

ASCO[®]

ASSOCIATION FOR CLINICAL ONCOLOGY
KNOWLEDGE CONQUERS CANCER

QOPI[®] Certification Standards Webinar

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Presentation Overview



- Benefits of Achieving Certification
- On-Site Survey Introduction
- On-Site Survey Preparations
- 2020 Standards Overview
- Standards Walkthrough

Benefits of Achieving Certification

- **Practice Improvement**
- **A Demonstration of Quality**
- **Improved Efficiency, Effectiveness**
- **Save up to 10% on your Malpractice Insurance Premiums with The Doctors Company**
- **ABIM MOC Points**
- **CME/CNE Credits**

For further information on QOPI Certification Benefits, please visit practice.asco.org/qopi-certification

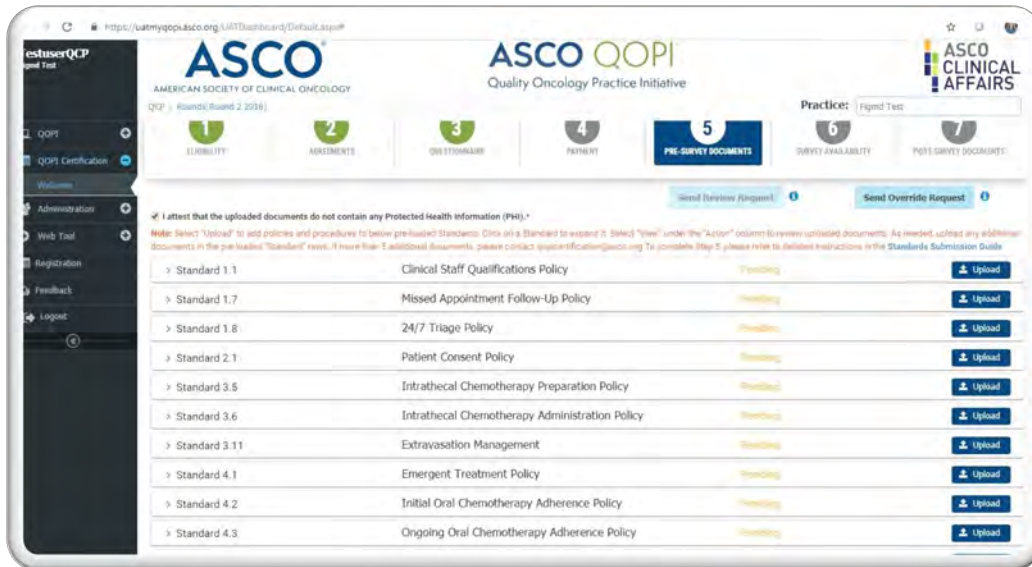


On-Site Survey Introduction

- To earn QOPI® Certification, a practice undergoes an **on-site survey** and peer review by a select team of oncology professionals **at least once every three years**.
 - Oncology Certified RNs
 - Oncology Certified Pharmacists
 - Nurse and Patient Navigators
 - Experienced Practice Administrators
- The purpose of the review is to evaluate your practice's performance in areas that affect patient care and safety.
- Ensures compliance with the QOPI® Certification Standards.
- For a look ahead at QOPI Certification process and details, please review the **[QOPI Certification Participation Guide](https://www.practice.asco.org/qopi-certification)** found on **[practice.asco.org/qopi-certification](https://www.practice.asco.org/qopi-certification)**.



On-Site Survey Preparation



Double Check

- Compare your policies against QCP's requirements; including pre-survey document submission for 8 standards
 - FYI: Upload available in QCP Application Step 5
- Do your policies have all the required elements?

Preparation

- Prepare all sites and check policy format and revision dates
- Prepare all staff involved with the chemotherapy administration process

Review

- Review processes and verifications for all routes of administration:
 - IV
 - Intrathecal
 - Oral

Survey Reference: Number of Sites to Visit

Number of Sites	Sites to be visited*
1-5	1
6-10	2
11-15	3
16-20	4
21-25	4
26-30	4
31-35	4

*Number of Sites a Surveyor Visits Per Sites Administering Chemotherapy

Patient Tracer Process

At least two IV patients on the schedule for chemotherapy will be selected for observation.

- Ideal patients are 2-4 cycles into treatment, and will consent for observation
- Oral chemotherapy patients will be selected separately and reviewed for documentation compliance only

Surveyors will review/observe:

- Chemotherapy Orders
- Preparation of chemotherapy
- Administration of chemotherapy
- Post-chemotherapy care including discharge instructions



Exit Summary

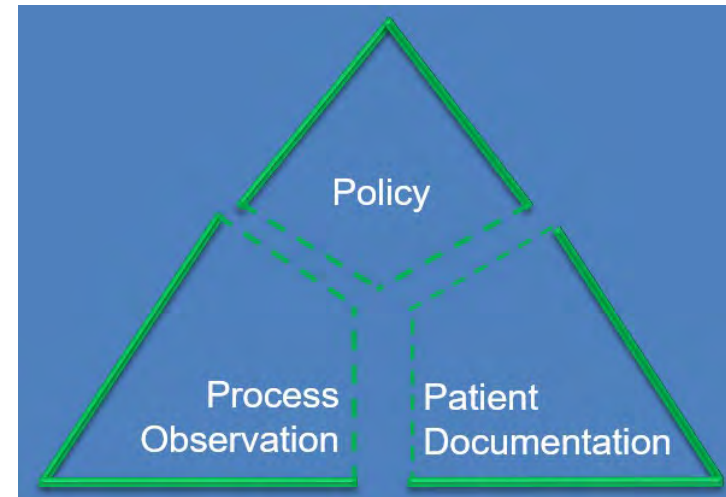


- Preliminary Report
 - Summarizes the findings from the materials submitted and the observations during the site visit, attendees are defined by the practice.
- Q&A Session
 - Surveyors share best practices and offer helpful advice on how to meet the standards

Certification Standards Overview







- 4 Domains → Standards → Element(s)

- 22 Total Standards
 - Policy
 - Process Observation
 - Patient Documentation



- Standards Manual
 - <https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program/about-qopi-certification>

Patient Population Key

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

Standards Walkthrough

Domain 1: Creating A Safe Environment – Staffing and General Policy



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

1.1.1 Orders for chemotherapy are signed manually or by using electronic approval by licensed independent practitioners who are determined to be qualified by the health care setting.





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.



1.1.4 At least one clinical staff member who maintains current certification in (age appropriate) basic life support is present during chemotherapy administration. *Certification should be from a nationally accredited course. Clinical staff includes staff involved in patient care, RNs, MDs, NPs, etc.*

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).

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:



- 1.3.1 Functional status and/or performance status.
- 1.3.2 Vital signs.
- 1.3.3 Weight is measured at least weekly when present in the health care setting.

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:



- 1.3.4 Height is measured at least weekly when present in the health care setting and when appropriate to the treatment population.
- 1.3.5 Age as appropriate to the treatment population.

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.





- 1.4 Staff assesses and documents psychosocial concerns and need for support with each cycle or more frequently, with action taken when indicated.
- 1.5 The health care setting provides information about financial resources and/or refers patients to psychosocial and other cancer support services.



1.6 The health care setting has a policy that identifies a process to provide 24/7 triage to a practitioner, for example, on-call practitioners or emergency department, to manage treatment-related toxicities and emergencies. If the patient's initial contact is not a practitioner from the treating health care setting, the person having initial patient contact must have continuous access to consultation from an experienced oncology practitioner and the opportunity for transfer of the patient to a facility with dedicated oncology services. *Practices in rural low population areas should consult with QCP staff if unable to comply with the standard.*

Domain 2: Treatment Planning, Patient Consent and Education





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.

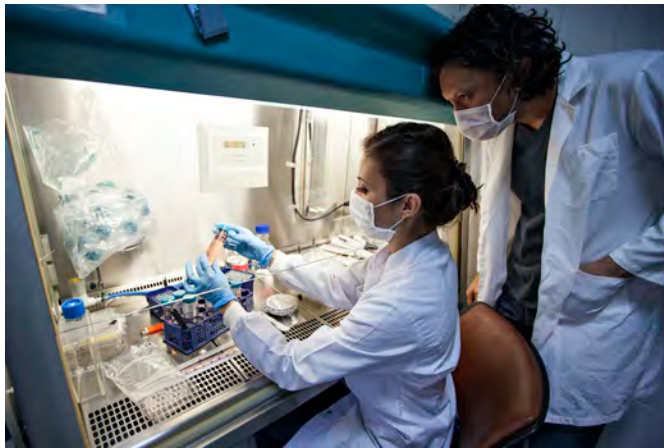
2.2 Patients are provided with comprehensive verbal and written or electronic information as part of an education process before starting each treatment plan.

2.2.3 Education information includes the following at a minimum:



- 2.2.3.1 Patient's diagnosis.
- 2.2.3.2 Goals of treatment, that is, cure disease, prolong life, or reduce symptoms.
- 2.2.3.3 Planned duration of treatment schedule of treatment administration,
- 2.2.3.4 Drug names and supportive medications, drug-drug and drug-food interactions, and plan for missed doses.
- 2.2.3.5 Potential long-term and short-term adverse effects of therapy, including infertility risks for appropriate patients.
- 2.2.3.6 Symptoms or adverse effects that require the patient to contact the health care setting or to seek immediate
- 2.2.3.7 Procedures for handling medications in the home, including storage, safe handling, and management of unused medication.
- 2.2.3.8 Procedures for handling body secretions and waste in the home.
- 2.2.3.9 Follow-up plans, including laboratory and provider visits.
- 2.2.3.10 Contact information for the health care setting, with availability and instructions on when and who to call.
- 2.2.3.11 Expectations for rescheduling or cancelling appointments.

Domain 3: Ordering, Preparing, Dispensing and Administering Chemotherapy



3.1 Chemotherapy orders include at least the following elements:



- 3.1.1 Patient's name.
- 3.1.2 A second patient identifier.
- 3.1.3 Date the order is written.
- 3.1.4 Regimen or protocol name and number.
- 3.1.5 Cycle number and day, when applicable.
- 3.1.6 All medications within the order set are listed by using full generic names.
- 3.1.7 Drug dose is written following standards for abbreviations, trailing zeros, and leading zeros.
- 3.1.8 The dose calculation, including:
 - 3.1.8.1 The calculation methodology.
 - 3.1.8.2 Variables used to calculate the dose.
 - 3.1.8.3 The frequency at which the variables are re-evaluated.
 - 3.1.8.4 The changes in the values that prompt confirmation of dosing.
- 3.1.9 Date of administration.
- 3.1.10 Route of administration.
- 3.1.11 Allergies.
- 3.1.12 Supportive care treatments that are appropriate for the regimen, including premedication, hydration, growth factors, and hypersensitivity medications.
- 3.1.13 Parameters that would require holding or modifying the dose, for example, laboratory values, diagnostic test results, and patient's clinical status.
- 3.1.14 Sequencing of drug administration, when applicable.
- 3.1.15 Rate of drug administration, when applicable.
- 3.1.16 An explanation of time limitation, such as the number of cycles for which the order is valid.

VERIFICATION 1

3.2 Before preparation, a second person – a practitioner or other personnel approved by the health care setting to prepare or administer chemotherapy - independently verifies:



- 3.2.1 Two patient identifiers.
- 3.2.2 Drug name.
- 3.2.3 Drug dose.
- 3.2.4 Route of administration.
- 3.2.5 Rate of administration.
- 3.2.6 The calculation for dosing, including the variables used in this calculation.
- 3.2.7 Treatment cycle and day of cycle.

VERIFICATION 2

3.3 Upon preparation, a second person approved by the health care setting to prepare parenteral chemotherapy verifies:



- 3.3.1 The drug vial(s).
- 3.3.2 Concentration.
- 3.3.3 Drug volume or weight.
- 3.3.4 Diluent type and volume, when applicable.
- 3.3.5 Administration fluid type, volume, and tubing.

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 sequence (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.



- 3.6 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.
- 3.7 Before chemotherapy administration: At least two individuals, in the presence of the patient, verify the patient identification by using at least two identifiers.

VERIFICATION 3

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.



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



- 3.10 Extravasation management procedures are defined and align with current literature and guidelines; antidote order sets and antidotes are accessible within the appropriate timeframe.

Domain 4: Monitoring After Chemotherapy is Given, Including Adherence, Toxicity and Complications



4.1 The health care setting has a policy for emergent treatment of patients, that aligns with current literature and guidelines and addresses:



- 4.1.1 Availability of appropriate treatment agents.
- 4.1.2 Procedures to follow and a plan for escalation of care, when required, for life threatening emergencies.



- 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 health 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**.



4.4 Cumulative doses of chemotherapy are tracked for agents associated with cumulative toxicity.

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 the QOPI Certification Team at:
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