

ASCO[®] Patient-Centered Oncology Payment

A Community-Based Oncology Medical Home Model

Proposal to the Physician-Focused Payment Model
Technical Advisory Committee

ASCO[®]

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Cover

Title: Patient-Centered Oncology Payment Model

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Abstract

The cancer care delivery system is facing extreme pressures amid rapidly developing science, rising costs, growing financial burden for patients, payer-imposed utilization management practices, and much more. As the healthcare landscape shifts from a fee-for-service to a value-based reimbursement system, innovative payment models are needed to help practices adapt and thrive in this high-stakes environment.

The American Society of Clinical Oncology (ASCO) has developed the *ASCO Patient-Centered Oncology Payment: A Community-based Oncology Medical Home Model*, a complete solution for transforming cancer care delivery and reimbursement while ensuring that all individuals with cancer have access to high-quality, high-value cancer care. In order to reach these goals, PCOP includes the following:

1. The creation of PCOP Communities, with multiple providers, payers, and other stakeholders agreeing upon a set of quality metrics, improvement projects, research collaboratives, and delivery of specialized care.
2. Clinical practice transformation required of each participating physician, to ensure that all patients affected by PCOP receive high-quality, well-coordinated care. Transformation categories include patient engagement, availability and access to care, comprehensive team-based care, quality improvement, safety, evidence-based medicine, and use of certified electronic health record technology.
3. A payment methodology that supports the required clinical practice transformation, provides incentives that recognize value-based care, and uses a consolidated payment framework that allows flexibility and innovation in care delivery.
4. A performance methodology that balances three categories: adherence to clinical treatment pathways, quality of care, and targeted cost metrics.
5. An implementation blueprint to guide PCOP stakeholder groups.

The ASCO model described in the following pages puts the needs of patients front and center, while solving critical challenges facing providers and the healthcare system as a whole:

- For **patients**, it offers access to an enhanced patient experience and world-class care.
- For **providers**, it enables them to successfully transition to value-based care.
- For **employers and health plans**, it offers a powerful way to incentivize quality and contain costs.

The *ASCO Patient-Centered Oncology Payment: A Community-based Oncology Medical Home Model* builds on more than five years of a dedicated effort by ASCO volunteer work groups consisting of leading medical oncologists from diverse practice settings, seasoned practice administrators, payer representatives, and experts in physician payment and business analysis.

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Alignment of the PCOP Model to PFPM Criteria

Since its original publication in 2015, the Patient-Centered Oncology Payment Model (PCOP) has been significantly updated. In doing so, ASCO has benefited from the criteria set forth for Physician-Focused Payment Models (PFPM) and guidance provided by the PFPM Technical Advisory Committee to authors of other proposals. The following introduction lays forth explanations on how PCOP is well-aligned with the criteria of scope, quality and cost, payment methodology, value over volume, flexibility, ability to be evaluated, integration and care coordination, patient choice, patient safety, and use of health information technology.

ASCO estimates that PCOP has a total available pool of 2,169 qualifying practices, consisting of 13,522 practicing hematologists/oncologists.¹ Assuming 40 new Medicare oncology beneficiaries per year, per hematologist/oncologist, we predict a potential pool of 540,880 Medicare beneficiaries annually, representing spending of \$46.8 billion. Financial modeling has shown savings opportunities up to 8% of total cost-of-care; a reasonable expectation is 4-6% reduction, totaling \$1.9 billion to \$2.8 billion in annual program savings.²

Much of payment reform in oncology today is payer-focused, with models developed, implemented and administered by a single commercial payer.³ Medicare's Oncology Care Model (OCM) is described as a multi-payer model with 10 participating commercial payers.⁴ However, only 51 of the 190 practices were working with another payer as of February 2017; only 11 were working with two or more non-Medicare payers.⁵ Further not all of these payers' models have the same requirements, measures, and incentives.^{6,7}

The PCOP model proposes an alternative approach to current payer-centric models. PCOP calls for true multi-payer, multi-practice participation, with mutually agreed upon clinical treatment pathways, performance metrics, and practice incentives. The PCOP model calls for the creation of "PCOP Communities" consisting of all payers, providers, employers and other stakeholders within a geographic region. These communities shall guide implementation of the PCOP methodologies to address their unique healthcare needs. The Comprehensive Primary Care Plus

¹ ASCO used the base enrollment file, reassignment file, and NPI Aggregate Report, CY 2017 to identify 13,522 hematologists/oncologists, reassigned to 2,169 groups (limit 1 group per oncologist). Data was pulled from data.cms.gov on October 28, 2019

² See Appendix A in the PCOP model, supplementary information

³ Aviki EM, Schleicher SM, Mullangi S, et al: Alternative payment and care-delivery models in oncology: a systematic review. *Cancer* 124(16), 3293-3306, 2018

⁴ Centers for Medicare & Medicaid Services: Oncology Care Model. <https://innovation.cms.gov/initiatives/oncology-care>

⁵ Abt Associates: Evaluation of the Oncology Care Model, Performance Period One. <https://innovation.cms.gov/Files/reports/ocm-secondannualeval-pp1.pdf>

⁶ Dangi-Garimella S: Aetna and RCCA collaborate on an oncology medical home. <https://www.ajmc.com/newsroom/aetna-and-rcca-collaborate-on-an-oncology-medical-home>

⁷ Kuntz G, Tozer JM, Snegosky J, et al: Michigan oncology medical home demonstration project: first-year results. *J Oncol Pract* 10(5), 294-297, 2014

(CPC+) model is similarly geographically organized, with 2,851 physician practices and 55 payers across 18 regions.⁸

PCOP's approach to quality and cost is rooted in evidence from prior demonstration projects in Medicare and private payers. Care delivery requirements are based on oncology medical home standards developed over the past decade.⁹ Electronically-capturable quality measures come from ASCO's Quality Oncology Practice Initiative (QOPI), most of which are endorsed by the National Quality Forum – see Appendix B. QOPI measures are used in the Merit-based Incentive Payment System, Oncology Care Model, and in commercial payer models.

PCOP addresses cost-of-care through use of clinical pathways and targeted cost measures, backed by studies having shown significant savings opportunities.

Clinical pathways play a key role in the success of PCOP. Communities are encouraged to adopt a single pathway for all payers and providers in the model. Studies have shown that application of value-based clinical pathways, such as those adhering to ASCO's Criteria for High-Quality Pathways in Oncology,¹⁰ result in lower anti-cancer and supportive care drug costs. Drug costs associated with use of on-pathway anti-cancer regimens can be up to 63% lower than off-pathway regimens.^{11,12} use of on-pathway regimens also result in lower supportive care drug, diagnostic, and hospitalization costs.^{13,14} Within PCOP, participating practices are required to implement, monitor, and report compliance with pathways.

PCOP's targeted cost measures – admissions, emergency and observation visits, and supportive and maintenance drug costs – are based on the aforementioned studies, which has shown that reductions in such costs may be achieved through value-based treatment selection and well-coordinated treatment delivery. ASCO firmly believes that cost measures must be based on evidence and subject to the same development and validation as our quality measure set.

The PCOP payment methodology addresses value over volume through strategic use of revenue to support practice transformation into the oncology medical home model; incentives tied to quality, cost, and clinical pathway adherence; and disruption of fee-for-service through PCOP's Consolidated Payments for Oncology Care. Within PCOP's consolidated payments, current fee-for-service rates are not only bundled into monthly amounts; practices place a portion of such

⁸ Centers for Medicare & Medicaid Services: Comprehensive Primary Care Plus. <https://innovation.cms.gov/initiatives/comprehensive-primary-care-plus>

⁹ Sprandio JD: Oncology patient-centered medical home. *J Oncol Pract* 8(3 Suppl), 47s-49s, 2012

¹⁰ Zon RT, Edge SB, Page RD, et al: American Society of Clinical Oncology criteria for high-quality clinical pathways in oncology. *J Oncol Pract* 13:207-210, 2017

¹¹ Hoverman JR, Cartwright TH, Patt DA, et al: Pathways, outcomes, and costs in colon cancer: retrospective evaluations in two distinct databases. *J Oncol Pract* 7, 52s-59s, 2011

¹² Neubauer MA, Hoverman JR, Kolodziej M, et al: Cost effectiveness of evidence-based treatment guidelines for the treatment of non-small-cell lung cancer in the community setting. *J Oncol Pract* 6(1), 12-18, 2010

¹³ Gautam S, Sylwestrzak G, Barron J, et al: Results from a health insurer's clinical pathway program in breast cancer. *J Oncol Pract* e711-e721, 2018

¹⁴ Shah S, Reh G: Value-based payment models in oncology: will they help or hinder patient access to new treatments? *Am J Manag Care* 23(5 Spec No.), SP188-SP190, 2017

amounts at risk based on their quality and cost performance. PCOP provides participants a roadmap to success, and the appropriate payment and incentives to reward the outcome.

The inclusion of flexibility in any payment model presents numerous challenges. The efficiency of our current fee-for-service system is built upon all parties having common standards on how to bill, reimburse, and judge the appropriateness of services given. In contrast, within existing alternative payment models, practices find themselves required to report disparate sets of performance measures¹⁵ and are reimbursed in a variety of methods.

To find a solution to this challenge, the architects of PCOP looked towards the CPC+ model of geographic communities, where multiple payers are called to agree upon and implement similar quality measures and payment methodologies. PCOP gives communities flexibility in the selection of quality measures for each performance period, use of a common clinical pathway, community-wide quality improvement projects, and public distribution of performance results. This flexibility is tempered through a set of quality measures with establish benchmarks, clinical pathways that meet ASCO's criteria, and standard cost measures, all of which allow for evaluation of each community against others within and outside of the PCOP model.

Within PCOP, each community is called to work together to better coordinate care within their own practice and among competing organizations. The use of research collaboratives and community-wide case conferences ensure that all patients within the community have equal access to clinical trials and specialized care.

Further, ASCO feels it is critical that all patients within the PCOP communities have access to the benefits afforded in the model. With current pilots, such as OCM, patients within the same county receive different standards of care, dependent on whether their physician was accepted in the model. Access to OCM's monthly enhanced oncology services is heavily dependent on state of residence, with 14 practices in Illinois, but only 1 in Colorado. Patients within PCOP communities can expect that all participating providers are implemented evidence-based standards of care delivery, and comply with chemotherapy safety standards developed by ASCO and the Oncology Nursing Society – see Appendix E.

Lastly, none of the ambitious goals of PCOP would be possible if not for careful consideration of the health information technology needs. Health information technology is imbedded throughout the PCOP model. Available quality measures were selected for their ability to be electronically captured, cost measures have been tested within the Maine Health Data Organization's all-payer database, and pathway adherence is to be provided by current providers of pathway decision-support tools. ASCO vision is to eventually bring these data sources together, using regional health information exchanges, all-payer claims databases, cancer registries, and the QOPI Reporting Registry, a qualified clinical data registry.

Through use of the criteria developed for physician-focused payment models, ASCO has been able to improve upon our original publication of PCOP.

¹⁵ Valuck T, Blaisdell D, Dugan DP, et al: Improving quality measurement in accountable care: filling gaps with cross-cutting measures. *J Manag Care Spec Pharm* 32(2), 174-181, 2017

Chapter 1: Introduction

1.1 *The PCOP Community-Based Oncology Medical Home*

The PCOP Community-Based Oncology Medical Home is a multi-stakeholder initiative, involving multiple payers, multiple provider practice groups, and other community stakeholders. As compared to each payer and practice group operating under separate proprietary models, this PCOP model provides the following benefits:

- Enhanced oncology care through implementation of a medical home model and specified care delivery requirements.
- A standardized collection of metrics to measure and share performance.
- Consistent care through a single compendium of clinical treatment pathways and other care guidelines.
- Reduced administrative expenses through a shared quality measurement platform, shared clinical treatment pathways, pooled data analysis, and other support services.
- Inclusion of employers, government agencies, and other community stakeholders in the Oncology Steering Committee.

1.2 *Implementation Options*

The PCOP model is intended to be implemented by a community of payers, practices, and community stakeholders within a defined geography. If implemented as a single-payer model, we encourage the payer to maintain the stakeholder collaboration components of the PCOP model.

1.3 *Stakeholder Collaboration*

As a multi-stakeholder initiative, this model requires significant collaboration between providers, employers, third-party payers, and other community stakeholders. While following the same basic framework, each community runs its own model and has flexibility in the selection of quality metrics, a shared oncology clinical pathway, and prioritization of community health needs.

1.4 *Care Delivery Requirements*

The PCOP model includes two tracks to advance the care of oncology patients, with specified care delivery requirements detailed in Chapter 2.

- Track 1 includes basic standards of patient engagement, access to care, comprehensive team-based care, quality improvement, safety, and use of certified EHR technology.
- Track 2 includes more advanced care delivery requirements to improve patient engagement, access to care, comprehensive team-based care, and quality improvement.

In Year 0 of the implementation schedule, practices shall elect to enter either Track 1 or 2, subject to verification of meeting the standards. Practices that elect Track 1 are expected to advance into Track 2 within 2 years or else be subject to discontinuation of care management and performance incentive payments.

1.5 Payment Methodology

The PCOP payment methodology, detailed in Chapter 3, is designed to evolve as a program progresses, increased data becomes available, and a community matures in its collaborative approach. Components of the payment model include:

- Use of monthly Care Management Payments to support treatment planning, care management, and active monitoring.
- Performance Incentive Payments that are based on quality measurement, cost-of-care, outcomes, and adherence to evidence-based clinical treatment pathways.
- The PCOP model is further advanced, in Track 2, through bundling of a portion of fee-for-service reimbursements into the monthly care management payments.

1.6 Quality Measurement

The PCOP model provides a necessary investment to support clinical practice transformation to improve the quality and value of care for cancer patients. Quality measurements are one of three key categories of performance and success of the model – the other two being adherence to evidence-based medicine (see Clinical Treatment Pathways) and total cost-of-care. In the community-model, stakeholders are challenged with the selection of metrics most impactful for their cancer population.

Quality metrics range from short-term process and care delivery metrics to medium and long-range outcomes. As PCOP involves continuous measurement of performance, metrics should be selected with consideration of the ability to calculate performance in a defined performance period – typically one-year. A list of potential metrics is included in Appendix B.

1.7 Clinical Treatment Pathways

Drugs and biological treatments represent the greatest component of oncology treatment costs, followed by surgery and radiation therapy. To ensure that selections of treatment are evidence-based and consider overall value, decision-support tools have been developed to guide providers in selection of the most appropriate option. High-quality clinical pathways reflect current medical evidence and consider these prioritized factors for available treatments: efficacy, potential toxicities, affordability, and individual patient



circumstances (e.g. level of functioning). Use of treatment pathways have been shown to reduce variation and control costs associated with cancer care.¹⁶

ASCO has developed criteria for evaluating the quality of clinical pathways – see Appendix C. Many providers and payers are using pathways as a medical management tool for their practices or networks. Consistent application of pathways that are high-quality, evidence-based and transparent can minimize or eliminate unwarranted – and costly – variation in care, improving both the patient experience and clinical outcomes. Clinical pathway adherence is a key metric for inclusion in performance dashboards and calculation of financial incentives and penalties.

In implementation of PCOP as a multi-payer model, participants are encouraged to adopt a single pathway for use with all patients, as opposed to following differing pathways dependent on the associated payer.

1.8 Performance Transparency

A successful component of the Medicare Shared Savings Program, Comprehensive Primary Care Plus, and the Oncology Care Model is open sharing of cost-of-care data assists providers and other stakeholders to identify opportunities to deliver high-value care, abandon low-value practices, and invest in a more efficient delivery system. In the above-mentioned models, providers receive access to detailed claims data, including utilization figures of which they may not have been previously aware: acute care hospital, oral drug, and costs of care delivered by other providers. Likewise, payers may benefit from additional clinical data to give clinical context to expenses.

Chapter 2: PCOP Communities

2.1 The PCOP Community

While it is possible to implement PCOP as a single payer, multiple provider model or single provider, multiple payer model, the envisioned and preferred option is to implement PCOP in a geographic community, with all relevant providers and payers participating.



Geographic communities may include a single metropolitan area, entire state or collection of states. Providers and payers with large operations may span multiple PCOP communities.

¹⁶ Hoverman JR, Cartwright TH, Patt DA, et al: Pathways, outcomes, and costs in colon cancer: retrospective evaluations in two distinct databases. J Oncol Pract, 7, 52s-59s. 2011.

2.2 *Oncology Steering Committee*

The Oncology Steering Committee is responsible for the implementation and governance of the PCOP model within their community. Providers or payers interested in implementation of PCOP should begin by discussing the model with other members of the oncology community. Once there is a commitment to implement PCOP, the Oncology Steering Committee shall begin meeting regularly to determine the scope and implementation parameters.

2.2.1 *Oncology Steering Committee Members*

As the PCOP model's primary goal is to advance oncology care within the community, the Oncology Steering Committee should include a wide range of stakeholders necessary to achieve its goals. Members should include:

- Providers participating in the model.
- Payers – include self-funded employee plans – participating in the model.
- Major employers interested in the advance of oncology care in their community.
- Patient advocates.
- Community leaders.

2.2.2 *Oncology Steering Committee Duties*

Key decisions in the design of the community model shall fall to the Oncology Steering Committee. Decisions include:

- Selection of quality metrics to be measured for each performance period.
- Selection of a community-wide Clinical Treatment Pathway or approval of provider-selected Clinical Treatment Pathways for inclusion in the performance methodology.
- Selection and oversight of community-wide quality improvement projects.
- Agreement of funding sources for the PCOP payment model.
- Identification and selection of partners to assist in facilitation.
- Public distribution of performance metrics.



2.2.3 *Executive Board*

Large communities may find it necessary to elect an Executive Board of the Oncology Steering Committee, whose role is to deliberate issues and present a recommendation to the entire group.

2.3 *Oncology Research Collaborative*

An optional, but recommended body is the Oncology Research Collaborative. A model priority is to ensure that each patient receives the most appropriate, high-value care. Access to clinical research trials are critical to the successful delivery of this priority. A



community-wide research collaborative can facilitate one or more activities:

- Sharing of clinical research trial menus from participating providers.
- Education of community providers on the goals and patient criteria of available trials.
- Facilitation of observational trials across all participating providers.
- Contracting and facilitation of pharmaceutical trials for community-wide enrollment.

2.4 Community Case Conference

Case conferences, including tumor boards and molecular tumor boards, allow a panel of multi-specialty providers to discuss cancer cases and determine the most appropriate care. Conferences are commonly held within each hospital with oncology services.

Community case conferences provide further resources for participating providers by including subspecialists and researchers who may provide further perspective and resources not contained within a single hospital or health system. Each community may decide the need, frequency, and scope of such conferences – for example, prioritizing rare disease or those involving significant health disparities.



Chapter 3: Clinical Practice Transformation

To achieve clinical practice transformation and advance the care of oncology patients, practices electing to enter Track 1 shall be required to implement the care delivery requirements notated as Track 1 in Table 3.1. Practice electing to initially enter Track 2 shall be required to implement the care delivery requirements noted as either Track 2 in Table 3.2.

Practices who deliver care to both oncology and non-oncology patients may implement the care delivery requirements to all patients of the practice, or else develop mechanisms to identify and track oncology patients to ensure compliance.

Table 3.1
PCOP Care Delivery Requirements

| Domain: Patient Engagement |
|--|
| Patients are provided education on the practice and PCOP model. (Tracks 1 and 2) |
| Patient financial counseling services are available and routinely provided in the practice. (Tracks 1 and 2) |
| All patients are provided with education on their cancer diagnosis and an individualized treatment plan. (Tracks 1 and 2) |
| Practice convenes a patient and family advisory council, to meet at least twice per year, and integrate recommendations into care, as appropriate. (Track 2) |

The practice develops and implements a process to disseminate a treatment summary/survivorship care plan to patients within 90 days of the completion of treatment. (Track 2)

Domain: Availability and Access to Care

Practice offers patients 24/7 access to an appropriate clinician, with real-time access to health records. (Tracks 1 and 2)

Practice has a policy for documentation and follow-up for patients who miss or cancel scheduled visits and/or chemotherapy treatments. (Tracks 1 and 2)

Practice uses triage data to determine and implement expanded patient access, including, as appropriate: extended hours, weekend hours, and/or urgent/walk-in visits. (Track 2)

Practice utilizes symptom management pathways/guidelines for triage and urgent care of patients experiencing symptoms from their cancer or cancer treatment. (Track 2)

Practice tracks patient ED visits, hospital admissions and re-admissions; analyzes the data regularly for process improvement and patient education purposes; and contacts patients within 48 hours of hospitalization or ED visits for follow-up. (Track 2)

Domain: Comprehensive Team-Based Care

A medical oncologist directs the patient's care team within the practice, directs care coordination with other pertinent physicians and services, and manages or co-manages the inpatient team-based care. (Tracks 1 and 2)

The 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. (Tracks 1 and 2)

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 is provided, as needed. (Track 2)

Practice adopts a risk stratification process for all oncology patients, addressing medical needs, behavioral diagnoses, and health-related social needs. (Track 2)

Practice provides dedicated advance care planning sessions, facilitated by a trained professional. (Track 2)

| | |
|---|---|
| Domain: Quality Improvement | |
| The practice records, reviews and monitors completeness of clinical data for initiating quality improvement activities (Tracks 1 and 2) | |
| The practice administers a patient satisfaction survey to cancer patients at least twice each calendar year or on an ongoing basis. The results of the survey are analyzed and used to guide quality improvement activities. (Tracks 1 and 2) | |
| Each calendar year, the practice participates in at least one quality improvement study associated with improving clinical outcomes and implements at least one quality improvement based on study results. (Track 2) | |
| Domain: Safety | |
| The practice follows QOPI safety standards for the administration of chemotherapy. (Tracks 1 and 2) |  |
| Domain: Evidence-Based Medicine | |
| The practice uses evidence-based treatment pathways; measures and reports on physician compliance with pathways; and requires documentation for off-pathway treatment. (Tracks 1 and 2) | |
| Patients are provided clinical research study information by the practice as appropriate for the patient’s clinical condition. (Tracks 1 and 2) | |
| Domain: Technology | |
| Practice is required to used certified EHR technology. (Tracks 1 and 2) |  |

The Care Delivery Requirements are based on work currently underway by ASCO and the Community Oncology Alliance, as well as ASCO’s Quality Oncology Practice Initiative standards. Further details on the standards may be found in Appendix D.

Chapter 4: Payment Methodology

4.1 Overview

The PCOP payment methodology involves three components to improve the management of cancer patients:

- Monthly Care Management Payments
- Performance Incentive Payments

- Adjustment to Fee-for-Service Reimbursement

Incentives to improve care management and quality are provided through Care Management Payments and Performance Incentive Payments. Accountability for providers is introduced through progressively greater adjustments to fee-for-service reimbursement, bundling a portion of traditional fees into monthly payments.

4.2 Monthly Care Management Payments

Care Management Payments (CMP) are intended to support providers in transformation of care delivery systems to increase quality and value of cancer care. Providers are expected to deliver enhanced care delivery not commonly found and reimbursed in the current fee-for-service model.



PCOP recognizes that the resources necessary to manage care differ throughout a patient's course of treatment and management. For this reason, PCOP involves three separate CMP amounts:

4.2.1 New Patient CMP

Providers will be responsible to bill payers for a New Patient CMP for each new oncology patient who begins treatment or active management with the practice. This would enable the practice to ensure the accuracy of diagnoses, identify appropriate treatment options and help patients choose the most appropriate treatments, and provide the education and support services that patients need when first diagnosed with cancer. This payment would also finance the initiation of ongoing support services patients need during treatment.

4.2.2 Cancer Treatment CMP

Providers will be responsible to bill payers for Cancer Treatment CMP for each month in which an oncology patient is receiving pharmaceutical or immunotherapy treatment prescribed by the practice, or for patients in hospice care for which the oncologist is the patient's hospice physician. This payment will enable the practice to deliver effective care management services for all patients and to deliver effective management of oral anti-cancer therapy. This payment would also be made for patients on clinical research trials and those in hospice where the provider is responsible for coordination of care. Excluded from Cancer Treatment CMP are patients who have completed their primary and adjuvant chemotherapy, and are currently receiving maintenance endocrine therapy – such patients qualify for the Active Monitoring CMP payment. See Appendix F for a full listing of drug ingredients qualifying for the Cancer Treatment CMP.

4.2.3 Active Monitoring CMP

Providers will be responsible to bill payers for Active Monitoring CMP for each month when an oncology patient is not receiving anti-cancer treatment, other than maintenance endocrine therapy, but remains actively managed by the oncology practice. This would include any months in which treatment was not received before a treatment regimen was completed and

up to twelve months after the completion of treatment. This CMP helps the provider to provide effective survivorship care and end-of-life care.

4.3 Performance Incentive Payment

A portion of the CMP fees will be allocated to a Performance Incentive Payment (PIP). Providers who are successful in quality metrics, adherence to clinical treatment pathways, and reduction in cost-of-care, as compared to national trends, will receive positively adjusted PIP amounts, whereas those who fail to achieve target rates will have their PIP amounts reduced. A community-based model will initially support the program through seed funding until initial cost-of-care reconciliation, after which a portion of savings will be allocated to determine an available pool of PIP amounts.



In the case that a provider fails to achieve minimum expectations for Care Management activities and adherence to Clinical Treatment Pathways, CMP and PIP amounts may be suspended until an improvement plan is developed and agreed upon with relevant stakeholders.

4.4 Value of Care Management and Performance Incentive Payments

The Oncology Steering Committee is responsible for establishing the value of care management and performance incentive payments, based on the following guidelines. When necessary, amounts may be adjusted for governmental vs. non-governmental payers.

Table 4.1
Value of Care Management and Performance Incentive Payments

| | Track 1 | Track 2 |
|--------------------------------|--------------------------------|--------------------------------|
| Care Management Payments | 2% of total cost-of-care | 3% of total cost-of-care |
| Performance Incentive Payments | Up to 2% of total cost-of-care | Up to 3% of total cost-of-care |

The value of Care Management Payments per stage of care shall be valued as:

- New Patient CMP: 2 times the value of the Cancer Treatment CMP
- Active Monitoring CMP: 1/3 times the value of the Cancer Treatment CMP

ASCO has utilized data from the state of Maine to model CMP and PIP amounts for Medicare beneficiaries, using the guidance above. Note that the amounts equal 2% or 3% of the patient’s total cost-of-care, in aggregate – costs included physician services, inpatient stays, diagnostics, provided drugs, and other claims received by Medicare.

**Table 4.2
Care Management and Performance Incentive Payments – Medicare Rates
(repeated as Table A.5)**

| | New Patient | Cancer Treatment | Active Monitoring |
|------------------------------------|------------------------|-----------------------------|------------------------------|
| Months of Care | 2,585 | 11,522 | 4,137 |
| Total Cost of Care | \$ 9,508 | \$ 13,443 | \$ 1,255 |
| Care Management – Track 1 | \$ 450 | \$ 225 | \$ 75 |
| Performance Incentive – Track 1 | up to 450 | up to 225 | up to 75 |
| Blended Percentage | | | up to 4.0% |
| Care Management – Track 2 | 675 | 337.50 | 112.50 |
| Performance Incentive – Track 2 | up to 675 | up to 337.50 | up to 112.50 |
| Blended Percentage | | | up to 6.0% |

4.5 Adjustment of Fee-for-Service Reimbursement

As few providers have the resources and actuarial systems to accept risk for the entirety of cancer treatment costs, the PCOP payment methodology is not intended to be used as full capitation. Therefore, existing fee-for-service reimbursements will continue for traditional services, along with provided drugs and other items.

Similar to the Comprehensive Primary Care Plus model, PCOP provides for Track 2 participants to adjust fee-for-service reimbursements and bundle a portion or all of such reimbursements through Consolidated Payments for Oncology Care – see Chapter 5.

Chapter 5: Consolidated Payments for Oncology Care

5.1 Overview

Practices in Track 1 continue to receive typical fee-for-service reimbursement in addition to the care management amounts. For communities with the desire and capability to disrupt current fee-for-service, practices in Track 2 shall participate in Consolidated Payments for Oncology Care (CPOC). Under this option, practices may elect to bundle either 50% or 100% of the value of specified services. 90% of bundled amounts will be guaranteed under Consolidated Payments for Oncology Care. 10% of bundled amounts will be subject to the same performance adjustment as monthly performance incentive



payments, times a 1.4 multiplier – the use of a 1.4 multiplier provides that a practices may earn between 90% and 104% of previous fee-for-service amounts, dependent upon their Aggregate Performance Score – see table 5.1.

5.2 Structure of Consolidated Payments for Oncology Care

5.2.1 Valuation of CPOC Amounts

Each payer and practice shall establish the value of CPOC amounts, considering their current contract amounts and escalation provisions. Application of site-neutrality or other changes to reimbursement are outside of the scope of CPOC and is a consideration of each organization’s contracting.

5.2.2 Stage of Care

Consolidated Payments for Oncology Care (CPOC) follows the same stages of care as the care management payments, to include:

- New Patient CPOC
- Cancer Treatment CPOC
- Active Monitoring CPOC

5.2.3 Disease of Care

In order to appropriately value each CPOC amount, the stages of care shall be further modified based on the primary disease treated. See Appendix G for further details on categorization of diseases for CPOC.

5.2.4 Services Subject to Consolidation

The scope of CPOC may vary in each community, based on the scope of services directly provided by model participants. At minimum, CPOC shall include:

- Evaluation and management services by oncology providers.
- Parenteral drug and biologic agent administration services.
- Care management services by oncology providers – e.g. advance care planning, smoking cessation, transitional care management.
- Drug and biologics reimbursement above the purchase cost of such agents – e.g. for Medicare Part B drugs, the +6% amount would be included consolidated payments, with the remaining average sales price reimbursed through fee-for-service billing.

CPOC may also include, or be addressed by other alternative payment models, the following services:

- Radiation planning, management and treatment delivery.
- Surgical services.
- Routine laboratory, imaging and other diagnostic services.

An example of consolidation is included in Appendix H.

5.2.5 Annual Updates to CPOC Amounts

Initial CPOC amounts will be established using valuation of historical fee-for-service services under scope. For payer-provider relationships with established contractual provisions addressing fee escalation, such provisions may be applied to update CPOC amounts, year-to-year. For other relationships, including government payers, PCOP recommends application of the Medical Care Index, as published by the Bureau of Labor Statistics.

5.3 Practice Risk under Consolidated Payment for Oncology Care

Practices in Track 2 subject themselves to risk through the consolidation of payment under CPOC. From the monthly amounts paid under CPOC, the practice is responsible for delivering, or contracting for the delivery of, services included in the scope of the CPOC payments.

90% of the value of CPOC is guaranteed for practices in Track 2. The remaining 10% is subject to adjustment based on the Performance Methodology. This places practice revenue at risk for practices performing poorly under the Performance Methodology. As shown in table 5.1, practices with poor performance will be subject to as much as a 10% reduction in reimbursement for services within scope of the CPOC.

5.4 Practice Incentives under Consolidated Payment for Oncology Care

When calculating the 10% of CPOC payments, they shall be multiplied by a factor of 1.4, allowing for a practice to earn additional revenue through delivery of high quality, low cost care. As shown in table 5.1, practices with good performance may earn up to a 4% increase in reimbursement for services within the scope of the CPOC.

Table 5.1
Examples of Practice Reimbursement



| | Practice A | Practice B | Practice C |
|-----------------------------|----------------|--------------------|-----------------|
| Pathway Compliance | Low Compliance | Average Compliance | High Compliance |
| Quality-of-Care | Low Quality | Average Quality | High Quality |
| Cost-of-Care | High Cost | Average Cost | Low Cost |
| Aggregate Performance Score | 0 pts | 50 pts | 100 pts |
| CPOC Amount | 90% | 97% | 104% |

Chapter 6: Performance Methodology

In return for the receiving CMP and PIP amounts under PCOP, the oncology practice would take accountability for providing high-value, evidence-based care under three performance categories:

- Adherence to clinical treatment pathways and other evidence-based guidelines for the appropriate use of drugs, and use lower-cost drugs, where evidence shows they are equivalent.
- Providing care consistent with standards of quality defined by the oncology community, including evidence-based guidelines for high-quality care near the end of a patient’s life.
- Accountability for cost-of-care metrics, including acute care hospital admissions, emergency and observation care visits, and supportive care drug costs.



6.1 Calculation of Adherence to Clinical Treatment Pathways

An aggregate pathway adherence rate will be calculated for each practice, weighted by disease, and reported to the Oncology Steering Committee on a quarterly basis. Adherence rates will be equal to the number of patients during the quarter who initiate a new or different course of treatment that is pathway-concordant divided by the total number of eligible patients with a new or difference course of treatment, as defined in 6.1.1. Patients who are treated off-pathway must have justification for the decision documented in the pathway decision-support system and/or medical record. Patients enrolled in clinical research trials involving investigational treatments will be deemed “on-pathway” automatically. During reconciliation, claims data may be cross-referenced to ensure concordance with documented treatment decisions.

In order to receive the greatest value from use of a clinical treatment pathway, it is imperative that patients receive guideline-recommended molecular testing and other diagnostic work-up. ASCO will work with pathway providers to develop and implement an additional measure for diagnostic completeness for de novo cases.

6.1.1 Step 1: Calculation of Clinical Treatment Pathways Adherence

$$\text{Pathways Adherence} = \frac{\text{Treatment Decisions Determined to be On-Pathway (incl. trials)}}{\text{Number of Treatment Decisions (by line of therapy)}}$$

6.1.2 Step 2: Adjustment of Overall Adherence by Disease

Current pathway programs have shown differing adherence rates by disease, which may impact a provider’s gross adherence rate. Overall adherence shall be adjusted by weighting a provider’s individual disease adherence against the overall proportion of treatments by disease within the pathway program’s aggregate.

Table 6.1
Example Adjustment of Overall Pathways Adherence by Disease

| | Practice A Adherence Rates | Practice B Adherence Rates | Aggregate Proportion of Treatment Decisions |
|------------------------|-------------------------------|-------------------------------|--|
| Breast Cancer | 90% | 80% | 65% |
| Colorectal Cancer | 75% | 82% | 10% |
| Lymphoma | 72% | 76% | 5% |
| Prostate Cancer | 92% | 85% | 15% |
| Uterine Cancer | 74% | 72% | 5% |
| Overall Adherence Rate | 87.1% | 80.4% | |

6.1.3 Step 3: Calculation of Clinical Treatment Pathways Category Performance

Providers shall receive the following score within the clinical treatment pathways category, based on their adherence, expressed as a percentile of adherence rates of providers participating in the same pathways program, or as targets established by the Oncology Steering Committee:

- Pathway adherence rate at or above the 75th percentile: 100%
- Pathway adherence rate between the 50th and 74th percentile: 75%
- Pathway adherence rate between 25th and 49th percentile: 50%
- Pathway adherence rate below the 25th percentile: 25%
- Failure to adopt and document use of approved clinical treatment pathways: 0%

6.2 Calculation of Quality Performance

Quality standards and appropriate use guidelines protect patients from both over- and underutilization. Participating providers agree to provide care consistent with accepted standards of quality and to collect and report on an Oncology Steering Committee-selected subset of six quality measures from ASCO’s Quality Oncology Practice Initiative (QOPI) – see Appendix B.



6.2.1 Step 1: Calculation of Quality Metric Adherence

Quality Metric Adherence will be based on criteria of numerators, denominators, exclusions and exceptions, as defined by measure stewards.

$$Quality\ Metric\ Adherence = \frac{(Numerator - Numerator\ Exclusions)}{(Denominator - Denominator\ Exclusions - Denominator)}$$

6.2.2 Step 2: Calculation of Quality Metric Performance

Providers will be expected to meet or exceed performance benchmarks calculated by ASCO or other measure steward. Providers that achieve metric adherence rates based on quartiles will receive the following score for each metric:

- Metric adherence rate above 75th percentile: 100%
- Metric adherence rate between 25th and 75th percentile: 25% - 100%
- Metric adherence rate below 25th percentile: 0%.

Following the methodology established within the Comprehensive Primary Care Plus model, providers or practice groups performing between the minimum and maximum thresholds will receive scores along a continuous distribution normalized to values between 0% and 100%

$$\text{Quality Metric Performance} = \frac{(\text{Metric Adherence} - 25\text{th percentile})}{(75\text{th percentile} - 25\text{th percentile})} * 0.75 + 0.25$$

It is possible that providers participating in the model improve performance to a level where all are performing at a high rate. In such a case, a PCOP community may adopt an alternative scoring method which aims to reward the high performance of all participants.

6.2.3 Step 3: Calculation of Quality Category Performance

Calculation of the overall Quality Care Performance will be calculated using an average of individual metric performance.

$$\text{Quality Category Performance} = \frac{(\text{Metric 1} + \text{Metric 2} + \text{Metric 3} + \dots + \text{Metric n})}{\text{Number of Applicable Metrics}}$$

6.3 Calculation of Cost-of-Care Performance

Performance in total cost-of-care is measured through three metrics:

- Unplanned hospital admissions per treatment month
- Emergency and observation care visits per treatment month
- Supportive and maintenance care drug costs per treatment month



6.3.1 Unplanned Hospital Admissions

Providers will be responsible to use resources from CMP amounts to provide services designed to help its patients avoid complications of treatment such as nausea, dehydration, and infections where possible and to obtain treatment for complications when they occur without having to be admitted to the hospital. For example, the provider might provide education to its patients about how to avoid complications, prescribe appropriate medications to avoid or control complications, and respond quickly when patients experience complications.

6.3.2 Emergency and Observation Care Visits

Efforts to reduce unplanned hospital admissions should also impact emergency and observation care visits not leading to hospital admissions. The mechanisms for the Unplanned Hospital Admissions measure apply equally to this metric.

6.3.3 Supportive and Maintenance Care Drug Costs

Drug expenditures represent the greatest proportion of expenses in cancer care. PCOP addresses the cost of most primary drug treatments – antineoplastic and immunosuppressive drugs – through the required use of clinical treatment pathways. Additional savings may be achieved through prudent selection of supportive and maintenance care drug costs.

This measure includes drug expenditures for the episode period, for the following classes of treatment: antianemics (e.g. iron, folic acid); antiemetics and antinauseants (e.g. ondansetron); gonadotropin releasing hormone analogues (e.g. leuprolide); hormone antagonists (e.g. letrozole); hypothalamic hormones (e.g. somatostatin); immunostimulants (e.g. filgrastim); detoxifying agents for antineoplastic treatment (e.g. leucovorin); and drugs for treatment of bone diseases (e.g. denosumab). See Appendix I for a full listing of drug ingredients for inclusion, subject to additions. Note that ASCO is planning further development of this measure, which may adjust the list of included drugs.

Note: analgesics were also considered for this measure. However, our analysis showed that they represented less than 1% of drug expenditures, while adding over 8,000 national drug codes for tracking.

6.3.4 Step 1: Identification of Treatment Months

Each cost-of-care measure has a denominator equal to the sum of the number of months each patient receives treatment. Treatment months shall be identified through the billing of a Cancer Treatment CMP or the billing of an antineoplastic or immunosuppressive agent.

6.3.5 Step 2: Attribution of Treatment Months to Providers and Practice Groups

To hold providers accountable for cost-of-care metrics, each episode is assigned to a provider or practice group based on the billing provider for the Cancer Treatment CMP or the billing of an antineoplastic, endocrine therapy, or select immunosuppressive agent. If more than one provider bills one of the previously listed services, all shall be attributed the treatment month and associated measures.

6.3.6 Step 3: Calculation of the Unplanned Hospital Admissions Rate

Numerator: Number of admissions to a short-term acute care hospital during the performance period, excluding planned admissions for surgery, bone marrow or stem cell transplant, or inpatient chemotherapy administration, during the performance period, concurrent with an identified treatment month.

Denominator: Number of treatment months calculated in Step 1.

$$\text{Unplanned Hospital Admissions Rate} = \frac{\text{Number of unplanned admissions}}{\text{Number of treatment months}}$$

6.3.7 Step 4: Calculation of the Emergency and Observation Care Rate

Numerator: Number of emergency and observation care visits, not leading to a hospital admission, during the performance period, concurrent with an identified treatment month.

Denominator: Number of treatment months calculated in Step 1.

$$\text{Emergency and Observation Care Rate} = \frac{\text{Number of emergency or observation visits}}{\text{Number of treatment months}}$$

6.3.8 Step 5: Calculation of the Supportive Care Drug Cost Rate

Numerator: Total expenditures for the following drug categories during the performance period, concurrent with an identified treatment month: antianemics; antiemetics and antinauseants; hypothalamic hormones; immunostimulants; detoxifying agents for antineoplastic treatment; and drugs for treatment of bone diseases.

Denominator: Number of treatment months calculated in Step 1.

$$\text{Supportive Care Drug Cost Rate} = \frac{\text{Total expenditures for included drugs}}{\text{Number of treatment months}}$$

6.3.9 Step 6: Calculation of Metrics for a Comparator Population

In order to translate each metric into performance scores, the unplanned hospital admissions, emergency and observation visits, and supportive care drug cost shall be calculated for a comparator population – that is, for patients whose providers are not participating in PCOP.

6.3.10 Step 7: Adjustment for Differences in Case Mix

As utilization and cost-of-care is dependent on patient disease and other contributing demographic and clinical factors, difference in case mix between practice groups can impact overall performance, absent appropriate adjustment. PCOP cost-of-care metrics shall be adjusted by including the following factors (**required**):

- **Cancer type**
- **Presence of a secondary malignancy**
- **Bone marrow or stem cell transplant**
- **Clinical trial participation**
- Stage of care – primary treatment, adjuvant treatment, monitoring
- Age and sex of patient
- Non-cancer comorbidities
- Castrate-sensitive vs resistant prostate cancer
- Low- vs high-risk bladder cancer

- Addition of further clinical factors when data is made available from electronic health records and/or clinical treatment pathway systems, including disease stage, genomic markers, line of therapy, and therapy intent.
- **Adjustments for missing cost data – e.g. prescription drug data**

Based on learnings from the Medicare Oncology Care Model, PCOP calls for separate model coefficients for each cancer type, allowing for a more accurate risk adjustment model.

6.3.11 Step 8: Calculation of Metric Performance

The rate for each provider shall be divided by the comparator rate, with the resulting ratio assigned a performance score based on the following thresholds:

- Ratio less than or equal to 0.85 (ie, 10% less than comparator): 100%
- Ratio greater than 0.85, and less than or equal to 0.95: 75%
- Ratio greater than 0.95, and less than 1.05: 50%
- Ratio greater than or equal to 1.05, and less than 1.15: 25%
- Ratio greater than or equal to 1.15 (ie, 15% greater than comparator): 0%

6.3.12 Step 9: Calculation of Cost-of-Care Category Performance

Calculation of the overall Cost-of-Care Category Performance will be determined by weights established by the Oncology Steering Committee.

$$\text{Cost-of-Care Category Performance} = \frac{(\text{Admissions Performance} * 1/3) + (\text{Emergency/Obs Performance} * 1/3) + (\text{Supportive Care Drug Cost Performance} * 1/3)}{3}$$

6.4 Calculation of Aggregate Performance Score

The Oncology Steering Committee will be responsible for weighting performance categories for calculation of an aggregate performance score.

$$\text{Aggregate Performance Score} = \frac{(\text{Clinical Treatment Pathways Score} * 1/3) + (\text{Quality Category Score} * 1/3) + (\text{Cost-of-Care Category Score} * 1/3)}{3}$$

It should be noted that Clinical Treatment Pathway adherence impacts both quality and cost-of-care and is a central component of the PCOP model.

6.5 Practice Group Performance

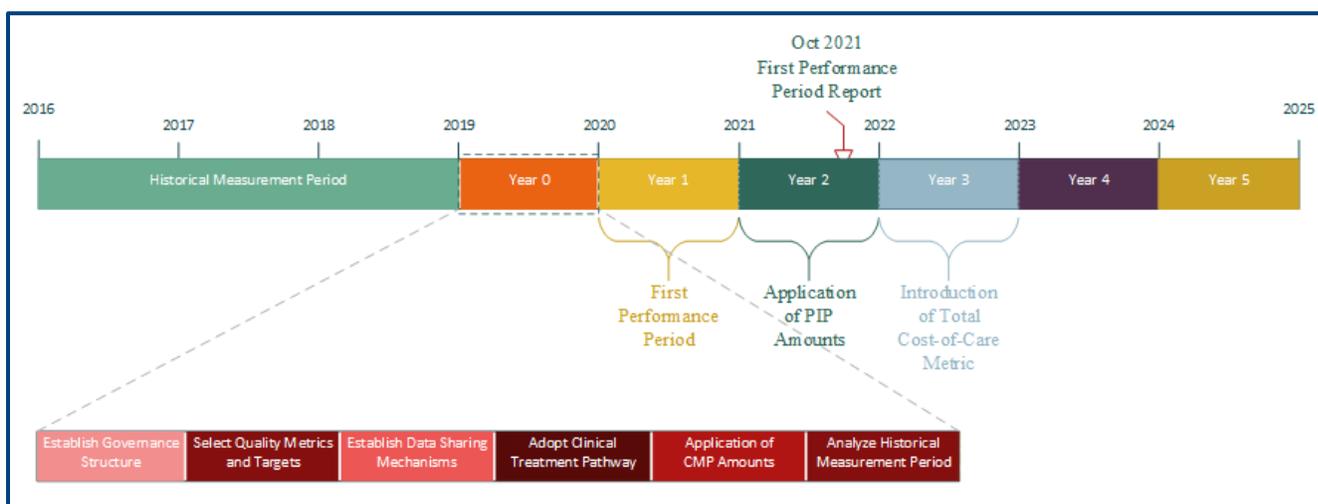
In order to establish appropriately aligned performance groups, providers will be assigned to practice groups – defined as one or more Tax Identification Numbers (TIN) – for purposes of patient and episode attribution, performance measurement, and calculation of PIP amounts. In cases where a provider is aligned with multiple performance groups, they will be presented in both groups, dependent on the TIN included on billed claims.

Chapter 7: Implementation Model

7.1 Timeline for PCOP Implementation

PCOP is proposed as a five-year model. As stakeholders are asked to make significant investments in infrastructure for clinical care delivery and model administration, it is important that PCOP participants start early to select quality metrics, adopt clinical treatment pathways, and establish mechanisms for the sharing of data and determination of performance. Figure 7.1 shows a potential timeline for the rollout of a PCOP model.

Figure 7.1
Example Implementation Timeline



7.2 Year 0 Activities

Year 0 involves building the infrastructure necessary for successful implementation of the model. Activities included in Year 0 include:

- Forming Oncology Steering Committee and other governance structures.
- Selecting quality metrics to measure in Year 1 and determining targets.
- Establishing data sharing mechanisms for clinical, quality metric, and cost data.
- Selecting and adopting a compendium of clinical treatment pathways.
- Application of New Patient, Cancer Treatment, and Active Monitoring CMP amounts.
- Analyzing claims data from historical measurement period and validating the prediction model.

7.3 Performance Measurement Periods

Each year represents a performance measurement period, by which clinical treatment pathway, quality metrics, and cost-of-care metrics will be collected. Except for the Total Cost-of-Care

metric, rapid collection and measurement of performance is necessary for establishing and adjusting PIP amounts the following year.

7.4 Reconciliation Process for Cost Measures

The admissions, emergency room and observation stays, and supportive care drug cost measures require a more extensive collection and measurement process. Following the conclusion of the performance period, a three-month claims runout period is recommended, to ensure that all claims have been received. Delays in data delivery to an accessible data warehouse may add another two months prior to analysis. A reasonable target for reconciliation and publishing of results is June of the following year.

7.5 Application of Performance Incentive Payments

Aggregate Performance Scores are established using data from the most recent concluded performance period for all metrics. As new performance data is available, PIP amounts will be adjusted based on the Aggregate Performance Score.

7.6 Implementation Partners

A community-based model requires several partners to facilitate successful implementation. Partners shall be selected by the Oncology Steering Committee and be funded through the model.

7.6.1 Project Manager

The Oncology Steering Committee requires project management support to coordinate efforts of model participants and implementation partners, to drive to completion of model milestones. Established regional healthcare improvement organizations are well-suited to act in this role.

7.6.2 Model Advisor

ASCO's Clinical Affairs Department is available to advise the Oncology Steering Committee on selection and implementation of clinical treatment pathways, quality metrics, establishment of targets, and analysis of performance data.

7.6.3 Data Custodian

PCOP involves health record data from participating providers, data extracted from clinical treatment pathway systems, and claims data from participating payers. To aggregate and synthesize data sources, participants shall provide their data sources to one or more data custodians, who shall be responsible for data management and distribution. A regional health information exchange or data custodian for other health projects may have the resources and skill to facilitate this activity.

7.6.4 Quality Registry

Qualified Clinical Data Registries are a data custodian for the collection, analysis, comparison against benchmarks, and distribution of quality metric performance. ASCO operates the QOPI Reporting Registry with medical and radiation oncology quality measures.

7.6.5 Clinical Treatment Pathway

Adherence to Clinical Treatment Pathways is one of three performance categories. The Oncology Steering Committee shall be responsible for evaluating and approving pathways for use in the PCOP model, based on the ASCO criteria – see Appendix C.

7.6.6 External Validation of Performance

While program participants and partners are responsible for determining performance of practice groups within the model, it is recommended that the Oncology Steering Committee identify a partner to validate community performance against a comparator community, to determine success of the model implementation. This activity is key if future years of funding will be based on overall savings achieved. The Hutchinson Institute for Cancer Outcomes Research is one such available partner.

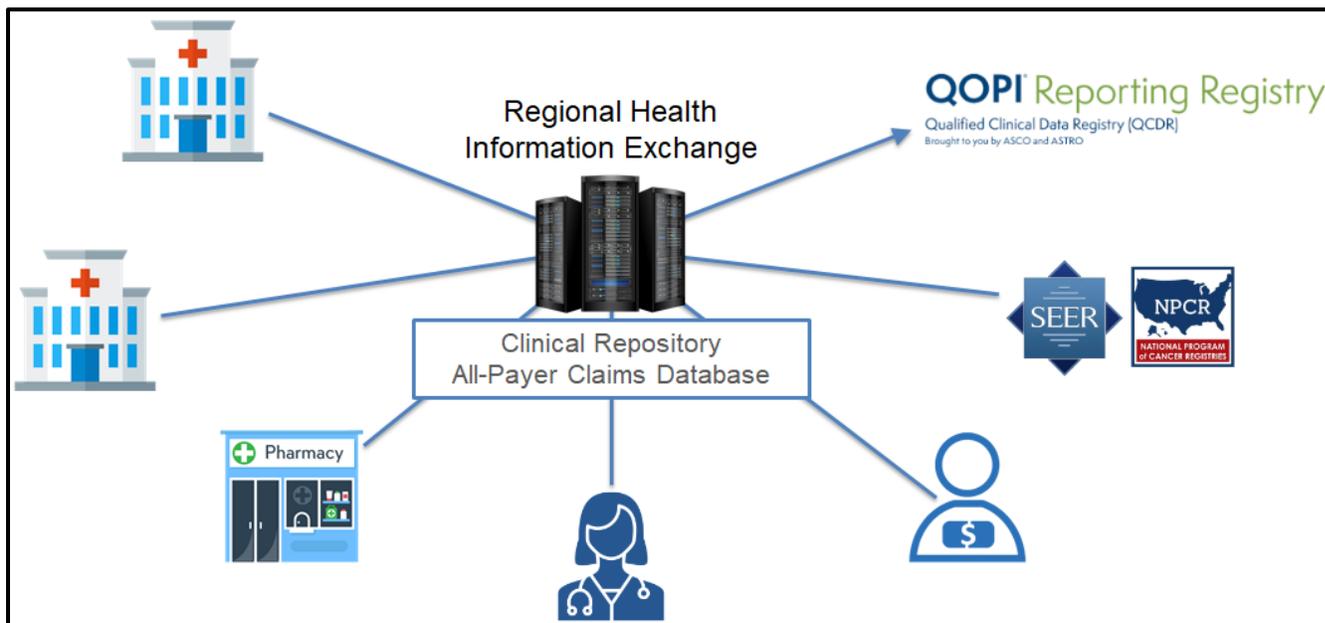


7.7 Performance Data Governance and Transparency

Performance Transparency is a key component of the model, and requires specific rules for data contribution requirements, selection of data custodians, a process for distributing appropriate data to model participants. Data management activities include:

- Participating providers will agree to participate in regional health information exchange efforts, which may involve sending of electronic health record data to a data custodian and/or making available any application programming interface for extraction of data.
- Participating payers will agree to contribute claims data for covered patients, to create an all-payer oncology database.
- The selected Clinical Treatment Pathway partner will agree to contribute patient-level treatment decision inputs and pathway adherence determinations.
- Other data contributors, such as tumor registries, may be identified and asked to contribute.
- Data contributors will agree that participating providers and payers will be given access to all available data for their patient populations.
- Model participants agree that aggregated performance data will be shared publicly after reconciliation, including identification of providers, practice groups, and all three performance categories.

Figure 7.2
Data Repository Model



7.8 Funding Considerations

In years 0 through 2 of the model, initial CMP and PIP amounts, as well as implementation of the model, will initial require seed funding from participating payers, grants, donations, and other sources.

In years 3 and beyond, model funding will come from an agreed upon percentage of savings achieved in the model from. This may result in an increase or decrease in funds available for performance incentive payments to model participants.

Supplementary Information

Appendix A: Analysis of Cost-of-Care Savings under PCOP

In order to fully inform the development of the refreshed PCOP model, ASCO analyzed records of 2,865 patients treated in the state of Maine between October 2015 and December 2017, as provided by the Maine Health Data Organization. Analyzed data included patients covered by Medicare Parts A, B, and D; Medicare Part C; Medicaid; and commercially offered insurance (including employer self-insurance).

Cost-of-care was divided into three phases:

- New Patient – the month in which the patient first received an evaluation and management service from a medical oncology provider.
- Cancer Treatment – subsequent months in which the patient received one or more identified anti-cancer drug treatments.
- Active Monitoring – subsequent months where the patient received one or more evaluation and management services, from a medical oncology provider, within a 3-month period.

In total, the analysis included study of 16,048 months of care. 47% of traditional Medicare months, and 97% of all other payer months, included oral drug coverage. All figures have been adjusted to simulate oral drug coverage for 100% of patients.

As detailed in Table A.1, evaluation and management, diagnostic imaging, laboratory and pathology, inpatient services, post-acute care, and other services are highest in the new patient phase of care. During the cancer treatment phase, drug and drug administration costs represent 70% of the total cost-of-care for patients covered by traditional Medicare.

Table A.2 includes a breakdown of drug costs. During the cancer treatment phase of care, identified anti-cancer agents equaled 71% of drug costs, selective supportive care drugs totaled 17%, and the administration of drugs totaled 9% for patients covered by traditional Medicare.

Inpatient services were higher during the new patient phase – it was found that the first evaluation and management service for medical oncology often coincided in the same month as anti-cancer surgical services. As shown in Table A.3, the rate of admissions per 100 months was 16.7 during the new patient phase, dropping to 9.0 during the cancer treatment phase. During active monitoring, a time at which the patient is no longer receiving anti-cancer drugs, the rate of admissions per 100 months rose to 10.0 – the increased rate during active monitoring may show a breakdown in coordination of care while the patient is no longer receiving intravenous drug therapy in the outpatient clinic.

Table A.4 compares costs for patients within the cancer treatment phase by the source of payment. Medicare Part C patients had \$2,020 greater costs per month than traditional Medicare patients, driven solely by higher drug costs. Commercially insured patients, including employer self-insurance products, had costs 68% greater than the average of patients covered by the government-sponsored plans.

Table A.1
Analysis of Average Costs for Medicare Parts A, B, and D

| | New Patient | Cancer Treatment | Active Monitoring |
|-----------------------------|------------------------|-----------------------------|------------------------------|
| Months of Care | 1,560 | 6,616 | 7,872 |
| Evaluation & Management | \$ 644 | \$ 423 | \$ 222 |
| Diagnostic Imaging | 616 | 216 | 206 |
| Lab & Pathology | 259 | 129 | 66 |
| Drugs & Drug Administration | 2,000 | 9,705 | 415 |
| Therapeutic Radiation | 1,232 | 797 | 287 |
| Emergency & Observation | 187 | 205 | 149 |
| Inpatient Services | 2,292 | 1,113 | 1,604 |
| Post-Acute Care | 450 | 208 | 368 |
| Hospice Care | 3 | 43 | 300 |
| Other | 1,826 | 604 | 520 |
| Total | 9,508 | 13,443 | 4,137 |

(Data from Table A.1-A.6 comes from analysis of 2,865 patients treated in the state of Maine between October 2015 and December 2017, as provided by the Maine Health Data Organization. Categories, payer types, and phases of care were assigned by ASCO.)

Table A.2
Breakdown of Drug Costs for Medicare Parts A, B, and D

| | New Patient | Cancer Treatment | Active Monitoring |
|-----------------------------------|------------------------|-----------------------------|------------------------------|
| Drug Administration | \$ 85 | \$ 771 | \$ 30 |
| Part B Drugs – Anti-cancer | 226 | 5,816 | - |
| Part B Drugs – Supportive Care | 231 | 1,542 | 82 |
| Part B Drugs – Other | 106 | 82 | 40 |
| Part D Drugs – Anti-cancer | 848 | 1,189 | - |
| Part D Drugs – Supportive Care | 265 | 26 | 17 |
| Part D Drugs – Other | 239 | 278 | 246 |
| Subtotal | 2,000 | 9,705 | 415 |

Table A.3
Inpatient Admissions During Phases of Care, All Payers

| | New Patient | Cancer Treatment | Active Monitoring |
|--|------------------------|-----------------------------|------------------------------|
| Months of Care | 2,585 | 11,522 | 12,606 |
| Inpatient Admissions | 432 | 1,034 | 1,255 |
| Rate of Admissions (per 100 months) | 16.7 | 9.0 | 10.0 |

Table A.4
Comparison of Cancer Treatment Months by Primary Payer

| | Medicare A, B, and D | Medicare Part C | Medicaid | Commercial |
|-----------------------------|---------------------------------|----------------------------|-----------------|-------------------|
| Months of Care | 6,616 | 1,178 | 858 | 2,870 |
| Evaluation & Management | \$ 423 | \$ 392 | \$ 348 | \$ 512 |
| Diagnostic Imaging | 216 | 179 | 180 | 642 |
| Lab & Pathology | 129 | 128 | 93 | 430 |
| Drugs & Drug Administration | 9,705 | 12,599 | 10,543 | 15,232 |
| Therapeutic Radiation | 797 | 588 | 748 | 1,896 |
| Emergency & Observation | 205 | 112 | 190 | 207 |
| Inpatient Services | 1,113 | 979 | 1,114 | 2,150 |
| Post-Acute Care | 208 | 237 | 233 | 68 |
| Hospice Care | 43 | 0 | 19 | 16 |
| Other | 604 | 506 | 759 | 1,021 |
| Total | 13,443 | 15,720 | 14,225 | 22,173 |

In estimating the savings potential associated with application of the PCOP model, ASCO reviewed studies on savings associated with adoption of clinical treatment pathways, triage and supportive care pathways, and principles of patient-centered medical home.

Studies have shown that the application of value-based clinical pathways, such as those adhering to ASCO's criteria (see Appendix C), result in lower anti-cancer and supportive care 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.^{1,2} Use of on-pathway regimens also result in lower supportive care drug, diagnostic, and hospitalization costs.^{2,3} Initiatives involving implementation of clinical treatment pathways have resulted in increased compliance with on-pathway selection and drug savings ranging from 5-37%.^{4,5,6,7}

Multiple studies have shown the potential for the care management strategies of Oncology Medical Home to reduce hospital admissions and emergency room visits.^{8,9,10} In one such study, hospital admissions per chemotherapy patient, per year started at a rate of 1.08 – this rate is identical to the rate of admissions as shown in Table A.3 for cancer treatment months (9.0/100*12=1.08). At the end of the study, the rate of hospital admissions had decreased 51%.⁸

In order to model the impact of PCOP on total cost-of-care, ASCO first calculated the value of proposed care management and performance incentive payments. As laid out in Section 4.4, the value of such payments shall total 2-4% for practices in Track 1 and 3-6% for practices in Track 2. Table A.5 calculates the value of such payments at Medicare rates.

Table A.6 illustrates the various changes in total cost-of-care through implementation of the PCOP model. ASCO assumes a reduction in drug costs by 15% for new patient and cancer treatment phases of care; followed by 5% reduction during active monitoring. Emergency, acute, and post-acute costs are assumed 10% lower during the new patient phase of care, followed by 25% during cancer treatment and active monitoring. An increase in hospice expenses is assumed during active monitoring, due to increased advance care planning and palliative care services. In total, a 12.1% savings is calculated, prior to the addition of up to 4% in care management and performance incentive payments.

¹ Hoverman JR, Cartwright TH, Patt DA, et al: Pathways, outcomes, and costs in colon cancer: retrospective evaluations in two distinct databases. *J Oncol Pract*, 7, 52s-59s. 2011.

² Neubauer MA, Hoverman JR, Kolodziej M, et al: Cost effectiveness of evidence-based treatment guidelines for the treatment of non-small-cell lung cancer in the community setting. *J Oncol Pract*, 6(1), 12-18. 2010.

³ Gautam S, Sylwestrzak G, Barron J, et al: Results from a health insurer's clinical pathway program in breast cancer. *J Oncol Pract*, e711-e721. 2018

⁴ Shah S, Reh G: Value-based payment models in oncology: will they help or hinder patient access to new treatments? *Am J Manag Care*, 23(5 Spec No.), SP188-SP190. 2017.

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⁶ Jackman DM, Zhang Y, Dalby C, et al: Cost and survival analysis before and after implementation of Dana-Farber clinical pathways for patients with stage IV non-small-cell lung cancer. *J Oncol Pract*, 13(4), e346-e352. 2017.

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⁹ Mendenhall MA, Dyehouse K, Hays J, et al: Practice transformation: early impact of the Oncology Care Model on hospital admissions. *J Oncol Pract*, 14(12), e739-e745. 2018.

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Table A.5
Care Management and Performance Incentive Payments – Medicare Rates

| | New Patient | Cancer Treatment | Active Monitoring |
|------------------------------------|------------------------|-----------------------------|------------------------------|
| Months of Care | 2,585 | 11,522 | 4,137 |
| Total Cost of Care | \$ 9,508 | \$ 13,443 | \$ 1,255 |
| Care Management – Track 1 | \$ 450 | \$ 225 | \$ 75 |
| Performance Incentive – Track 1 | up to 450 | up to 225 | up to 75 |
| Blended Percentage | | | up to 4.0% |
| Care Management – Track 2 | 675 | 337.50 | 112.50 |
| Performance Incentive – Track 2 | up to 675 | up to 337.50 | up to 112.50 |
| Blended Percentage | | | up to 6.0% |

Table A.6
Model of PCOP's Impact on Total Cost-of-Care – Track 1

| | Baseline Costs | Assumed Change | Modeled Costs |
|-------------------------------|---------------------------|---------------------------|--------------------------|
| New Patient | | | |
| Evaluation & Management | \$ 644 | | \$ 423 |
| Care Mgmt. & Perf. Incentive | | + \$900 | 900 |
| Diagnostics | 875 | | 875 |
| Drugs & Drug Administration | 2,000 | -15% | 1,700 |
| Emergency, Acute & Post-Acute | 2,928 | -10% | 2,635 |
| Other | 3,061 | | 3,061 |
| Total | 9,508 | | 9,815 |
| Cancer Treatment | | | |
| Evaluation & Management | \$ 423 | | \$ 423 |
| Care Mgmt. & Perf. Incentive | | + \$450 | 450 |
| Diagnostics | 345 | | 345 |
| Drugs & Drug Administration | 9,705 | -15% | 8,249 |
| Emergency, Acute & Post-Acute | 1,526 | -25% | 1,220 |
| Other | 1,444 | | 1,444 |
| Total | 13,443 | | 12,056 |
| Active Monitoring | | | |
| Evaluation & Management | \$ 423 | | \$ 222 |
| Care Mgmt. & Perf. Incentive | | + \$150 | 150 |
| Diagnostics | 272 | | 272 |
| Drugs & Drug Administration | 415 | -5% | 394 |
| Emergency, Acute & Post-Acute | 2,121 | -25% | 1,591 |
| Hospice | 300 | +40% | 420 |
| Other | 808 | | 808 |
| Total | 4,137 | | 3,857 |

Table A.6
(continued)

| | Baseline Costs | Assumed Change | Modeled Costs |
|--|---------------------------|---------------------------|--------------------------|
| Blended Cost per Month | 8,496 | | 7,816 |
| Savings prior to Care Management & Incentives | | | 12.1% |
| Net Savings | | | 8.0% |

Appendix B: Available Quality Metrics

| QOPI Measure | Description | NQF Endorsed Measure |
|--------------|--|----------------------|
| QOPI 5 | Chemotherapy administered to patients with metastatic solid tumor with performance status of 3, 4, or undocumented (Lower Score - Better) | |
| QOPI 15 | GCSF administered to patients who received chemotherapy for metastatic cancer (Lower Score - Better) | |
| QPP 47 | Care Plan | NQF #0326 |
| QPP 134 | Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan | NQF #00418 |
| QPP 317 | Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented | |
| QPP 450 | Trastuzumab Received By Patients With AJCC Stage I (T1c) - III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy | NQF #1858 |
| QPP 451 | KRAS Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy | NQF #1859 |
| QPP 452 | Patients with Metastatic Colorectal Cancer and KRAS Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies | NQF #1860 |
| QPP 453 | Proportion Receiving Chemotherapy in the Last 14 Days of Life (Lower score - Better) | NQF #0210 |
| QPP 456 | Proportion Not Admitted To Hospice | NQF #0215 |
| QPP 457 | Proportion Admitted to Hospice for less than 3 days (Lower score - Better) | NQF #0216 |
| QPP 462 | Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Therapy | |

Appendix C: ASCO Criteria for High-Quality Clinical Pathways

In 2017, the ASCO released its Criteria for High-Quality Clinical Pathways in Oncology. Subsequently, the programs of four pathway vendors were evaluated against these criteria. It is expected that a vendor sufficiently meets the criteria in order to be selected for participation within PCOP.

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 (ie, rapid learning health care systems)?

- Patient focused
 - Do the pathways include evidence-based options to account for differences in patient characteristics and/or preferences (ie, 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 (ie, 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 (ie, 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 D: PCOP Care Delivery Requirements

Patient Engagement – Patients are provided education on the practice and PCOP model. (Tracks 1 and 2)

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 care model.

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

- Definition, goals, and importance of an oncology medical home.
- 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 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.
- Identify members of the patient’s primary care team and provide contact information.
- Process for reinforcement of this education throughout the patient care journey.
- Explanation of care management fees and other alternative payment components.

Patient Engagement – Patient financial counseling services are available and routinely provided in the practice. (Tracks 1 and 2)

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.

Patient Engagement – All patients are provided with education on their cancer diagnosis and an individualized treatment plan. (Tracks 1 and 2)

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 must be documented in the patients’ EHR. The practice develops and annually reviews policies and procedures on new patient education.

The patient and caregiver(s) are educated and provided with a care plan prior to receiving cancer 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 including 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
- The missed appointment policy of the health care setting and expectations for rescheduling or cancelling

The Institute of Medicine (IOM) 13-point care plan as outlined in the 2013 IOM report “Delivering High Quality Cancer Care: Charting a New Course for a System in Crisis” should be considered when developing the individualized care plan.

Patient Engagement – Practice convenes a patient and family advisory council, to meet at least twice per year, and integrate recommendations into care, as appropriate. (Track 2)

Practice shall convene an advisory council of patients and advocates (e.g. family members). The practice shall report to the advisory council the practice’s progress towards implementing the care delivery requirements and performance under this model.

The practice shall consider the advisory council’s recommendations to inform quality improvement activities, expanded access, and new services to be offered.

Patient Engagement – The practice develops and implements a process to disseminate a treatment summary/survivorship care plan to patients within 90 days of the completion of treatment. (Track 2)

The 2005 Institute of Medicine report, From Cancer Patient to Cancer Survivor, 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.

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.

Practices must develop and implement a process to monitor the dissemination of a SCP as a part of the standard care for all cancer patients who are treated with curative intent for initial

cancer occurrence and who have completed active therapy (other than long-term hormonal therapy). If two different practices or facilities are providing treatment, both practices should work together to collaborate in providing a completed SCP. The practice providing follow-up and monitoring of the patient (i.e. medical oncology) should provide the SCP. In all cases, facilities and practices should work together to provide the information necessary for completion of a SCP that contains all required information

The American Society of Clinical Oncology (ASCO) has defined the minimal data elements to be included in a treatment summary and survivorship care plan (Mayer DK, et al. American Society of Clinical Oncology Clinical Expert Statement on Cancer Survivorship Care Planning. Journal of Oncology Practice, 2014). This core set of data elements and templates are available on the ASCO website and in the References section of this manual. 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).

Availability and Access to Care – Practice offers patients 24/7 access to an appropriate clinician, with real-time access to health records. (Tracks 1 and 2)

The practice is required to provide patients with a means to contact an appropriate clinician – options include a physician, advanced practice provider, or nurse – whenever necessary to address symptoms and complications related to their cancer or cancer treatment. Appropriate means of contact may include an external call service, provided that the practice has a policy and regular monitoring of availability and timeliness of response.

Availability and Access to Care – Practice has a policy for documentation and follow-up for patients who miss or cancel scheduled visits and/or chemotherapy treatments. (Tracks 1 and 2)

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

Availability and Access to Care – Practice uses triage data to determine and implement expanded patient access, including, as appropriate: extended hours, weekend hours, and/or urgent/walk-in visits. (Track 2)

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. Urgent (same day) appointments must be made available at the practice.

Practices offer extended coverage or expanded access during morning, evening, and/or weekend hours so patients requiring care can be seen either at the practice or another designated location thus avoiding unnecessary emergency department (ED) visits.

Availability and Access to Care – Practice utilizes symptom management pathways/guidelines for triage and urgent care of patients experiencing symptoms from their cancer or cancer treatment. (Track 2)

A triage system is in place to support active symptom management of patients. Using pathways to triage symptoms ensures that symptoms are addressed 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.

Availability and Access to Care – Practice tracks patient ED visits, hospital admissions and re-admissions; analyzes the data regularly for process improvement and patient education purposes; and contacts patients within 48 hours of hospitalization or ED visit for follow-up. (Track 2)

When patients present to the ED or are hospitalized, the Home practice shall have processes in place to know that the ED visit or admission has occurred and then follow-up with the patient within 48 hours of the ED visit or hospital discharge.

Comprehensive Team-Based Care – A medical oncologist directs the patient’s care team within the practice, directs care coordination with other pertinent physicians and services, and manages or co-manages the inpatient team-based care. (Tracks 1 and 2)

Under the 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 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.

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, including the primary care physician, informed of a mutual patient’s treatment plan and current status.

As medically appropriate, the practice provides the following services on-site or by referral:

- Rehabilitation
- Nutritional support/counseling
- Surgical and radiation oncology
- Diagnostic imaging
- Laboratory studies
- Psychosocial evaluation and support
- Genetic counseling
- Palliative care/symptom management
- Home care and hospice care

Comprehensive Team-Based Care – The 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. (Tracks 1 and 2)

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. 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. The Oncology Medical Home practice prioritizes team-based care.

The OMH 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 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 OOC at least annually.

Comprehensive Team-Based Care – 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 is provided, as needed. (Track 2)

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

Practices must develop a process to incorporate the screening of distress into the standard care of oncology patients including a plan and review of psychological, vocational, disability, legal, or financial concerns, their management and their ability to impact treatment plans and outcomes. All cancer patients must be screened for distress a minimum of one time during a pivotal medical visit as determined by the practice. 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.

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.

Comprehensive Team-Based Care – Practice adopts a risk stratification process for all oncology patients, addressing medical need, behavioral diagnoses, and health-related social needs. (Track 2)

Utilize data from the comprehensive patient assessment to identify patients at higher risk for symptoms, complications, and/or non-adherence with their cancer treatment plan. Methods for risk-stratification may include an algorithm based on diagnoses, events and other data, or a structured scoring system administered by trained clinicians. Results from risk assessments shall be documented in the patient's medical record within standards set by practice policy, but no later than 30 days after the initiation of treatment interventions (i.e. chemotherapy, radiation therapy, or surgery). For patients identified as higher risk, practice shall have standards for enhanced care management services.

Comprehensive Team-Based Care – Practice provides dedicated advance care planning sessions, facilitated by a trained professional. (Track 2)

Practice offers patients the opportunity to participate in a dedicated advance care planning (ACP) session, to include their current or prospective healthcare surrogate, family members, relevant care team members, and a trained professional in the facilitation of such sessions. ACP sessions shall be offered at least once at the initiation of cancer treatment, and as appropriate thereafter – e.g. progression of disease or change in functional status.

Practice may adopt tools such as Respecting Choices®, Five Wishes®, Your Conversation Starter Kit, ACP Decisions, or a practice-developed tool.

Quality Improvement – The practice records, reviews and monitors completeness of clinical data for initiating quality improvement activities. (Tracks 1 and 2)

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). The practice 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. Core data elements which must be documented in the EHR include:¹¹

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

Quality Improvement – The practice administers a patient satisfaction survey to cancer patients at least twice each calendar year or on an ongoing basis. The results of the survey are analyzed and used to guide quality improvement activities. (Tracks 1 and 2)

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. Practices must administer patient satisfaction surveys using a validated, oncology-specific patient satisfaction tool that includes benchmarks. The Oncology Medical Home Patient Satisfaction Survey is recommended as a tool to help drive quality improvement but is not required.¹²

Practices will evaluate and take actions to improve cancer patient satisfaction scores. Practices may consider implementing Patient and Family Advisory Councils 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 meeting minutes.

Quality Improvement – Each calendar year, the practice participates in at least one quality improvement study associated with improving clinical outcomes and implements at least one quality improvement based on study results. (Track 2)

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 practice has a process in place to identify a process of care for review and regularly use data to evaluate that process. 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.

Each calendar year, the practice participates in at least one quality improvement study associated with improving clinical outcomes and implements at least one quality improvement

¹¹ For more information, see <https://mcodeinitiative.org/access-mcode/>

¹² <http://www.medicalhomeoncology.org/coa/patient-satisfaction.htm>

based on study results. The Oncology Steering Committee shall either select a community-wide quality improvement study for all participants, or share community health priorities, under which participants may develop their own study.

Study topics must be selected based on a problematic quality-related issue relevant to the practice and local cancer patient population and is aimed at continuous quality improvement. For example:

- Demonstrated use of reporting/benchmarking within the Quality Oncology Practice Initiative.
- Meaningful quality improvement study with implementation of clinical improvement based on identified need for improvement in one or more performance measures.
- Quality studies can evaluate various spectrums of cancer care, including diagnosis, treatment, and supportive care of patients; within that spectrum can be issues related to structure, process, and outcomes.

Each calendar year, at least one quality improvement project is fully implemented as a result of data collected from a quality study as directed by the practice. Studies should measure longitudinal performance over time with a minimum 24-month study period recommended. The recommendations and improvements are reported to the practice and are documented in meeting minutes.

Safety – The practice follows QOPI safety standards for the administration of chemotherapy. (Tracks 1 and 2)

Practices shall follow chemotherapy safety standards as established by the Quality Oncology Practice Initiative's Certification Program (QCP). Complete QCP Standards are provided in Appendix E. Practices are not required to meet the QOPI chart abstraction/participation requirement but must meet all standards and measures in the QCP program. Practices with current QCP Certification status are considered to have meet this requirement

DOMAIN 1: Creating a safe environment – staffing and general policy (QCP Standards 1.1 – 1.8)

DOMAIN 2: Treatment planning, patient consent and education (QCP Standards 2.1 – 2.4)

DOMAIN 3: Ordering, preparing, dispensing and administering chemotherapy (QCP Standards 3.1 – 3.11)

DOMAIN 4: Monitoring after chemotherapy is given, including adherence, toxicity and complications (QCP Standards 4.1 – 4.5)

Evidence-Based Medicine – The practice uses evidence-based treatment pathways; measures and reports on physician compliance with pathways; and requires documentation for off-pathway treatment. (Tracks 1 and 2)

As discussed in Section 1.7, delivery and documentation of evidence-based medicine, through use of clinical treatment pathways, is a key component of PCOP.

Practices shall implement evidence-based clinical treatment pathways based on cancer stage, appropriate biomarkers, and patient performance status, as appropriate for individual clinical

circumstances. Reference of pathway materials, selection of appropriate treatment, and documentation of relevant data shall be personally performed by the treating provider and care team. Deviation from the established pathway, expected in 15% to 20% of cases, shall be supported by documented clinical or patient circumstances that warrant the treatment selected.

Compliance with the pathways shall be measured and aggregated by provider and disease and shall be made available for scoring within the performance methodology – see Chapter 6.

To ensure the quality of clinical treatment pathways used within PCOP, the Oncology Steering Committee shall be responsible for evaluating and approving pathways for use in the PCOP model, based on ASCO criteria – see Appendix C.

Evidence-Based Medicine – Patients are provided clinical research study information by the practice as appropriate for the patient’s clinical condition. (Tracks 1 and 2)

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 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.

Technology – Use of certified EHR technology. (Tracks 1 and 2)

Practice is required to use certified EHR technology (CEHRT) throughout participation in the model. The practice shall use CEHRT in a manner sufficient to meet the requirements for an “eligible alternative payment entity” under section 1833(z)(3)(D)(i)(I) of the Act, as implemented.

Appendix E: QOPI® Certification Program Standards

*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 a policy to document the qualifications of clinical staff who order, prepare, and administer chemotherapy and documents:

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

1.1.1.1 Description of credentialing processes (licensed independent practitioners) and how credentialing is documented.

1.1.2 Chemotherapy is prepared by a licensed pharmacist, pharmacy technician, physician, or registered nurse with documented chemotherapy preparation education, training and annual competency validation. *Documentation of qualifications to prepare chemotherapy includes:*

1.1.2.1 Description of initial educational requirements and competencies.

1.1.2.2 Description of (at least) annual, ongoing continuing education requirements.

1.1.2.3 Description of competency demonstration and how competency is documented.

1.1.3 Chemotherapy is administered by a qualified physician, physician assistant, registered nurse or advanced practice nurse. *Documentation of qualifications to administer chemotherapy includes:*

1.1.3.1 Description of initial educational requirements and competencies.

1.1.3.2 Description of (at least) annual, ongoing continuing education requirements.

1.1.3.3 Description of competency demonstration and how competency is documented.

1.1.4 The health care setting uses a comprehensive education program for initial educational requirements for all staff who prepare and administer chemotherapy.

1.1.5 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 eight 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 including pregnancy status, as applicable. *Medical history and physical examination is defined in the glossary.*
 - 1.2.4 Presence or absence of allergies and history of other hypersensitivity reactions.
 - 1.2.5 Assessment of the patient’s and/or caregiver’s comprehension of information regarding the disease and the treatment plan.
 - 1.2.6 Initial psychosocial assessment, with action taken when indicated. *Psychosocial assessment is defined in the glossary.*
 - 1.2.7 The chemotherapy treatment plan, including, at minimum, the patient diagnosis, drugs, doses, anticipated duration of treatment, and goals of therapy.
 - 1.2.8 The planned frequency of office visits and patient monitoring that is appropriate for the individual chemotherapy agent(s).
- 1.3 On each clinical encounter or day of treatment, staff performs and documents a patient assessment that includes at least the following 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.
- 1.4 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 patient’s medications are updated at every visit and reviewed by a practitioner when a change occurs.**

- 1.7 The healthcare setting has a policy for documentation and follow-up for patients who miss or cancel scheduled visits and/or chemotherapy treatments.**
- 1.7.1 The healthcare setting has a policy that addresses mandates and processes for pediatric patients that account for legal requirements.
- 1.8 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.**
- 2.2 Informed consent and assent (optional) for chemotherapy treatment, as appropriate to the treatment population, is documented before initiation of a chemotherapy regimen. *The consent process should follow appropriate professional and legal guidelines.***
- 2.3 Patients are provided with verbal and written or electronic information as part of an education process before the first administration of treatment of each treatment plan. The content of this educational material will be documented. Educational information includes the following at a minimum:**
- 2.3.1 Patient’s diagnosis.
- 2.3.2 Goals of treatment, that is, cure disease, prolong life, or reduce symptoms.
- 2.3.3 Planned duration of treatment, schedule of treatment administration, drug names and supportive medications, drug-drug and drug-food interactions, and plan for missed doses.
- 2.3.4 Potential long-term and short-term adverse effects of therapy, including infertility risks for appropriate patients.
- 2.3.5 Symptoms or adverse effects that require the patient to contact the health care setting or to seek immediate attention.
- 2.3.6 Procedures for handling medications in the home, including storage, safe handling, and management of unused medication.
- 2.3.7 Procedures for handling body secretions and waste in the home.
- 2.3.8 Follow-up plans, including laboratory and provider visits.

- 2.3.9 Contact information for the health care setting, with availability and instructions on when and who to call.
- 2.3.10 The missed appointment policy of the health care setting and expectations for rescheduling or cancelling.

2.4 Education includes family, caregivers, or others based on the basis of the patient's ability to assume responsibility for managing therapy. Educational activities will be performed based on the patient's learning needs, abilities, preferences, and readiness to learn.

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 Sequencing of drug administration (when applicable) and the individual product sequence within the total drug order (e.g., 1 of 5, 2 of 2, etc.).
- 3.4.10 When dose is divided, the total number of products to be given and the individual product sequence within the total drug order (e.g., 1 of 5, 2 of 2, etc.).
- 3.4.11 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 Prepared separately.
- 3.5.2 Stored in an isolated container or location after preparation.
- 3.5.3 Labeled with a uniquely identifiable intrathecal medication label.
- 3.5.4 Delivered to the patient only with other medications intended for administration into the CNS.
- 3.5.5 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.

3.6 The health care setting that administers intrathecal chemotherapy has a policy that specifies that intravenous vinca alkaloids are administered only by infusion for example, mini-bags.

3.7 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.

3.8 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:

3.9 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:

- 3.9.1 Drug name.
- 3.9.2 Drug dose.

- 3.9.3 Infusion volume or drug volume when prepared in a syringe.
 - 3.9.4 Rate of administration.
 - 3.9.5 Route of administration.
 - 3.9.6 Expiration dates and/or times.
 - 3.9.7 Appearance and physical integrity of the drugs.
 - 3.9.8 Rate set on infusion pump, when used.
- 3.10 Documentation of chemotherapy administration confirms the verification of the eight elements of standard 3.9 and also includes the patient’s clinical status during and upon completion of treatment.**
- 3.11 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 monitor an initial assessment of patients’ adherence to chemotherapy that is administered outside of the health care setting. 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 clinically meaningful intervals to address any issues identified. Documentation of assessment is available in the patient record.**
- 4.4 The health care setting has policy that requires evaluation and documentation of treatment-related toxicities, dose modification related to toxicities, and how these are communicated before subsequent administration.**
- 4.5 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 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.

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. |
| 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 |

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| | 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: <ol style="list-style-type: none"> 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 |
| 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 |

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| | 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 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). |

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| 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 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: <ul style="list-style-type: none"> • 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, or intra-cavitary routes. |

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|--------------------------------|--|
| 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. |
| 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 (American Society of Health-System Pharmacists: Am J Health Syst Pharm 63:1172-1193, 2006; National Institute for Occupational Safety and Health: DHHS publication No. 2004-165, 2004; Occupational Safety and Health Administration: OSHA technical manual, 1995; Polovich M: Pittsburgh, PA, Oncology Nursing Society, 2011; US Pharmacopeial Convention, Rockville, MD, 2016). Education, training, and competency validation for chemotherapy administration must necessarily include this aspect of practice. Organizations should focus on a culture of safety because of the relationship between patient and health care worker safety (Friese CR et al: BMJ Qual Saf 21:753-759, 2012; Polovich M, Clark PC: Oncology Nursing Forum, 2012). 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.

Appendix F: Drug Ingredients Qualifying for Cancer Treatment CMP

| | | | |
|------------------|-----------------------|---------------|-----------------|
| ado-trastuzumab | daratumumab | mogamulizumab | teniposide |
| emtansine | dasatinib | necitumumab | thalidomide |
| afatinib | daunorubicin | nelarabine | thioguanine |
| aflibercept | decitabine | neratinib | thiotepa |
| alectinib | denileukin diftitox | nilotinib | topotecan |
| alemtuzumab | dinutuximab | nintedanib | tositumomab |
| alitretinoin | docetaxel | niraparib | trabectedin |
| altretamine | doxorubicin | nivolumab | trametinib |
| anagrelide | durvalumab | obinutuzumab | trastuzumab |
| arsenic trioxide | elotuzumab | ofatumumab | valrubicin |
| asparaginase | epirubicin | olaparib | vandetanib |
| atezolizumab | eribulin | olaratumab | vemurafenib |
| avelumab | erlotinib | omacetaxine | venetoclax |
| axitinib | estramustine | osimertinib | vinblastine |
| azacitidine | etoposide | oxaliplatin | vincristine |
| belinostat | everolimus | paclitaxel | vinorelbine |
| bendamustine | floxuridine | palbociclib | vismodegib |
| bevacizumab | fludarabine | panitumumab | vorinostat |
| bexarotene | fluorouracil | panobinostat | ziv-aflibercept |
| binimetinib | gefitinib | pazopanib | |
| bleomycin | gemcitabine | pegaspargase | |
| blinatumomab | gemtuzumab ozogamicin | pembrolizumab | |
| bortezomib | ibritumomab | pemetrexed | |
| bosutinib | ibrutinib | pentostatin | |
| brentuximab | idarubicin | pertuzumab | |
| brigatinib | idelalisib | pomalidomide | |
| busulfan | ifosfamide | ponatinib | |
| cabazitaxel | imatinib | pralatrexate | |
| cabozantinib | inotuzumab ozogamicin | procarbazine | |
| capecitabine | ipilimumab | radium ra 223 | |
| carboplatin | irinotecan | ramucirumab | |
| carfilzomib | ixabepilone | regorafenib | |
| carmustine | ixazomib | ribociclib | |
| ceritinib | lapatinib | rituximab | |
| cetuximab | lenalidomide | romidepsin | |
| chlorambucil | lenvatinib | rucaparib | |
| cisplatin | lomustine | ruxolitinib | |
| cladribine | mechlorethamine | siltuximab | |
| clofarabine | melphalan | sipuleucel-t | |
| cobimetinib | mercaptopurine | sonidegib | |
| crizotinib | methotrexate | streptozocin | |
| cyclophosphamide | midostaurin | sunitinib | |
| cytarabine | miltefosine | talimogene | |
| dabrafenib | mitomycin | laherparepvec | |
| dacarbazine | mitotane | temozolomide | |
| dactinomycin | mitoxantrone | temsirolimus | |

Appendix G: Disease Categories for CPOC Payments

| | Average New Patient Costs per Month (Medicare) | Average Cancer Treatment Costs per Month (Medicare) | Average Active Monitoring Costs per Month (Medicare) |
|--|--|---|--|
| Cohort A | 9,885 | 17,799 | 4,435 |
| Acute Leukemia – C91.0, C91.3, C91.5, C91.6, C91.A, C92.0, C92.3, C92.4, C92.5, C92.6, C92.A, C93.0, C94.0, C94.2, C94.3, C95.0 Head and Neck Cancers – C00, C01, C02, C03, C04, C05, C06, C07, C08, C09, C10, C11, C12, C13, C14, C30, C31, C32, C33 Lymphomas – C81, C82, C83, C84, C85, C86, C88 Malignant Melanoma – C43 Multiple Myeloma – C90.xx | | | |
| Cohort B | 9,144 | 13,592 | 3,661 |
| Bronchus and Lung – C34, C45 Chronic Leukemia – C91.1, C91.4, C92.1, C93.1 Endocrine – C73, C74, C75 Kidney – C64 Prostate (w/ chemotherapy) – C61 | | | |
| Cohort C | 9,473 | 10,511 | 4,069 |
| Brain and Central Nervous System – C69, C70, C71, C72 Breast (female) – C50.x1; D05 Gastric – C16 Esophageal – C15 Urinary – C65, C66, C67, C68 | | | |
| Cohort D | 6,908 | 8,472 | 3,994 |
| Colon and Rectum – C18, C19, C20 Gynecologic – C51, C52, C53, C54, C55, C56, C57, C58 Pancreas – C25 Small Intestine – C17 All other cancers | | | |

Appendix H: Example of CPOC Payment Model

**Table H.1
Comparison of Cancer Treatment Months Under Traditional FFS
Versus Consolidated Payments for Oncology Care**

| | Traditional FFS | CPOC Scenario |
|--|------------------------|----------------------|
| Care Management, Performance Incentive, and Consolidated Payment | \$ 450 | \$ 1,790 |
| Evaluation & Management | 423 | - |
| Diagnostic Imaging | 216 | 216 |
| Lab & Pathology | 129 | 129 |
| Drug Administration | 656 | - |
| IV (Part B) Drugs | 6,324 | 6,063 |
| Oral (Part D) Drugs | 1,269 | 1,269 |
| Therapeutic Radiation | 797 | 797 |
| Emergency & Observation | 154 | 154 |
| Inpatient Services | 835 | 835 |
| Post-Acute Care | 156 | 156 |
| Hospice Care | 43 | 43 |
| Other | 604 | 604 |
| Total | 12,056 | 12,056 |

Appendix I: Drug Ingredients for Inclusion in Supportive and Maintenance Care Drug Cost Measure

| | |
|---------------------------|-------------------------------|
| abiraterone | lanreotide |
| aldesleukin | letrozole |
| alendronic acid | leucovorin |
| amifostine | leuprolide |
| anastrozole | levoleucovorin |
| aprepitant | mecobalamin |
| bcg | mesna |
| bicalutamide | methoxy polyethylene glycol- |
| burosumab | epoetin beta |
| cetrorelix | nabilone |
| cobamamide | nafarelin |
| darbepoetin alfa | nilutamide |
| degarelix | octreotide |
| denosumab | ondansetron |
| dexrazoxane | oprelvekin |
| dolasetron | palifermin |
| enzalutamide | palonosetron |
| epoetin alfa | pamidronate disodium |
| exemestane | pasireotide |
| ferric carboxymaltose | pegademase bovine |
| ferrous fumarate | pegfilgrastim |
| ferrous gluconate | peginterferon alfa-2a |
| ferrous sulfate | peginterferon alfa-2b |
| ferumoxytol | peginterferon beta-1a |
| filgrastim | plerixafor |
| flutamide | rasburicase |
| folic acid | risedronate sodium |
| fosaprepitant | rolapitant |
| fulvestrant | sargramostim |
| ganirelix | scopolamine |
| glatiramer acetate | sodium ferric gluconate |
| glucarpidase | supprelin implant (histrelin) |
| gonadorelin | tamoxifen |
| goserelin | tetrahydrocannabinol |
| granisetron | tiludronic acid |
| histamine dihydrochloride | toremifene |
| histrelin | triptorelin |
| hydroxocobalamin | vitamin b 12 |
| ibandronic acid | zoledronic acid |
| Interferon alfa-2a | |
| interferon alfa-2b | |
| interferon beta-1a | |
| interferon beta-1b | |
| iron sucrose | |
| iron-dextran | |

Appendix J: How the Patient-Centered Oncology Payment Model Was Developed

In the spring of 2013, the American Society of Clinical Oncology convened an Oncology Payment Reform Workgroup to explore better ways to pay oncology practices. The members of the Workgroup included:

- Jeffery Ward, MD, Chair
- Anupama Kurup Acheson, MD, Vice-Chair
- John Cox, DO
- Michael Diaz, MD
- Omar Eton, MD
- Shelagh Foster
- James Frame, MD
- Karen Hagerty, MD
- Denis Hammond, MD
- Dan Hayes, MD
- John Hennessy
- Andrew Hertler, MD
- Don Moran
- Roscoe Morton, MD
- Ray Page, DO
- Kavita Patel, MD
- Charles Penley, MD
- Blase Polite, MD
- Christian Thomas, MD
- Robin Zon, MD
- Dan Zuckerman, MD

ASCO formed the Oncology Payment Reform Workgroup because of the widespread recognition of the need to control healthcare spending by Medicare, Medicaid, and commercial payers and the interest in new payment models to enable physicians in general and oncologists in particular to help control spending without harming patients or jeopardizing the viability of high-quality, independent oncology practices. Moreover, Medicare and commercial payers are not the only ones who bear the burden of the rising costs of healthcare; an increasing share of these costs is being passed on to patients. The cost of cancer diagnosis and treatment, even for patients with insurance, can lead to treatment delays, noncompliance, and exhaustion of savings. In fact, medical expenses are the leading cost of personal bankruptcy.

Over the course of the following year, the Payment Reform Workgroup developed a proposal for improving the way oncology practices are paid called Consolidated Payments for Oncology Care (CPOC). Harold Miller, President and CEO of the Center for Healthcare Quality and Payment Reform, assisted the Workgroup with its discussions and analyses.

In May 2014, ASCO released the proposal for Consolidated Payments for Oncology Care and invited comment. Many ASCO members and other stakeholders endorsed the need for payment reform in oncology and provided suggestions on ways to improve the CPOC proposal.

In the fall of 2014, ASCO formed an Implementation Workgroup to incorporate the comments and suggestions into a revised proposal and to begin working with oncology practices and payers to implement it. Harold Miller and CHQPR also provided assistance to the Implementation Workgroup in its work. The members of the Workgroup include:

- Christian Thomas, MD, Co-Chair
- Dan Zuckerman, MD, Co-Chair
- Tammy Chambers
- James Frame, MD
- Bruce Gould, MD
- Ann Kaley
- Justin Klamerus, MD
- Lauren Lawrence
- Barbara McAneny, MD
- Roscoe Morton, MD
- Julie Moran
- Ray Page, DO, PhD
- Scott Parker
- Charles Penley, MD
- Gabrielle Rocque, MD
- Barry Russo
- Joel Saltzman, MD
- Laura Stevens
- Jeffery Ward, MD
- Kim Woofter
- Robin Zon, MD

In developing the Patient-Centered Oncology Payment (PCOP) proposal, the Implementation Workgroup built on the work done by the Payment Reform Workgroup in developing the Consolidated Payments for Oncology Care (CPOC) proposal. For example, the payment categories in Option A in the Patient-Centered Oncology Payment proposal are similar to those that were defined in the CPOC proposal, and the basic PCOP payment model was designed to achieve many of the same goals as CPOC but in a way that would be easier for many oncology practices and payers to implement with current billing and payment systems.

In the fall of 2018, ASCO formed a small workgroup to develop this Implementational Guide for the PCOP model and prepare it for submission to the Physician-Focused Payment Model Technical Advisory Committee for consideration by the Centers for Medicare and Medicaid Services. The members of this group include:

- Ray Page, DO, Chair

- Stephen Barlow, MD
- Roger Brito, MD
- Alexander Chin, MD
- Michael Kolodziej, MD
- Craig Osterhues
- Jeff Ward, MD
- Joanna Yang, MD, MPH
- Robin Zon, MD

In considering various concepts and strategies to consider within PCOP, the workgroup would also like to thank the authors of three other alternative payment models, which have been shared to effect change in the delivery and payment of high-value oncology care:

- Oncology Bundled Payment Program Using CNA-Guided Care (Andrew Pecora, MD)
- Making Accountable Sustainable Oncology Networks (Barbara McAneny, MD)
- Oncology Care Model 2.0 (Michael Diaz, MD)