

Program Participation Guide March 2025

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Section One: Introduction

The Importance of the Oncology Medical Home

ASCO Certified: Patient-Centered Cancer Care Standards powered by ASCO and the Community Oncology Alliance Oncology Medical Home standards ("Certification") aims to help oncology practices build care models to deliver quality, patient-centered cancer care. It is designed around patient needs aiming to improve access to care, increase care coordination and enhance overall quality, while simultaneously reducing costs. "The oncology medical home model of care demonstrates a reduction of the "cancer spend" by 7% to 13% through the implementation of structured care management and communications processes." (Cox, Sprandio and Barkley, 2013). The reduction in cancer spend is supported through avoiding admissions and ED visits; "Medical homes can reduce costly emergency department (ED) visits by 15% to 50% and inpatient admissions by 10% to 40% in a variety of populations." (Waters, Webster, Stevens, et.al., 2015). The Oncology Medical Home care delivery model is about delivering, ensuring, and measuring quality cancer care. It is a patient-focused system of delivering cancer care that is coordinated, efficient and designed to meet the needs of patients, providers, and payers.

A significant amount of sophisticated care is necessary to deliver optimal care to cancer patients. This is where the role of the Oncology Medical Home care delivery model becomes evident, with the specific goal of providing better access to cancer care for patients by a physician-led care team focused on providing the right care at the right time and in the right place. "The most important element is the process of translating lessons and insights from clinical practice to a more rational model of care that allows physicians to practice evidence-based, patient-centered care." (Patel, Morin, Nadel, et.al., 2013).

ASCO and COA Oncology Medical Home standards focus on seven areas: Patient Engagement; Availability and Access to Care; Evidence-based Medicine; Comprehensive Team-based Care; Quality Improvement; Goals of Care, Palliative and End of Life Care Discussions; and Chemotherapy Safety.

QOPI Certification Program, LLC d/b/a ASCO Certification Program ("ACE") conducted a Patient-Centered Cancer Care Certification as a new, two-year pilot certifying twelve participating practice groups and health systems in a variety of outpatient oncology settings, including community, hospital, and academic sites that met a single set of comprehensive, expert-backed standards for patient-centered care delivery. The Pilot was conducted from July 2021-June 2023 with demonstration of value to practices, patients, and payers.

ASCO Certified: Patient-Centered Cancer Care Standards

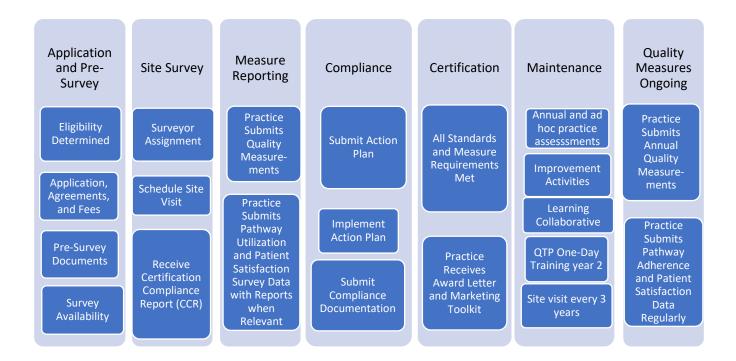
Certification of practices as an Oncology Medical Home is a program by ACE, an affiliate of ASCO, demonstrating that Certification adds value to practices, patients, and payers through collection of data on quality, utilization, and satisfaction of cancer care delivery (the "Program"). A demonstration of the Program's success is through a review of practices' quality of cancer care delivery through audit and measurement.

Benefits for ASCO Certified Practices

- Recognition for high quality, Patient-Centered, value-based care through the oncology professional society
- Access to a single set of care delivery standards for all practice types/sizes that support gap
 analysis and provides a comprehensive roadmap to high quality cancer care for the entire
 patient journey
- Consistency and clarity for high quality, Patient-Centered, value-based care
- A fostered culture of self-examination, ongoing assessment, and continual quality improvement
- **Participation in a learning collaborative** for practice/health system sharing to approach to standards implementation and successful experiences
- **Prepares the cancer care teams for the reformation** and recognition of care delivery based on quality and value
- Certification and Standards utilized as the value-based care delivery program by some plans/payers

This participation guide is a companion to the Oncology Medical Home Program Standards Manual (June 2023), as such may be revised from time to time (the "Standards Manual").

Program Task and Timeline



The tasks and timeline for quality measures reporting:

Progra	m Task	Timeframe		
1.	Report quality, pathways, and satisfaction measures for measurement to Registry.	Annually end of Q1 (March 31) receipt from practice. Quality measures also due upon application.		
2.	Report Pathway Utilization to Registry. Initial data collection to Registry with practice attestation upon application.	Application, Annually end of Q1 (March 31) and by the end of the month following each quarter (Q1 due April 30 etc.)		
3.	Report Patient Satisfaction to Registry. Initial data collection to Registry with practice attestation upon application.	Upon Application and Annually end of Q1 (March 31)		

Section Two: Practice Eligibility for Program Participation

Screening for Eligibility

Practices will complete an eligibility questionnaire that will determine practice's ability to participate in the Certification Program. Utilization of an Oncology Treatment Pathway System is a certification applicant requirement. A practice may have QOPI Certification designation or may apply for ASCO Certified including the antineoplastic therapy safety standards (exact same standards as QOPI Certification). The practice will receive Certification Application Packet including access to a practice questionnaire, participation agreement and resources including participation guide and standards manual.

Practice Definition

Practices are encouraged to participate in the Program with all their oncology clinic sites. Some practices may opt for a portion of their sites to be certified for learnings and capability. The Program recommends progression to all oncology sites with certification designation. For Certification purposes, a practice must use the same policies and procedures across all participating sites. Certification of a practice is only meaningful if standards apply to all participating 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 pursue Certification separately. To become Certified under the Program, an applicant must demonstrate to ACE's satisfaction that all its sites are functionally integrated. Sharing of a single physician faculty, rotation of staff, existence of a centralized person or entity as responsible for implementing policies/quality across all sites, use of a common EMR, and operation under a shared governance and management are all indicators of functional integration.

Oncology groups that have unique practice arrangements should contact ACE staff to discuss participation.

Oversight of Infusion Services

Practices must provide comprehensive medical oncology services, including infusion services. A practice that does not administer antineoplastic therapy on site or refers most of their patients to unaffiliated infusion centers, may be eligible for participation by demonstrating a sufficient relationship with one or more unaffiliated infusion center(s) to which it refers its patients. The practice must have operational and clinical oversight of the infusion processes. Practices that do not provide infusion services should contact ACE staff to determine their eligibility.

Use of Oncology Treatment Pathways

Practices will be required to utilize an oncology treatment pathways system with capabilities of reporting physician utilization including on-pathway and off-pathway data. Prospective practices will be asked whether they currently utilize pathways in compliance with the Certification standards requirements.

Practices may use one the following commercially available oncology clinical pathways programs:

- Elsevier ClinicalPath
- McKesson Value Pathways powered by NCCN

- New Century Health
- OneOncology Pathways
- Philips IntelliSpace Precision Medicine Oncology Pathways powered by Dana-Farber

Alternatively, practices may implement NCCN Categories of Preference as integrated into their EHR or decision support tool. Practices implementing Categories of Preference must track and report utilization compliance according to the standard. Flatiron Assist™ is an example of an oncology-specific clinical decision support tool that includes NCCN Categories of Preference.

Practices utilizing another pathway program will be screened to determine whether the pathway meets criteria as described in ASCO's "Criteria for High-Quality Clinical Pathways in Oncology" and that necessary adherence data is available for submission.

Practices must also measure and demonstrate physician/prescriber utilization compliance with oncology clinical pathways; and have a governance process in place within the practice for managing lack of compliance with pathways including on-pathway and off-pathway utilization data. Documentation for non-compliance with pathways must be clearly indicated in the medical record.

(Reference: Daly B, Zon R. Page R, et al. (2018). Oncology Clinical Pathways: Charting the Landscape of Pathway Providers. Journal of Oncology Practice, 14, no. 3, e194-e200. Retrieved from https://ascopubs.org/doi/full/10.1200/JOP.17.00033 and Clinical Pathways | ASCO)

Section Three: Requirements for Certification

Practice Requirements

Initial and Ongoing Certification will require compliance with all standards identified in the Standards Manual. ACE will evaluate compliance through review of policies and procedures, site survey validating standards including chemotherapy safety practices, collection and submission of required clinical quality measures, with supporting documents/reports as relevant, through ASCO's designated Registry Provider. Additionally, receipt and review of pathway utilization compliance, patient satisfaction measures, aggregated De-Identified Data, and related reports.

- Practice leadership, including administrators and physicians, must support the Oncology Medical Home concept and adopt policies and procedures to achieve Certification, including, without limitation, the following:
 - a. The practice establishes an Oncology Medical Home Oversight Committee which documents these processes and activities and confirms each eligibility requirement annually. The Oversight Committee may be an existing Quality Committee/Program or Value-based Committee.
 - b. The practice orients current physicians, allied health professionals, and administrative staff on the importance and significance of Oncology Medical Home principles. New physicians and staff are oriented to Oncology Medical Home practices and standards when joining the practice.
 - c. The practice designates one physician as the program leader for practice's participation in the Program ("Program Leader"). The Program Leader chairs the Oversight Committee and ensures Oncology Medical Home policies and procedures are followed by the practice. In addition to the Oversight Committee, practices may choose to establish subcommittees or workgroups to manage specific activities, noting that activities and reports must be presented and approved by the Oversight Committee.
 - d. The Program Leader oversees:
 - i. Annual review and revision of policies and procedures that address Oncology Medical Home standards.
 - ii. Audit of compliance with Oncology Medical Home standards in each Standards Manual chapter.
 - iii. Evaluation of compliance and monitoring of Oncology Medical Home performance measures.
 - iv. Encourages, supports, and documents ongoing efforts to achieve and maintain the high standards of care that are described throughout this Participation Guide.
 - v. Promotion of a culture of ongoing assessment and continual quality improvement activities

DOCUMENTATION REQUIREMENTS: The practice identified members of Oversight Committee and its Program Leader and reviews policies and procedures annually.

2. Program practices are responsible to submit quality measure data/results on regular intervals as detailed in the participation guide. The Program may also partner with payers, clinical registries, and other third-party entities that may submit data on the practices' behalf. The practice implements tools and methods to record and track data that are needed to evaluate the Program's mandatory performance measures. Data results are applied to the quality improvement process to improve performance and patient outcomes. This data will reflect the outcome of the successful implementation and management of the described standards and will assist with payer-defined payment methodology.

DOCUMENTATION REQUIREMENT: The practice reports performance measures as required in Sections Nine and Thirteen of the Program Participation Guide.

- 3. Practices are required to report intent to use certified EHR technology (CEHRT) throughout participation in the model. The practice shall use CEHRT in a manner sufficient to meet the requirements for an "eligible alternative payment entity" under section 1833(z)(3)(D)(i)(I) of the Social Security Act, as implemented.
 - DOCUMENTATION REQUIREMENT: The practice attests to utilizing certified EHR technology. CMS EHR Certification ID may be requested.
- 4. Program Practices must meet Antineoplastic Therapy Safety Standards—the Oncology Medical Home Antineoplastic Therapy Safety Standards are identical to the QOPI® Certification Program (QCP)—through one of the following options:
 - a. Current QOPI Certification status within the last 24 months of the 36-month re-Certification cycle OR
 - b. Demonstration of compliance through ASCO Certified site survey.
- 5. ASCO Certified Site Visit and QOPI Certification
 - a. ASCO Certified as a program includes the antineoplastic therapy safety standards (22 standards) and Patient-Centered care delivery standards (17 standards).
 - b. ASCO Certified is one certification for both sets of standards.
 - c. For practices with QOPI Certification designation, upon ASCO Certified designation is the certification award to include all 39 standards.
 - d. With ASCO Certified including the antineoplastic therapy safety standards, there is not a requirement for QOPI Certification maintenance. The ASCO Certified Quality Measures submission and ASCO Certified application and survey processes meet this requirement.

Reference:

2020 QOPI Certification Program Standards

https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program/about-qopi-certification

Seven Essential Elements of an Effective Oncology Medical Home

1. Patient Engagement

- 2. Availability and Access to Care
- 3. Evidenced-Based Medicine
- 4. Comprehensive Team-Based Care
- 5. Quality Improvement
- 6. Goals of Care, Palliative and End of Life Care Discussions
- 7. Chemotherapy Safety and QOPI Certification Program Standards

(Reference: Oncology Medical Home Standards Manual)

Practice Responsibility

- 1. Demonstrate compliance with the Oncology Medical Home standards through site visit(s), ongoing assessment, improvement activities and annual practice review
- 2. Submit to a site review of compliance with standards initially and every three years for ongoing certification
- 3. Participate in an approved clinical pathway program with demonstrated utilization for a minimum of 50% of patient treatment plans
- 4. Conduct and analyze results for improvement of a patient satisfaction survey.
- 5. Track and submit clinical quality measures data for quality measures to ACE's Registry Provider along with required documentation/reports
- 6. Track and submit clinical pathway utilization compliance data.
- 7. Track and submit required data for patient satisfaction and pathway utilization to ACE's Registry Provider along with documentation/reports as needed
- 8. Participate in Practice calls with other participants and provide feedback to ACE regarding participation in the Certification Program, as requested from time to time

Section Four: Certification Process

Practices will complete the eligibility form with approval from ACE to process with the and application process. The application process will be completed electronically using the Certification Program Application Portal with guidance from the ACE team.

Certification Performance

Throughout the Certification process, the Program uses the following status designations for participating practices:

Certification Status	Definition
Full Certification	A practice which has successfully demonstrated compliance and is active in participating in Ongoing Assessment and Improvement Activities
Action Plan	A practice which has yet to successfully demonstrate compliance with Oncology Medical Home standards and is in the process of preparing and submitting compliance documentation for a deficiency identified during Certification site visit
Certified with Action Plan	A certified practice which is in the process of preparing and submitting compliance documentation due to a deficiency identified during Ongoing Assessment and Improvement Activities. Practice has a timeline determined by ACE to complete compliance documentation.
Provisional Certification	A certified practice which is in Certified with Action Plan status that is non-compliant in submission of compliance documentation per timeline determined by ACE.
Terminated	A practice which has failed to complete Certification site visits or active participation in Ongoing Assessment and Improvement Activities

Section Five: Application

This section describes the processes required to apply for Certification once a practice has been determined eligible for participation in the Program.

Calculating Practice Size

A practice must include in its application the number of oncology physicians within the practice, as well as a roster with names and national provider identifiers. For purposes of completing the application, the number of physicians is determined by a unique count of the following physicians, without proration:

- Hematology, Hematology/Oncology, and Medical Oncology physicians
- Gynecologic Oncology physicians who prescribe chemotherapy
- Physicians of other specialties who prescribe chemotherapy for cancer patients
- Chemotherapy/Antineoplastic therapy is defined as: All chemotherapy 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.

Certification Fees

There is a one-time application fee required in connection with submission of a practice's initial application (or new application after lapse in Certification status). Application fees are non-refundable.

Ongoing Certification fees are structured as an annual amount for the duration of a practice's Certification. The first such annual fee is due upon Certification, and subsequent annual fees are due each year thereafter on the anniversary of Certification, to maintain Certification. Annual fees cover ongoing reporting of quality, pathway, and patient satisfaction measures, Ongoing Assessment and Improvement Activities including every three-year site visits. The QOPI Certification standards are exact to the Chemotherapy Safety standards in the ASCO Certified Program. Practices who are currently QOPI Certified, will receive credit towards ASCO Certified application fee based on timeframe of QOPI Certification award.

<u>Fees</u>	<u>Price</u>	<u>Basis</u>
Application Fee	 \$1000 per NPI with a minimum of \$15,000 fee Some discounts may apply based on total number of NPIs An additional site cost fee for greater than 5 sites 	One time per new application per oncology physician (NPI)

Annual Fee	 \$500 per NPI with a minimum of \$7500 fee Some discounts may apply based on total number of NPIs Every three-year site visit included in annual fee 	Per oncology physician (NPI)
Ongoing certification site visit(s) every three years	 An additional site cost fee for greater than 5 sites 	

Site Cost Calculation

Sites	<u>Additional Fee</u>		
1-5 Sites	No additional fee		
6-10 Sites	\$1,500		
11-15 Sites	\$2,250		
16-20 Sites	\$3,275		

Greater than 20 sites contact ASCO Certification Program Team for site cost calculation and fees.

Application Steps

Practices must complete and submit an application to ACE staff, which includes the following steps:

Step 1: Eligibility

Step 2: Complete Agreements (Participation, Business Associate Agreement)

Step 3: Practice Questionnaire

Step 4: Payment of Application Fee

Step 5: Submission of Pre-Survey Documents and Data

Step 6: Site Survey Availability

Section Six: Document Submission & Review

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

Supporting Standards Documentation

Practices are required to submit supporting policies and required documentation for Certification Standards at the time of application electronically through the Certification Program Application Portal. A concise summary of the policy is completed by the practice with relevant policies uploaded into the application. Applicants must submit supporting policies and required documentation for the following Certification Standards:

- Standard A: Patient Engagement
 - o A.1 Patient Oncology Medical Home education
 - A.2 Financial Counseling Services
 - o A.3 Patient and Caregiver Education
 - A.4 Survivorship Care Program
- Standard B: Availability and Access to Care
 - B.1 24/7 Triage and Same Day Appointments
 - B.2 ED/Hospitalization Management with Follow-up Post Admission
 - B.3 Missed or Cancelled Appointments
- Standard C: Evidence-based Medicine
 - C.1 Source of Treatment Pathways and Measurement/Reporting Results
 - o C.2 Clinical Trials
- Standard D: Comprehensive Team-based Care
 - D.1 Physician Directed Oncology Medical Home Practices
 - D.2 Staffing Requirements
 - D.3 Referring Patients for Support Services
 - D.4 Health Outcomes
- Standard E: Quality Improvement
 - E.1 Patient Experience Survey
 - E.2 Quality Improvement and EMR Completeness
- Standard F: Goals of Care, Palliative and End of Life Care Discussions
 - o F.1 Advance Care Planning
 - o F.2 Patient Goals of Care Discussion
- Standard G.1 Antineoplastic Therapy Safety
 - Antineoplastic Therapy Safety Standard Requirements include eight required standard policies.
 - 1.1 Clinical Staff Qualifications
 - 1.6 24/7 Triage
 - 2.1 Patient Consent
 - 3.5 Intrathecal Chemotherapy Preparation
 - 3.10 Extravasation Management
 - 4.1 Emergent Treatment

- 4.2 Initial Oral Chemotherapy Adherence Assessment
- 4.3 Ongoing Oral Chemotherapy Adherence Assessment

Section Seven: Survey Site Visit

Practices must participate in a site survey where a qualified oncology professional will perform a site assessment to evaluate compliance with each Oncology Medical Home standard. Site surveys occur six to eight weeks from the application submission date depending on surveyor availability and practice readiness. Practices will be notified of their site surveyor's name and visit date within four weeks of submitting their application and will have the opportunity to confirm that they do not have a conflict of interest with the assigned surveyor. Surveys will be conducted at reasonable times during ordinary business hours to minimize disruption to the practice. After the surveyor and date selection clears, the surveyor will conduct a pre-survey virtual meeting with the practice to discuss logistics and a working agenda for the site survey.

Practice Preparation for the Site Survey

To ensure a smooth and effective site survey, please follow these steps:

- Ensure that someone who is familiar with the practice's EHR system (if applicable) is available to work with the Site Surveyor on the day of the site visit to review records and identify Oncology Medical Home standards elements within existing medical records. Surveyors are not permitted are not to access EHR system without staff present.
- 2. If chemotherapy is prepared/compounded by an off-site pharmacy or at another location, please let the surveyor know during the scheduling process. The practice will need to arrange for the surveyor to observe chemotherapy being prepared. The observation logistics will be discussed during the scheduling process.
- 3. Ensure the availability of a conference room or quiet area for the day to allow the team to work with the surveyor in reviewing the patient records and other associated documents.
- 4. Provide the surveyor with access to the practice's electronic policy/procedure manual that is consistent for all sites. The policies that correspond to the Oncology Medical Home standards must be readily accessible to the surveyor. Please inform practice staff they may be selected for observation and that participation is mandatory to continue with the site survey process.

Note: The site surveyor will randomly choose the patients to review. It is part of the site survey process to ask the patient's permission first. Practice staff will be asked to confirm and receive approval from the patient for the surveyor to observe the chemotherapy process. The practice bears responsibility for obtaining all required consents and authorizations.

Number of Practice Sites, Sites to Visit, and Charts to Review

For Oncology Medical Home Standards domains 1 through 6 there is a guide below of the number of practice sites, sites to visit, and minimum charts to review. This same guide is used for Oncology Medical Home Standard domain 7, Chemotherapy/Antineoplastic Therapy Safety Standards. As an example, a practice with ten sites that will be surveyed for all Oncology Medical Home Standards (domains 1 through 7) will have two sites surveyed for domains 1 through 6 and two sites surveyed for domain 7.

Number of Practice Sites	Sites to Visit/ Observe	Minimum Medical Record Review for Domains 1-6	Minimum Medical Record Review for Domain 7
1-5 Sites	1 site	2 IV or Oral	2 IV & 2 Oral
6-10 Sites	2 sites	2 IV or Oral	2 IV & 2 Oral (1 each per site visited)
11-15 Sites	3 sites	3 IV or Oral	3 IV & 3 Oral (1 each per site visited)
16-20 Sites	4 sites	4 IV or Oral	4 IV & 4 Oral (1 each per site visited)
21-25	4 sites	4 IV or Oral	4 IV & 4 Oral (1 each per site visited)
26-30	4 sites	4 IV or Oral	4 IV & 4 Oral (1 each per site visited)
31-35	4 sites	4 IV or Oral	4 IV & 4 Oral (1 each per site visited)

If greater than 35 sites, site visits and chart review will be determined at time of application.

Site Survey Agenda

The surveyor will contact the practice after a survey date is confirmed to discuss logistics and their working agenda. The site surveyor's objective is to review practice compliance with the Oncology Medical Home standards using a patient tracer method through:

- Review of medical record documentation
- Review of policies, procedures, guidelines, and required documentation and data
- Observation of antineoplastic therapy preparation
- Observation of antineoplastic therapy administration
- Interviewing key team members including Oncology Medical Home Oversight Committee members

The Standards Manual includes detail and specificity for each Standard and its underlying elements containing a summary of four sections:

• Standard Definition and Requirements: This section provides an explanation of how to interpret the Standard and its elements.

- Standard Specifications: A thorough explanation of the standard and expectations in the care delivery of the standard.
- Documentation Requirement: This section contains the requirements for written materials a practice/institution must have in place to meet the Standard and its elements and/or the processes the Surveyor must observe during the site survey.
- Tools & Resources: Information and references that may be helpful to a practice/institution seeking Certification.

Report & Summary Findings by Surveyor

The surveyor will provide the practice with a preliminary overview of the findings for each of the Oncology Medical Home standards. The exit summary will take 45-60 minutes and will provide the practice with an opportunity to clarify the standards and the surveyor's observations. During the exit summary, practices are provided the opportunity to invite team members who may benefit from the discussion of the findings. Any standard designations the surveyor might give at this point are subject to change, as they must be reviewed by a Program Steering Group Reviewer prior to finalization.

Section Eight: Compliance Report and Action Plan

Program Steering Group members, including community and academic oncologists and oncology professionals, evaluate the Certification Compliance Report (CCR) and any responses to determine the Certification award decision. Practices may appeal Certification decisions using a structured appeals process.

Certification Compliance Report and Response Timeline

Upon completion of the site survey, practices will receive a report assessing compliance with each Certification standard and detailing those requirements (if any) that must be addressed before Certification status can be awarded.

Certification Compliance Report Response Timeline

- 1. The Certification Compliance Report (CCR) is written by the site surveyor and submitted to ACE staff for initial review ten calendar days after the site survey.
- 2. The CCR is finalized by ACE staff and sent to the Program Steering Group member for final review within seven calendar days.
- 3. The final CCR is sent to the practice with instructions for submitting a Certification Action Plan if there are any outstanding requirements. The Certification Action Plan is sent by the practice to ACE staff within thirty calendar days from the day the final CCR is received.
- 4. The Certification Action Plan will be reviewed by ACE staff for clarity, accuracy, and acceptable timeline for Certification.
- 5. The practice will work on the requirements and submit any corresponding documentation to demonstrate compliance with all previously unmet standards within 120 calendar days of receiving the final CCR. ACE staff are available for weekly check-ins for program practices throughout this period.
- 6. Once all required documentation has been submitted, it will be summarized for completeness and accuracy, as specified in the CCR, and sent to the original Program Steering Group member for final review and approval within seven calendar days.
- 7. When the Program Steering Group member approves the document submission, the practice will be notified of their Certification award.

Re-Survey

Following review of a practice's Certification Application and Certification Compliance Report (CCR), the Program Steering Group may determine that a re-survey is necessary to evaluate the practice's qualification for Certification. The practice will be responsible for the financial cost associated with a re-survey.

Section Nine: Measures Submission

Following the final decision by assigned member of Program Steering Group, the practice will receive Certification status that will include required participation in submission of quality measures, oncology treatment pathways, and patient experience. Upon Certification, the practice will submit data on applicable measures for each reporting period to the Registry Provider. The Registry Provider will then provide aggregated, de-identified performance reports to ACE for their evaluation.

Clinical Quality Measures

Practices will be required to report aggregated data to the Registry Provider upon Application prior to Certification and at least an annual basis, at the end of Quarter 1, on the following group of measures, listed below, as evidence of compliance with the Program. Measures are a key component of demonstrating quality care.

Clinical Quality Measures

- Oncology: Medical and Radiation Plan of Care for Pain
- Oncology: Medical and Radiation Pain Intensity Quantified
- Preventive Care and Screening: Screening for Depression and Follow-Up Plan
- Percentage of Patients who Died from Cancer Receiving Systemic Cancer-Directed
 Therapy in the Last 14 Days of Life (lower score better)
- The Registry staff will report the clinical quality measures results to ACE every April.

Oncology Treatment Pathway Adherence

Practices are required to submit pathway utilization compliance data upon Application prior to Certification, by the end of the month following every Quarter (Q1 due: April 30, Q2 due: July 31, Q3 due: October 31, and Q4 due: January 31 of the following year) thereafter following Certification, and annual (calendar year) data due end of Q1 (March 31) via the Registry provider.

The following information is required to be submitted via the Registry Provider:

- Pathway Source
- Pathway Utilization Rate Overall
- On-Pathway Rate Overall
- Off-Pathway Rate Overall

If a PDF is available from the pathway system, please upload, otherwise, uploading a report is optional but strongly encouraged. Compliance reports must include primary disease cohort, number of regimens selected, and number of selected regimens considered on-pathway. Practices must record reason for off-pathway regimens in the pathway system and/or electronic health record.

Practice performance will be reported by Registry staff to ACE every May, August, November, and February.

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Patient Satisfaction

Practices are required to submit patient satisfaction results upon Application and annual submission at the end of Q1 thereafter to demonstrate compliance with patient satisfaction standard following Certification via the Registry provider.

Administration and monitoring of a patient satisfaction survey is a critical tool for implementing quality improvement. Patient satisfaction surveys are to be continuously reviewed and results acted upon if changes are warranted. The goals of the surveys are to educate and inform the practice of any patient concerns and to focus and facilitate quality improvement efforts. Oncology Medical Home practices must administer patient satisfaction surveys using oncology-specific provider benchmarks, targets, internal comparisons with trends that drive performance improvement. The Oncology Medical Home Patient Satisfaction Survey (Community Oncology Alliance) is an example of a high-quality tool that meets the need for evaluation of the patient experience and helps drive quality improvement.

Practices will evaluate and take actions to improve cancer patient satisfaction scores. The results of patient satisfaction surveys are regularly reviewed by the practice and utilized for clinical and quality improvement activities. The practice documents its activities, improvements, and benchmarks in the OOC minutes.

The following information is required to be submitted via the Registry Provider:

- Patient Satisfaction Tool
- Patient Satisfaction Survey Completion
- Patient Satisfaction Survey Distribution
- Patient Satisfaction Completion Rate
- Frequency of Survey Distribution
- Key Performance Indicator (KPI)

If a PDF is available from the pathway system, please upload, otherwise, uploading a report is optional.

The Registry staff will report the patient satisfaction results to ACE every April.

Resources:

Oncology Medical Home Patient Satisfaction Survey

http://www.medicalhomeoncology.org/coa/patient-satisfaction.htm

CAHPS Cancer Care Survey

https://www.ahrq.gov/cahps/news-and-events/news/news2017-3.html

Section Ten: Certification Award

Certification is awarded when a practice is deemed by ACE to have met all Program requirements for Certification, site assessment, and measures reporting. The award indicates that by achieving Certification, a practice has participated in the Certification process, has met, or exceeded a performance threshold on measures that compared the quality of its care against national standards, and participated in a site survey and peer review by a select team of oncology professionals.

Full certification status should be achieved within 15 months of participation agreement completion.

Following initial certification award, the practice will have an ongoing certification site survey every three years.

Oncology Medical Home Certification Term

Certification begins at the time when the practice achieves Certified status under the Program. To maintain Certification, the practice will participate in required Ongoing Assessment and Improvement Activities, to include:

- Submission of quality measure data to the Program's Registry Provider (annually end of Q1 for previous calendar year).
- Submission of pathway utilization compliance results on a quarterly and annual basis.
- Annual submission of patient satisfaction results necessary to demonstrate compliance with Patient Satisfaction standard (every end of Q1).
- Annual submission of documentation necessary to demonstrate Ongoing Assessment and Improvement Activities.
- An annual review of practice performance will determine continued designation of the practice as Certified.
- Submission of documentation necessary to demonstrate compliance with any new or modified Certification standards.
- Maintenance of all Oncology Medical Home Standards including Antineoplastic Therapy Safety Standards with a site visit for validation and compliance occurring every three years.
- Additional, site visits determined by ACE based on practice needs.

Marketing Certification Status

Certified practices receive resources from ACE staff to help recognize and promote their status. When Certification is awarded, ASCO's and ACE's marketing and communications teams are available and ready to assist practices as requested. In addition, each certified practice receives one complimentary award plaque to display at their facility.

Any practice who has failed to maintain Certification or submit annual fees and are moved to Terminated status must immediately suspend use of Certification status in marketing materials and remove any displayed plaques or mention of Certification in practice sites.

Section Eleven: Ongoing Assessment and Improvement Activities

To maintain Certified status, all practices must participate in required Ongoing Assessment and Improvement Activities. Practices will have an annual assessment conducted with ACE staff to assure continued compliance with standards and measure requirements. There can be ad hoc practice assessments as deemed appropriate or required.

Ongoing Assessment and Improvement Activities assessment will review:

- Pathway Utilization compliance data (OMH standard C.1)
- Health Outcomes initiatives (OMH standard D.4)
- Patient Experience Survey data and analysis for improvement (OMH standard E.1)
- Quality Improvement Program initiatives (OMH standard E.2)
- Standard compliance monitoring for sustainability (identified by practice and ACE)

The practice will be provided an electronic template to upload required documentation. The Ongoing Assessment and Improvement Activities may be updated from year to year.

Quality Measure Reporting and Performance

Practices will be required to report aggregated data to the Registry Provider on at least an annual basis on the following group of measures, listed below, as evidence of compliance with the Program. Practices who fail to submit necessary quality measure data by due dates will be formally notified and will be required to resolve outstanding data within 30 days.

Data required in connection with the Program will be submitted to ACE's designated Registry Provider. The current Registry Provider is the ASCO Quality Reporting Registry (AQRR) hosted by Armature. After receipt of required data, the Registry Provider will provide reports, including measure performance reports, to ACE for the purpose of ACE's evaluation of practice's eligibility for Certification.

Data from the Program will be utilized to evaluate established performance thresholds for use in the Program.

Practices who drop below performance thresholds for two straight reporting periods will be formally notified and will be required to submit evidence of compliance within 90 days.

Pathway Utilization Reporting and Performance

Practices are required to submit pathway utilization compliance data prior to Certification and at least every quarter and annually following Certification via the Registry provider in a format determined by ACE. Compliance reports must include primary disease cohort, number of regimens selected, and number of selected regimens considered on-pathway. Practices must record reason for off-pathway regimens in the pathway system and/or electronic health record.

Practices who fail to submit necessary pathway utilization data by the due date will be formally notified and will be required to resolve outstanding data within 30 days.

Patient Satisfaction Reporting

Practices are required to submit patient satisfaction results prior to Certification and annual submission (end of every Q1) to demonstrate compliance with patient satisfaction standard following Certification via the Registry provider in a format determined by ACE.

Practices who fail to submit necessary patient satisfaction data by the due date will be formally notified and required to resolve outstanding data within 30 days.

Program Participant Calls

ACE staff will facilitate a call with all participating Program practices on a regular basis. Program practices are expected to participate with one or more practice staff.

Communications with the Program participants will include:

- Routine discussions on current findings, program updates, and improvement opportunities.
- Feedback from practice regarding how value is being realized and to determine if ACE staff can assist.
- Feedback from practice to ACE regarding Program implementation.
- Learning collaborative with best practice and information sharing from Program Practices, ACE, and others.
- General communication that would promote the ongoing collaboration.

Compliance with New Standards and Measures

Following completion of the Program, ACE may introduce new standards and measures. Program practices will be provided at least 180 calendar days to demonstrate compliance with any such new standards and measures.

Section Twelve: Payer Participation

Inclusion of Payers in the Oncology Medical Home Certification Program

Practices may engage with payers. Payer engagement may include the sharing of de-identified, aggregate reports on measure performance. The data provided will be used for the purpose of claims measure development. During the application process, practices will elect for which payers they wish to engage during the program. Once the measures are developed, payers will implement in their systems and Practice will report the required data elements in the Registry.

Claims-Based Measurement

ASCO and ACE's Registry Provider will utilize claims-based data to specify and calculate new administrative claims measures relevant to the Oncology Medical Home standards. Claims-based measures, and possibly measures reflecting both claims and EHR data, will be added to Registry dashboards as they become available.

Practice Sharing of Quality Measures, Satisfaction, and Pathway Adherence Data with Payers

As detailed in Section Eleven, practices must submit clinical quality measures, pathway utilization, and patient satisfaction data to maintain Certified status. ACE will ask each practice to elect which payers may have access to the practice's results; practices may revoke this access at any time.

Payer Sharing of Claims-Based Data

The Registry Provider will act as a data custodian and business associate to the practice, accepting claims-based data and calculating measures related to acute-care admissions, emergency room visits, end-of-life care, and cost of care on behalf of the practice, if desired.

Section Thirteen: ASCO Quality Reporting Registry

Overview of ASCO Quality Reporting Registry

Practice measure reporting and payer claims reporting will be supported by the ASCO Quality Reporting Registry ("Registry"). ASCO has engaged Armature as the technology vendor supporting the Registry ("Registry Provider"). The Registry will bring together data submitted by practices, calculate measures using standard business rules, and display results in a report available to participating practices and ACE. Practices participating in the Program will use the ASCO Quality Reporting Registry (AQRR) to submit data for the Program.

Requirements for Practice Data Sharing

Practices will fulfill quality measure requirements, as discussed in previous sections, through participation in the Registry. Practices will report data to the Registry through the Armature application's measure track. Once submitted, Registry staff will validate the submission of aggregated data along with validating the supporting documents submitted. If a submission fails validation, Registry staff will contact the Practice to notify them on what needs to be addressed for a successful submission.

Quality Reporting Registry product and service offerings

Practices participating in the Registry will have access to a calculation of measure scores through the Armature application along with tools to assist in understanding measure performance as it relates to the Program. Practices will also have access to reports showing their performance in comparison to set floors and targets, as well as the aggregate of the other Practices participating in the Registry. Registry staff will notify Practices when reports are available at the end of the submission period. Practices will have access to the Care Delivery Registries Help Desk. The help desk is available Monday through Friday 9am to 5pm Eastern and can be reached at cdr@asco.org. Please avoid sending Protected Health Information via email.

Armature Application Required Data Fields

The following data elements must be reported to successfully calculate quality measures required to obtain and maintain certification. The data elements below are for the initial four measures included in the Program.

Data Element	Quality ID #144 Care Plan For Pain	Quality ID #134 Depression Screening	Quality ID #453 Chemo EOL	Quality ID #143 Pain Med/Rad Intensity	Pathway Utilization (Every end of Q1 and Q3)	Patient Satisfaction (Every End of Q1)
Numerator	X*	Х	Х	Х*	Х	Х
Numerator NPI Count	Χ*	X	X	Х*		
Denominator	Χ*	X	X	Χ*	Х	Х
Denominator NPI Count	Χ*	X	X	Χ*		
Denominator Exclusion		Х				
Denominator Exception		Х				
Reporting Period	Х	Х	Х	Х	Х	Х
Report (File Upload)	Х	Х	Х	Х	X (Optional)	X (Optional)

^{*} Indicates the measure has two criteria for the field, these will need to be added together before entry into the Data Element Field. Guidance is provided in the Armature Application for these measures.

File Upload Requirements

The Registry requires Practices to upload reports to support the information entered for each measure data element. Report uploads are optional for Pathway Utilization and Patient Satisfaction.

The Armature Application will not accept .cvs, .xlsx, or .xls file types as uploads.

Section Fourteen: Certification Program Policies

Information and Data Released from the Program

ASCO will not release any performance data without the specific request or permission of the participating practice, except as authorized under the participation agreement. Current certified practice names, addresses, and statuses will be displayed on the ACE website.

Repeat Site Survey Policy

Following review of a practice's Program Certification Application and completion of the site survey, ACE staff may determine that an additional site survey is necessary to evaluate the applicant practice's qualification for Certification. In accordance with the procedures set forth in this policy, ACE may require a repeat site survey if the practice is found not to be compliant with policies and procedures relating to standards based on the surveyor's observations during the site survey; or if ACE otherwise determines that further personal observation is needed to assess the practice's qualifications for Certification.

- ACE 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.
- ACE staff will assign a site surveyor to perform the re-survey, consistent with the procedures in the Conflict of Interest of Policy for Oncology Medical Home Certification, Appeals, and Revocation.
- The practice shall bear the financial cost of re-survey.

Automatic Denial of Certification

ACE may issue an Automatic Denial of Certification if Certification reviewers determine that, due to the volume or severity of missed Standard elements, it would be impossible or highly unlikely for a practice to obtain Certification within the allotted timeframe under the current application.

Certification Appeals Process

Practices that apply for but do not achieve Certification may appeal the decision to deny Certification. ACE staff may be contacted for the request for an appeal.

Notification of Appeals Decision

Based on its review, the Primary Appeal Panel may grant Certification or affirm the denial of Certification by majority vote. If the Primary Appeal Panel does not order a re-survey of the practice, the Practice will be notified of the decision of the Primary Appeal Panel within ten (10) business days of the meeting of the Primary Appeal Panel. If the Primary Appeal Panel orders a re-survey of the practice, ACE will use commercially reasonable efforts to arrange for the resurvey to occur within six (6) weeks. The Primary Appeal Panel will meet within fifteen (15) business days of receipt of the re-survey report and the Practice will be notified of the decision of the Primary Appeal Panel within ten (10) business days of such meeting of the Primary Appeal Panel.

The decision of the Primary Appeal Panel will be in writing and will state the basis for the decision in reasonable detail.

Conflict of Interest Policy for Oncology Medical Home 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 Certification and Appeals Process.

Conflict of Interest Screens

ACE will assign both the site surveyor and a Program Steering Group member to review the practice application and responses to requirements, before awarding Certification. Practices will receive an email containing the name(s) of their assigned site surveyor(s). Practices will be asked to notify ACE via email within five business days to confirm whether the practice does or does not consider the assigned site surveyor to have a disqualifying relationship with their practice. Disqualifying relationship criteria may include:

- 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 ACE.

If a disqualifying relationship is identified, an alternate Site Surveyor will be assigned by ACE. ACE reserves the right to determine if the noted conflict of interest meets the program threshold.

Practice Mergers and Transactions Policy

Significant practice transactions, such as mergers and name changes, must be reported to ACE within thirty (30) business days. ACE does not automatically transfer Certification to new owners or practices that have merged or otherwise been involved in a significant transaction. ACE will assist practices in determining whether the sites that have current Certification terms are eligible to retain their certified status following such significant transaction, pursuant to ACE's policies. Failure to notify ACE of major changes to your organization may result in a loss of Certification.

Practice Transactions

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

Certification is practice-specific and non-transferable. In the event a practice undergoes a re-organization or other significant transaction*, ACE will have the discretion to determine whether one or more of the post-transaction entities may continue to be entitled to 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. Alternatively, practices can opt to have that practice site designated as non-certified and, when applying for re-Certification, incorporate that practice site into the data abstraction and application process.

* The term "transaction" as used in this guide is intended to capture significant corporate changes that might impact a practice's operations, compliance, policies, and procedures, including but not limited to the sale or acquisition of a practice, merger of one or more practices, and/or split of a practice into two or more separate entities. Since Certification is awarded on the practice level, changes that solely involve staffing or a corporate name will not affect a practice's Certification status.

Policy for Certification Revocation

To continue to ensure that Oncology Medical Home standards are met, ACE has adopted revocation procedures that allow ACE to investigate complaints concerning a Certified practice. Each practice investigated under the procedure is provided with due process, including written notice and review by the appropriate steering group or committee. The basis for revocation of Certification under these procedures includes, without limitation, 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 Certification; and
- Breach by a Certified practice or any member thereof of the Practice's Participation
 Agreement and Program related requirements, including but not limited to failure to
 adhere to the Program Practice Participation Guide, Logo Use Guidelines, ACE License
 Terms and Conditions, and other related policies.

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, ASCO and ACE 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 Program. All members of ASCO's workforce, including staff, are obligated to comply with ASCO's and ACE's Privacy and Security Policies. Registry Providers are required to comply with Privacy and Security Policies no less rigorous than ASCO's policies. If a practice has any questions regarding these policies and procedures or would like to receive a copy of the written procedures, please email patientcenteredcare@asco.org.

Contact Us

For more information regarding Certification, the application process, site surveys, or other matters concerning the Program, contact ACE staff at ascocertified@asco.org. Visit the ASCO Certified website at ASCO Certified: Patient-Centered Cancer Care Standards | ASCO. For matters pertaining to the ASCO Quality Reporting Registry, please contact the Care Delivery Registries team at cdr@asco.org.

References

- 1.) ASCO Practice Central <u>Patient-Centered Cancer Care Certification | ASCO Practice</u> Central
- 2.) John V. Cox, John D. Sprandio, and Ronald Barkley. "Understanding and Surviving the Transition to Value-Based Oncology." American Society of Clinical Oncology Educational Book 2013 :33, e361-e368
- 3.) Kavita K. Patel, Alexander J. Morin, Jeffrey L. Nadel, and Mark B. McClellan. "Meaningful Physician Payment Reform in Oncology." Journal of Oncology Practice 2013 9:6S, 49s-53s
- 4.) Oncology Medical Home Standards Oncology Medical Home Standards | ASCO
- 5.) QOPI Certification Program Standards. About QOPI Certification | ASCO Practice Central
- 6.) Teresa M. Waters, Jennifer A. Webster, Laura A. Stevens, Tao Li, Cameron M. Kaplan, Ilana Graetz, and Barbara L. McAneny. "Community Oncology Medical Homes: Physician-Driven Change to Improve Patient Care and Reduce Costs." Journal of Oncology Practice 2015 11:6, 462-467