the drug.
- 3.4.7 Date the medication is to be administered.
- 3.4.8 Expiration dates and/or times.
- 3.4.9 When dose is divided, the total number of products to be given and the individual product (e.g., 1 of 5, 2 of 2, etc.).
- 3.4.10 A warning or precautionary label or sticker, as applicable, to storage and handling; may be included within the label or on an auxiliary label.

3.5 The health care setting that administers intrathecal medication maintains policy that specifies :

- 3.5.1 Intrathecal medications are:
  - 3.5.1.1 Prepared separately.
  - 3.5.1.2 Stored in an isolated container or location after preparation.
  - 3.5.1.3 Labeled with a uniquely identifiable intrathecal medication label.
  - 3.5.1.4 Delivered to the patient only with other medications intended for administration into the CNS.
  - 3.5.1.5 Administered immediately after a time-out, double-check procedure that involves two licensed practitioners or other personnel approved by the health care setting to prepare or administer chemotherapy.
- 3.5.2 Intravenous vinca alkaloids are administered only by infusion.

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

- 3.8.1 Drug name.
- 3.8.2 Drug dose.
- 3.8.3 Infusion volume or drug volume when prepared in a syringe.
- 3.8.4 Rate of administration.
- 3.8.5 Route of administration.
- 3.8.6 Expiration dates and/or times.
- 3.8.7 Appearance and physical integrity of the drugs.
- 3.8.8 Rate set on infusion pump, when used.
- 3.8.9 Sequencing of drug administration.

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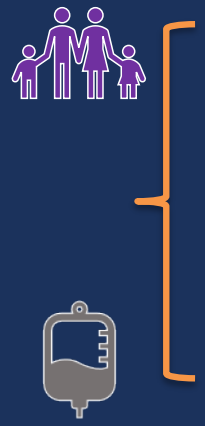

3.9 Documentation of the patient's clinical status during and upon completion of treatment.

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- 4.2 The health care setting has a policy that outlines the procedure to assess patients' ability to adhere to chemotherapy that is administered outside of the heath care setting prior to the start of treatment. Documentation of assessment is available in the patient record.

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

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Retired Standards/Elements

- 1.1.1.1 Description of credentialing processes (licensed independent practitioners) and how credentialing is documented.
- 1.7 The healthcare setting has a policy for documentation and follow up for patients who miss or cancel scheduled visits and/or chemotherapy treatments.
- 1.7.1 The healthcare setting has a policy that addresses mandates and processes for pediatric patients that account for legal requirements.

Note: Numbering for Retired Standards reflects 2018 version

Retired Standards/Elements (cont.)

- 3.4 Chemotherapy drugs are labeled immediately upon preparation and labels include:
  - 3.4.9 Sequencing of drug administration (when applicable) and the individual product sequence within the total drug order (e.g., 1 of 5, 2 of 2, etc.).
- 4.4 The health care setting has policy that requires evaluation and documentation of treatment-related toxicities, dose modification related to toxicities, and how these are communicated before subsequent administration.

Note: Numbering for Retired Standards reflects 2018 version

Questions? Contact QOPI Certification Help Desk

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