ASCO Patient-Centered Cancer Care Certification
Featuring ASCO and COA
Oncology Medical Home

Oncology Medical Home

Standards Manual

June 2023

Oncology Medical Home Standards Manual Statement

The ASCO Patient-Centered Cancer Care Certification Program will require compliance with all Oncology Medical Home Standards identified in this Standards Manual, as may be updated from time to time (this "Standards Manual"). QOPI Certification Program, LLC d/b/a ASCO Certification Program ("ACE"), an affiliate of American Society of Clinical Oncology, Inc. ("Society"), will ensure compliance through review of policies and procedures, site survey standards review, and receipt of quality, pathway adherence, and patient satisfaction measures. This Standards Manual may be updated with new information from standards review.

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Section One: Introduction

The Importance of the Oncology Medical Home

ASCO Patient-Centered Cancer Care Certification: Featuring ASCO and COA Oncology Medical Home ("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)[1]. 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)[2]. 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)[3].

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

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[1] Cox, JV, Spandio, JD and Barkley,R. (2013). Understanding and surviving the transition to value-based oncology. American Society of Clinical Oncology Education Book 33 (May 16, 2013), e361-e368.

[2] Waters TM, Webster JA, Stevens LA, et al. (2015). Community oncology medical homes: physician-driven change to improve patient care and reduce costs. Journal of Oncology Practice 11(6), 462-467.

[3] Patel KK, Morin AJ, Nadel JL & McClellan MB. (2013). Meaningful physician payment reform in oncology. Journal of Oncology Practice 9(6S), 49s-53s.

Section Two: Essential Elements of the Oncology Medical Home

The Oncology Medical Home is the optimal care delivery model for value-based payment programs. The Oncology Medical Home focus is on value – value to patients, physicians, and payers. Oncology Medical Home practices concentrate on the processes of care, using data driven decision-making to improve patient safety and satisfaction, reduce adverse events such as avoidable admissions, and make value-based treatment decisions.

Health equity is achieved when everyone has the opportunity to attain their highest level of health; equity is a priority for practices throughout the continuum of cancer care.

This Standards Manual is a companion to the Oncology Medical Home Practice Participation Guide (June 2023), as such may be revised from time to time (the "**Participation Guide**")

Patient Engagement

The goals of an Oncology Medical Home are to enhance patient care experiences, clinical outcomes, quality of life, and patient satisfaction. These goals may be accomplished by the oncology practice staff providing patient education to empower the patient with knowledge about his or her disease so that expectations are realistic and shared by the team throughout the treatment plan. Understanding the side effects patients may encounter and knowing who and when to call a health care professional have been found to significantly reduce costs of care by keeping patients out of the emergency department (ED) and the hospital as much as possible.[4] An Oncology Medical Home should also have staff to provide financial counseling and access to financial assistance programs. Lastly, patients should have real-time access to their personal medical record, plan for treatment, and educational materials.

Availability and Access to Care

Data suggests that lack of access to a patient's oncology practice when the patient has symptoms during the day, in the early evening, and on weekends leads to more ED visits and unplanned hospitalizations. An Oncology Medical Home practice is required to develop the capability to provide expanded access and an evidence-based symptom triage system to ensure that patients can easily access the practice and their providers. There is urgent care through same day appointments, with 24 hours per day/7 days per week access to a clinician who has real-time access to patients' medical records.

Multiple studies have shown the potential for Oncology Medical Home care management strategies to reduce hospital admissions and emergency room visits.[5],[6,7] In one such study,

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[4] Mendenhall MA, Dyehouse K, Hays J, et al. (2018). Practice transformation: early impact of the Oncology Care Model on hospital admissions. Journal of Oncology Practice, 14(12), e739-e745.
[5] Ibid.
[6] Handley NR, Schuchter LM & Bekelman JE. (2018). Best practices for reducing unplanned acute care for patients with cancer. Journal of Oncology Practice, 14(5), 306-313.
[7] Sprandio JD, Floudeers, BP, Lowry M & Tofani S. (2018). Data-driven transformation to an oncology patient-centered medical home. Journal of Oncology Practice, 9(3), 130-132.

hospital admissions per chemotherapy patient, per year started at a rate of 1.08. By the end of the study, the rate of hospital admissions had decreased 51%.[8]

This capability is more than simply having a physician on call. Ideally labs, imaging, hydration, antibiotics, and other symptom management medications are available on-site or at least in a coordinated, expedited manner with the ability to elevate inquiries to the appropriate level clinician. This may be in the form of remote access, including telephone access and arrangements with urgent care facilities. Patients are informed that they should contact the practice when they don't feel well instead of going to the ED. All members of the care team contribute to the enhanced access offered in the Oncology Medical Home.

Evidenced-Based Medicine

Studies have shown that the application of value-based clinical pathways – clinical pathways are built upon guidelines, yet are more restrictive, by selecting the most appropriate option based on efficacy, potential for side effects, patient preferences, and cost – result in lower anti-cancer and supportive drug costs. Drug costs associated with use of off-pathway anti-cancer regimens can be upwards of 2.7 times that of on-pathway regimens.[9,10] Use of on-pathway regimens also result in lower supportive care drug, diagnostic, and hospitalization costs.[11,12] Initiatives involving implementation of clinical treatment pathways have resulted in increased compliance with on-pathway selection and drug savings from 5-37%.[13,14,15]

Oncology Medical Home practices either use practice-developed pathways for their common cancers or implement a commercially available oncology clinical pathways program such as New Century Health, Elsevier's ClinicalPath, Value Pathways powered by NCCN, or 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 adherence according to the standard. Practices may use a single-institution oncology

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[8] Ibid.

[9] Hoverman JR, Cartwright TH, Patt DA, et al. (201). Pathways, outcomes, and costs in colon cancer: retrospective evaluations in two distinct databases. Journal of Oncology Practice, 7, 52s-59s.

[10] Neubauer MA, Hoverman JR, Kolodziej M, et al. (2010). Cost effectiveness of evidence-based treatment guidelines for the treatment of non-small-cell lung cancer in the community setting. Journal of Oncology Practice, 6(1), 12-18.

[11] Ibid

[12] Gautam S, Sylwestrzak G, Barron J, et al. (2018). Results from a health insurer's clinical pathway program in breast cancer. Journal of Oncology Practice, e711-e721.

[13] Shah S & Reh G. (2017). Value-based payment models in oncology: will they help or hinder patient access to new treatments? American Journal of Managed Care, 23(5 Spec No.), SP188-SP190.

[14] Kreys ED, Koeller, JM. (2013). Documenting the benefits and cost savings of a large multistate cancer pathway program from a payer's perspective. Journal of Oncology Practice, 9(5), e241-e247.

[15] Jackman DM, Zhang Y, Dalby C. (2017). Cost and survival analysis before and after implementation of Dana-Farber clinical pathways for patients with stage IV non-small-cell lung cancer. Journal of Oncology Practice, 13(4), e346-e352.

clinical pathways program that has been assessed against ASCO's Criteria for High-Quality Clinical Pathways.[16]

Equitable and Comprehensive Team-Based Care

Health equity is a priority for the practice throughout the continuum of cancer care. The practice should address health equity guided by the ASCO policy statement on cancer care disparities which endeavor to: (1) ensure equitable access to high-quality care, (2) ensure equitable research, (3) address structural barriers, and (4) increase awareness and action. Practice policies will address developing awareness of conscious and unconscious biases of all practice team members and should be a focus of the practice and resources made available to assess & drive change where appropriate.

Within an Oncology Medical Home practice, the care team is created by determining the medical, psychosocial, economic, and support needs of the patient, determining how the practice can meet those needs and assigning the team member with the appropriate level of education and training to perform each service. Members of the team must be able to discern from the electronic medical record that the patient's needs are met. In addition, data to evaluate the outcomes of all facets of treatment must be available in real time to allow the practice to improve on the services given. Within the Oncology Medical Home practice itself, a team is led by a physician and comprised of nurses, pharmacists, medical technicians, care coordinators, first responders (telephone operators), and other appropriate team members. Disease management, patient education, and on/near site laboratory, imaging and pharmacy services are all delivered in a caring environment that enhances patient satisfaction.

Not all the care needed can be delivered within the walls of the practice, so an Oncology Medical Home practice must have established relationships with outside physicians when needed for the management of non-cancer symptoms. Oncology Medical Home practices have established communication processes in place to keep other physicians informed of the patient's treatment plan and current health care status. Patient navigation and care coordination includes support services and community resources specific to the patient's needs, such as translation, transportation, nutrition, rehabilitation, and social services. Health equity is a priority for the practice throughout the cancer care continuum of medically underserved populations including the identification and mitigation of disparities among racial and ethnic minorities, sexual and gender minorities, older adults, rural populations, poverty, socioeconomic, low literacy, inadequate health insurance, and cultural differences.

If a patient requires hospitalization, the care team focuses on an established inpatient care plan where the oncologist either manages the patient or co-manages the patient with hospitalists and the patient's primary care physician. And when implementation of an end-of-life care plan is needed, this team collaborates with palliative care and hospice to facilitate the transition of patients off of active treatment.

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[16] Zon RT, Edge SB, Page, R, et al. (2017). American Society of Clinical Oncology Criteria for High-Quality Clinical Pathways in Oncology. Journal of Oncology Practice, 13, no. 3, 207-210. Retrieved from https://ascopubs.org/doi/full/10.1200/JOP.2016.019836

Quality Improvement

Cancer care that is continuously improved by measuring and benchmarking results against physicians within the same practice (peer review), as well as against other oncology groups, helps to ensure continuous improvement and adoption of best practices. As quality goals are achieved or as standards of care evolve, those measures should be retired and replaced with new measures. Doing so continues to "raise the bar" in care delivery. In order to capture and exchange information for practices to continually monitor, report and improve processes and outcomes, a practice must have a fully implemented certified electronic health records system.

Oncology practices that wish to achieve Certification will be required to submit data to be used to monitor compliance with mandatory quality measures. Administration and monitoring of an oncology-specific patient satisfaction survey with evaluation of benchmarking 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.

Goals of Care, Palliative and End of Life Care Discussions

In 2010, Medicare costs for cancer care in the last year of life totaled $37 million, mainly due to undesired hospitalizations, ED visits, and intensive care unit stays. High utilization of cancer treatment at the end of life poses a burden to the health care system and may represent poor outcomes from the perspective of patients. Studies suggest that patients with advanced cancer prefer to have less aggressive life-prolonging treatment and more comfort-focused care including support for existential and physical suffering, and to avoid intensive inpatient settings at the end of life.[17,18] The National Quality Forum endorsed the use of several measures as indicators of poor quality of care at the end of life such as the use of chemotherapy in the last 14 days of life, stays in the intensive care unit in the last 30 days of life, and enrollment in hospice for fewer than three days.[19]

Oncology Medical Home practices will offer an advance care planning discussion and complete a goals of care discussion with all patients that recognizes the individual patient's needs and preferences. Palliative care will be introduced early in the patient care process for all patients with cancer; for patients with advanced cancer and/or metastatic cancer or patients with limiting co-morbid conditions the practice performs an advance care planning discussion including review of advance directives, agent for medical decision making, goals of care, and symptom management; and provide patient-centered access to care for patients at the end of life to avoid unnecessary and unwanted ED visits and potential hospitalizations.

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[17] Zang B, Nilsson M & Prigerson HG. (2012). Factors important to patients' quality of life at the end of life. Archives of Internal Medicine, 172(15), 1133-1142.

[18] Khan SA, Gomes B & Higginson IJ. (2014). End-of-life care – what do cancer patients want? National Reviews Clinical Oncology, 11(2), 100-108.

[19] National Quality Forum. (2012). Cancer endorsement maintenance 2011 (final report). Retrieved from: http://www.qualityforum.org/Publications/2012/12/Cancer_Endorsement_Maintenance_2011.aspx

Chemotherapy Safety and QOPI Certification Program Standards

Chemotherapy Safety Standards serve as a framework for practices to be recognized for exemplary commitment to quality and safety in oncology patient care. Practices desiring to achieve Certification must meet Chemotherapy Safety Standards – Oncology Medical Home Chemotherapy Safety Standards are identical to the QOPI® Certification Program (QCP) standards for chemotherapy administration safety – through one of the following options:

a. Current QOPI Certification status within the last 24 months of the 36-month re-certification cycle. QOPI Certification status must be maintained to maintain Certification status; OR
b. Demonstration of compliance through Certification site visit.

Reference:

2020 QOPI Certification Program Standards

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

Section Three: Standards

Use of the Standards Manual for Certification

This Standards Manual is intended to be a tool for use by practices and institutions participating in the Program and by surveyors who evaluate these organizations. To achieve certification, a practice/institution must meet all the Certification standards and elements, as assessed during a site survey. If an organization meets all the elements for a particular standard, it meets the standard. This tool aims to provide the information required for each standard.

This Manual contains references to other sites, applications, and resources provided by third parties. ACE is *providing these as resources* and is not responsible for the availability of such external sites or resources. All links and identifications are provided solely for your convenience and for other informational purposes. ACE does not endorse and is not responsible or liable for any content, advertising, products, or other materials on or available from such sites, resources, or their affiliations.

There are seven defined standards of responsibility:

- Patient Engagement
- Availability and Access to Care
- Evidence-based Medicine
- Equitable and Comprehensive Team-based Care
- Quality Improvement
- Goals of Care, Palliative and End of Life Care Discussions
- Chemotherapy Safety

Within each standard there are elements that provide more specificity for the standard. Each standard and its underlying elements in this manual contain 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 deeper 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 in order 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.

Global Statement

Health equity is achieved when everyone has the opportunity to attain their highest level of health:[20] equity is a priority for practices throughout the continuum of cancer care. Within each domain of these standards, practices should be guided by the ASCO policy statement on cancer care disparities endeavor to: (1) ensure equitable access to high-quality care, (2) ensure equitable research, (3) address structural barriers, and (4) increase awareness and action.[21]

Standards Scoring

To achieve Certification, a practice/institution must meet all the Certification standards and elements, as assessed during a site survey. Site survey scoring is based on required policies and documentation, surveyor observation, and medical record review. A practice has the opportunity to resolve any partially met/unmet standards to achieve a 100% score during the compliance phase of the certification process. The following is the Oncology Medical Home standards scoring guide:

- All standard/standard elements met = 100%
- 75% or greater of the standard/standard elements met = partially met (e.g., 3 of 4 standard elements or 3 of 4 medical record documentation met = 75% partially met)
- Less than 75% of the standard/standard elements met = not met (e.g., 2 of 4 standard elements or 2 of 4 medical record documentation met = 50% not met)

[20] Winkfield K: Cancer does not affect all people equally: an expert Q and A on cancer disparities and health equity, June 30, 2020

[21] Patel MI, Lopez AM, Blackstock W, et al: Cancer Disparities and Health Equity: A Policy Statement From the American Society of Clinical Oncology. Journal of Clinical Oncology:JCO.20.00642, 2020

Domain A: Patient Engagement

Standard A.1: All patients are provided with an initial orientation to the Oncology Medical Home model, and ongoing reinforcement of policies related to this model.

STANDARD DEFINITION AND REQUIREMENTS

The practice ensures that a process is in place to educate all cancer patients – both at the beginning of the patient journey and throughout their care in the practice – regarding the Oncology Medical Home cancer care concept, the policies and procedures of the individual practice, and patient responsibilities within the Oncology Medical Home model.

STANDARD SPECIFICATIONS

Educational information to be provided must include, but is not limited to:

- Definition, goals, and importance of an Oncology Medical Home with specific mention of the Oncology Medical Home care delivery model
- The importance of the medical oncologist and the care team as the coordinators for patients before, during and after active cancer care treatment. (includes initial diagnosis, second opinions, survivorship, palliative care and end of life planning)
- Information on how and when to contact the medical oncologist, including evenings and weekends, with issues that need to be addressed
- Responsibilities of the patient and of the practice
- Impact on cost related to care services (e.g., primary care, oncology practice, urgent care, emergency room)
- Identify members of the patient's primary care team and provide contact information emphasizing care coordination and communication
- Process for reinforcement of this education throughout the patient care journey

DOCUMENTATION REQUIREMENT

- Policies and procedures for providing all patients with verbal and written education on standard specifications for the Oncology Medical Home practice including initial patient orientation and process for ongoing reinforcement regarding access to care and impact on cost.
- Patient educational and ongoing reinforcement materials provided at encounters as defined by the practice policies.
- Documentation in patient record that initial orientation and ongoing reinforcement to the Oncology Medical Home education was provided.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: 1) policies and procedures and 2) specific education materials related to initial and ongoing reinforcement of the Oncology Medical Home care delivery model
- Provide for site review: 1) medical record documentation and 2) patient education materials

Standard A.2: Patients will routinely be provided with a best estimate of out-of-pocket expenses for any new therapy that is offered. Patient financial counseling services, including assistance programs that are available, are routinely provided in the Oncology Medical Home practice.

STANDARD DEFINITION AND REQUIREMENTS

Financial counseling (sometimes referred to as financial advocacy or financial navigation) assists patients with understanding and addressing financial concerns during cancer treatment and care. Counseling includes patient and caregiver education on financial responsibility and the availability of resources, if needed. The practice has a policy in place to regularly review the policies and procedures for financial services and monitor the available resources and funds for patients.

STANDARD SPECIFICATIONS

Financial counseling and support services are available to all patients.

Financial counseling and support services include:

- insurance verification and pre-authorizations (or liaising with other staff) as needed
- ensuring demographic, insurance and eligibility information is current;
- documenting precertification and communicating with staff to ensure that patient care is not delayed
- screening and monitoring patients regularly to avoid risk of financial toxicity

Financial counseling staff maintain up-to-date knowledge of manufacturer, state and local assistance programs and foundations; Medicare prescription benefits; Social Security low-income subsidy; and any state and/or federal assistance subsidy. Ensure patients receive information about financial assistance programs and assistance with applications as needed.

Financial counseling staff provide patients with a best estimated out of pocket costs of cancer treatment, and total cost of care when available.

DOCUMENTATION REQUIREMENT

- Policies and procedures for financial counseling services as described in standard specifications including how patients are identified for the service; the elements that are covered in financial counseling visits; list of assistance programs available to patients.
- A summary of the number of patients receiving financial counseling support and amount of support provided for the prior 12 months.
- Documentation of annual review of financial counseling program with Oncology Medical Home Oversight Committee (OOC).

- *APPLICATION AND SITE REVIEW REQUIREMENT* Provide for application: 1) policies and procedures, 2) financial counseling support summary including quantified amount of support provided and 3) documentation of annual review with OOC
- Provide for site review: 1) medical record documentation review and 2) patient education materials (if applicable)

TOOLS & RESOURCES

Association of Community Cancer Centers Financial Advocacy Network
www.accc-cancer.org/home/learn/financial-advocacy

www.accc-cancer.org/docs/ossn-network/AZ/presentations/fall-2018/sherman-dan
https://ascopubs.org/doi/abs/10.1200/JCO.2018.36.30_suppl.124?af=R

Standard A.3: All patients are provided with education on their cancer diagnosis, goals of treatment, and an individualized treatment plan.

STANDARD DEFINITION AND REQUIREMENTS

Ongoing communication with patients and caregiver(s) is essential to keep patients engaged and informed about their cancer care. Practices must provide all patients with education and information regarding their disease and treatment plan. Indication that education and a treatment plan was provided is documented in the patients' EHR. The Oncology Medical Home Oversight Committee (OOC) ensures that the practice develops and annually reviews the policies and procedures on new patient education.

The Institute of Medicine (IOM) 13-point care plan should be considered when developing the individualized care plan.[22] The 13 elements are included in Appendix 2.

1. Patient information (e.g., name, date of birth, medication list, and allergies)
2. Diagnosis, including specific tissue information, relevant biomarkers, and stage (e.g., chemotherapy safety/QCP 2.2 Patient Education standard)
3. Prognosis (e.g., likely course of disease)
4. Treatment goals (curative, life-prolonging, symptom control, palliative care) (e.g., chemotherapy safety/ QCP 2.2 Patient Education standard)
5. Initial plan for treatment and proposed duration, including specific chemotherapy drug names, doses, and schedule as well as surgery and radiation therapy (if applicable) (e.g., chemotherapy safety/QCP 2.2 Patient Education standard)
6. Expected response to treatment (e.g., chemotherapy safety/QCP 2.1 Informed Consent standard)
7. Treatment benefits and harms, including common and rare toxicities and how to manage these toxicities, as well as short-term and late effects of treatment (e.g., chemotherapy safety/QCP 2.2 Patient Education standard)
8. Information on quality of life and a patient's likely experience with treatment (e.g., chemotherapy safety/QCP 2.1 Informed Consent standard)
9. Who will take responsibility for specific aspects of a patient's care (e.g., the cancer care team, the primary care/geriatrics care team, or other care teams)? (e.g., Oncology Medical Home Standard A.1)
10. Advance care plans, including advanced directives and other legal documents (e.g., Oncology Medical Home Standard F.1)
11. Estimated total and out-of-pocket costs of cancer treatment (e.g., Oncology Medical Home Standard A.2)
12. A plan for addressing a patient's psychosocial health needs, including psychological, vocational, disability, legal, or financial concerns and their

[22] Institute of Medicine. (2013). Delivering High-Quality Cancer Care. Retrieved from: https://www.nap.edu/catalog/18359

management (e.g., chemotherapy safety/QCP 1.2.7 standard initial psychosocial assessment, 1.4 ongoing psychosocial assessment, and Oncology Medical Home Standard D.3)

13. Survivorship plan, including a summary of treatment and information on recommended follow-up activities and surveillance, as well as risk reduction and health promotion activities (e.g., Oncology Medical Home Standard A.4)

STANDARD SPECIFICATIONS

The patient and caregiver(s) are educated and provided with a care plan prior to receiving cancer treatment. The education process will be tailored to the patient's learning needs, abilities, preferences, and readiness to learn as assessed and documented prior to treatment. The education and treatment plan include discussion between patient and caregiver and the opportunity for questions about the following areas (not all inclusive):

- Diagnosis
- Goals of treatment
- Planned duration of treatment, schedule of treatment administration
- Drug names and supportive medications, drug-drug and drug-food interactions, and plan for missed doses
- Potential long-term and short-term adverse effects of therapy, including infertility risks for appropriate patients
- Symptoms or adverse effects that require the patient to contact the health care setting or to seek immediate attention
- Procedures for handling medications in the home, including storage, safe handling and management of unused medication
- Procedures of handling body secretions and waste in the home
- Follow-up plans, including laboratory and provider visits
- Contact information for the health care setting, with availability and instructions for when and who to call
- Expectations for rescheduling or canceling appointments
- Patients are also educated about the use of the Patient Portal and how to access educational materials available on the Patient Portal. Oncology Medical Home education is reinforced as part of the treatment plan discussion

DOCUMENTATION REQUIREMENT

- Policies and procedures for patient and caregiver education with a minimum of listed standard specifications. Practice must be compliant with chemotherapy safety standard/QCP Standard 2.2.
- Patient education materials provided during new treatment teach.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures
- Provide for site review: 1) medical record documentation and 2) patient education materials

TOOLS & RESOURCES

Cancer.Net
www.cancer.net
ASCO Treatment Plan template
https://www.cancer.net/survivorship/follow-care-after-cancer-treatment/asco-cancer-treatment-and-survivorship-care-plans

Standard A.4: The Oncology Medical Home practice develops and implements a team-based survivorship care program, for all eligible patients, including identification of responsible staff, timeline for implementation, and documentation of existing supports and new services in development; treatment summary and survivorship care plan are encouraged as part of the survivorship care program, but are not required. Inclusive in the survivorship care program are appropriate strategies for transition back to primary care in appropriate patients.

STANDARD DEFINITION AND REQUIREMENTS

A 2005 Institute of Medicine report outlines the importance of providing cancer survivors a comprehensive care summary and follow-up plan once they complete their primary cancer care that reflects the treatment they received and addresses post-treatment needs and follow-up care to improve health and quality of life.[23]

Oncology Medical Home practices must develop and implement a team-based survivorship care program. The survivorship program includes services utilized to address the needs of cancer survivors. These program services may be treatment summaries, survivorship care plans, surveillance for recurrence, providing screening recommendations for second cancers, provide health education to survivors regarding their diagnoses, treatment exposures, and potential late and long-term effects., providing referrals to specialists and resources as indicated, familial genetic risk assessment, guidance on diet, exercise and health promotion activities, providing resources to assist with financial and insurance issues, and empowering survivors to advocate for their own health care needs. [24] Eligible cancer patients include those who are treated with curative intent for initial cancer occurrence and who have completed active therapy (other than long-term hormonal therapy). The practice may include patients with controlled metastatic disease in their survivorship care program services. This includes patients with cancer from all disease sites. If two different practices or facilities are providing treatment, both practices should work together to collaborate in providing survivorship care program support. The practice providing follow-up and monitoring of the patient (i.e., medical oncology) should provide the survivorship care program and discuss the services with the patient. In all cases, facilities and practices should work together to provide the support services necessary for a survivorship care program.

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[23] Institute of Medicine. (2006). From Cancer Patient to Cancer Survivor. Retrieved from: https://www.nap.edu/catalog/11468

[24] Providing High Quality Survivorship Care in Practice: An ASCO Guide https://www.asco.org/sites/new-www.asco.org/files/content-files/practice-and-guidelines/documents/2018-Survivorship-Guide.pdf

Treatment summary and survivorship care plan are encouraged as part of the survivorship care program, but are not required. If a survivorship care plan is utilized by the practice the following information is a resource.

The Survivorship Care Plan (SCP) is a record that summarizes and communicates what transpired during active cancer treatment, recommendations for follow-up care and surveillance testing/examination, referrals for support services the patient may need going forward, and other information pertinent to the survivor's short- and long-term survivorship care. It includes a summary of treatment and information on recommended follow-up activities and surveillance, as well as risk reduction and health promotion activities.

ASCO has defined the minimal data elements to be included in a treatment summary and survivorship care plan.[25] This core set of data elements and templates are available on the ASCO website and in this section's tools and resources. At a minimum, all SCPs should include ASCO-recommended elements to be included in the treatment summary and follow-up care plan to meet compliance for this standard. The treatment summary/survivorship care plan should include information about the patient's diagnosis, cancer treatment including drugs, doses, number of cycles; surgeries done; hormonal therapy; radiation therapy. It should also include guidelines for follow-up care including the specialties involved, frequency of visits and testing requirements (both laboratory and imaging).

DOCUMENTATION REQUIREMENT

- Policies and procedures for developing and providing a survivorship care program for all eligible patients, including identification of responsible staff and timeline for implementation, and documentation of existing supports and new services in development.
- During the site visit, surveyors will review of minimum of two survivorship patient visit notes.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: 1) policies and procedures and 2) sample treatment summary and survivorship care plan if utilized
- Provide for site review: medical record documentation (a minimum of two survivorship care program visits/encounters will be reviewed)

TOOLS & RESOURCES

ASCO Cancer Treatment and Survivorship Care Plans
https://www.cancer.net/survivorship/follow-care-after-cancer-treatment/asco-cancer-treatment-and-survivorship-care-plans
Cancer.Net
https://www.cancer.net/survivorship
National Comprehensive Cancer Network (NCCN) Patient and Caregiver Resources
https://www.nccn.org/patients/resources/life_after_cancer/survivorship.aspx
Association of Community Cancer Centers

[25] Mayer DK, Nekhlyudov L, Snyder CF, et al. (2014). American Society of Clinical Oncology Clinical Expert Statement on Cancer Survivorship Care Planning. Journal of Oncology Practice, 10(6), 345-351.

https://www.accc-cancer.org/home/learn/patient-centered-care/survivorship-care

Domain B: Availability and Access to Care

Standard B.1: The Oncology Medical Home practice institutes expanded access and an evidence-based symptom triage system to ensure that patients can easily access the practice and their providers.

STANDARD DEFINITION AND REQUIREMENTS

The heart of the Oncology Medical Home practice is patient accessibility when a medical problem arises that can be successfully and safely addressed in the physician's office. Oncology Medical Home practices must ensure that new and established patients have access to their own physician(s) and care team when they require oncology-related care. The practice establishes specific processes to expedite appointments for new patients, as medically required or requested. Established patients must have access to urgent/same day appointments as medically indicated.

An Oncology Medical Home practice is required to develop the capability to provide expanded access and an evidence-based symptom triage system to ensure that patients can easily access the practice and their providers. Examples of extended coverage may include morning, evening, and/or weekend hours. Expanded access may include a triage unit or urgent appointment availability at the practice or another designated location thus avoiding unnecessary emergency department (ED) visits. There is urgent care through same day appointments, with 24 hours per day/7 days per week access to a clinician who has real-time access to patients' medical records. Practice must show how it has utilized triage data to determine and implement extended coverage or expanded access to care and continuous quality improvement.

A triage system is in place to support active symptom management of patients. Triage pathways guide the nurses in the patient assessment process and facilitate decisions about when self-care at home is appropriate, when patients need to come to the office for urgent visits, and when patients may need care in a more acute setting. Using pathways to triage symptoms ensures that symptoms are addressed consistently, early and managed appropriately to prevent unnecessary ED visits and hospital admissions.

Policies and procedures are established to standardize the triage system management of walk-in patients. The patients are to be educated and repeatedly encouraged to contact the practice early to address symptoms that can be managed before the patient requires hospitalization or ED use.

STANDARD SPECIFICATIONS

Evidence-based symptom triage system infrastructure and policies to be formulated and reviewed by the Oncology Medical Home Oversight Committee (OCC) must include, but are not limited to:

- 24 hours per day/7 days per week (afterhours, weekends, and holidays) access to care that may include extended hours, expanded access, and weekend availability to manage patient issues and reduce ED visits and hospitalizations. This might necessitate a relationship with urgent care facilities
- At least one oncologist with access to the EHR on call overnight and on weekends to manage emergencies

- Oncology nurses manage the triage system with authority to schedule patients as indicated by the triage protocols and practice policies
- Availability to schedule same-day appointments for patients requiring urgent care on physician or Advanced Practice Provider schedules
- Accommodation of walk-in patients on physician or Advanced Practice Provider schedules
- Policy and procedures for direct admissions (bypassing the ED when medically appropriate and available)
- Specific policies and procedures that expedite appointments for urgent and new patients. These policies and procedures should include a provision for urgent scheduling of appointments based on medical need or patient anxiety.
- New anticancer treatment follow-up
- Patient call-backs including maximum call back time for urgent and non-urgent patient situations according to medical condition

STANDARD EXCEPTIONS

Some Oncology Medical Home practices may not find it financially feasible to offer extended office hours for a number of reasons, including small practice size, several oncology medical homes in local area leading to redundancy of infrastructure, or rural populations that are unlikely to drive to a centralized clinic during evening hours. For this reason, the definition of extended hours is purposefully broad and could include weekend injection clinic, full extended practice hours, or physician and staff on call and able to see patients presenting with medical problems in a lower-cost site of care compared with an ED.

DOCUMENTATION REQUIREMENT

- Policies and procedures to include: 1) symptom triage system and processes as described in standard specifications; 2) patient education and utilization of telemedicine visits; 3) staff initial and ongoing training requirements for performing patient symptom triage; 4) utilization of symptom triage data to determine and implement extended coverage or expanded access to care and continuous quality improvement; and 5) practice must be compliant with QCP Standard 1.6.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures including source of symptom triage system
- Provide for site review: 1) medical record documentation and 2) patient education materials

TOOLS & RESOURCES

Telephone Triage for Oncology Nurses (Third Edition)
https://www.ons.org/books/telephone-triage-oncology-nurses-third-edition

Office-Hours Telephone Triage Protocols User's Guide 2016
https://www.cleartriage.com/wp-content/uploads/STCC-OH-Users-Guide.pdf

Telehealth Standards in Oncology | ASCO

Standard B.2: The Oncology Medical Home practice tracks patient ED visits, hospital admissions and re-admissions; analyzes the data regularly for process improvement and patient education purposes; and provides patient follow-up within an appropriate timeline post-hospitalization or ED visit.

STANDARD DEFINITION AND REQUIREMENTS

One goal of the Oncology Medical Home practice is to minimize unnecessary visits by the oncology patient to the Emergency Department and in-patient hospital setting whenever possible and clinically appropriate. This goal is twofold: first to provide care to patients in the office or most appropriate care setting; and second to maximize cost savings for the overall health system and patient. EDs and hospitals are generally high-cost sites of care and the literature suggests that a large proportion of oncology patients who present to the ED for any reason are hospitalized simply because of their oncology diagnosis.[26]

Because many treatment side effects can be treated more appropriately in the office setting, Oncology Medical Home practices should have policies, procedures and patient education in place to encourage that process. When patients present to the ED or are hospitalized, the Oncology Medical Home practice should have processes in place to know that the ED visit or admission has occurred and ensure patient follow-up within an appropriate timeline post-hospitalization or ED visit.

Standard Specifications:

- Tracking of ED visits, hospital admissions, and readmissions
- Contacting patients for follow-up within a consistent, appropriate timeframe post-ED visit and hospitalization
- Patient education on practice access to care and avoidance of ED and hospital visits when applicable (e.g., emergent, urgent, same day/sick visit)
- Process for analyzing data and implementing practices changes to reduce frequency of avoidable ED visits and hospital admissions

DOCUMENTATION REQUIREMENT

- Policies and procedures including standard specifications..

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures
- Provide for site review: 1) medical record documentation; 2) patient education materials; and 3) ED visits, hospital admissions, and readmission tracking data with data analysis and continual quality improvement to reduce frequency

[26] Waters TM; Kaplan CM, Graetz I, et al. (2019) Patient-Centered Medical Homes in Community Oncology Practices: Changes in Spending and Care Quality Associated with the COME HOME Experience. Journal of Oncology Practice, 15(1), e56-e64.

TOOLS & RESOURCES

Quality Improvement Library | ASCO Practice Central

Standard B.3: Documentation and follow-up for patients who miss or cancel scheduled visits and/or chemotherapy treatments.

STANDARD DEFINITION AND REQUIREMENTS

The practice has a well-defined process for documentation and follow-up of patients who miss or cancel scheduled visits and/or anticancer treatments. Patients will be educated on this process. Failure to follow-up for visits, treatment or tests is an important patient safety concern. The Oncology Medical Home practice must have a policy that addresses these important patient safety issues and must demonstrate compliance with the policy.

DOCUMENTATION REQUIREMENT

- Policies and procedures regarding follow-up of patients who miss or cancel appointments: 1) include standards for number of attempts to contact; 2) timeframe for contacting patient; 3) process for informing physicians of no-show patients, and medical record documentation of follow-up; 4) tracking patients lost to follow-up; and 4) patient education process. Practice must be compliant with QOPI Certification Standard 2.2.3.11.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures
- Provide for site review: 1) medical record documentation and 2) patient education materials

Domain C: Evidence-based medicine

Standard C.1: The Oncology Medical Home practice uses evidence-based treatment pathways; measures and reports on physician compliance with pathways; and requires documentation for off-pathway treatment.

STANDARD DEFINITION AND REQUIREMENTS

All patients are to be treated in accordance with principles of evidence-based medicine, consistent with clinical guidelines of ASCO, NCCN, or other nationally recognized clinical guidelines AND use an oncology clinical pathways program as an essential element of chemotherapy and immunotherapy treatment planning process for at least 50% of cancer patients receiving such therapies. Practices may use a commercially available oncology clinical pathways program or a practice-developed oncology clinical pathways program that substantially meets "American Society of Clinical Oncology Criteria for High-Quality Clinical Pathways in Oncology".[27] These criteria are included Appendix 3.

At minimum, pathways must meet the following criteria:

[27] Zon RT. Criteria for High-Quality Clinical Pathways.

- Practicing oncology providers with relevant disease and/or specialty expertise play a central role in pathway development.
- There is a clear process or methodology for pathway development that is transparent to all pathway users and stakeholders, including methodology used for development; strengths and types of evidence used to generate consensus; specific evidence used to support the pathway recommendation; and the way in which efficacy, toxicity, and cost are assessed and balanced in determining the pathway recommendation.
- Pathways are based on the best available scientific evidence as documented or disseminated in clinical practice guidelines, peer-reviewed journals, scientific meetings, Medicare compendia, FDA labeling indications and/or dissemination vehicles.
- Pathways include evidence-based options to account for differences in patient characteristics and/or preferences (i.e., patient comorbidities, prior diagnoses and treatments, risk of treatment-related toxicities, treatment schedule, and/or financial toxicity).
- Cost is factored into pathway recommendations of therapeutically similar or equivalent treatments.
- Pathways are updated in a timely way as relevant new information, including new FDA indication approvals, becomes available.
- The pathway includes, at minimum, preferred chemotherapy and immunotherapy regimens and utilizes necessary staging and precision diagnostic results in order to determine the appropriate indication. Regimen-dictated antiemetic and granulocyte colony-stimulating factor therapies should be included in the pathway or built into standard order sets.
- Information is provided on the specific cancer type, stage, and molecular profile that the pathway is intended to cover.
- There is clear information provided to pathway users and other stakeholders on what constitutes treatment on pathway, treatment off pathway, and warranted variation from pathway recommendations.
- The pathway program informs providers of pathway compliance, preferable in real time.
- There is a mechanism for choosing an off-pathway recommendation and documenting the rationale for this choice.
- Regular reports are provided to participating providers that demonstrate the level of current pathway performance, goals for pathway adherence, performance over time, and comparisons to the performance of other providers.
- Adherence rates incorporate precision medicine based on current FDA-approved indications.
- Performance reports provided include reasons for non-concordance.
- Pathway program demonstrates a commitment to research aimed at assessing and improving the impact of pathways on patient and provider experience, clinical outcomes, and value.

The following public and commercially available pathway programs have been previously reviewed and determined appropriate for use in the Certification program. Practices adopting one of these programs must implement them according to ASCO criteria and follow vendor-provided training materials.

- New Century Health
- Elsevier's ClinicalPath
- McKesson Value pathways Powered by NCCN™
- 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 adherence according to this Standard.

Oncology Medical Home practices must measure and demonstrate physician/prescriber compliance with oncology clinical pathways; and have a governance process in place within the practice for managing lack of compliance with pathways. Documentation for non-compliance with pathways must be clearly indicated in the medical record.

Notes:

- *Pathway programs which are determined to partially meet one or more of the minimum criteria will be judged on the totality of their assessment against the criteria. Practices utilizing such programs may be asked to implement additional controls.*
- *The pathway criteria require that pathways be used as a decision support tool informing providers of pathway compliance. Ideally, pathway information is presented and documented in real time. Pathways solely used by administrative staff in order to obtain authorization do not meet this requirement.*
- *Pathway adherence rates must account for patient characteristics and precision medicine. Pathway programs that automatically calculate adherence based on electronic health information and prescribed regimens are preferred. Practices who rely on physician attestation of pathway concordance must do so per course of therapy and demonstrate methods of auditing adherence rates through analytics and/or chart review.*
- *In order to meet the standard that pathways are used for at least 50% of cancer patients receiving such therapies, pathways should cover major diseases treated by the practices and should not be limited to a single payer. Practices may be asked for additional reports documenting for what percentage of patients the practice used treatment pathways.*

STANDARD EXCEPTIONS

- Documentation in the Electronic Health Record (EHR) that patient was offered guideline-adherent care but declined.
- The patient's clinical circumstances (performance status, comorbidities) make guideline-adherent care inappropriate for the patient. Reason(s) for deviations from standard pathways and/or guidelines should be documented in the patient's EHR.

- The patient's clinical circumstances are not included in the guideline/pathway's recommendations.

DOCUMENTATION REQUIREMENT

- Policies and procedures that document:
    - The source of treatment pathways.
    - Standard operating procedure for treatment pathway utilization to include:
        - **Utilization:**
            - # of treatment plans navigated through Pathway System / defined treatment plans*
        - **On pathway**:
            - # of treatment plans on-pathway using Pathway System / # of treatment plans navigated through pathway system
            - # of treatment plans utilizing NCCN Categories of Preference + Category 2A** / # of treatment plans on pathway (if applicable for pathway system)
        - **Off pathway**:
            - # of treatment plans off pathway using Pathway System / # of treatment plans navigated through pathway system
            - # of treatment plans not utilizing NCCN Categories of Preference + Category 2A** / # of treatment plans on pathway assigned (if applicable for pathway system)
            - Off-pathway treatment and documentation of such in medical record
        - **Note:** Clinical Trial enrollment is considered on pathway
        - **Governance of pathway utilization and off-pathway**
            - define documentation and data collected for pathway utilization and off-pathway oversight
            - define method and frequency of monitoring utilization and off pathway data
            - action taken for provider communication of utilization and off pathway data results
            - The practice will use the pathway system data to drive quality improvement

***denominator of treatment plans defined by the practice/health system (**e.g., IV, oral, new treatments only, all treatments including plan changes**)**

****Category 2A included in numerator**

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: 1) policies and procedures and 2) example report including pathway utilization rates, benchmarks/targets, and recorded reasons for non-adherence. Note: practices with a practice-developed oncology clinical pathway program must also include the following materials:
    - Self-assessment against ASCO criteria
    - Index of diseases for which clinical pathways have been developed and available for implementation.
    - Example clinical pathways for at least three diseases, including diagnostic inputs and preferred regimens.
    - Policies specifying methodologies for literature search, evidence review, criteria and weighting of inputs, and final selection.

Example documentation and/or minutes from an expert panel meeting demonstrating use of clinical evidence and decision-making.

- Provide for site review: 1) most current pathway utilization report, off-pathway data, and 2) example governance meeting minutes for pathway review and action taken

TOOLS & RESOURCES

Clinical Pathways | ASCO

Standard C.2: Patients are provided clinical research study information by the Oncology Medical Home practice as appropriate for the patient's clinical condition.

STANDARD DEFINITION AND REQUIREMENTS

Clinical research advances science and ensures that patient care approaches the highest possible level of quality. Providing information about the availability of cancer-related clinical research studies, in the Oncology Medical Home practice or otherwise accessible to patients, offers patients the opportunity to enroll in treatment or observational research studies and trials. Policies and procedures outline the process of providing clinical research information and available studies that are open for enrollment.

DOCUMENTATION REQUIREMENT

- Policies and procedures regarding patient screening for clinical trials; availability of oncology clinical research studies, either on-site or by referral; monitoring and reporting on clinical trial referrals and accruals.
- Policies to be provided at time of application and reviewed at site visit; practice documentation reviewed at site visit.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: 1) policies and procedures regarding screening for clinical trials, availability of oncology clinical research studies, either on-site or by referral, monitoring and reporting on clinical trial referrals and accruals

- Provide for site review: 1) clinical trials policies and procedures with clinical trial referrals and accruals data for a year's timeframe.

- Clinical trial accrual calculation:
    - **CT AIM Matrix reference**
        - Accrual % = Number of patients enrolled onto trials divided by the Number of new cancer patients seen by physicians in your program in the **past 1 year**
        - Reference: ReCAP: Clinical Trial Assessment of Infrastructure Matrix Tool to Improve the Quality of Research Conduct in the Community | JCO Oncology Practice (ascopubs.org)
    - **Commission on Cancer:**
        - The denominator used to calculate compliance with this standard is the number of annual analytic cases the **past 1 year (2021)**
        - The numerator is the number of subjects enrolled in eligible research studies (**the past 1 year 2021**) who were:
        - • Diagnosed and/or treated at your program or facility and enrolled in a cancer-related clinical research study within your program or facility, • Diagnosed and/or treated at your program or facility and enrolled in a cancer-related clinical research study within a staff physician's office of your program or facility, • Diagnosed and/or treated at the program or facility, then referred by your program or facility for enrollment onto a cancer-related clinical research study through another program or facility, or • Referred to your program or facility for enrollment onto a cancer-related clinical research study through another program or facility
        - Reference: optimal_resources_for_cancer_care_2020_standards.ashx (facs.org) page 85

TOOLS & RESOURCES

Cancer.Net
https://www.cancer.net/research-and-advocacy

ClinicalTrials.gov
https://clinicaltrials.gov

ReCAP: Clinical Trial Assessment of Infrastructure Matrix Tool to Improve the Quality of Research Conduct in the Community | JCO Oncology Practice (ascopubs.org)

Domain D: Equitable and Comprehensive Team-based Care

Standard D.1: In most instances, a medical oncologist directs the patient's care team within the Oncology Medical Home practice, directs care coordination with other pertinent physicians and services; including ongoing collaboration with the in-patient team.

STANDARD DEFINITION AND REQUIREMENTS

Under the Oncology Medical Home model, the medical oncologist is responsible for the coordination of oncology care. A newly diagnosed cancer patient is often overwhelmed with tests, treatments, appointments, communications, and instructions between the various teams of providers who are entrusted with their care. The Oncology Medical Home practice must have processes in place for care coordination for all new cancer diagnoses.

The National Institutes of Health defines care coordination as *the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient's care to facilitate the appropriate delivery of health care services. Organizing care involves the marshalling of personnel and other resources needed to carry out all required patient care activities and is often managed by the exchange of information among participants responsible for different aspects of care.*[28] Care coordination is an essential component of the Oncology Medical Home model.

Oncology care is coordinated with other providers as clinically appropriate as well as outside agencies, such as home care agencies, rehabilitation, and/or hospice. Communication processes through a patient's medical oncologist are established to keep other providers beyond the medical oncology care team, including the primary care physician, informed of a mutual patient's treatment plan and current status. The process is monitored, and findings are reported to the Oncology Medical Home Oversight Committee (OOC).

DOCUMENTATION REQUIREMENT

- Policies and procedures on medical oncologist-directed care including: 1) clear delineation of staff roles in care coordination processes to carry out all required patient care activities with exchange of information among team members; 2) communication standards to ensure timely communication to referring physicians, primary care physicians, palliative care/symptom management teams, and hospice; 3) process for timely ordering of tests and tracking results, including communication to patients; and 4) documentation of annual review of policies and procedures with Oncology Medical Home Oversight Committee (OOC).

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures
- Provide for site review: documentation of annual review with OOC

TOOLS & RESOURCES

Academy of Oncology Nurse and Patient Navigators (AONN)
https://aonnonline.org

[28] Agency for Healthcare Research and Quality (2007). Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK44012/.

CMS Care Coordination Toolkit
https://innovation.cms.gov/Files/x/aco-carecoordination-toolkit.pdf
Oncology Patient Navigator Training: The Fundamentals
https://smhs.gwu.edu/cancergate/best-practice/oncology-patient-navigator-training-fundamentals
Team-Based Care in Oncology | ASCO

Standard D.2: The Oncology Medical Home practice prioritizes team-based care with policies and practices that clearly delineate roles and responsibilities; implements and prioritizes team huddles as a communication and patient safety tool; and regularly assesses how the practice team is functioning.

STANDARD DEFINITION AND REQUIREMENTS

High quality cancer care requires coordination among multiple groups of clinicians and staff at all levels of the medical organizations involved in the patient's care – team-based care. Clear communication and transparent, defined roles and responsibilities help ensure that care needs are addressed and timely decisions are made.[29] Eight hallmarks of effective teams have been described that are applicable to team-based care in the oncology practice: communication, cooperation, coordination, cohesion, collective efficacy, collective identity, cognition, and coaching.[30] The Oncology Medical Home practice prioritizes team-based care.

The practice has clear position descriptions for all members of the team and outlines roles and responsibilities, both in general for specific duties with a focus on interaction between team members. Communication in the practice is prioritized with clear and standardized documentation in the electronic medical record and the use of regularly scheduled team huddles or other methods as a communication and patient safety tool. The practice also has an ongoing process in place to discuss and assess team functioning which is reviewed by the Oncology Medical Home Oversight Committee (OOC) at least annually.

DOCUMENTATION REQUIREMENTS

- Policies and procedures that require: 1) standardize position descriptions, roles and responsibilities for all staff; 2) team huddles or other methods as communication with frequency, staff required to attend, and issues discussed; 3) patient safety tool used to assess and evaluate risks, preventive measures, and CQI; and 4) ongoing process to assess team functioning and well-being with review by the OOC at least annually.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures
- Provide for site review: 1) team huddles review 2) patient safety tool assessment, evaluation, and CQI 3) team functioning assessment and 4) documentation of annual review with OOC

[29] Kosty MP, Bruinooge SS & Cox JV, (2015). Intentional Approach to Team-Based Oncology Care: Evidence-Based Teamwork to Improve Collaboration and Patient Engagement. Journal of Oncology Practice, 11, 247-248.
[30] Taplin SH, Weaver S, Salas E, et al. (2105). Reviewing Cancer Care Team Effectiveness. Journal of Oncology Practice, 11(3), 239-246.

TOOLS & RESOURCES

AHRQ's Quality & Patient Safety Programs by Setting: Ambulatory Care | Agency for Healthcare Research and Quality

Standard D.3: All patients are provided navigation for support services and community resources specific to their individual needs and preferences; psychosocial distress screening is performed and referral for the provision of psychosocial care, as needed. Support services may be delivered on-site or through an off-site collaboration.

STANDARD DEFINITION AND REQUIREMENTS

A cancer diagnosis changes everything. The patient and caregiver's emotional response and resource needs related to the diagnosis and treatment are important to assess and address initially and ongoing throughout treatment and survivorship. Support services and community resources tailored to the practices' patient population are an essential component of care and should be demonstrated in the Oncology Medical Home model. To address the psychosocial issues experienced by patients with cancer, the 2007 report of the Institute of Medicine (IOM), *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*, emphasizes the importance of screening patients for distress and psychosocial health needs as a critical first step to providing high-quality cancer care. In addition, this report emphasizes that all patients with cancer need to be referred for the appropriate provision of care and that high-quality psychosocial cancer care includes systematic follow-up and reevaluation.

Practices must develop a process to incorporate the screening of distress into the standard care of oncology patients including a plan and review of physical, psychological and emotional, social, practical, spiritual or religious, vocational, disability, legal, or financial concerns, their management and their ability to impact treatment plans and outcomes. The process must provide the appropriate resources and/or referral to address the patients' psychosocial needs. Distress should be recognized, monitored, and documented and treated at all stages of cancer.*PROCESS REQUIREMENTS*

Support services: The practice will provide the patient and caregivers with support services and community resources initially and ongoing throughout treatment and survivorship.

Psychosocial distress and timing of screening:

- All cancer patients must be screened for distress a minimum of one time during a pivotal medical visit as determined by the practice. The Oncology Medical Home Oversight Committee (OOC) defines one or more medical visits that are part of a pivotal time for the distress screening process. Examples of a "pivotal medical visit" may include postsurgical visits, first visit with a medical oncologist to discuss chemotherapy, routine visit with a radiation oncologist, or a post-chemotherapy follow-up visit. Preference should be given to pivotal medical visits when there are known times of greatest risk for distress, such as at the time of diagnosis, transitions during treatment (such as from chemotherapy to radiation therapy), and completion of treatment.
- Patients on active chemotherapy treatment must have an initial psychosocial assessment before the first administration of chemotherapy and at each cycle of chemotherapy, or more frequently as clinically indicated, as required by QOPI

Certification Standards 1.2.7 and 1.4. Action must be taken when indicated by the assessment tool.

- Method: The mode of administration (i.e., patient questionnaire or clinician-administered questionnaire) is to be determined by the OOC and may be tailored to the workflow of the practice. Medical staff, including medical assistants, nurses, and physicians must be trained to properly administer the screening tool.
- Tools**:** The OOC selects and approves the screening tool to be administered to screen for current distress. Preference should be given to standardized, validated instruments or tools with established clinical cutoffs. The OOC determines the cutoff score used to identify distressed patients. While not required, the National Comprehensive Cancer Network (NCCN) Distress Thermometer is a recognized tool used by many oncology practices. In patients age 65 and older receiving chemotherapy, geriatric assessment (GA) the evaluation of functional status, physical performance and falls, comorbid medical conditions, depression, social activity/support, nutritional status, and cognitive-should be used to identify vulnerabilities or geriatric impairments that are not routinely captured in oncology assessments.
- Questionnaires or forms that are distributed or returned by mail and/or phone interviews without discussion at a medical visit do not meet the standard because this method does not allow for immediate attention for severe distress or suicidal ideation, if patient reported, and does not allow for active dialogue with the patient. Practices may have patients complete the distress screening tool through a patient portal or electronic screening method within 24 hours of the pivotal medical visit as long as the screening results are reviewed and discussed with the patient face-to-face at the visit.
- Assessment and Referral: The distress screening results must be discussed with the patient at the medical visit. If there is clinical evidence of moderate or severe distress based on the results of the distress screening, a member of patient's oncology team (physician, nurse, social worker, and/or psychologist) must identify and examine the psychological, behavioral, financial and/or social problems instigating the distress. This evaluation will confirm the presence of physical, psychological, social, spiritual, and financial support needs. The process developed by the OOC includes the psychosocial services or resources available to patients on-site or by referral.
- Documentation: Patient education on support services and community resources. The psychosocial screening process, timing of screening, identified tool, and distress level triggering a referral to services are documented in the OOC minutes. The distress screening(s) results, referral for provision of care, and any follow-up measures are documented in the patient medical record to facilitate integrated, high-quality care.

DOCUMENTATION REQUIREMENTS

- Policies and procedures for the process of: 1) performing psychosocial distress screening, resultant trigger for action taken, identifying and addressing patient psychosocial and other support service needs; and 2) referring patients for support services within the medical oncology care team and community resources

- Documentation of annual review of policies, health disparities data findings, and mitigation actions taken by OOC.

Practice must be compliant with QCP standards 1.2.7, 1.4 and 1.5.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures
- Provide for site review: 1) medical record documentation 2) distress screening tool and 3) documentation of annual review with OOC

TOOLS & RESOURCES

Geriatric Oncology | ASCO

National Comprehensive Cancer Network (NCCN) Distress Thermometer
https://www.nccn.org/patients/resources/life_with_cancer/pdf/nccn_distress_thermometer.pdf

Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Chemotherapy: ASCO Guideline for Geriatric Oncology | Journal of Clinical Oncology (ascopubs.org)

Staff Well-Being & Development | ASCO Practice Central

Standard D.4: Health equity is a priority for the practice throughout the continuum of cancer care. The practice should have a policy that address the health equity domains outlined in the Global Statement. Developing awareness of conscious and unconscious biases of all practice team members should be a focus of the practice and resources made available to assess & drive change where appropriate**.**

STANDARD DEFINITION AND REQUIREMENTS

Global Statement: Health equity is achieved when everyone has the opportunity to attain their highest level of health: equity is a priority for practices throughout the continuum of cancer care. Within each domain of these standards, practices should be guided by the ASCO policy statement on cancer care disparities endeavor to: (1) ensure equitable access to high-quality care, (2) ensure equitable research, (3) address structural barriers, and (4) increase awareness and action.

Cancer does not affect all people equally. The phrase “cancer disparities” refers to the differences in the number of new cancer cases, as well as differences in cancer outcomes, that exist among different populations. These populations continue to suffer the greatest rates of cancer and the poorest outcomes for each of the most common types of cancer, despite incredible progress in reducing overall deaths from cancer. Cancer outcomes are worse in people who experience health disparities.

Practices must develop a process of identifying and addressing health care disparities within patient population including factors that contribute.

PROCESS REQUIREMENTS

Health equity and identification of heath care disparities: All cancer patients must be screened for identifying and addressing health care disparities. The practice focuses on addressing the

needs of medically underserved populations while increasing awareness of organizational cultural competency needs and support for minority patient populations.

DOCUMENTATION REQUIREMENTS

- Policies and procedures that address the health equity priorities outlined in the Global Statement for the Oncology Medical Home standards (1) ensure equitable access to high-quality care, (2) ensure equitable research, (3) address structural barriers, and (4) increase awareness and action.
- Documentation of identifying and addressing health care disparities within the practice patient population through data findings and mitigation actions taken through CQI with an annual review by Oncology Medical Home Oversight Committee (OOC).

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures
- Provide for site review: 1) medical record documentation and 2) documentation of annual review with OOC

TOOLS & RESOURCES

Cancer Does Not Affect All People Equally: An Expert Q&A on Cancer Disparities and Health Equity (Cancer.net)
https://www.cancer.net/blog/2020-06/cancer-does-not-affect-all-people-equally-expert-qa-cancer-disparities-and-health-equity

Enhancing Oncology Model (EOM) Health Equity Strategy (cms.gov)

PRAPARE-English.pdf

The AHC Health-Related Social Needs Screening Tool (cms.gov)

Domain E: Quality Improvement

Standard E.1: The Oncology Medical Home practice administers a patient experience survey to cancer patients at least twice each calendar year or on an ongoing basis (this includes surveys completed to fulfill other requirements). Results of the survey are analyzed and used to guide quality improvement activities.

STANDARD DEFINITION AND REQUIREMENTS

Patient satisfaction is an important component for measuring health care quality due to the impact on patient outcomes. Patients place a high value on the interaction and communication with their providers. In addition, the management of their issues, such as psychosocial distress, pain, and depression, improves patient satisfaction. Oncology Medical Home practices must administer patient satisfaction surveys using oncology-specific provider benchmarks, targets, internal comparisons with trends that drive performance improvement. Practices should follow

guidance from AHRQ[31] or the practices survey vendor to determine desired number of completed surveys. The Oncology Medical Home Patient Satisfaction Survey (Community Oncology Alliance)[32] 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. Practices may consider implementing Patient and Family Advisory Councils or Patient Advocacy initiatives as one means of responding to patient satisfaction survey 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 Oncology Medical Home Oversight Committee (OOC) minutes.
Share results with care team including providers (physicians and APPs). Include in documentation requirements. Care team functions.

DOCUMENTATION REQUIREMENTS

- Policies and procedures for administration of a patient satisfaction survey, benchmarking, review and analysis including frequency of survey distribution and governance review
- Sample patient satisfaction tool
- Report(s) of patient satisfaction survey and benchmarked results
- Documentation of review of process and results with OOC and discussion of quality improvement activities implemented to improve patient satisfaction.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: 1) policies and procedures and 2) sample patient satisfaction tool
- Provide for site review: 1) reports of patient satisfaction survey and benchmarked results and 2) documentation of governance review including quality improvement activities implemented

TOOLS & RESOURCES

Community Oncology Alliance Oncology Medical Home Patient Feedback Survey Resources: For Cancer Centers & Care Providers
(medicalhomeoncology.org)
Community Oncology Alliance Patient Advocacy Network
Home Page New - CPAN COA Patient Advocacy Network (coaadvocacy.org)
Community Oncology Alliance Oncology Medical Home Model
https://medicalhomeoncology.org/
Patient and Family Advisory Council (PFAC) is a partnership between the practice patients, family members, staff and healthcare providers who are dedicated to improving care and the

[31] Fielding the CAHPS® Clinician & Group Survey. https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/cg/survey3.0/fielding-the-survey-cg30-2033.pdf
[32] Oncology Medical Home Patient Satisfaction Survey. https://www.medicalhomeoncology.org/coa/patient-satisfaction.htm

experiences of patients and their families provided by the practice. PFACs integrate, elevate, and promote the patient and family voice and perspective to make the cancer patient experience better - PFAC is the voice of the customer in health care. While not required for Certification, practices may find this a useful tool for addressing patient satisfaction.
Two articles that describe Patient and Family Advisory Councils
https://catalyst.nejm.org/pfac-quality-memorial-sloan-kettering/
https://www.uhcc.com/about-us/patient-advisory-council/

Standard E.2: The Oncology Medical Home practice demonstrates a commitment to quality improvement by regularly using data to evaluate a process of care, implementing changes if/when indicated from analysis, and monitoring sustainability of improvement over time. Patient-reported outcomes may be used as part of this improvement process.

STANDARD DEFINITION AND REQUIREMENTS

The goal of quality improvement in health care is to improve the overall care and outcomes for patients and providers. Quality improvements are the actions taken, processes implemented, or services created to improve cancer care. The results of a cancer-related quality study provide a baseline to measure and improve quality. The Oncology Medical Home practice has a process in place to regularly review and identify care delivery improvements using data to analyze and evaluate current state and continual quality improvement. Changes are made as indicated from the review and monitored/measured over time. Continual Quality Improvement and Lean principles may be utilized, including, plan, do, study, act (PDSA) cycles to monitor ongoing improvement initiatives.
Key performance measures for health care quality include safety and outcomes of care; timely and appropriate care; care provision that is efficient and equitable; and care that is patient centered; and documentation of care that is monitored for completeness of clinical data for initiating quality improvement activities. While not all are required, these areas are recommended for quality improvement assessment.
Internal policies and procedures within the practice must identify for physicians and other clinicians the specific clinical data elements that must be captured within the Electronic Health Record (EHR). Oncology Medical Home practices must implement, maintain, and monitor EHR documentation to ensure the completeness of clinical data in searchable areas of the practice health data system(s).
Certain data elements are essential for data-driven, continuous quality improvement. Quality improvements are the actions taken and processes implemented to improve the documentation of the required clinical data elements. The methods used to monitor the EHR data and action plans to correct problematic findings are set by the Oncology Medical Home Oversight Committee (OOC). The findings of the studies are documented in the OOC minutes and shared with the staff at the practice.
Core data elements which must be documented in the EHR include:[33]

- Clinical stage*

[33] Li EC, D'Amato SL, Barr TR & Weisberg T (2012). The "Big 6 Spotlight": Baseline assessment and implementation of a process to systematically collect critical oncology data elements for quality improvement and research. Journal of Clinical Oncology, 30(34_suppl), 312.

- Treatment intent*
- Adverse events
- Clinical status*
- Cancer disease status*
- Line of therapy

* https://mcodeinitiative.org/access-mcode/

STANDARD EXCEPTIONS

Sentinel events are defined by The Joint Commission as any unanticipated event in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients not related to the natural course of the patient's illness. Sentinel events must be addressed in addition to other quality improvement activities. Such events should be immediately identified and reported to the OOC (and any other appropriate practice oversight committee) for root cause analysis and development of preventative measures.

DOCUMENTATION REQUIREMENTS

- Policies and procedures that describe the quality improvement process in the practice including responsible staff, frequency of meetings (recommend quarterly), sources of data, records/ description of projects and processes, and assessment of improvement over time. Continual Quality Improvement and Lean principles may be utilized including plan, do, study, act (PDSA) cycles to monitor ongoing improvement initiatives.
- Practice policies and procedures for completion of EHR with core data elements and measurement of same.
- Projects, recommendations, and improvements are reported to the OOC and documented in the OOC minutes.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures
- Provide for site review: 1) quality improvement meeting minutes including data analysis, projects and priorities, and ongoing improvement initiatives and 2) EHR core data elements for measurement and improvement

TOOLS & RESOURCES

Quality Training Program | ASCO Practice Central
Quality Improvement Library | ASCO Practice Central

Domain F: Goals of Care, Palliative and End of Life Care Discussions

Standard F.1: Practice routinely offers an advance care planning discussion and completes a goals of care discussion with all patients that recognizes the individual patient's needs and preferences. If the advance care planning discussion is conducted, it would include advanced directives and consideration/selection of an agent for medical decision making.

STANDARD DEFINITION AND REQUIREMENTS

The Oncology Medical Home practice routinely offers all patients the opportunity to participate in a dedicated advance care planning (ACP) session. Session will ideally include the patient's current or prospective healthcare surrogate, family members, relevant care team members and

a professional trained in the facilitation of such sessions. The ACP session will be offered at the initiation of cancer treatment and as appropriate thereafter (progression of disease or change in functional status).
The Oncology Medical Home practice will have staff trained in the facilitation of the advance care planning sessions. Practices may adopt tools such as Respecting Choices, Five Wishes, Your Conversation Starter Kit, ACP Decisions or a practice-developed tool to facilitate these discussions.
A goals of care discussion is completed during the patient comprehensive verbal and written education process before starting each chemotherapy/immunotherapy treatment plan. Goals of treatment that is cure disease, prolong life, or reduce symptoms (referencing chemotherapy safety standard/QOPI Certification standard 2.2.3.2)

DOCUMENTATION REQUIREMENTS

- Policies and procedures that describe the process, contents, participants and timing for advanced care planning discussion. Including the specifics to how the practice routinely offers an advance care planning discussion at the initiation of cancer treatment and as appropriate thereafter (progression of disease or change in functional status).
- Medical record documentation should include offering an advance care planning discussion. If the advance care planning discussion occurs either an advanced directive, medical orders (e.g., Physician Orders for Life Sustaining Treatment POLST Paradigm Program form), or medical durable power of attorney or name/phone number of appointed agent(s) in the EMR and will be reviewed at site visit. Decisions made as a result of these conversations must be included in the medical record in a format that it can easily be found by providers not directly part of the oncology care team (e.g., hospitalists on the inpatient service). Note: POLST are not intended for everyone; they are for people with serious illnesses or frailty whose health care professionals would not be surprised if they died within the next year, based on their current health status and prognosis.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures
- Provide for site review: 1) medical record documentation and 2) patient education materials and documentation related to goals of care discussion

TOOLS & RESOURCES

Advance Care Planning (ACP) Decisions
https://acpdecisions.org

Advanced Cancer Care Planning (Cancer.net)

Standard F.2: For patients with advanced cancer and/or metastatic cancer OR patients with limiting co-morbid conditions, the practice performs an advance care planning discussion, which includes a review of advance directives in place; consideration/selection of an agent for medical decision making; discussion regarding symptom management; and discussion of patient goals for end of life care.

STANDARD DEFINITION AND REQUIREMENTS

Oncology Medical Home practices will introduce palliative care early in the patient care process for all patients with cancer; complete a goals of care discussion with all patients with advanced cancer; and provide patient-centered access to care for patients at the end of life to avoid unnecessary and unwanted ED visits and potential hospitalizations. Palliative care concurrent with usual oncology care is now the standard of care that is recommended for any patient with advanced cancer to begin within 8 weeks of diagnosis on the basis of evidence-driven national clinical practice guidelines. Palliative care provides relief from pain and other symptoms, supports quality of life, and is focused on patients with serious advanced illness and their families. The Oncology Medical Home practice routinely completes a goals of care discussion with all patients diagnosed with advanced care and/or metastatic disease. The session will ideally include the patient's current or prospective healthcare surrogate, family members, relevant care team members and a professional trained in the facilitation of such sessions. Discussion will include a review of advanced directives in place and modifications as appropriate or Physician Orders for Life Sustaining Treatment POLST Paradigm Program; discussion of patient goals for end-of-life care; and address symptom management at end of life.

Symptom management should be per consensus of ASCO and AAHPM for pain, N/V, dyspnea and anxiety. Documentation template resource Serious Illness Conversation Guide. See reference below.

DOCUMENTATION REQUIREMENTS

- Policies and procedures that describe the process, contents, participants and timing for patients with advanced cancer and/or metastatic cancer OR patients with limiting co-morbid conditions advance care planning discussion including review of advance directives, agent for medical decision making, goals of care, and symptom management.
- Medical record documentation should include discussion and symptom management per ASCO/AAHPM consensus and will be reviewed at site visit.

APPLICATION AND SITE REVIEW REQUIREMENT

- Provide for application: policies and procedures
- Provide for site review: 1) medical record documentation

TOOLS & RESOURCES

Advance Care Planning (ACP) Decisions
https://acpdecisions.org
Advanced Cancer Care Planning (Cancer.net)

Characteristics of Advance Care Planning in Patients With Cancer Referred to Palliative Care | JCO Oncology Practice (ascopubs.org)
Anthony L. Back, MD on Improving Communication Between Patient and Provider
https://ascopost.com/archive/meetings/2015-palliative-care-in-oncology-symposium/anthony-l-back-md-on-improving-communication-between-patient-and-provider/
ASCO and AAHPM Define Primary Palliative Care in Oncology
https://www.ascopost.com/issues/december-25-2015/asco-and-aahpm-define-primary-palliative-care-in-oncology/
Five Wishes
https://fivewishes.org/
Institute of Medicine: Dying in America
http://www.nationalacademies.org/hmd/~/media/Files/Report%20Files/2014/EOL/Report%20Brief.pdf
National POLST Paradigm
https://polst.org
"REMAP: A Framework for Goals of Care Conversations"
https://ascopubs.org/doi/full/10.1200/JOP.2016.018796
Respecting Choices | Person-Centered Care
https://respectingchoices.org
Serious Illness Conversation Guide
SI-CG-2017-04-21_FINAL.pdf (ariadnelabs.org)
The Edmonton Symptom Assessment System
https://www.jpsmjournal.com/article/S0885-3924(16)31213-1/pdf

The TEAM Approach to Improving Oncology Outcomes by Incorporating Palliative Care in Practice (Sept. 2017)

https://ascopubs.org/doi/full/10.1200/JOP.2017.022939
VITALtalk
https://www.vitaltalk.org/
Your Conversation Starter Kit – The Conversation Project
https://theconversationproject.org

Chemotherapy Safety

Standard G.1: Practice meets QOPI Certification Program (QCP) Standards

Practices must meet Chemotherapy Safety Standards— the Oncology Medical Home Chemotherapy Safety Standards are identical to the QOPI® Certification Program (QCP) standards for chemotherapy administration safety—through one of the following options:

a. Current QCP Certification status within the last 24 months of the 36-month re-certification cycle. QCP Certification status must be maintained to maintain Certification status; OR
b. Demonstration of compliance through Certification site survey.

Complete QCP Standards are provided in Appendix 4. Practices are not required to meet the QOPI chart abstraction/participation requirement but must meet all standards and measures in the QCP program.

- DOMAIN 1: Creating a safe environment – staffing and general policy (QCP Standards 1.1 – 1.6)
- DOMAIN 2: Treatment planning, patient consent and education (QCP Standards 2.1 – 2.2)
- DOMAIN 3: Ordering, preparing, dispensing and administering chemotherapy (QCP Standards 3.1 – 3.10)
- DOMAIN 4: Monitoring after chemotherapy is given, including adherence, toxicity and complications (QCP Standards 4.1 – 4.4)

DOCUMENTATION REQUIREMENTS

- Practices must meet Chemotherapy Safety Standards— the Oncology Medical Home Safety Standards are identical to the QOPI® Certification Program (QCP) standards for chemotherapy administration safety. QOPI Certification requirements provided in Appendix 4.
- Demonstrated either through current QOPI Certification or review of compliance during Certification activities.

Appendix 1: Summary of Standards & Documentation Requirements

Standard	Summary of Documentation Requirements
Patient Engagement	
Standard A.1: All patients are provided education on the Oncology Medical Home practice and concept.	Policies and procedures for providing all patients with verbal and written education on the Oncology Medical Home practice including initial patient orientation and ongoing reinforcement regarding access to care (and impact on cost); copy of educational materials provided; documentation in patient record that Oncology Medical Home education was provided. *Policies and educational materials to be provided at time of application; medical record documentation reviewed at site visit.*
Standard A.2: Patient financial counseling services are available and routinely provided with a best estimate of out-of-pocket expenses for any new therapy in the Oncology Medical Home practice.	Policies and procedures for financial counseling services including how patients are identified for the service; the elements that are covered in financial counseling visits; list of assistance programs available to patients; number of patients receiving financial counselling support and amount of support provided; documentation of annual review of financial counseling program with Oncology Medical Home Oversight Committee (OOC). Some overlap with QCP Standard 1.5; both standards must be met. *Policies to be provided at time of application and reviewed at site visit; patient data and annual report reviewed at site visit.*
Standard A.3: All patients are provided with education on their cancer diagnosis, goals of treatment, and an individualized treatment plan.	Policies and procedures for patient and caregiver education regarding cancer diagnosis, goals of treatment, treatment plan and expected side effects. Practice must be compliant with QCP Standard 2.2. *Policies to be provided at time of application; medical record documentation reviewed through QOPI Certification visit or Certification site visit.*

Standard A.4: The Oncology Medical Home practice develops a team-based survivorship care program, for all eligible patients, including identification of responsible staff, timeline for implementation, and documentation of existing supports and new services in development; treatment summary and survivorship care plan are encouraged as part of the survivorship care program, but are not required. Inclusive in the survivorship care program are appropriate strategies for transition back to primary care in appropriate patients.	Policies and procedures for developing and providing a survivorship care program for all eligible patients, including identification of responsible staff and timeline for implementation, and documentation of existing supports and new services in development; A sample treatment summary and survivorship care plan may be included, if utilized as a component of the survivorship care program; During the site visit, surveyors will review of minimum of two survivorship patient visit notes. *Policies with sample documents to be provided at time of application and reviewed at site visit; medical record documentation and data requirements reviewed at site visit.* *During the site visit, surveyors will review of minimum of two survivorship patient visit notes.*
Availability and Access to Care	
Standard B.1: The Oncology Medical Home practice institutes expanded access and an evidence-based symptom triage system to ensure that patients can easily access the practice and their providers.	Policies and procedures to include availability of same day appointments; practice documentation of ER visits for patients on active chemotherapy; admissions direct from practice; patient call-backs including maximum call back time for urgent and non-urgent patients according to medical condition; staff initial and ongoing training requirements for performing patient symptom triage. Documentation requirements include the source of symptom triage pathways. Practice must be compliant with QCP Standard 1.6. *Policies to be provided at time of application and reviewed at site visit; practice documentation reviewed at site visit.*
Standard B.2: The Oncology Medical Home practice tracks patient ED visits, hospital admissions and re-admissions; analyzes the data regularly for process improvement and patient education purposes; and provides patient follow-up within an	Policies and procedures including: 1) tracking of ED visits; 2) hospital admissions and re-admissions; 3) process for analyzing data and implementing practices changes to reduce frequency; and 4) contacting patients for follow-up within an appropriate timeline post-hospitalization and ED visit. *Policies to be provided at time of application and reviewed at site visit.*

appropriate timeline post-hospitalization or ED visit.	
Standard B.3: Documentation and follow-up for patients who miss or cancel scheduled visits and/or chemotherapy treatments.	Policies and procedures regarding follow-up of patients who miss or cancel appointments; include standards for number of attempts to contact, timeframe for contacting patient, process for informing physicians of no-show patients, and medical record documentation of follow-up. Practice must be compliant with QCP Standard 2.2.3.11. *Policies to be provided at time of application and reviewed at site visit; medical record documentation reviewed at site visit.*
Evidence-based Medicine	
Standard C.1: The Oncology Medical Home practice uses evidence-based treatment pathways; measures and reports on physician compliance with pathways; and requires documentation for off-pathway treatment.	Policies and procedures that document the source of treatment pathways; policies for measurement and reporting on physician compliance including frequency of reporting and results of not utilizing pathways; policy for off-pathway treatment and documentation of such in medical record. *Policies to be provided at time of application and reviewed at site visit.*
Standard C.2: Patients are provided clinical research study information by the Oncology Medical Home practice as appropriate for the patient's clinical condition.	Policies and procedures regarding patient screening for clinical trials; availability of oncology clinical research studies, either on-site or by referral; monitoring and reporting on clinical trial referrals and accruals. *Policies to be provided at time of application and reviewed at site visit; practice documentation reviewed at site visit.*
Evidence-based standardized symptom triage pathways covered in Standard B.1	
Comprehensive Team-based Care	

Standard D.1: In most instances, a medical oncologist directs the patient's care team within the Oncology Medical Home practice, directs care coordination with other pertinent physicians and services; including ongoing collaboration with the in-patient team.	Policies and procedures on medical oncologist-directed care including: 1) clear delineation of staff roles in care coordination processes; 2) communication standards to ensure timely communication to referring physicians, primary care physicians, palliative care/symptom management teams, and hospice; 3) process for timely ordering of tests and tracking results, including communication to patients; and 4) documentation of annual review of policies and procedures with OOC. *Policies to be provided at time of application and reviewed at site visit; annual report reviewed at site visit.*
Standard D.2: The Oncology Medical Home practice prioritizes team-based care with policies and practices that clearly delineate roles and responsibilities; implements and prioritizes team huddles as a communication and patient safety tool; and regularly assesses how the practice team is functioning.	Policies and procedures that require and standardize position descriptions, roles and responsibilities for all staff; team huddle or other method of team communication process – frequency, staff required to attend, issues discussed; ongoing process to assess team functioning with review by the OOC at least annually. *Policies to be provided at time of application and observed/reviewed at site visit; annual report reviewed at site visit.*
Standard D.3: All patients are provided navigation for support services and community resources specific to the practice patient population; on-site psychosocial distress screening is performed and referral for the provision of psychosocial care, as needed.	Policies and procedures for the process of: 1) identifying and addressing patient psychosocial and other support service needs; 2) referring patients for support services and community resources; and 3) performing psychosocial distress screening and resultant interventions; Documentation of annual review of policies by OOC, health disparities data findings, and mitigation actions taken by OOC. Practice must be compliant with QCP standards 1.2.7, 1.4 and 1.5. *Policies to be provided at time of application and reviewed at site visit; annual report reviewed at site visit.*

Quality Improvement	
Standard E.1: The Oncology Medical Home practice administers a patient experience survey to cancer patients at least twice each calendar year or on an ongoing basis (this includes surveys completed to fulfill other requirements). Results of the survey are analyzed and used to guide quality improvement activities.	Copy of patient satisfaction tool; annual report of patient satisfaction survey and benchmarked results; documentation of review of process and results with OOC and discussion of quality improvement activities implemented to improve patient satisfaction. *Policies and sample patient satisfaction tool to be provided at time of application and reviewed at site visit; annual report and documentation review at site visit.*
Standard E.2: The Oncology Medical Home practice demonstrates a commitment to quality improvement by regularly using data to evaluate a process of care, implementing changes if/when indicated from analysis, and monitoring sustainability of improvement over time. Patient-reported outcomes may be used as part of this improvement process.	Policies and procedures that describe the quality improvement process in the practice including responsible staff, frequency of meetings (recommend quarterly), sources of data, records/ description of projects and processes, and assessment of improvement over time. Continual Quality Improvement and Lean principles may be utilized including plan, do, study, act (PDSA) cycles to monitor ongoing improvement initiatives. Practice policies and procedures for completion of EHR with core data elements and measurement of same. Projects, recommendations and improvements are reported to the OOC and documented in the OOC minutes. *Policies to be provided at time of application and reviewed at site visit; OCC report and minutes reviewed at site visit.*
Palliative and End of Life Care	

Standard F.1: Practice routinely offers an advance care planning discussion and completes a goals of care discussion with all patients that recognizes the individual patient's needs and preferences. If the advance care planning discussion is conducted, it would include advanced directives and consideration/selection of an agent for medical decision making.	Policies and procedures that describe the process, contents, participants and timing for advanced care planning discussion; medical record documentation should include either an advanced directive or POLST form or name/phone number of appointed agent(s) in the EMR and will be reviewed at site visit. Decisions made as a result of these conversations must be included in the medical record in a format that it can easily be found by providers not directly part of the oncology care team (e.g. hospitalists on the inpatient service). Note: POLST are not intended for everyone; they are for people with serious illnesses or frailty whose health care professionals would not be surprised if they died within the next year, based on their current health status and prognosis. *Policies to be provided at time of application and reviewed at site visit; medical records to be reviewed at site visit.*
Standard F.2: For patients with advanced cancer and/or metastatic cancer OR patients with limiting co-morbid conditions, the practice performs an advance care planning discussion, which includes a review of advance directives in place; consideration/selection of an agent for medical decision making; discussion regarding symptom management; and discussion of patient goals for end of life care.	Policies and procedures that describe the process, contents, participants and timing for patients with advanced cancer and/or metastatic cancer OR patients with limiting co-morbid conditions advance care planning discussion including review of advance directives, agent for medical decision making, goals of care, and symptom management; Medical record documentation should include discussion and symptom management per ASCO/AAHPM consensus and will be reviewed at site visit *Policies to be provided at time of application and reviewed at site visit; medical records to be reviewed at site visit.*
Chemotherapy Safety	
Standard G.1: Practice meets QOPI Certification Program (QCP) Standards	Practices must meet Chemotherapy Safety Standards—the Oncology Medical Home Chemotherapy Safety Standards are identical to the QOPI® Certification Program (QCP) standards for chemotherapy administration safety. QOPI Certification requirements provided in Appendix 4.

	Demonstrated either through current QOPI Certification or review of compliance during Certification activities.

Appendix 2: Components of the Institute of Medicine Care Management Plan

1. Patient information (e.g., name, date of birth, medication list, and allergies)
2. Diagnosis, including specific tissue information, relevant biomarkers, and stage
3. Prognosis
4. Treatment goals (curative, life-prolonging, symptom control, palliative care)
5. Initial plan for treatment and proposed duration, including specific chemotherapy drug names, doses, and schedule as well as surgery and radiation therapy (if applicable)
6. Expected response to treatment
7. Treatment benefits and harms, including common and rare toxicities and how to manage these toxicities, as well as short-term and late effects of treatment
8. Information on quality of life and a patient's likely experience with treatment
9. Who will take responsibility for specific aspects of a patient's care (e.g., the cancer care team, the primary care/geriatrics care team, or other care teams)?
10. Advance care plans, including advanced directives and other legal documents
11. Estimated total and out-of-pocket costs of cancer treatment
12. A plan for addressing a patient's psychosocial health needs, including psychological, vocational, disability, legal, or financial concerns and their management
13. Survivorship plan, including a summary of treatment and information on recommended follow-up activities and surveillance, as well as risk reduction and health promotion activities

Appendix 3: ASCO Criteria for High-Quality Clinical Pathways

Pathway development

- Expert driven
    - Do practicing oncology providers with relevant disease and/or specialty expertise play a central role in pathway development?
- Reflects stakeholder input
    - Is there a mechanism in place for patients, payers, and other stakeholders to provide input during the development process?
- Transparent
    - Is there a clear, consistent process and methodology for pathway development that is transparent to all pathway users, stakeholders, and the general public? Is information disclosed on:
        - The methodology used for development?
        - The strength and types of evidence used to generate consensus?
        - The specific evidence used to support the pathway recommendation (including key literature, citations, guidelines, or other evidence)?
        - The way in which efficacy, toxicity, and cost are assessed and balanced in determining the pathway recommendation?
    - Is there a policy in place and adhered to that requires public disclosure of all potential conflicts of interest by oncology pathway panel members and any other individuals or entities that contribute to the development of pathway content? Does this policy describe:
        - The nature of relationships required for disclosure?
        - The manner in which disclosure information is made publicly available?
        - The required steps for managing conflicts of interest?
        - The required steps to ensure policy adherence and enforcement?
- Evidence based
    - Are the pathways based on the best available scientific evidence as documented or disseminated in clinical practice guidelines, peer- reviewed journals, scientific meetings, Medicare compendia, US Food and Drug Administration (FDA) labeling indications, and/or other dissemination vehicles?
    - Is a mechanism in place for considering high-quality evidence generated from validated real-world data (i.e., rapid learning health care systems)?
- Patient focused
    - Do the pathways include evidence-based options to account for differences in patient characteristics and/or preferences (i.e., patient comorbidities, prior diagnoses and treatments, risks of treatment-related toxicities, treatment schedule, and/or financial toxicity)?
- Clinically driven
    - Is there an established methodology for prioritizing efficacy, safety, and cost?
    - How is cost factored into pathway recommendations of therapeutically similar or equivalent treatments?

    - Are stakeholder assessment and pathway analysis used for pathway revision?
- Up to date
    - Are pathways updated in a timely way as relevant new information, including new FDA indication approvals, becomes available?
    - How rapidly are new, practice-changing data incorporated into pathway recommendations?
    - What is the process used to ensure timely updates are made?
    - Is a full review of the entire pathway performed and documented at least annually, and does a mechanism exist for ongoing rapid evaluation?
- Comprehensive
    - Do the pathways address the full spectrum of cancer care from diagnostic evaluation through first course of therapy, supportive care, post-treatment surveillance, treatment of recurrent cancer (lines of therapy), survivorship, and end-of-life care? Do they include medical, surgical, and radiation treatments; imaging and laboratory testing; and molecular diagnostics/precision medicine?
    - If the pathways are not comprehensive, do they clearly describe the phase and elements of care they are intended to address?
- Promotes participation in clinical trials
    - Are available clinical trials options incorporated into the pathway program?
    - Is the treatment provided to patients participating in phase I to III clinical trials always considered pathway-appropriate treatment?

Implementation and use

- Clear and achievable expected outcomes
    - Is information provided on the specific cancer type, stage, and molecular profile (if applicable) that the pathway is intended to cover?
    - Is there clear information provided to pathway users and other stakeholders on what constitutes treatment on the pathway, treatment off the pathway, and warranted variation from pathway recommendations?
    - Does the pathway program report and communicate to all stakeholders the goal adherence rates?
    - Are expected adherence rates established in a way that reflects the strength of evidence for the disease and stage?
    - Do adherence rates incorporate precision medicine based on current FDA-approved indications as on- pathway?
    - Do adherence rates allow for evidence-based variation and take into account individual patient differences and the resources
- Integrated, cost-effective technology and decision support
    - Does the pathway program comply with current federal mandates for meaningful use of electronic health record (EHR) technology or other requirements?

    - Does the pathway program offer—or plan to offer—clinical decision support or other resources (i.e., automated payer authorization, links to order sets, data collection tools) in a way that is integrated into commonly used EHRs? How does it communicate these offerings to users and other stakeholders?
- Efficient processes for communication and adjudication
    - Does the pathway program provide references or links to references that may support pathway variation?
    - Does the pathway program inform the provider in real time of pathway compliance?
    - Is the mechanism for choosing an off-pathway recommendation and documenting the rationale for this choice easily imbedded in the pathway program?

Analytics

- Efficient and public reporting of performance metrics
    - Are regular reports provided to participating providers that demonstrate the level of current pathway performance and performance over time with comparisons to the performance of other groups of providers?
    - Is there a mechanism in place for the provider to record reasons for going off-pathway?
    - Will the performance reports provided include these reasons for nonconcordance?
    - Will public reporting of providers' pathway adherence be disclosed as a composite report only (i.e., not at an individual provider or provider group level)?
    - Do providers have an opportunity to review performance reports and revise any areas in need of adjustment?
- Outcomes-driven results
    - Does the pathway program have analytics in place to enable a movement over time from adherence-driven compliance to outcome- driven results?
- Promotes research and continuous quality improvement
    - Does the pathway program demonstrate a commitment to research aimed at assessing and improving the impact of pathways on patient and provider-patient experience, clinical outcomes, and value? For example, do data generated from the pathway program incorporate patient and treatment variables to allow and foster discovery of important unanticipated knowledge?
    - Are patient assessment and pathway analysis used for pathway revision? For example, are reasons for off-pathway treatment captured, tracked, and reviewed for consideration in modifying pathways?
    - Are the analytics generated from pathway programs publicly available to patients and/or participating providers for benchmarking and understanding of complex cancer outcomes?

Appendix 4: QOPI® Certification Program Standards

QOPI® Certification Program Standards January 1, 2020

*Based on 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, including Standards for Pediatric Oncology

DOMAIN 1: Creating a safe environment - staffing and general policy

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

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

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

1.1.3 Chemotherapy is administered by a qualified physician, physician assistant, registered nurse or advanced practice nurse with documented comprehensive chemotherapy administration education, initial training, and (at least) annual continuing education and competency validation

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

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

1.2.1 Pathologic confirmation or verification of initial diagnosis.

1.2.2 Initial cancer stage or current cancer status. *Cancer stage/Cancer status is defined in the glossary.*

1.2.3 Complete medical history and physical examination. *Medical history and physical examination is defined in the glossary.*

1.2.4 Pregnancy status for women of childbearing age.

1.2.5 Presence or absence of allergies and history of other hypersensitivity reactions.

1.2.6 Assessment of the patient's and/or caregiver's comprehension of information regarding the disease and the treatment plan.

1.2.7 Initial psychosocial assessment, with action taken when indicated. *Psychosocial assessment is defined in the glossary.*

1.2.8 The chemotherapy treatment plan, including, at minimum, the patient diagnosis, drugs, doses, anticipated duration of treatment, and goals of therapy

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

1.3.1 Functional status and/or performance status.

1.3.2 Vital signs.

1.3.3 Weight is measured at least weekly when present in the health care setting.

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

1.3.5 Age as appropriate to the treatment population.

1.3.6 Allergies, previous treatment related reactions.

1.3.7 Treatment toxicities.

1.3.8 Pain assessment.

1.3.9 Patient's medications are updated and reviewed by a practitioner when a change occurs.

1.4 Staff assesses and documents psychosocial concerns and need for support with each cycle or more frequently, with action taken when indicated.

1.5 The health care setting provides information about financial resources and/or refers patients to psychosocial and other cancer support services.

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

DOMAIN 2: Treatment planning, patient consent and education

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

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

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

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

2.2.3 Educational information includes the following at a minimum:

2.2.3.1 Patient's diagnosis.

2.2.3.2 Goals of treatment, that is, cure disease, prolong life, or reduce symptoms.

2.2.3.3 Planned duration of treatment and schedule of treatment administration.

2.2.3.4 Drug names and supportive medications, drug-drug and drug-food interactions, and plan for missed doses.

2.2.3.5 Potential long-term and short-term adverse effects of therapy, including infertility risks for appropriate patients.

2.2.3.6 Symptoms or adverse effects that require the patient to contact the health care setting or to seek immediate attention.

2.2.3.7 Procedures for handling medications in the home, including storage, safe handling, and management of unused medication.

2.2.3.8 Procedures for handling body secretions and waste in the home.

2.2.3.9 Follow-up plans, including laboratory and provider visits.

2.2.3.10 Contact information for the health care setting, with availability and instructions on when and who to call.

2.2.3.11 Expectations for rescheduling or cancelling appointments.

DOMAIN 3: Ordering, preparing, dispensing and administering chemotherapy

3.1 Chemotherapy orders include at least the following elements:

3.1.1 Patient's name.

3.1.2 A second patient identifier.

3.1.3 Date the order is written.

3.1.4 Regimen or protocol name and number.

3.1.5 Cycle number and day, when applicable.

3.1.6 All medications within the order set are listed by using full generic names.

3.1.7 Drug dose is written following standards for abbreviations, trailing zeros, and leading zeros.

3.1.8 The dose calculation, including:

3.1.8.1 The calculation methodology.

3.1.8.2 Variables used to calculate the dose.

3.1.8.3 The frequency at which the variables are re-evaluated.

3.1.8.4 The changes in the values that prompt confirmation of dosing.

3.1.9 Date of administration.

3.1.10 Route of administration.

3.1.11 Allergies.

3.1.12 Supportive care treatments that are appropriate for the regimen, including premedication, hydration, growth factors, and hypersensitivity medications.

3.1.13 Parameters that would require holding or modifying the dose, for example, laboratory values, diagnostic test results, and patient's clinical status.

3.1.14 Sequencing of drug administration, when applicable.

3.1.15 Rate of drug administration, when applicable.

3.1.16 An explanation of time limitation, such as the number of cycles for which the order is valid.

Verification 1

A second person (a practitioner or other personnel approved by the practice/institution to prepare or administer chemotherapy) performs the following independent verification:

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

3.2.1 Two patient identifiers.

3.2.2 Drug name.

3.2.3 Drug dose.

3.2.4 Route of administration.

3.2.5 Rate of administration.

3.2.6 The calculation for dosing, including the variables used in this calculation.

3.2.7 Treatment cycle and day of cycle.

Verification 2

A second person (a practitioner or other personnel approved by the practice/institution to prepare or administer chemotherapy) performs the following independent verification:

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

3.3.1 The drug vial(s).

3.3.2 Concentration.

3.3.3 Drug volume or weight.

3.3.4 Diluent type and volume, when applicable.

3.3.5 Administration fluid type, volume, and tubing.

3.4 Chemotherapy drugs are labeled immediately upon preparation and labels include the following 11 elements:

3.4.1 Patient's name.

3.4.2 A second patient identifier.

3.4.3 Full generic drug name.

3.4.4 Drug dose.

3.4.5 Drug administration route.

3.4.6 Total volume required to administer the drug.

3.4.7 Date the medication is to be administered.

3.4.8 Expiration dates and/or times.

3.4.9 When dose is divided, the total number of products to be given and the individual product sequence (e.g., 1 of 2, 2 of 2, etc.).

3.4.10 A warning or precautionary label or sticker, as applicable, to storage and handling; may be included within the label or on an auxiliary label.

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

3.5.1 Intrathecal medications are:

3.5.1.1 Prepared separately.

3.5.1.2 Stored in an isolated container or location after preparation.

3.5.1.3 Labeled with a uniquely identifiable intrathecal medication label.

3.5.1.4 Delivered to the patient only with other medications intended for administration into the CNS.

3.5.1.5 Administered immediately after a time-out, double-check procedure that involves two licensed practitioners or other personnel approved by the health care setting to prepare or administer chemotherapy.

3.5.2 Intravenous vinca alkaloids are administered only by infusion.

3.6 **Before initiation of each chemotherapy administration cycle, the practitioner who is administering the chemotherapy confirms the treatment with the patient, including, at a minimum, the name of the drug, infusion time, route of administration, and infusion related symptoms to report—for example, but not limited to, hypersensitivity symptoms or pain during infusion.**

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

Verification 3

A second person (a practitioner or other personnel approved by the practice/institution to prepare or administer chemotherapy) performs the following independent verification:

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

3.8.1 Drug name.

3.8.2 Drug dose

3.8.3 Infusion volume or drug volume when prepared in a syringe.

3.8.4 Rate of administration.

3.8.5 Route of administration.

3.8.6 Expiration dates and/or times.

3.8.7 Appearance and physical integrity of the drugs.

3.8.8 Rate set on infusion pump, when used.

3.8.9 Sequencing of drug administration.

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

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

DOMAIN 4: Monitoring after chemotherapy is given, including adherence, toxicity and complications

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

4.1.1 Availability of appropriate treatment agents.

4.1.2 Procedures to follow and a plan for escalation of care, when required, for life threatening emergencies.

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

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

4.4 Cumulative doses of chemotherapy are tracked for agents associated with cumulative toxicity. The standards are not deemed comprehensive and do not account for individual patient.

The standards are not deemed comprehensive and do not account for individual patient variation. It is the responsibility of each administering agent to determine the best methods for chemotherapy administration for each patient. The standards are not medical advice or legal advice. To the extent that the standards conflict with applicable federal, state, or local legal requirements, practitioners should comply with those requirements. The administering agent is solely responsible for, and assumes all risks of, administering chemotherapy drugs notwithstanding any adherence to the standards herein. ASCO and ONS disclaim any and all liability with respect to the standards and the execution of the standards by any party.

QOPI Certification Program Standards. https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program/about-qopi-certification

GLOSSARY: ASCO/ONS CHEMOTHERAPY ADMINISTRATION SAFETY STANDARDS

Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards	
Term	Definition
Acronyms	ASCO, American Society of Clinical Oncology; APHON, Association of Pediatric Hematology/Oncology Nurses; ASPHO, American Society of Pediatric Hematology/Oncology; ONCC, Oncology Nursing Certification Corporation; ONS, Oncology Nursing Society
Adherence	The degree or extent of conformity to the provider's recommendations about day-to-day treatment with respect to timing, dosing, and frequency.
Assent	Assent expresses a willingness to participate in a proposed treatment by persons, who are by definition, too young to give informed consent, but who are old enough to understand the diagnosis and proposed treatment in general, its expected risks and possible benefits. Assent, by itself, is not sufficient, however. If assent is given, informed consent must still be obtained from the subject's parents or guardian, both which must be done according to all applicable state and federal laws. (see Consent below)
Basic Life Support	Certification through an accredited class in provisioning resuscitation, and management and assessment of life-threatening conditions, including CPR, controlling bleeding, treating shock and poisoning, stabilizing injuries and/or wounds, and basic first aid. An example would be the American Heart Association's BLS. Higher medical functions use some or all of the Advanced Cardiac Life Support (ACLS) protocols, in addition to BLS protocols.
Cancer Stage	A formal, standardized categorization of the extent to which a cancer has spread at diagnosis. Systems vary by tumor type and staging should be specific to the tissue of tumor origin. Stage should be distinguished from Cancer Status. Cancer status does change over time.

Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards	
Term	Definition
Cancer Status	Description of the patient's disease since diagnosis, if relevant (e.g. recurrence, metastases).
Cancer Support, Information and Financial Resources	A list of resources that is available for cancer support.
Chemotherapy	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.
Chemotherapy Preparation Verification: Use of technology	Preparation of chemotherapy should be independently verified by a second healthcare provider who did not prepare the chemotherapy. Independent verification should include checking the preparation for completeness and accuracy of content, with particular attention given to special preparation instructions. Technology can serve as a surrogate; if practitioners follow procedures in using appropriately developed and applied procedures. Verification may include bar code and/or gravimetric verification and may be performed on site or remotely via digital images or video as allowed by state law or other regulations.
Chemotherapy Regimen	One or more chemotherapeutic agents used alone or in combination in a well- defined course of treatment, generally administered cyclically.
Chemotherapy Treatment Plan	A plan of treatment specific to the patient that is developed prior to the initiation of chemotherapy. The core elements of a chemotherapy treatment plan are: 1. Diagnosis, including the cancer site, histology and stage 2. Goals of therapy (may be specified by the type of template; e.g., adjuvant chemotherapy plan) 3. Patient health status and co-morbidities 4. Surgical history and notable pathology findings 5. Chemotherapy regimen and starting dosages 6. Duration of treatment and number of planned cycles 7. Major side effects of chemotherapy

Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards	
Term	Definition
Clinical encounter	Clinical encounters include each inpatient day, scheduled or unscheduled practitioner visits, home visits and chemotherapy administration visits, but not laboratory or administrative visits.
Clinical Staff	Staff involved in patient care (e.g. practitioners, registered nurses, etc.)
Comprehensive Education Program	A comprehensive educational program is current, evidence-based, and age appropriate. It may be internally developed or use an established educational curriculum, includes all routes of chemotherapy administration used in the health care setting and concludes in clinical competency assessment. Example of education programs for staff administering chemotherapy agents includes the ONS/ONCC Chemotherapy Biotherapy Certificate Course, and APHON Pediatric Chemotherapy & Biotherapy Provider Program.
Consent	Consent to treatment is an important part of delivering quality cancer care. Consent is the process by which a patient is provided with sufficient information about the disease diagnosis and treatment options so that the individual can make a reasonable decision about treatment, based on an understanding of the potential risks and anticipated benefits of the treatment. Informed consent is not a waiver of rights.
Dosage	Includes the amount or quantity of medicine to be taken or administered and implies the duration or the frequency of the dose to be administered (e.g., daily, every 21 days, etc.).
Dose	The amount or quantity of medicine to be taken or administered to the patient each time in a day.
Exception Order	Notation that the standard treatment is contraindicated as a result of pre- existing comorbidity, organ dysfunction or prior therapy.
Functional Status	An individual's ability to perform normal daily activities required to meet basic needs, fulfill usual roles, and maintain health and well-being.
Handoff	The transfer of patient information and knowledge, along with authority and responsibility, from one clinician or

Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards	
Term	Definition
	team of clinicians to another clinician or team of clinicians during transitions of care across the continuum.
Healthcare Setting	A medical office or practice, clinic, agency, company, hospital or institution that provides healthcare, and home environment where healthcare is provided.
Hypersensitivity Reaction	A symptomatic interaction between antibodies and allergens that causes an exaggerated and harmful response in the body. Hypersensitivity reactions range from mild to life threatening in severity and symptoms.
Identifier (patient identification)	Minimum patient identifiers for positive patient identification are: Last name, first name, date of birth, unique identification number such as medical record number. Whenever possible, ask patients to state their full name and date of birth. For patients who are unable to identify themselves (pediatric, unconscious, confused or language barrier) seek verification of identity from a parent or caregiver at the bedside. This must exactly match the information on the identity band, order, drug label (or equivalent).
Immediate Use	For the purposes of these Standards, immediate use is defined as “use within 2 hours” in accordance with drug stability, state and federal regulations.
Label	A small piece of material attached to the medication or a container for the medication giving information about it
Labeling	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. (If their machines have not caught up)
Medical History and Physical	Includes, at minimum, height, weight, pregnancy screening (when applicable), treatment history, and assessment of organ-specific function as appropriate for the planned regimen. Example of assessment of organ-specific function

Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards	
Term	Definition
	as appropriate for the planned regimen: patient plan for cisplatin requires pretreatment assessment of kidney function.
On-site and immediately available	Physically present, interruptible and able to furnish assistance and direction throughout the performance of the procedure
Orders: Written and Verbal	Orders that are written or sent electronically can be on paper, emailed from a secure encrypted computer system, written, or faxed; and includes the prescriber's signature, and in some instances, an identifying number. Verbal Orders are those that are spoken aloud in person or by telephone and offer more room for error than orders that are written or sent electronically.
Pain Assessment	Assessment of pain in the oncology patient using a multidimensional approach, with determination of the following: • Chronicity • Severity • Quality • Contributing/associated factors • Location/distribution or etiology of pain, if identifiable • Barriers to pain assessment
Parenteral	Introduction of substances by intravenous, intra-arterial, subcutaneous, intramuscular, intrathecal, intravesical, or intra-cavitary routes.
Patient	The recipient of health care, and when applicable, includes parents, family members, significant others, lay caregivers, and healthcare proxies (e.g. legal surrogates, guardians/conservators, healthcare agents).
Performance Status	The use of standard criteria for measuring how the disease impacts the patient’s daily living abilities.
Policy	A written course of action (e.g. procedure, guideline, protocol, algorithm).
Practitioner	Licensed independent practitioner, including physicians, advanced practice nurses (nurse practitioner or clinical nurse specialist), and/or physician assistants, as determined by state law.

Common Definitions for ASCO/ONS Chemotherapy Administration Safety Standards	
Term	Definition
Provider	Anyone who administers care to a patient including, for example, therapists, nurses, and physicians
Psychosocial Assessment	An evaluation of a person's mental health, social status, and functional capacity within the community. May include the use of a distress, depression, or anxiety screening form, patient self-report of distress, depression, or anxiety, or medical record documentation regarding patient coping, adjustment, depression, distress, anxiety, emotional status, family support and caregiving, coping style, cultural background and socioeconomic status.

Additional Notes:

The ASCO/Oncology Nursing Society (ONS) Chemotherapy Administration Safety 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 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.[34,35,36,37,38] 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.[39,40] The standards are not deemed comprehensive and do not account for individual patient variation. It is the responsibility of each administering agent to determine the best methods for chemotherapy administration for each patient.

The standards are not medical advice or legal advice. To the extent that the standards conflict with applicable federal, state, or local legal requirements, practitioners should comply with those requirements. The administering agent is solely responsible for, and assumes all risks of, administering chemotherapy drugs, notwithstanding any adherence to the standards herein.

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