



QOPI Certification Program

Quality Cancer Care: Recognizing Excellence

QOPI® Certification Participation Guide

Spring 2015

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1 INTRODUCTION

The QOPI[®] Certification Program builds upon the success of the American Society of Clinical Oncology's (ASCO) Quality Oncology Practice Initiative (QOPI[®]). QOPI Certification is conducted by the QOPI Certification Program (QCP[™]), a Virginia limited liability company wholly owned by ASCO. QOPI Certification demonstrates a commitment to excellence and ongoing quality improvement in the hematology-oncology outpatient practice. The goals of the QOPI Certification program are to:

- Promote the highest quality cancer care as defined by the clinician experts
- Provide a trusted solution to satisfy external demand for quality activities
- Reduce multiple assessment and improvement programs or requirements for your practice, including health plan programs
- Provide a three year designation of QOPI Certification status
- Provide resources to communicate your practice's QOPI certification to your patients and the local community

This guide provides detailed instructions to practices entering the QOPI Certification Program. For information regarding QOPI, QOPI data abstraction, or other documentation related to the QOPI Certification Program, go to <http://qopi.asco.org>.

2 ELIGIBILITY FOR QOPI® CERTIFICATION

This section describes the QOPI Certification, and the steps required for a practice to achieve Certification.

2.1 PRACTICE DEFINITION

QCP awards QOPI® Certification to practices, rather than individual office sites. Practices are expected to come into Certification with all of their office sites. However, QCP may grant exceptions to this rule for special circumstances. Practices that would like to participate with less than all of their office sites should contact the QOPI Certification help desk for more information. Practices that want to test the certification waters are allowed to come in with a pioneer site. Practices applying for Certification using a pioneer site should intend to certify the practice as a whole in future years. Sites coming into Certification separately should discuss with QCP staff how to merge any existing certified practice sites in the QOPI database, so they can apply for Certification as a whole at a later date.

For Certification purposes, the defining feature of a practice is the use of the same policies and procedures across all office sites. Certification of a practice is only meaningful if standards apply to all sites. Loosely affiliated organizations, with multiple office sites that do not operate under the same policies and procedures at all office sites, will be required to come into Certification separately. To become QOPI Certified as a practice, an applicant must demonstrate to QCP's satisfaction that all of its office sites are functionally integrated. Staffs that rotate across all sites, identifying a centralized person or entity as being in charge of implementing policies/quality across all sites and the use of a common EMR and operation under a single tax ID number are all indicators of functional integration.

Oncologists or oncology groups that have unique practice arrangements, but would like to apply for Certification, should contact QCP staff to discuss Certification participation. Only practice sites that provide hematology-oncology, or medical oncology care, are eligible to apply for QOPI® Certification.

2.1.1 DESIGNATION OF QOPI® CERTIFICATION

Designation of QOPI® Certification Applies Only to Participating Practice Sites. A site is not allowed to present itself as QOPI® Certified because of its affiliation with other QOPI Certified

entities. That site must be included in the Certification assessment of the applicant's practice, including (but not limited to) being subject to potential survey. Only practice sites that are subject to the full QOPI Certification review process may be deemed as being QOPI Certified.

2.1.2 LARGE, MULTI-SITE PRACTICES

A large, multi-site practice may submit a single Certification application, where each site of the practice is located within a geographic distance of 250 road miles from at least one other site of the practice, as measured by the shortest route between such sites.

For practices that have one or more sites located more than 250 road miles from the next closest site, as measured by the shortest route between such sites, QCP may divide the practice into regions. The practice should consult QCP regarding the appropriate manner of applying for Certification, but QCP retains sole discretion to establish the geographic regions.

2.1.3 PRACTICES THAT DO NOT PROVIDE INFUSION SERVICES

A practice that does not administer chemotherapy on site, or refers a majority of their patients to unaffiliated infusion centers, may come into Certification by demonstrating a sufficient relationship with one or more unaffiliated infusion center(s) to which it generally refers its patients. Practices which do not provide infusion services should contact the QOPI® Certification helpdesk to determine their eligibility.

2.1.4 PARTICIPATION IN QOPI® CHART DATA ABSTRACTION

To be eligible for the QOPI® Certification Program, a practice must participate in the QOPI® spring 2015 collection and meet or exceed the Certification scoring threshold. The practice must submit data for the core measures and five modules required for Certification. The required modules are:

- Care at the End of Life
- Symptom/Toxicity Management
- Breast Cancer
- Colorectal Cancer
- Non-Small Cell Lung Cancer

2.1.5 QOPI® CERTIFICATION QUALITY SCORING THRESHOLD

The QOPI® Certification Report provides the practice score on the 26 designated measures and the overall quality score. The Overall Quality Score is an aggregate score, based on these 26 certification measures, within the required modules designated for QOPI® Certification

Note: The practice must meet or exceed a 75% Overall Quality Score

2.1.6 TARGET CHART REQUIREMENTS

Practices must follow the QOPI® sampling methodology and meet the target chart requirements for their practice size and applicable modules. If all charts from all medical oncologist and hematologist oncologists from all office locations were not included in the pool from which charts were sampled, an attestation form must be completed when applying for Certification to justify why exclusion does not compromise the validity of the abstraction from an assessment standpoint. Specifically, the following apply:

1. Target for each module should be met
2. If target for certain modules is not met – confirm that all eligible charts for that module have been abstracted
3. After confirming that all targets are met for each module and, if not met, that all eligible charts have been abstracted, then confirm minimum unique chart requirements are met.
4. If below the minimum unique chart requirements, you are allowed to add additional charts of patients that qualify for core or symptom with cases, with any invasive malignancy in the allowable range.

2.1.7 DETERMINING FTEs AT YOUR PRACTICE

Full Time Equivalent (FTE) is the ratio of the total number of clinical hours during a period (part time, full time, contracted) with the number of working hours in that period; or the proportion of time a medical oncologist or hematologist provides clinical care, relative to a full time schedule. The ratio units are FTE units, or equivalent employees working full-time (one FTE equals one employee working full-time).

For example: You have three clinicians and they work 50 hours, 40 hours, and 10 hours per week – totaling 100 hours. Assuming a full-time employee works 40 hours per week, your full time equivalent calculation is 100 hours divided by 40 hours, or 2.5 FTE.

Table 2-1: Target Chart Numbers

Medical/Hematologist Oncologist Clinical FTEs	1	2-3	4-6	7+
Target Number of Charts per Module	24	32	34	40
Target Total Number of Charts for QOPI® Certification (five modules)	72-120	96-160	102-170	120-200
Minimum Unique Chart Requirement	48	64	68	80

2.1.8 WHEN TO PARTICIPATE IN QOPI®

Practices must apply for Certification *after* participating in the QOPI® chart abstraction.

Recertifying practices should participate in QOPI® chart abstraction at least 9 months prior to certification expiration. Practices that have not completed QOPI® data abstraction, and have concerns about timelines, are encouraged to contact QCP staff at qopicertification@asco.org

Detailed information on QOPI® collection requirements can be found on the QOPI website at <http://qopi.asco.org>.

3 QOPI® CERTIFICATION PROCESS OVERVIEW

This section describes the processes required to initiate and achieve QOPI® Certification.

3.1 PROCESS FOR NEW AND RECERTIFYING PRACTICES

At the time of application, practices are asked to identify a main contact person. This person will be responsible for all steps of the Certification process, and will receive all important information regarding the status of their application. At the QOPI® Certification application Webpage (http://qopi.asco.org/LOG_IN.htm), practices can complete the QOPI® Certification practice application, submit appropriate fees, and complete the Site Assessment Questionnaire.

Practice completes and submits QOPI® Certification application, which includes the following steps:

1. Review the QOPI® Certification report and confirm that the QOPI Certification scoring requirements were met.
2. Confirm that they participated in QOPI® data abstraction with the same sites that will be included on the QOPI® Certification application.
3. Sign the QOPI Certification Practice Agreement
4. Completes practice specific demographic information
5. Submits the QOPI Certification Site Assessment Questionnaire online, attesting that they comply with 20 certification program standards which are based on the ASCO/ONS Safe Administration of Chemotherapy Standards.

Please see QOPI® Certification Site Assessment section for additional details about the questionnaire.

6. Submit payment (based on practice size) online, wires payment or mails a check. The payment must be postmarked one week after the completion of the application and questionnaire.

3.2 ALTERNATE RE-CERTIFYING PRACTICE APPLICATION PATHWAY

Recertifying Practices should participate at least nine months prior to certification expiration.

Practices that have not completed QOPI® data abstraction and risk expiration before the next QOPI round, may in some circumstances be allowed to apply, complete the QOPI Certification Steps 3 through 6 above, and proceed through the on-site review process; after which they will participate in QOPI data abstraction, as required to obtain the threshold quality score, before being

awarded Recertification. Recertifying practices are encouraged to participate in QOPI data abstraction prior to applying, to avoid a lapse in certification if they do not meet the scoring requirement.

Recertifying Practices should apply and submit payment early in the application round in order to meet all recertification deadlines.

4 SUBMITTING DOCUMENTATION

This section describes the process and procedures to follow when submitting supporting documentation for QOPI® Certification.

4.1 STANDARDS

Practice submits supporting documentation for three selected Certification program standards. Practices can refer to the Standards Documentation Submission Manual. QCP Staff will provide the selected standards and guidance on the types of documentation required to support compliance with the standards.

4.2 CHART MEASURES VALIDATION

- Practice submits supporting documentation for three Charts from spring 2015 QOPI®. Practices can refer to the Chart Documentation Submission Manual.
- Charts are randomly selected by QCP staff from the charts submitted for QOPI data abstraction. Staff will use the selected practice ID to identify the charts.
QOPI Certification Staff will evaluate submitted materials.

4.3 REQUIRED INTERVIEWS

4.3.1 STANDARDS COMPLIANCE INTERVIEW

New and Re-Certifying Practices: Interview will be scheduled to determine practice specific implementation of the standards. The purpose of the interview is twofold:

- To verify standard submission to confirm readiness for the QOPI® Certification Program On-Site Review Process.
- To provide you an opportunity to speak directly with QOPI® Certification Staff regarding your standard submission and on-site review readiness.

4.3.2 CHART VERIFICATION INTERVIEW

New and Re-Certifying Practices: Interview will be scheduled to determine practice specific abstraction methods of the required measures for the QOPI Certification Quality Score. The purpose of the interview is two-fold:

- To verify chart selection methodology for QOPI® participation to confirm eligibility for the QOPI® Certification Program
- To provide you an opportunity to speak directly with QOPI® Staff regarding your experience with and suggestions for the program

5 QOPI® CERTIFICATION PENDING STATUS

Once a practice has submitted the complete Certification application and initial program materials, the practice will be awarded QOPI-Certification Pending status. Practices are granted Pending Status upon receipt of the supporting documentation (standards 1, 15, and 18) and (randomly selected charts from spring 2015). The practice is labeled as having achieved QOPI® Certification-Pending, indicating they have achieved the threshold quality score and are actively pursuing certification. New Practices have one year from the designation of Certification Pending status to meet all requirements for Certification.

5.1 QOPI® RE-CERTIFICATION AND PENDING STATUS

Recertifying practices have up until their current term to achieve QOPI® Re-Certification. The Recertification Pending Status is an internal marker indicating that the recertifying practice has achieved the threshold quality score, submitted a completed application and is actively pursuing re-certification. While new practices have one year from the designation of Certification Pending status to meet all requirements for Certification, Re-certifying Practices must participate in the process early enough to achieve Re-Certification by the end of the current three year certification. Extensions on certification terms cannot exceed three months, and the practice must demonstrate hardship to QCP's satisfaction. When a practice is granted re-certification, it extends the current Certification date an additional three years.

5.2 QCP ON-SITE SURVEY

- The practice on-site survey is scheduled when Pending Status has been achieved. All practices (Re-Certifying and New) must participate in an on-site survey. Surveys are scheduled two to eight weeks from pending, depending on surveyor availability and practice readiness.
- Upon completion of the scheduled survey, the practice receives a report detailing any requirements which must be addressed before Certification can be awarded. New Practices have up to one year from their Certification Pending date to meet all requirements for Certification.

Note: Recertifying Practices have up until one month before their term ends to meet all requirements.

6 REPEAT PRACTICE SITE SURVEY

Following review of a practice's QOPI® Certification Application and completion of the on-site survey, the QOPI Certification Program (QCP) may, in its sole discretion, determine that an additional on-site survey is necessary to evaluate the applicant practice's qualification for QOPI® Certification. QCP™ may require an additional on-site survey, if there is discord between the practice's reported adherence to one or more policies and procedures relating to QCP standards, and the Certification Surveyors observations during the initial on-site survey or if QCP otherwise determines that further personal observation is needed to assess the practice's qualifications for Certification.

- Certification Surveyors and Committee Reviewers determine if a second review is necessary;
- QCP Staff will contact the practice to review the on-site survey report and identified requirements within four weeks.
- QCP Staff will determine the date of the new review and timelines for responses due prior to the on-site review.
- A new surveyor will be assigned to do the review and will not have access to previous review materials.

6.1 COST OF REPEATED ON-SITE SURVEY

If an additional site visit is required to demonstrate practice improvement, the practice will bear the cost. Practices may appeal Certification decisions using a structured appeals process. The policy for appeals will be sent to a practice upon request.

7 FINAL REVIEW

QOPI® Certification Committee Reviewers, including community and academic oncologists and oncology professionals evaluate the on-site survey report and any responses, and determine whether to award QOPI® Certification.

8 QOPI® CERTIFICATION AWARD

Certification is awarded when a practice is deemed to have met QCP's standards. The award indicates that by achieving QOPI Certification or Recertification, a practice has participated in the QOPI Certification process and met or exceeded a benchmark score on measures that compared the quality of its care against national standards. The practice has then undergone an on-site review and peer review, by a select team of oncology professionals, such as physicians and nurses, at least once every three years.

8.1 CERTIFICATION TERM

QOPI® Certification has a three-year term, starting at the time when the practice achieves QOPI® Certification status. Recertifying Practices will maintain their original certification date and a subsequent three year term then added to the original date.

9 MAINTAINING CERTIFICATION STATUS

To maintain QOPI® Certification status, all QOPI® Certified Practices must participate in QOPI® chart abstraction by submitting data for at least all core measures plus one module of their choice once per year, based on the Certification date. For example, if a practice is certified in April 2015, it must participate in QOPI® to maintain a certified status in fall 2015 or spring 2016.

If the practice does not participate in QOPI® chart abstraction once per year they will receive a warning notice. After one warning notice has been sent, the practice must participate in the next QOPI® chart abstraction process or the practice will lose their Certification status

There is no need to register or apply for maintenance; the QOPI® Certification team tracks participation. Additionally, there is no scoring requirement for maintenance rounds. While the requirement is only one module, practices are encouraged to abstract modules that enhance their quality initiatives and to try modules that are not specific to the certification modules.

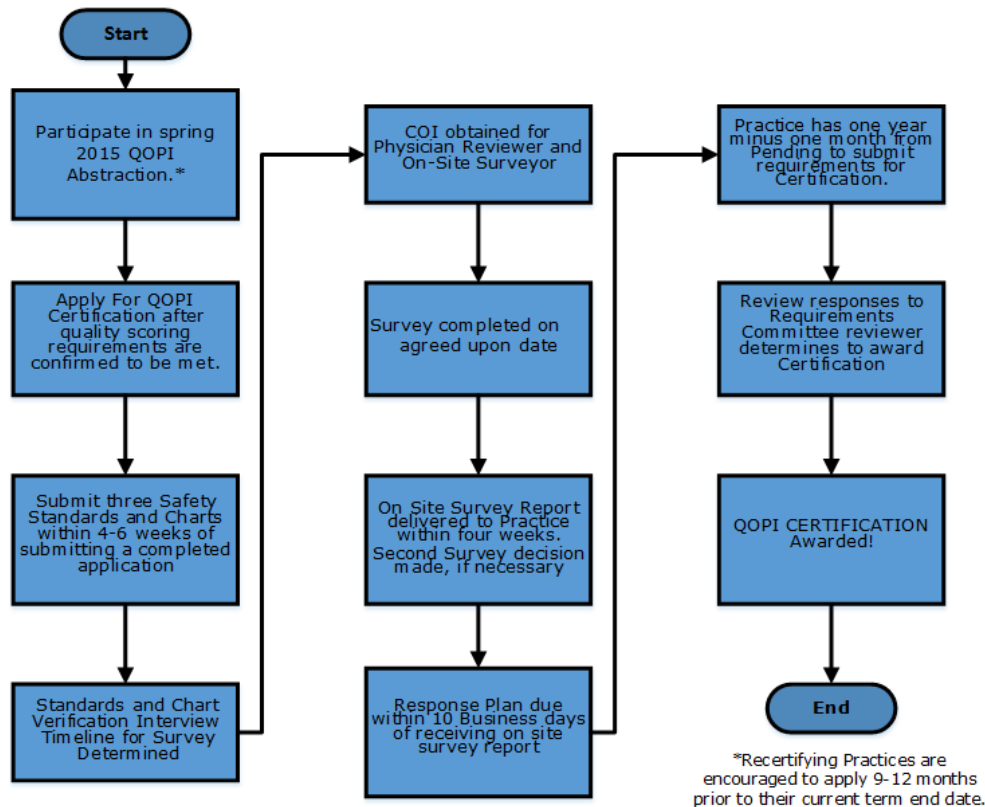


Figure 1: QOPI® Certification Applicant Timeline

10 PRACTICE TRANSACTIONS

The QOPI® Certification Program is for outpatient hematology-oncology or medical oncology adult practices. For purposes of the QOPI® Certification Program, a practice is a group of oncologists that share a common business address and tax identification number or key features, such as unified policies and procedures that are implemented consistently across the practice.

QOPI® Certification is practice-specific and non-transferable. In the event a practice undergoes a re-organization or other significant transaction*, QCP will have the discretion to determine whether one or more of the post-transaction entities may continue to be entitled to QOPI® Certification-Pending or QOPI Certification status.

Practices have the option of bringing the newly acquired site or affiliate into certification by participating in the entire application process, prior to the end of the three year term for Certified sites; or Practices can opt to have that practice site designated as non-certified and, when applying for re-certification, incorporating that practiced site into the data abstraction and application process.

Note: QCP requires that sites coming into Certification separately and the existing Certified sites must apply for Certification as a whole at a later date, and that this must occur no later than the second re-Certification date for the currently Certified practice after the transaction.

A particular site is not entitled to hold itself as QOPI Certified simply by virtue of its affiliation with a particular practice. That site must be included in the Certification assessment of the applicant practice, including (but not limited to) being subject to potential survey.

**QOPI Certification Program staff must be notified of any such transaction within 30 days of its being finalized.*

* Transaction is intended to capture significant corporate changes such as sale of a practice, merger of one or more practices, and/or split of a practice into two or more separate entities.

For questions about your practice network and sites, please contact QCP staff at qopicertification@asco.org.

11 MEASURES

ASCO oncologist members lead the QOPI® Certification Program, including developing measures, and standards and performance thresholds. Other stakeholders, including patient advocates, non-oncologist clinicians, private-payer representatives and government agencies serve as advisors in their development. All QOPI® Certification Measures are pilot tested, and used in previous reporting periods as quality improvement measures.

QOPI® Certification Program performance thresholds are based on statistical analyses of performance during preceding reporting periods; in 2014, the QOPI Certification program adopted a 75% threshold score. A complete list of the QOPI Certification designated measures, including their specifications, scoring thresholds and the overall scoring methodology, are found in the Appendix

11.1 QOPI® DATA COLLECTION ROUND DETAILS

The pathway to the QOPI® Certification Program is participation in a QOPI® data collection round, in accordance with the QOPI methodology. A practice must first meet the QOPI Certification measures scoring requirements (75%) to be eligible to apply for QOPI Certification.

The QOPI data collection, which includes a retrospective chart review, is currently offered twice each year, in the spring and in the fall. Practice staff identifies cases as specified by the QOPI methodology, and abstract data from paper medical records and/or electronic health records (EHR). A detailed QOPI® User Manual is available in the QOPI® System to assist practice staff in appropriately selecting charts for review, and successfully completing the chart abstraction. All data are submitted using a secure, online Web-based application. Work is now underway to facilitate the electronic transfer of QOPI data from EHR systems to the QOPI System, but is unavailable at this time.

The QOPI® measures are organized into a required core set, and disease- and domain-specific modules. Practices seeking Certification select and submit chart data for each QOPI module (5) that includes a measure designated for Certification applicable to the practice's patient population (refer to the QOPI User Manual in the QOPI® System). QOPI® Certification designated measures are clearly noted for each module. QOPI measures marked as quality improvement measures are reported to participating practices, but not included in QOPI Certification scoring calculations.

11.2 SAMPLING REQUIREMENTS FOR QOPI CERTIFICATION

Certification designated measures are included in the QOPI Core, Symptom/Toxicity management, End of life, Breast cancer, Colon/rectal cancer, and Non-Small Cell Lung cancer modules (Refer to the QOPI User Manual in the QOPI® System). All modules that are applicable to the practice's patient population must be selected and completed, for that practice to be eligible for Certification. For example, if a practice treats breast cancer patients only, the breast cancer, symptom/toxicity management, and care at End of life modules are required.

Practice selection of appropriate modules and sampling will be verified upon application to the QOPI Certification Program. Deviation from this methodology is grounds for denying the initial designation of *QOPI Certification-Pending*.

The QOPI sample sizes per module are described in detail below and in Figure 1 in the QOPI User Manual. Smaller practices which are not able to meet the chart requirements should contact QOPI for information on how to proceed at qopi@asco.org.

The QOPI sampling methodology requires that practices identify their eligible, most recently seen patients, and proceed backwards in time – to a maximum of 6 months - to achieve the required sample size. The complete methodology and eligibility criteria are included in the QOPI User Manual.

11.3 MULTI-SITE PRACTICE SAMPLING

Large, multi-site practices, within 250 miles of each other, may elect to sample as one practice, or with all of the practice sites expected to participate in Certification. Practices with more than 25 sites are required to participate as geographic regions. For additional information on practice sampling, refer to Practice Definition in the QOPI User Manual. The entire practice must participate in QOPI in the way that best represents the whole practice. Multi-site practices can do this in two ways (with differing sample size requirements). The first option involves pulling one sample across the multiple office sites within the practice. The second involves a distinct chart pull at each office site. Practices can select whichever methodology is most feasible and appropriate for their quality improvement goals.

11.4 CERTIFICATION REPORTS AND SCORING

Interim Certification Report: This report is available one week prior to the close of the collection round and shows the practice/office (depending on sampling approach) performance on the 26

Certification designated measures. The report is released during collection, to allow practices time to investigate potential abstraction errors and make corrections prior to the close of the round. Once the round closes, the database is locked and changes cannot be made. It is important to review data as it is entered, throughout the collection period.

11.5 FINAL CERTIFICATION REPORT

This report is available after the close of the collection round and shows the practice/office's (depending on sampling approach) performance on the 26 Certification designated measures. The final report indicates if the scoring requirements have been met. If the overall quality score has been met, the target number of charts per module abstracted (or all eligible charts if targets cannot be met), the minimum unique chart requirement was met, the QOPI sampling approach followed, then the practice may be eligible to apply for Certification.

11.6 RE-CERTIFYING PRACTICES: ONE-TIME PASS ON CERTIFICATION SCORING

If the re-certifying practice's performance on the 26 Certification designated measures does not meet scoring requirements on the initial try, the practice is allowed to participate in the next round, following the same process as outlined above. If the final report indicates that scoring requirements have been met on this subsequent round, and all other requirements have been met, the practice will not lose its certification status.

If the overall quality score is not met on both collection rounds, then the practice loses its certification status and is allowed to apply after a subsequent score again shows eligibility.

12 SITE SELF-ASSESSMENT QUESTIONNAIRE

The QOPI® Certification Program includes an assessment of a practices' concordance with 20 program standards, based on the ASCO/ONS Chemotherapy Safety Standards. QCP's Site Assessment includes an evaluation of the responses and information submitted by the practice. A practice must pass the QOPI® Site Assessment to achieve QOPI® Certification. Practices are asked to attest to their compliance with the 20 selected standards, using the structured online QOPI® Certification Site Assessment Questionnaire.

Although there is the option of selecting No on the Site Assessment Questionnaire, a practice must be able to answer in the affirmative to all 20 standards, within the timeframe specified for achieving Certification (one year from the date of Certification -Pending status). If you check No, be certain that the practice will be able to provide proof of compliance for this standard, within the specified time frame.

13 DETERMINING SURVEY SITES AND ADDITIONAL FEES

All practices receive an on-site survey. QCP™ staff randomly selects the sites to be visited. Practices with more than five office locations are required to have multiple sites visited with additional site fees.

For practices that have one or more sites located more than 250 road miles from the next closest site, as measured by the shortest route between such sites, QCP may divide the practice into regions. The practice will consult QCP regarding the appropriate manner of applying for QCP, but QCP has the sole discretion to establish the geographic regions.

Regardless of whether a large, multi-site practice is divided into geographic regions or permitted to apply for Certification under a single application, QCP may assess additional fees to cover the cost of the on-site surveys and travel related costs if sites being surveyed are separated by more than a one hour driving distance. Examples include:

1. A multi-site practice with one or more sites, serving a large number of patients (measured by whether the site services more than an average of 30 infusion visits in one day) and/or has greater than seven (7) FTE medical or hematology oncologists, may be required to submit additional fees to cover on-site surveys of these high-volume practice sites.
2. An oncology practice with greater than three (3) campus infusion centers may be subject to additional fees to cover expenses associated with extended visits.
3. An oncology practice that has a separate, specialty office may be subject to additional on-site survey visits requiring additional fees, if the specialty practice extends beyond general medical oncology infusions, such as intraperitoneal or intra-thoracic.

In addition, QCP reserves the right to assess additional fees to cover any unexpected and significant costs associated with conducting on-site surveys.

Refer to the Cost section for Certification on the QCP Website, or consult with the QCP staff at qopicertification@asco.org

14 CONFLICT OF INTEREST SCREENS

QCP will assign a primary committee reviewer and two alternates to review the certification application and responses to requirements, before awarding certification. QCP staff will assign an on-site surveyor who will visit your practice. The on-site survey/s will be conducted by a certified oncology nurse. You will receive an email informing you of the reviewer's name and the on-site surveyor's name, and will be asked to notify the Certification Program within five (5) business days by email to confirm that you do/do not consider this surveyor or reviewer to have a disqualifying relationship with your practice. The disqualifying relationship criteria may be defined as:

1. A substantial personal or professional relationship with the practice (e.g., self or immediate family member employed by the practice);
2. An appreciable financial interest in the outcome (e.g., self or immediate family member employed by a direct competitor of the practice) of the review; or
3. Any other relationship with the practice that would cast considerable doubt on his or her ability to provide an objective review, as determined by the Certification Program.

If a disqualifying relationship is identified, an alternate reviewer and/or an alternate surveyor will be named by the Certification Program. QCP reserves the right to determine if the noted conflict of interest meets the program threshold.

14.1 SCHEDULING THE ON-SITE VISIT

The on-site surveyor will contact the practice to schedule the on-site survey date. The visit must take place within two to eight weeks from the first contact with the On-site surveyor. Once a mutual date has been decided, and the surveyor has notified the certification team, the Certification Team sends a confirmation email to you. Once the date is agreed upon, it cannot be changed without penalty. If the practice changes the initial, agreed upon date, it will be required to bear the cost associated with the travel fees, surveyor stipends, etc., that occur because of the change.

Please be advised that a QOPI Certification staff member may accompany the on-site surveyor for quality assurance or other purposes.

14.2 ON-SITE SURVEY AGENDA

The surveyor's goal is to review your practice's agreement with the 20 ASCO/ONS Chemotherapy Safety Standards, using a patient tracer method through:

- Review of Medical Record documentation
- Review of policies, procedures, and guidelines
- Observation of Chemotherapy Preparation
- Observation of Chemotherapy Administration
- Interview two - three RN's and an Administrator/Educator

14.3 PRACTICE PREPARATION FOR THE ON-SITE SURVEY

1. Ensure that someone who is familiar with the practice's EHR system (if applicable) will be available to spend approximately 1-4 hours with the surveyor on the day of the site visit to review records and find standards elements within medical records. Surveyors are not allowed to access EHR system without staff present.
2. If chemotherapy is prepared/mixed by an off-site pharmacy or at another location, please let the reviewer know during the scheduling process. The practice will need to make arrangements for the surveyor to observe chemotherapy being prepared.
3. Ensure the availability of a conference room or quiet area for the day to allow the surveyor to review patient records and other associated documents.
4. Provide the surveyor with access to the practice's policy/procedure manual for each site (if there is only one site, then provide one policy binder). The policies that correspond to the 20 ASCO/ONS safety standards must be readily accessible to the on-site surveyor; if the policies are only available online, have someone available to show the surveyor how to access them online. Many practices find that creating a binder with policies specific to the 20 ASCO/ONS safety standards saves time during the review day.

Please inform practice staff they may be selected for observation and that participation is mandatory to continue with the on-site survey process.

Note: We randomly choose the patients to follow. It is part of our process to ask the patient's permission first. If the practice does not provide infusion services on-site, please contact the QOPI® Certification Helpdesk before applying.

Because the potential for bias in such situations is real and significant, practice staff refusal to participate in the on-site survey process is grounds for certification failure.

14.4 EXIT SUMMARY OF FINDINGS

The Surveyor will provide the practice with a preliminary overview of the findings for each of the 20 ASCO/ONS Safety Standards. A brief review of each standard with observations and findings will be conducted. The exit summary provides the practice with an opportunity to clarify the

standards and the surveyor's observations, at the practice's discretion, invite team members, including those who may benefit from the discussion of the findings. The exit summary takes approximately 30-45 minutes.

14.5 THE ON-SITE SURVEY REPORT AND RESPONSE TIMELINE

- The On-Site Survey Report (OSR) is written and submitted to the QCP staff by the Surveyor for review (approximately **one week**)
- The OSR is finalized by the QCP staff and sent to the QCP Committee member for final review (approximately **2-3 weeks**)
- The final OSR is sent to the practice with instructions (a Response Plan and Document Submission guide will be attached to the email) for submitting a 'Response Plan' or action plan, which is then sent to the QCP staff at qopicertification@asco.org within **10 business days** from the day you receive the final OSR
- The Response Plan will be reviewed by the QCP staff for clarity, accuracy and within your timeline for certification/recertification, with an email sent to you (within **3 business days**) with approval to move forward with the plan
- If the Response Plan requires any change or modification, the QCP staff will include this feedback in an email to you (**within 3 business days**). A modified Response Plan will need to be re-submitted to the QCP staff (**within 3 business days**) for final approval
- The practice works on the requirements and the corresponding document submission (see Response Plan and Document Submission guide for instructions) and submits all documents to databank to meet the final document submission timeline, as outlined in the OSR
- When all required documents have been submitted to Databank, they will be summarized (**within 10 business days**) for completeness and accuracy, as specified in the OSR, and sent to the original QCP Committee member for final review and approval (**within 10 business days**)
- When the practice submits the required documentation, the QCP staff will review and summarize the information. If there is additional information needed, the QCP staff emails or calls the practice with further instructions regarding document submission. Once all documents have been submitted, the summary of the final documents are sent to the original QCP Committee member for final review and approval (**within 10 business days**)

- When the QCP Committee member approves the document submission, certification is awarded and the practice notified (**within 5 business days**) of having attained QOPI Certification

Table 14-1: QOPI Certification Program – Levels of Certification

QOPI CERTIFICATION PROGRAM: LEVELS OF CERTIFICATION AND TERMS		
Program	Definition	Term
QOPI® Certification-Pending	Applied for QCP and submitted initial documentation.	Until QOPI Certification is awarded or expires; within 12-14 months, if QOPI Certification is not achieved.
QOPI® Certification	<ol style="list-style-type: none"> 1. Met or exceeded QOPI® Certification Measure scoring requirements in one or more QOPI rounds 2. Met QOPI Site Assessment safety standards. 3. Participated in QOPI abstraction at least once per year during three year Certification term. 	For three years or until renewal, as long as Certification maintenance requirements are met.

15 QOPI[®] CERTIFICATION LEGAL POLICIES AND PROCEDURES

All Policies can be requested by writing to qopicertification@asco.org or at the ASCO website:

www.asco.org

15.1 INFORMATION AND DATA RELEASED FROM THE QOPI[®] CERTIFICATION PROGRAM

ASCO will not release any information or performance data, without the specific request of the participant. However, with practice opt-in, ASCO will transfer a practice's certification status to health plans or other entities selected by that practice. Complete details regarding information being sent will be included at the time of opt-in.

16 POLICY SUMMARIES

The section describes QOPI Certification policies.

16.1 QOPI CERTIFICATION SCORE WAIVER REVIEW

- Practices that did not achieve the QOPI Certification scoring requirement can request that the QOPI Certification Oversight Council review the scoring decision.
- Reception of a waiver is based on a finding that unique characteristics of a practice unfairly disadvantaged the practice's performance, relative to specific QOPI measures, impacting their overall score.
- Requests must be received within 10 days of receiving quality scores.

16.2 REPEAT ON-SITE SURVEY POLICY

Following review of a practice's QOPI Certification Application and completion of the on-site survey, the QOPI Certification Program (QCP) may, in its sole discretion, determine that an additional on-site survey is necessary to evaluate the applicant practice's qualification for QOPI Certification. QCP may, in accordance with the procedures set forth in this policy, require an additional on-site survey, if there is discordance between the practice's reported adherence to one or more policies and procedures relating to QCP standards and the Certification Surveyor's observations during the initial on-site survey or if QCP otherwise determines that further personal observation is needed to assess the practice's qualifications for Certification.

- QCP staff shall notify the applicant practice that a repeated survey is required within eight (8) weeks of completion of the survey report for the prior survey.
- QCP will appoint a different Certification Surveyor to perform the repeated survey, consistent with the procedures in the Conflict of Interest Policy Implementation for QOPI® Certification, Waiver, Appeals, and Revocation.
- The practice shall bear the cost of repeated survey.

16.3 QOPI CERTIFICATION APPEALS PROCESS

Practices that apply for, but do not achieve QOPI Certification, may appeal the decision to deny Certification in accordance with the terms of the QOPI Certification Appeals Process.

16.4 CONFLICT OF INTEREST POLICY FOR QOPI CERTIFICATION, APPEALS AND REVOCATION

Consistent with the ASCO Conflict of Interest Policy, this Policy Implementation provides mechanisms for minimizing potential conflicts of interest through each phase of the QOPI Certification and Appeals Process.

16.5 QCP POLICY FOR THE EXTENSION OF PRACTICE'S FINAL DEADLINE

QCP recognizes and appreciates that achieving Certification is time consuming and requires the commitment of scarce practice resources. For this reason, practices are given a full year from their Certification Pending date to complete the requirements to achieve Certification. QCP will only grant extensions to meet the requirements for Certification when an unforeseen and uncontrollable act of nature occurs within 60 days of the end of the practice's Certification Pending period. Staffing and personnel changes are not grounds for an extension. QCP strongly recommends that all practices complete the requirements for Certification at their earliest opportunity.

Requesting an Extension

New Practices seeking an extension must make a formal request in writing to qopicertification@asco.org. The request must include information regarding the basis for the extension. Extensions will be granted at the sole discretion of QCP and will be for a maximum of 30 days. Practices requesting an extension will be assessed a \$250 administrative fee.

16.6 PRACTICE MERGERS AND TRANSACTIONS POLICY

Significant practice transactions, such as mergers, must be reported to the QCP within thirty (30) business days. We do not automatically transfer Certification to new owners or practices that have merged. QCP will assist you in determining whether the sites that were QOPI® Certified will retain their certified status following the merger, pursuant to QCP™'s policies. Failure to notify us of major changes to your organization can result in a loss of certification.

16.7 QOPI CERTIFICATION PROGRAM REVOCATION PROCEDURE

To continue to ensure that our standards are met, the Certification Program has adopted revocation procedures that allow the Certification Program to investigate complaints concerning a Certified Practice. Each practice investigated under the Procedures is provided with due process, including written notice and opportunity for a hearing. The basis for revocation of Certification under these Procedures includes the following:

- Final conviction or admission of a crime by a Certified Practice or any member thereof that is related to the delivery of quality oncology care;
- A final finding or admission of gross negligence or willful misconduct by a Certified Practice or any member thereof that is related to the delivery of quality oncology care;
- Fraud or misrepresentation by a Certified Practice or any member thereof in the application or maintenance of QOPI Certification; and
- Breach by a Certified Practice or any member thereof of the Practice's Participation Agreement, including but not limited to failure to adhere to the QOPI® Certification Participation Guide, QCP's Logo Use Guidelines, QCP's License Terms and Conditions, QOPI® Certification Participation Agreement, and other related policies.

16.8 APPROPRIATE USE PROTOCOL AND USER ACCESS PROTOCOL

In accordance with the Health Information Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act, the American Society for Clinical Oncology (ASCO) and the QOPI Certification Program have adopted Privacy and Security Policies to ensure the security of Protected Health Information (PHI), including but not limited to Electronic Protected Health Information (EPHI) and Paper Protected Health Information (PPHI) acquired from physician practices who participate in the Quality Oncology Practice Initiative (QOPI), and the QOPI Certification Program. All members of ASCO's workforce, including staff, are obligated to comply with these Policies.

Refer to Documentation Guides:

- Chart Submission Guide
- Response Plan and Documentation Submission Guide
- Standards Documentation Submission Guide

If a practice has any questions regarding these policies and procedures, or would like to receive a copy of the written procedures, please email qopicertification@asco.org

16.9 WEBINARS, CONSULTATIONS AND CERTIFICATION HELP DESK

ASCO provides a variety of resources for QOPI Certification education, and information regarding QOPI Certification processes. These programs include:

- QCP Resource Library (coming soon)

- Monthly webinar presentations
- One-on-One Standards Review (via appointment)
- Standards Interview for review readiness

The QOPI Certification Help Desk is available for participants from 9:00 am – 5:00 pm EST. QCP staff can be contacted by emailing qopicertification@asco.org calling 571-483-1669. For questions regarding account set-up in the QOPI web-based application or data abstraction, contact the QOPI Help Desk at gopi@asco.org or 571-483-1660.

16.10 CONTACTUS

For more information, please contact qopicertification@asco.org. For information on QOPI registration, participation or measures, please contact gopi@asco.org.

APPENDIX A SCORED QOPI MEASURES

Table A-1: QOPI® Spring 2015 - Summary of Measures

Module	#	Measure	Changes
Core	1	Pathology report confirming malignancy*	
Core	2	Staging documented within one month of first office visit* NQF Endorsed #0386 (adapted)	
Core	3	Pain assessed by second office visit NQF Endorsed #0383/#384 (adapted)	
Core	4a	Pain intensity quantified by second office visit (includes documentation of no pain) NQF Endorsed #0384 (adapted)	
Core	5	Plan of care for moderate/severe pain documented NQF Endorsed #0383/#0384 (adapted)	
Core	6	Pain addressed appropriately (defect-free measure, 3, 4a, and 5)* NQF Endorsed #0383 (adapted)	
Core	6a	Pain assessed on either of the two most recent office visits NQF Endorsed #0383/#0384 (adapted)	
Core	6b	Pain intensity quantified on either of the two most recent office visits NQF Endorsed #0383/#0384 (adapted)	
Core	6c	Plan of care for moderate/severe pain documented on either of the two most recent office visits NQF Endorsed #0383/#0384 (adapted)	
Core	6d	Pain addressed appropriately on either of the two most recent office visits (defect-free measure, 6a, 6b, and 6c) NQF Endorsed #0383/#0384 (adapted)	
Core	6e	Pain addressed appropriately by second office visit and during most recent office visits (defect-free measure, 6 and 6d) NQF Endorsed #0383/#0384 (adapted)	

Module	#	Measure	Changes
Core	7	Effectiveness of narcotic assessed on visit following prescription	
Core	8	Constipation assessed at time of narcotic prescription or following visit	
Core	9	Documented plan for chemotherapy, including doses, route, and time intervals*	
Core	10	Chemotherapy intent (curative vs. non-curative) documented before or within two weeks after administration *	Add timing (within 60 days prior or two weeks after) to intent question and changed 'palliative' to non-curative.
Core	11	Chemotherapy intent discussion with patient documented	
Core	12	Number of chemotherapy cycles documented	
Core	13	Chemotherapy planning completed appropriately (defect-free measure, 9, 10, and 12)	
Core	13a	Performance status documented prior to initiating non-curative chemotherapy regimen (Test Measure)	
Core	13a1	Chemotherapy administered to patients with metastatic solid tumor with performance status of 3, 4, or undocumented (Lower Score - Better) (Test Measure - Top 5)	
Core	13a2	PET, CT, or radionuclide bone scan within 3 months after diagnosis of early stage prostate cancer with low risk of metastases (Lower Score - Better) (Test Measure - Top 5)	
Core	13oral1	Documented plan for oral chemotherapy (defect-free measure, 13oral1a-13oral1e) (Test Measure)	
Core	13oral1a	Documented plan for oral chemotherapy: dose (Test Measure)	

Module	#	Measure	Changes
Core	13oral1b	Documented plan for oral chemotherapy: administration schedule (days of treatment/rest and planned duration) (Test Measure)	
Core	13oral1c	Documented plan for oral chemotherapy: lab and toxicity monitoring (Test Measure)	
Core	13oral1d	Documented plan for oral chemotherapy: frequency of office visits/contacts (Test Measure)	
Core	13oral1e	Documented plan for oral chemotherapy: provided to patient prior to start of therapy (Test Measure)	
Core	13oral2	Oral chemotherapy education provided prior to the start of therapy (defect-free measure, 13oral2a-13oral2g) (Test Measure)	
Core	13oral2a	Oral chemotherapy education provided prior to the start of therapy : safe handling (Test Measure)	
Core	13oral2b	Oral chemotherapy education provided prior to the start of therapy : indications (Test Measure)	
Core	13oral2c	Oral chemotherapy education provided prior to the start of therapy : schedule and start date (Test Measure)	
Core	13oral2d	Oral chemotherapy education provided prior to the start of therapy : missed doses (Test Measure)	
Core	13oral2e	Oral chemotherapy education provided prior to the start of therapy : food and drug interactions (Test Measure)	
Core	13oral2f	Oral chemotherapy education provided prior to the start of therapy : side effects and toxicities (Test Measure)	
Core	13oral2g	Oral chemotherapy education provided prior to the start of therapy : clinic contact instructions (Test Measure)	

Module	#	Measure	Changes
Core	13oral3	Oral chemotherapy monitored on visit/contact following start of therapy (defect-free measure, 13oral3a-13oral3e) (Test Measure)	
Core	13oral3a	Oral chemotherapy monitored on visit/contact following start of therapy: start date documented (Test Measure)	

Table A-2: Common Definitions for 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.
Chemotherapy setting (site)	All chemotherapy treatment settings (inpatient and outpatient).
Adherence	The degree or extent of conformity to the provider's recommendations about day-to-day treatment with respect to timing, dosing, and frequency.
Clinical encounter	Clinical encounters include each inpatient day, practitioner visits and chemotherapy administration visits, but not laboratory or administrative visits.

APPENDIX B QOPI 2015 CERTIFICATION STANDARDS 1 - 20**Staffing Related Standards**

1. The practice /institution has policies s, procedure s, and/or guideline s 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/institution according to the practice's/institution'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/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 (e.g., parenteral, oral, intrathecal, intraperitoneal, intravascular), and safe handling of hazardous chemotherapy agents.
An example of an established educational program is the ONS Chemotherapy and Biotherapy Course.
 - E. The practice/institution has a standard mechanism for monitoring chemotherapy administration competency at specified intervals.
 - F. Annual competency reassessment is recommended.
 - G. 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.*

Chemotherapy Planning: Chart Documentation Standards

2. Before the first administration of a new chemotherapy regimen, chart documentation available to the practice /institution includes:
 - A. Pathologic confirmation or verification of initial diagnosis.
 - B. 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.
 - C. Initial cancer stage or current cancer status.
 - D. 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).
 - E. 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.

- F. Presence or absence of allergies and history of other hypersensitivity reactions
- G. Documentation of patient's comprehension regarding chemotherapy regimens (and associated medications), including information regarding disease.
- H. Assessment regarding psychosocial concerns and need for support, with action taken when indicated.

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.

- I. The chemotherapy treatment plan, including, at minimum, chemotherapy drugs, doses, anticipated duration, and goals of therapy.
- J. 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.

General Chemotherapy Practice Standards

- 3. The practice/institution maintain a policy for how informed consent is obtained and documented for chemotherapy.

The practice/institution 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/institution.

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.

- 5. Complete orders must include :

- A. Patient's 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 laboratory results and toxicities)
- G. Allergies

Reference to the methodology of the dose calculation or standard practice equations (e.g.,

calculation of creatinine clearance)

- H. Height, weight, and any other variables used to calculate the dose
- I. Dosage
- J. Doses do not include trailing zeros; use a leading zero for doses <1 mg.
- K. Route and rate (if applicable) of administration
- L. Length of infusion (if applicable)
- M. Supportive care treatments appropriate for the regimen (including pre-medications, hydration, growth factors, and hypersensitivity medications)
- N. Sequence of drug administration (if applicable)

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.

Drug Preparation

- 6. A second person (a practitioner or other personnel approved by the practice/institution 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. Route of administration
- F. Rate of administration
- G. The calculation for dosing (including the variables used in this calculation)
- H. Treatment cycle and day of cycle

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

- A. Patient's 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
- H. Date and time of expiration when not for immediate use*

**Immediate use must be defined by institutional policy, state, and federal regulations (e.g. use within 2 hours). 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*

8. Practice s/institutions 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.

Chemotherapy Administration

9. Before chemotherapy administration:
 - A. A practitioner who is administering the chemotherapy confirms with the patient his/her planned treatment prior to each cycle;
 - B. At least two practitioners or personnel approved by the practice/institution to prepare or administer chemotherapy, verify the accuracy of:
 1. Drug name
 2. Drug dose
 3. Drug volume
 4. Rate of administration
 5. Route of administration
 6. Expiration dates/times; if applicable; expiration date/time is not required if for immediate use
Immediate use must be defined by institutional policy, state, and federal regulations (e.g. use within 2 hours).
 7. Appearance and physical integrity of the drugs
 8. Rate set on infusion pump, when utilized
 - C. A practitioner who is administering the chemotherapy documents that the verification in B was done
 - D. At least two individuals, in the presence of patient, verify the patient identification using at least two identifiers (e.g., medical record number, DOB)
10. Extravasation management procedures are defined and align with current literature and guide lines:
 - A. Antidote order sets and
 - B. Antidotes are accessible.

Monitoring and Assessment

11. The practice /institution maintains protocols for responses to life threatening emergencies, including escalation of patient support beyond basic life support.

It is recommended that emergency protocols are reviewed annually.
12. On each clinical visit or day of treatment during Chemotherapy administration, staff:
 - A. Assess and document clinical status and/or performance status
 - B. Document vital signs and weight
 - C. Verify allergies, previous reactions, and treatment-related toxicities

D. Assess and document psychosocial concerns and need for support; taking action when indicated.

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

For the purpose of Certification; section C “known allergies” and section D “psychosocial assessment” do not need to be assessed more than once per week. [I.e. during multi-day treatments]

13. At each clinical encounter, staff review 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 visit and chemotherapy administration visits but not laboratory or administrative visits).

For the purpose of Certification standard 12 does not need to be assessed more than once per week [i.e. during multi-day treatments].

14. The practice/institution maintains referral resources for psychosocial and other supportive care services.
15. The practice/institution establishes a procedure for documentation and follow-up for patients who miss office visits and/or scheduled chemotherapy treatments.
16. The practice/institution 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
 - B. If an oncology LIP does not provide initial triage, a mechanism to provide oncology consultation must be available 24/7.
 - C. This should include a policy to define how to transfer a patient to a center with oncology expertise, if needed.
Practices in rural low population areas should consult with QCP staff if unable to comply with the standard.
17. Toxicity assessment documentation is available for planning subsequent treatment cycles.
18. The practice/institution has a process to track cumulative doses of chemotherapy agent’s associated with a risk of cumulative toxicity.
19. 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.

Patient Consent and Education

20. Before initiation of a chemotherapy regimen, each patient is given written and/or electronic information, 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, including infertility risks
- E. Regimen- or drug-specific risks or symptoms that require notification and emergency contact information, including:
 - 1. How to contact the practice or organization
 - 2. Symptoms that should trigger a call
 - 3. Who should be called in specific circumstances (oncologist or other provider)
- F. Plan for monitoring and follow-up, including appointments with the practitioners or laboratory testing

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.

Note: 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>.

All standards are from Neuss, MN, Jacobson JO, Polovich M, Polovich M, et al: 2013 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards Including Standards for the Safe Administration and Management of Oral Chemotherapy. J. Oncol. Pract. 2013; 95s-13s.

The current version of these consensus standards reflects modifications that are intended to extend the standards to address the safe use of oral chemotherapeutic agents. The American Society of Clinical Oncology/Oncology Nursing Society (ASCO/ONS) standards are intended to reflect current thinking on best practices and, as such, are intended to be a "living" document; future modifications are expected.

Although the ASCO/ONS standards were not developed to address this issue, ASCO and ONS endorse the safe handling of chemotherapy agents. Published guidelines define the expectations for organizations and health care workers related to the use of safe handling precautions (American Society of Health System Pharmacists: Am J Health Syst Pharm 63:1172-1193, 2006; National Institute for Occupational Safety and Health: DHHS publication No. 2004-165, 2004; Occupational Safety and Health Administration: OSHA technical manual, 1995; Polovich M et al: Pittsburgh, PA, Oncology Nursing Society, 2009; US Pharmacopeia Convention, Rockville, MD, 2008). Education, training, and competency validation for chemotherapy administration must necessarily include this aspect of practice. Organizations should focus on a culture of safety, because of the relationship between patient and health care worker safety (Friese CR et al: BMJ Qual Saf, 2011; Polovich M, Clark PC: Oncology Nursing Forum, 2012).

APPENDIX C QCP ON-SITE REVIEW – A DAY IN THE LIFE

Table C-1 presents proposed time estimates for QCP On-Site Review activities.

Table C-1: QCP On-Site Review Activities

Time Estimate	Activities
20-30 minutes	Introductions/brief tour of facility/overview of on-site review activities for the day
1-2 hours [depending on the flow of the chemotherapy infusion room and the timing of chemotherapy preparation]	Review of chemotherapy orders and observation of chemotherapy order checking. Observation of chemotherapy preparation and labeling. Observation of double check of prepared chemotherapy.
2-4 hours	Review of chart documentation for two patients receiving IV chemotherapy and two patients receiving oral chemotherapy (on-site reviewer will select records to review). <i>If possible, this review should occur in an area away from the pharmacy or patient care areas, and a staff member familiar with the EMR/paper chart is needed to assist in locating needed items.</i> Review and/or discussion of policies and procedures for the 20 QCP standards. Review of pharmacy and nursing personnel records (licensure, orientation/training, etc.).
1 hour [10-15 minutes each]	Interview of 2-3 nurses who administer chemotherapy. Additional interviews of the nurse educator and administrative staff may be requested. <i>Interviews will occur at a mutually convenient time in a private area away from the patient care area. One nurse is interviewed at a time.</i> Interview of personnel who prepare chemotherapy and/or dispense oral chemotherapy (when applicable).
1 hour	Reviewer in quiet space alone to review notes.
30 minutes to 1 hour	Summary and discussion (practices may invite whomever they wish to attend) <ul style="list-style-type: none"> • On-site review observations • Timeline for follow up