Preliminary Review Team Report to the Physician-Focused Payment Model Technical Advisory Committee on the *Patient-Centered Oncology Payment Model (PCOP)*

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Physician-focused payment model (PFPM) proposals submitted to the Physician-Focused Payment Model Technical Advisory Committee (PTAC) in accordance with PTAC's proposal submission instructions are assigned to a preliminary review team (PRT). Each PRT prepares a report of its findings on the proposal for discussion by the full PTAC. The report is not binding on PTAC; PTAC may reach different conclusions from those contained in the report. Each report and related materials are available on the PTAC section of the Office of the Assistant Secretary for Planning and Evaluation (ASPE) website.

A. Proposal Information

1. **Proposal Name:** Patient-Centered Oncology Payment Model (PCOP)
2. **Submitting Organization or Individual:** American Society of Clinical Oncology (ASCO)
3. **Submitter's 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 of 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."

B. Summary of the PRT Review

The proposal submitted by the American Society of Clinical Oncology (ASCO) was submitted to PTAC and found to have met the Committee's administrative requirements on January 14, 2020. The PRT conducted its review of the proposal between February 10, 2020 and August 4, 2020. The PRT's findings are summarized below.

PRT Rating of Proposal by Secretarial Criteria

Criteria Specified by the Secretary (at 42 CFR § 414.1465)	PRT Rating	Unanimous or Majority Conclusion
1. Scope (High Priority)	Does Not Meet Criterion	Unanimous
2. Quality and Cost (High Priority)	Does Not Meet Criterion	Unanimous
3. Payment Methodology (High Priority)	Does Not Meet Criterion	Unanimous
4. Value over Volume	Meets Criterion	Unanimous
5. Flexibility	Meets Criterion	Unanimous
6. Ability to Be Evaluated	Does Not Meet Criterion	Unanimous
7. Integration and Care Coordination	Meets Criterion	Unanimous
8. Patient Choice	Meets Criterion	Unanimous
9. Patient Safety	Meets Criterion	Unanimous
10. Health Information Technology	Meets Criterion	Unanimous

C. Information Reviewed by the PRT

1. Proposal and Additional Information Provided by the Submitter

The PRT reviewed the ASCO proposal, including additional information provided by the submitter in response to written questions, and held a one-hour teleconference call with the submitter during which the submitter responded to additional PRT questions. In addition, two public comment letters were received in response to the proposal, and three letters of support were provided by the submitter.

Proposal Summary

Objectives. The proposed Patient-Centered Oncology Payment Model (PCOP) is designed to support Community-based Oncology Medical Homes. The objectives of the five-year[1], multi-payer PCOP model are to transform cancer care delivery and reimbursement while promoting high-quality, well-coordinated, and high-value cancer care.

Participating Communities. The proposal calls for the creation of "PCOP communities" comprised of multiple payers, employers, hematology/oncology practices,[2] and other stakeholders in a geographic region that could represent a single metropolitan area, a

[1] The model also assumes a one-year start-up ("Year 0") during which the participating PCOP communities would build the necessary infrastructure for successful implementation of the model.

[2] The term hematology/oncology is used throughout this report and includes medical oncology and hematologic oncology practices and physicians.

single state, or multiple states. Each PCOP community would be led by an Oncology Steering Committee (OSC) that would select high-quality clinical pathways, focusing on the use of chemotherapy/biologic therapy pathways[3], either by recommending pathways themselves or approving pathways suggested by providers, and select a sub-set of six quality measures from ASCO's Quality Oncology Practice Initiative (QOPI®) most relevant to their patient population. The OSC would also identify partners to facilitate successful implementation of the model (including agreeing on funding sources and obtaining project management support to coordinate the efforts of model participants), potentially set target pathway adherence rates, and distribute performance metrics. The OSC would also be responsible for establishing the value of care management and performance management payments based on PCOP guidelines.

Although the proposal does not specify minimum criteria for PCOP community participation, the submitter has indicated that the 18 regions participating in the Comprehensive Primary Care Plus (CPC+) model would be most appropriate for initial implementation of the PCOP model based on their ability to leverage Certified Electronic Health Record Technology (CEHRT), existing Health Information Exchanges (HIEs), oncology-specific All Payer Claims Database (APCD) capability, and/or ASCO's Quality Oncology Practice Initiative (QOPI®) program to efficiently collect, integrate, and report quality and cost metrics.[4] The submitter has also identified the states of Maine, Maryland, and Washington as promising communities for initial implementation of the PCOP model due to their strong HIEs, APCDs, and regional healthcare improvement organizations.

Although the proposed PCOP model is designed to be multi-payer, the proposal does not specify a minimum threshold for payer-participation, and the model could also be implemented by a single payer such as Medicare. However, the submitter has indicated that models in which there is relatively little or no private payer participation can be problematic for two reasons: first, Medicare fee-for-service (FFS) alone cannot provide the necessary financial support for oncology practice transformation, particularly in regions with high Part C (Medicare Advantage) penetration; and second, the administrative burden for oncology practices is high as practices have to maintain multiple FFS billing systems while also developing financial systems to participate in alternative payment models (APMs).

Provider and Patient Eligibility. The PCOP model is intended for practices and physicians providing hematology/oncology services, specifically those prescribing and managing chemotherapy and immunotherapies, as well as those providing early survivorship, palliative, or hospice care services. Multi-specialty practices with hematology/oncology providers may also participate. The practices would serve as the APM entity for purposes of provider assignment, patient and episode attribution, and performance measurement.

[3] Source: ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team.
[4] Source: ASCO's 3-16-2020 response to Questions Received from the Preliminary Review Team.

There are no restrictions on the type of oncology practices (e.g., free-standing, hospital-based) that can participate in the PCOP model. However, the submitter notes that participants in the model are clinically responsible for certain management and delivery of care requirements, so some practices may need to partner with another entity in order to participate. For example, when a participating physician practice refers to a hospital outpatient department for chemotherapy, the physician practice would need to ensure that the hospital outpatient department is meeting all quality and safety standards for delivery of chemotherapy within the model.[5]

The proposal indicates that patients who would be eligible for the PCOP model are those being cared for by a hematologist/oncologist with any of the cancer diagnoses listed in Table 1, which groups these cancers into four cohorts (A through D). The submitter's rationale for developing these cohorts of major cancers was based on similar treatment costs and a goal of administrative simplification of the process of case-mix adjustment.[6] Patients would be eligible to participate in the PCOP model as soon as they are diagnosed, during chemotherapy treatment, and up to 12 months after they complete their chemotherapy treatment.

Table 1. PCOP Model Eligible Diagnoses By Cohort

Cohort	Eligible Diagnoses
Cohort A	Acute Leukemia
	Head and Neck Cancers
	Lymphomas
	Malignant Melanoma
	Multiple Myeloma
Cohort B	Bronchus and Lung
	Chronic Leukemia
	Endocrine
	Kidney
	Prostate (w/ chemotherapy)
Cohort C	Brain and Central Nervous System
	Breast (female)
	Gastric
	Esophageal
	Urinary
Cohort D	Colon and Rectum
	Gynecologic
	Pancreas
	Small Intestine
	All Other Cancers

Source: ASCO Proposal, Appendix G, Disease Categories for CPOC Payments.

Payment Model. PCOP proposes two payment tracks ("Track 1" and "Track 2") for participating hematology/oncology practices and associated physicians, both with monthly payments and performance-based adjustments similar to those in the Center for Medicare & Medicaid Innovation (CMMI)'s CPC+ Model. Distinct from Track 1, Track

[5] Source: ASCO's 3-16-2020 response to Questions Received from the Preliminary Review Team.
[6] Source: ACCO's 7-24-2020 response to Questions Received from the Preliminary Review Team.

2 practices would also assume greater upside and downside risk through bundling of payments for specified services.

The proposed monthly Care Management Payments (CMPs) are designed to support practice transformation for the delivery of enhanced care management services. The OSC would establish the value of CMPs so that providers in Track 1 practices would receive CMPs worth 2 percent of total cost of care (TCOC), which includes all Medicare FFS payments (i.e., "physician services, inpatient stays, diagnostics, provided drugs, and other claims received by Medicare"). Providers in Track 2 practices would receive 3 percent of TCOC.[7] The value of the CMPs would also vary based on the resources required for care management in each phase of care. The segments are New Patient, followed by Cancer Treatment, and finally, Active Monitoring. The CMP for New Patients is two times the value of the CMP for patients in the Cancer Treatment phase, and the CMP for patients in the Active Monitoring phase is one-third the value of the CMP patients in the Cancer Treatment phase. The proposal indicates that OSCs would have flexibility to adjust CMP amounts for governmental vs. non-governmental payers when necessary. The submitter has indicated that the initial CMP amounts would be based on historical TCOC, and may be adjusted annually based on trends.[8]

PCOP provider payments also include a Performance Incentive Payment (PIP) for meeting quality metrics, adhering to clinical pathways, and reducing cost-of-care. The cost-of-care portion of the performance methodology includes three metrics: unplanned acute care hospital admissions, unplanned emergency and observation care visits, and supportive and maintenance drug costs.[9] National trends will be used to establish the benchmarks for the cost-of-care metrics. The Aggregate Performance Score (APS) will be calculated on a scale of 0 to 100 points. For purposes of participation in the Medicare program, each of the three performance categories (i.e., quality metrics, adherence to clinical pathways, and cost-of-care) will contribute equally to the APS, which determines the PIP amount. However, the submitter has indicated that PCOP communities will have flexibility to adjust the weighting for non-Medicare payers.[10] Providers in Track 1 practices will be eligible for PIPs worth up to 2 percent of TCOC, and providers in Track 2 practices can receive up to 3 percent of TCOC.

Table 2 provides additional details on the performance measures that will be used for determining the PIP. Quality metric adherence will be based on criteria for a subset of six quality measures selected by the PCOP community's OSC. Because clinical pathway

[7] Source: Proposal, page 12, and ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically question 1.
[8] Source: ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team.
[9] Source: Proposal and ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team.
[10] Source: ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically questions 2b and 3a.

adherence rates vary by cancer type, a provider's total adherence score will be weighted by the proportion of treatments by cancer type.[11] Cost-of-care measures will be case-mix adjusted for cancer type, presence of a secondary malignancy, bone marrow or stem cell transplant, clinical trial participation, and missing cost data, at a minimum, with the option to control for additional factors.[12] If a provider fails to achieve minimum expectations for Care Management activities and adherence to Clinical Treatment Pathways, CMP and PIP amounts may be suspended pending the development and approval of an improvement plan.

Table 2: Overview of PCOP's Performance Incentive Payment (PIP) Measures

Performance Measure	Description
Quality Metrics	• Participating providers will report on a subset of six quality measures from ASCO's Quality Oncology Practice Initiative (QOPI®) that have been selected by the PCOP community's Oncology Steering Committee (OSC). • Quality metric adherence will be based on criteria of numerators, denominators, exclusions, and exceptions, as defined by measure stewards. • Participating providers will be expected to meet or exceed performance benchmarks calculated by ASCO or other measure stewards, and will receive scores for their metric adherence rates based on quartiles. • If participating providers are all performing at a high rate, a PCOP community may adopt an alternative scoring method that aims to reward the high performance of all participants. • The overall Quality Care Performance will be calculated using an average of individual metric performance.
Adherence to Clinical Pathways	• Represents the number of patients 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 different course of treatment during the quarter. • Patients who are treated off-pathway must have justification for the decision documented. • A provider choosing a non-pathway regimen will not receive partial credit based on overlap of specific ingredients. • Patients enrolled in clinical research trials involving investigational treatments will be deemed "on-pathway." • Clinical pathway adherence rates will be adjusted by disease. • The submitter has indicated that expected pathway adherence is 80-90%. • Participating practices will receive a score based on their adherence as a percentile of adherence rates of participating practices, or based on targets established by the OSC.

[11] Source: ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically questions 9c-e and 2b.
[12] Source: ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically question 7a.

Performance Measure	Description
Cost-of-Care	• There are three cost-of-care metrics: unplanned acute care hospital admissions, unplanned emergency and observation care visits, and supportive and maintenance drug costs. • The cost-of-care metrics related to unplanned emergency department (ED) visits/observation stays and unplanned hospitalizations are for any condition (e.g., cancer or non-cancer, and for all Part A and B claims). In this context, "unplanned" would exclude planned surgeries, transplants, and admissions for chemotherapy. • The cost-of-care metric related to supportive and maintenance drug costs is for total expenditures for the following drug categories during an identified treatment month: antianemics; antiemetics and antinauseants; hypothalamic hormones; immunostimulants; detoxifying agents for antineoplastic treatment; and drugs for treatment of bone diseases.* • The denominator for all of the cost-of-care metrics is the number of treatment months. • Cost-of-care metrics will be calculated for a comparator population that is not enrolled in the PCOP model, a ratio will be calculated, and a performance score will be assigned based on various thresholds. • Cost-of-care measures will be case-mix adjusted for cancer type, presence of a secondary malignancy, bone marrow or stem cell transplant, clinical trial participation, and missing cost data, at a minimum, with the option to control for additional factors. • For purposes of participation in the Medicare program, the submitter recommends equal weighting of the three PCOP cost-of-care metrics in order to calculate cost-of-care performance; however, PCOP communities would have flexibility relating to the weighting of the cost-of-care metrics for non-Medicare payers.

* The proposal indicates that the submitter is planning further development of the supportive and maintenance drug costs performance measure, which may result in adjustments to the list of included drugs.

Sources: ASCO Proposal, pages 16-21; ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically question 2.

The proposal describes a potential timeline for implementation of the proposed five-year model, including a start-up year.[13] The start-up year, or "Year 0," would be used to implement necessary infrastructure such as the mechanisms for data sharing; selection of quality measures and performance targets; selection/adoption of clinical pathways; and analysis of historical claims data. The CMP amounts would begin to be applied in "Year 0" so that practices can begin managing assigned beneficiaries' care and continue strengthening their capacity to improve quality and reduce cost. Year 1 would serve as the first full performance year from which the APS is calculated and on which the first PIP is established and paid in Year 2 if performance targets are met.[14] Metrics related to cost-of-care would be taken into account in Years 3 through 5, and a portion of any savings achieved related to TCOC would be allocated to determine an available pool of PIP amounts.[15] The proposal states that beginning in Year 3, model funding, including funding for the CMP and PIP amounts, will come from an agreed-upon percentage of savings that have been generated. Thus, funds available for the CMPs and PIPs could be

[13] ASCO Proposal, pages 22-24.
[14] Source: ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically question 5a.
[15] Source: ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically question 5b.

positively or negatively adjusted depending on whether and how much savings have been generated.

While Track 1 practices will receive regular Medicare FFS payments plus the CMP, practices that elect Track 2 will also receive Consolidated Payments for Oncology Care (CPOC) that bundle 50 percent or 100 percent of Medicare fee-for-service (FFS) payments for hematology/oncology-specific professional services, as well as drug costs.[16] The CPOC would vary by the specific segment of cancer care the patient falls into (New Patient, Cancer Treatment, and Active Monitoring), and would also be adjusted using the four proposed cancer cohorts (A-D) displayed in Table 1 (above). Ninety percent of the CPOC would be guaranteed, which may help to provide predictability to practices considering accepting greater risk, while the remaining 10 percent would be subject to the same performance-based adjustments of the PIP methodology times a 1.4 multiplier. Track 2 practices receiving the CPOC would thus be able to earn between 90 percent and 104 percent of previous Medicare FFS amounts depending on their APS. Table 3 below summarizes some key features of PCOP's two-track payment model.

The proposal states that practices that elect Track 1 are expected to advance into Track 2 within two years, or be subject to discontinuation of CMPs and PIPs. However, the submitter has indicated that if practices do not advance to Track 2 within two years, participating payers in the PCOP model would have flexibility to decide whether to discontinue CMP and PIP payments to these practices or extend the deadline based on their own business interests.[17]

For purposes of the CPOC, the minimum set of covered services includes evaluation and management (E&M) and care management services by hematology/oncology providers, parenteral drug and biologic agent administration services, and drug and biologic reimbursement above the purchase cost of such agents. The proposal states that the scope of the services included in the CPOC could vary by community, with flexibility to include the following services: radiation planning, management, and treatment delivery; surgical services; and routine laboratory, imaging, and other diagnostic services. However, the submitter has indicated that the CPOC payments that have been modeled in the proposal were limited to medical and hematology oncology services (i.e., no costs or savings related to radiation or surgical oncology services were included), and adding radiation and surgical services would require an additional component of an

[16] Source: ASCO Proposal page 14.

[17] Source: ASCO's 3-16-2020 response to Questions Received from the Preliminary Review Team. Additionally, ASCO's 7-24-2020 response to question 10 Received from the Preliminary Review Team indicates that PCOP is designed to address the services and phase of care managed by the medical or hematology oncologist.

accountable care organization (ACO), which is not part of the proposed PCOP model.[18] The submitter has also stated that a community could potentially apply multiple models for cancer patients, including surgical episodes, radiation, and PCOP; however, no additional details were provided; therefore, it is unclear how multiple models might work in a community.[19]

Table 3: Key Features of PCOP's Two-Track Payment Model

Component	Track 1	Track 2
Care Management Payments (CMPs)	• CMPs in Track 1 are 2 percent of total cost of care (TCOC): ○ New Patient CMP (amount is twice that of Cancer Treatment) ○ Cancer Treatment CMP ○ Active Monitoring CMP (amount is one-third that of Cancer Treatment)	• CMPs in Track 2 are 3 percent of TCOC: ○ New Patient CMP (amount is twice that of Cancer Treatment) ○ Cancer Treatment CMP ○ Active Monitoring CMP (amount is one-third that of Cancer Treatment)
Performance Incentive Payments (PIPs)	• PIPs in Track 1 are up to 2 percent of TCOC. • The PIP amount is determined by the practice's Aggregate Performance Score (APS) based on meeting quality metrics, adhering to clinical pathways, and reducing cost-of-care. The APS would be based on equal weighting of the performance measures for purposes of participation in the Medicare program, but PCOP communities may adjust the weighting for other payers. • In Years 1-2, a portion of the CMP would be allocated to create the pool for the PIP. Starting in Year 3, a portion of any savings achieved would be allocated to a PIP pool. Funds available for the CMP and PIP can be positively or negatively adjusted based on savings or cost increases.[20]	• PIPs in Track 2 are up to 3 percent of TCOC. • The PIP amount is determined by the practice's APS based on meeting quality metrics, adhering to clinical pathways, and reducing cost-of-care. The APS would be based on equal weighting of the performance measures for purposes of participation in the Medicare program, but PCOP communities may adjust the weighting for other payers. • In Years 1-2, a portion of the CMP would be allocated to create the pool for the PIP. Starting in Year 3, a portion of any savings achieved would be allocated to a PIP pool. Funds available for the CMP and PIP can be positively or negatively adjusted based on savings or cost increases.

[18] Source: ASCO's 4-28-2020 response to Questions Received from the Preliminary Review Team. See also ASCO's 7-24-2020 response to question 10 Received from the Preliminary Review Team, which indicates that it would like to see a community apply multiple models for cancer patients, including surgical episodes, radiation, and PCOP.
[19] Source: ASCO's 7-24-2020 response to Additional Questions Received from the Preliminary Review Team, specifically question 10.
[20] See ASCO proposal pages 12, 18, 22-25 for information on the relationship between the CMP and PIP and the proposed timeline for the implementation of the CMP, PIP, and possible Track 2 CPOC described below.

Component	Track 1	Track 2
Fee-for-service (FFS) vs. Consolidated Payments for Oncology Care (CPOC)	• In addition to the CMP and PIP amounts, Track 1 practices will continue to receive the typical FFS reimbursement for oncology services.	Practices in Track 2 are required to participate in CPOC, in which practices may elect to bundle either 50 percent or 100 percent of the value of specified services which may vary in each community: • 90 percent of bundled amounts will be guaranteed under CPOC. • 10 percent of bundled amounts will be subject to the same performance adjustment used in monthly PIPs (times a 1.4 multiplier). • Using the 1.4 multiplier allows practices to earn between 90 percent and 104 percent of the previous FFS amounts, depending upon their Aggregate Performance Score. • CPOC follows the same segments of care as the CMPs, including New Patient, Cancer Treatment, and Active Monitoring CPOCs.

Care Model. The proposed care model builds on the Oncology Medical Home (OMH) model developed over the past decade, which features team-based care led by a hematology oncologist. Practices must meet "PCOP care delivery requirements" in the areas of patient engagement, availability and access to comprehensive team-based care, quality improvement (including patient satisfaction), patient safety, evidence-based medicine, and certified electronic health records technology (CEHRT).

Track 2 practices would be subject to some additional requirements, including patient and family advisory councils, triage and urgent care, patient navigation, risk stratification, and advanced care planning. Table 4 below summarizes the PCOP model's care delivery requirements for Track 1 and Track 2 participating practices.

The submitter states that PCOP's two tracks, and associated care delivery requirements, were designed to meet practices where they are in their journey toward value-based care. Practices who have not participated in CMMI's Oncology Care Model (OCM) or private payer pilots may gravitate toward Track 1, as it gives them time to implement new practice transformations throughout the model. Those who have already participated in CMMI's OCM or applied an oncology medical home (OMH) model may choose Track 2.[21]

Currently, no OMH certification program is available, but the submitter has indicated that ASCO is working with the Community Oncology Alliance (COA) to develop such a program. As an alternative to certification, payer participants could conduct periodic audits to encourage practice compliance with requirements.[22]

[21] Source: ASCO's 7-24-2020 Response to Questions Received from the Preliminary Review Team, specifically question 8.

[22] Source: ASCO's 3-16-2020 response to Questions Received from the Preliminary Review Team.

Table 4: PCOP Model Care Delivery Requirements For Participating Practices

Care Delivery Requirement	Track 1	Track 2
Patient Engagement		
Patient education on the practice and PCOP model	X	X
Routine availability and provision of patient financial counseling	X	X
Patient education on cancer diagnosis and individualized treatment plan	X	X
Convening a patient and family advisory council and integrating recommendations		X
Disseminating treatment summary/survivorship care plan within 90 days of completion of treatment		X
Availability and Access to Care		
24/7 access to appropriate clinician and real-time access to health records	X	X
Documentation and follow-up for patients who miss or cancel scheduled visits and/or chemotherapy treatments	X	X
Use of triage data to implement expanded access as appropriate (e.g., extended hours, weekend hours and/or urgent/walk-in visits)		X
Use of symptom management pathways/guidelines for triage and urgent care of patients experiencing symptoms from cancer/cancer treatment		X
Tracking patient ED visits, hospital admissions, and readmissions; analyzing the data for process improvement and patient education; and contacting patients within 48 hours for follow-up		X
Comprehensive Team-Based Care		
Medical oncologist directs the patient's care team, directs care coordination with other physicians and services, and manages/co-manages the inpatient team-based care	X	X
Prioritizes team-based care with policies and practices that clearly delineate roles and responsibilities; implements and prioritizes team huddles and a communication and patient safety tool; regularly assesses how the team is functioning	X	X
Provides all patients with navigation for support services and community resources specific to the practice patient population; performs on-site psychosocial distress screening; provides referral for psychosocial care as needed		X
Adopts a risk stratification process for all oncology patients, addressing medical needs, behavioral diagnoses, and health-related social needs		X
Provides dedicated advance care planning sessions, facilitated by a trained professional		X
Quality Improvement		
Reviews and monitors completeness of clinical data for initiating quality improvement activities	X	X
Administers a patient satisfaction survey at least twice each calendar year or on an ongoing basis; results are analyzed and used to guide quality improvement activities	X	X
Each calendar year, participates in at least one quality improvement study associated with improving clinical outcomes and implements at least one quality improvement based on study results		X
Safety		
Follows QOPI® safety standards for the administration of chemotherapy	X	X
Evidence-Based Medicine		
Uses evidence-based treatment pathways; measures and reports on physician compliance with pathways; requires documentation for off-pathway treatment	X	X
Provides patients with clinical research study information as appropriate for the patient's clinical condition	X	X
Technology		
Required to use certified EHR technology	X	X

Data Management Requirements. In order to implement the proposed model, PCOP communities will need to establish mechanisms for sharing electronic health data from participating providers via CEHRTs, data extracted from clinical treatment pathway systems, and claims data from participating payers. They must provide their data sources to one or more data custodians who would be responsible for data management and distribution. A regional HIE may be able to fulfill this role. Qualified Clinical Data Registries may serve as data custodians for collecting quality metrics and assessing performance.

The proposed PCOP model will also include specific requirements related to the transparency of performance data. For example, participating providers must agree to contribute EHR data to regional HIEs, and participating payers will be required to contribute claims data for covered patients to create an all-payer oncology database. All participating data contributors must ensure that participating providers and payers will be given access to all available data for their patient populations and that aggregated performance data in all three categories will be shared publicly after reconciliation.

2. Current Utilization and Reimbursement For Hematology/Oncology Services

According to analyses conducted at the request of the PRT, Medicare FFS claims data show that there were 2,857 hematology/oncology practices in the United States during calendar year 2017 (CY 2017). Three-quarters of these practices were comprised of fewer than six such practitioners; these practices averaged about 160 FFS beneficiaries per oncologist.

A total of 2.3 million Medicare FFS beneficiaries were diagnosed with some form of cancer and seen by a hematological or medical oncologist in CY 2017. Approximately 82 percent of these beneficiaries were treated in a single oncology practice, although some saw practitioners in two or more practices.

Among the 2.3 million beneficiaries in the study population, most were diagnosed in only one of the proposed cancer cohorts (A-D), though some were diagnosed in more than one cohort.

The Medicare TCOC for these beneficiaries in CY 2017 was $68.4 billion for the prevalent population (i.e., beneficiaries living with cancer regardless of when the disease was diagnosed and treated), $33.5 billion of which was for the incident subpopulation (i.e., beneficiaries diagnosed and treated for cancer cases during the calendar year).[23]

Trend Analysis: A trend analysis of use of ED and inpatient care for the Medicare fee-for-service (FFS) population diagnosed with cancer was conducted for the PRT. In addition to overall utilization, the analysis assesses utilization for five conditions that

[23] The estimated TCOC based on the 2017 Medicare claims analysis is higher than the $46.8 billion that the submitter estimated for a potential pool of 540,880 Medicare beneficiaries and 2,169 qualifying practices annually because the claims analysis used Medicare claims data (20 percent sample) from CY 2017, and ASCO used data from Maine only from 2015-2017.

could potentially be averted with more care coordination from a medical/hematological oncologist: nausea, dehydration, central line infection, pain, and sepsis.[24]

Total ED visits and observation stays per 1,000 cancer months increased modestly from 2014 to 2017 but then dropped slightly in 2018. The same pattern occurred overall for the five selected conditions identified as being potentially amenable to care coordination. Trends varied for the individual conditions; pain accounted for the highest proportion of ED/observation stay events, followed by nausea.

The rate of inpatient stays per 1,000 cancer months decreased continuously between 2014 and 2018 for all events, while those for the combined selected conditions increased through 2017 before a slight decrease in 2018. Trends varied by the individual five conditions, with some increasing and some decreasing; dehydration and sepsis accounted for the highest proportion of inpatient stay events among these conditions that might be amenable to care coordination.

Medicare payments per cancer month (for all events and for the five selected diagnoses) increased over time for both service types (ED and observation visits/stays and inpatient stays), although these payments have not been adjusted for inflation.

3. Literature Review and Environmental Scan

ASPE, through its contractor, conducted a targeted environmental scan of peer-reviewed and non-peer-reviewed publications. The review included a formal search of major medical, health services research, and general academic databases; relevant grey literature, such as research reports, white papers, conference proceedings, and government documents; and websites of professional associations and societies, and CMS for relevant evaluation reports and program documentation. Key words guiding the environmental scan and literature review were identified from the proposal. The search may not be comprehensive and was limited to documents that met predetermined parameters, generally including a five-year look-back period, a primary focus on United States-based literature and documents, and relevancy to the proposal.

4. Data Analyses

The PRT sought additional information regarding the proposal. ASPE, through its contractor, conducted analyses of CY 2017 Medicare claims data and produced tables on issues related to the proposal. Information from the analysis included cancer prevalence and incidence in the Medicare FFS population; TCOC; use of selected services (emergency department and observation visits, unplanned hospital admissions, and treatment and maintenance drug expenditures); geographic concentration of cancer patients; and Medicare monthly payments by treatment phase (i.e., New Patient, Cancer Treatment, Active Monitoring).

[24] The objective of this analysis was not to identify a population that would potentially be treated under the proposed PCOP model, nor to suggest that the selected diagnoses are the only ones that would potentially be amenable to care coordination. Rather, the selected diagnoses were used to assess trends in ED visits and inpatient hospitalizations associated with these potentially avertable conditions.

ASPE, through its contractor, also conducted a trend analysis of CY 2014-2018 Medicare claims data and produced tables relating to use of ED/observation stays and inpatient care for the Medicare fee-for-service (FFS) population diagnosed with cancer. Information from the trend analysis included overall utilization, and utilization for five conditions that could potentially be averted with more care coordination from a medical/hematological oncologist.

5. Public Comments

There were two public comments for this proposal, both from medical societies. Additionally, three letters of support were provided by the submitter.

6. Other Information

The PRT sought additional information regarding how the proposed model compares with CMMI's OCM and CPC+ Models. ASPE, through its contractor, summarized this information. ASPE also communicated with staff in CMMI regarding the comparison with the OCM and CPC+ Models. The PRT also sought additional information by communicating with staff in the CMS Office of the Actuary to gain a fuller understanding of the implications of the proposed model for Medicare program spending.

D. Evaluation of Proposal against Criteria

Criterion 1. Scope (High Priority)

The proposal aims to either directly address an issue in payment policy that broadens and expands the CMS APM portfolio or include APM Entities whose opportunities to participate in APMs have been limited.

PRT Qualitative Rating: Does Not Meet Criterion

Strengths:

- The proposed PCOP model seeks to provide a comprehensive approach to delivering and paying for high-quality cancer care, which is an important clinical area for the Medicare program and beneficiaries.
- The PCOP model's proposed use of geographically-based, multi-payer stakeholder communities, led by OSCs, could encourage the development of innovative solutions that better address local needs and facilitate greater participation by private payers.
- The proposal could expand medical and hematology oncologists' opportunity to participate in an APM, including small practices. Approximately 5 percent[25] of the nation's hematology/oncology practices participate in CMMI's OCM, and those

[25]As of February, 2020, 139 practices participate in CMMI's OCM (See: https://innovation.cms.gov/files/slides/ocm-overview-slides.pdf, slide 6). As shown in the claims analysis, as of CY 2017 there were 2,857 hematology/oncology practices. Therefore, approximately 5 percent (139 divided by 2,857) of all hematology/oncology practices nationally are participating in OCM.

participating practices are relatively large.[26] Small practices, such as those with fewer than six medical and hematology oncologists, treat three-quarters of Medicare FFS beneficiaries[27] and may be more willing and able to participate in PCOP.

- The PCOP model includes features that are designed to increase participation – such as stakeholder participation in OSCs, community-specific flexibility in selection of clinical pathways and metrics, and a payment methodology that may make it more feasible and attractive for more practices to participate.
- Additionally, the PCOP model's inclusion of two tracks is designed to allow participating payers to meet practices where they are while engaging them in value-based care. For example, smaller and medium-sized practices, with less OMH capacity or less experience with APMs, may elect to participate in Track 1, while those that are larger, have more OMH capacity, and more experience with APMs may elect to participate in Track 2.
- The PCOP model's focus on the use of chemotherapy/biologic therapy pathways due to the high cost of these agents, and its inclusion of supportive and maintenance care drug costs as a performance metric, are consistent with CMMI's potential Oncology Care First (OCF) Model's emphasis on accountability for drug costs.
- The proposed PCOP model could provide an opportunity to test some alternative approaches relating to value-based oncology care, in addition to those in CMMI's OCM and potential Oncology Care First (OCF) Model. For example, instead of focusing solely on the period of chemotherapy treatment as OCM does, the proposed PCOP model seeks to be a "life-cycle-based" cancer model that also includes CMPs for newly diagnosed patients and those who are in the active monitoring phase.
- Additionally, the proposed PCOP model's Track 2 CPOC would hold hematology/oncology providers responsible for the quality and cost of hematology/oncology cancer services they have control over.
- The submitter has indicated that for implementation in the Medicare program, the performance methodology for the PIP weights participating practices' performance on quality metrics, clinical pathway adherence, and cost metrics equally. For non-Medicare payers, the PCOP communities would have flexibility to adjust the weighting of the performance metrics to meet collective stakeholder goals.
- There appears to be interest by other payers in the PCOP model. For example, the submitter indicates that it has engaged with Maryland to discuss the inclusion of PCOP under the state's Episode Quality Improvement Program (EQIP).

[26] The OMC Evaluation Report states reports OCM practices were larger, on average, than comparison practices (using Tax ID Numbers) or the broader national set of practices. See First Annual Report from the Oncology Care Model Evaluation, February, 2018, pp. 57-58

[27] ASCO PCOP: Quantitative Analyses for the PTAC Preliminary Review Team, 2020

Weaknesses:

- The CMS portfolio already includes an APM that addresses the proposal's clinical area (cancer) and target providers (hematology/oncology), specifically, the OCM. Although OCM ends in 2021, CMS is reportedly working on possible revisions of the model.
- CMMI has also been working on a proposed APM for hematology/oncology (OCF) and a proposed APM for radiation oncology (RO). Hematologist/oncologists can also participate in CMMI's Accountable Care Organization (ACO) models.
- Although the proposal included an option for PCOP communities to expand the covered services under Track 2, to potentially include some radiation and surgical oncology services, which could potentially foster cost savings, the submitter clarified that these services are not included in the proposal's savings estimates. Additionally, the submitter has stated that combining these specialties under a consolidated payment would require an additional component of an accountable care organization comprised of multiple specialties, which is not part of this proposed PCOP model.[28]
- The data management activities that are necessary for managing performance data governance and transparency would practically limit participation in the PCOP model to communities that already have in place, or are committed to developing, regional HIE and APCD capabilities – such as the 18 regions that are currently participating in the CPC+ model.
- It is also unclear to what extent other potential start-up costs associated with the proposed model may affect various communities' ability to garner greater private payer participation and attract more hematology/oncology participation in APMs – including costs associated with forming and supporting community-level OSCs, and paying for practices' CMPs and PIPs during the initial years of the model's operation.
- The proposed PCOP payment methodology seeks to make it more feasible for small and medium-sized hematology/oncology practices to participate, but the model's care delivery requirements and increased financial risk associated with Track 2 may still make it challenging for these types of practices to participate.
- The proposed structure and functions of the community-level OSCs may require consideration of potential issues related to the participation of competing providers and payers in determining oncology care payment.

Summary of Rating:

The PRT unanimously believes that the proposed PFPM does not meet the criterion. It is unclear how the proposed PCOP model would significantly broaden the CMS APM portfolio or increase opportunities for hematologist/oncologists to participate in an APM. While the PCOP could potentially provide an opportunity to test some innovative alternative approaches to value-based oncology care, certain aspects of the proposed model may limit

[28] Source: ASCO's 4-28-2020 response to Additional Questions Received from the Preliminary Review Team.

the potential number of communities, payers, and practices (particularly smaller practices) that may be able to participate.

Criterion 2. Quality and Cost (High Priority)

The proposal is anticipated to (1) improve health care quality at no additional cost, (2) maintain health care quality while decreasing cost, or (3) both improve health care quality and decrease cost.

PRT Qualitative Rating: Does Not Meet Criterion

Strengths:

- The proposed PCOP model, which builds on the OMH concept, emphasizes quality improvement through practice transformation and a community-wide, multi-payer, hematology/oncology care provider and stakeholder approach. The proposed model would allow some flexibility so that each PCOP community can address quality issues that are most salient to them, their local Medicare FFS, and other payer populations by selecting appropriate clinical pathways and metrics.
- The OMH concept, and other key care delivery requirements of the PCOP model, such as adherence to high-quality clinical pathways, have been shown to improve quality and safety and have the potential to reduce costs.
- The proposed model can potentially help to address existing issues relating to the quality of oncology care provided to Medicare FFS beneficiaries by improving adherence to high-quality evidence-based clinical pathways; improving and increasing consistency of care coordination requirements; and reducing variation and disparities in cancer treatment and outcomes by practice size, sociodemographic characteristics, and geography.
- The proposed model would require all participating practices to collect and analyze patient satisfaction data, and use this information in quality improvement activities.
- The proposed PCOP model includes financial incentives (PIPs for practices in Track 1 and Track 2, and a CPOC performance adjustment for practices in Track 2) that are related to quality and cost of care. Encouraging practices to focus on adherence to clinical pathways, adherence to quality metrics, and performance on cost-of-care metrics (e.g., emergency and observation care visits, unplanned hospital admissions, and supportive and maintenance care drug costs) could result in improvements in quality and reductions in cost.

Weaknesses:

- While the proposed PCOP model has the potential to improve quality, there could be variations in the model's impact on quality across the various PCOP communities because each OSC would have some discretion regarding the clinical pathways and performance metrics that it selects and, for non-Medicare payers, the weighting of the performance metrics.

- Track 2 of the model, in which hematology/oncology practices assume greater financial responsibility and risk, could potentially result in some stinting on care or the use of costly drugs despite adherence to clinical pathways and quality metrics.
- There is a risk that any quality improvements that are achieved under the PCOP model may not be offset by sufficient reductions in the TCOC to achieve neutral or net savings. For example, the proposed model includes start-up costs associated with operating the OSCs and making the CMP and PIP payments to participating practices during the initial years of operation. Additionally, the PCOP model's proposed CMP payment amounts for new patients and cancer treatment patients were at least double the 2017 mean payment amounts for E&M visits for oncology patients.
- The PCOP model assumes that savings related to reductions in inpatient admissions and ED and observation visits would eventually offset the cost of the CMPs and PIPs. However, over the past decade, the overall trend has been continued declines in the number and rate of inpatient hospitalizations for cancer patients. Although the submitter and recent trend data suggest that there may still be an opportunity to further reduce hospitalizations, as well as ED visits and observations stays, the potential reductions in these rates and associated TCOC may be smaller than assumed.
- There is emerging evidence from the most recent CMMI OCM Evaluation that care management payments are not resulting in reductions in significant net cost savings to Medicare. Although the OCM Evaluation found statistically significant reductions in aspects of hospital care (i.e., ICU stays) and ED visits,[29] it had no impact on the use of antiemetic (anti-nausea) therapy according to guidelines, ED visits, or hospitalizations for chemotherapy-associated complications, or the rate or timing of hospice initiation. The OCM Evaluation also found that there were no statistically significant effects on any category of Medicare expenditures or TCOC. Finally, recent analyses of Medicare beneficiaries with cancer in ACOs have found no evidence of reduced spending or utilization in this population – either overall, or at the end of life.[30]
- The potential savings achieved under the proposed PCOP model could also vary because the participating PCOP payers will have discretion in determining when practices transition to Track 2 – where there is more potential for cost savings because participants are at risk for 10 percent of the bundled amounts for CPOC service payments. Additionally, providers have been slow to accept risk in some other APMs.
- Programs, software, and tools necessary for hematology/oncology practices to meet the proposed model's care delivery requirements or for PCOP communities to develop the cost-of-care metrics that are necessary to implement the model may be proprietary or add burden and expense. For example, ASCO's QOPI® program and related registry and

[29] Patient-Centered Oncology Payment Model Environmental Scan, pp. 13-14; Abt Associates. Evaluation of the Oncology Care Model: Performance Period One. https://innovation.cms.gov/Files/reports/ocm-secondannualeval-pp1.pdf. Published December 2018. Accessed February 11, 2020.

[30] Source: Patient-Centered Oncology Payment Model Environmental Scan, page 11.

regional HIEs or APCDs may be proprietary or involve fees for participating practices and PCOP communities that could affect the proposed model's net impact on cost.

- In the absence of a new national OMH certification program,[31] local PCOP communities or payers could be responsible for assessing whether participating practices are meeting the proposed model's care delivery requirements.

Summary of Rating:

The PRT unanimously believes that the proposed PFPM does not meet the criterion. Although the proposed model has a potential to improve quality of care, there may not be sufficient reductions in TCOC to achieve no cost increase or net savings.

Criterion 3. Payment Methodology (High Priority)

Pay APM Entities with a payment methodology to achieve the goals of the PFPM Criteria. Addresses in detail through this methodology how Medicare, and other payers if applicable, pay APM Entities, how the payment methodology differs from current payment methodologies, and why the PFPM cannot be tested under current payment methodologies.

PRT Qualitative Rating: Does Not Meet Criterion

Strengths:

- The proposed payment model provides financial support for clinical practice transformation through CMPs, and also includes financial incentives related to quality and cost of care (through PIPs for practices in Track 1 and Track 2, and a CPOC performance adjustment for practices in Track 2).
- The proposed payment model's components — such as the use of CMPs and PIPs, and the proposed transition of participating practices from Track 1 to Track 2 after two years– are designed to facilitate transitioning hematology/oncology practices from FFS to more accountability and value-based payment.
- The submitter has indicated that for purposes of implementation in the Medicare program, the proposed PCOP model's performance methodology would weight participating practices' performance on quality metrics, cost metrics, and clinical pathway adherence equally. This feature of the proposed payment methodology may make it possible for more practices, particularly small to medium-sized ones, to participate because they have less financial risk due to common cause variation.
- Track 2 of the proposed PCOP model seeks to increase the potential for cost savings by introducing financial risk through CPOCs using a bundle that would be adjusted on a prospective basis based on performance, which would allow participating practices to know their expected revenue for the next period. Through the CPOC, participating practices would bundle 50 or 100 percent of their Medicare FFS payments for oncology-

[31] ASCO has indicated that it is working on a new OMH certification program with the COA, but it is not clear when this program will be available.

related professional services (i.e., evaluation and management, and care management) and drug administration and costs into the CMP. The practices would face up to 10 percent downside risk and 4 percent upside risk depending on their aggregate performance score. The prospective adjustment of the CPOCs could make participation in Track 2 of the PCOP model more attractive to practices than participation in models that make retrospective adjustments to revenue based on performance.

- Track 2 of the proposed PCOP model would test several alternative approaches that differ from CMMI's current OCM in two ways. First, OCM has no option for bundled payment akin to the CPOC. Second, OCM practices in the one-sided risk arrangement are not responsible for Medicare expenditures that exceed the target price.
- The inclusion of beneficiaries in the New Patient and Active Monitoring phases of care is another innovative aspect of the proposed PCOP model. By contrast, CMMI's OCM requires patients to be actively receiving chemotherapy or other oncology drug treatment. In the PCOP model, patients may be aligned and begin receiving care management to help them decide the best course of treatment (e.g., radiation or surgery before chemotherapy or vice versa) before chemotherapy begins and may also remain aligned to the model up to one year after their last chemotherapy treatment. This provides an incentive for participating providers to manage patient care before and after the administration of chemotherapy.

Weaknesses:

- Several of the features of the proposed model's payment methodology that have the greatest potential to reduce costs are either optional, or could be delayed. For example, although the proposal states that Track 1 practices would be required to accept the increased financial risk associated with participation in Track 2 after two years, the submitter has indicated that participating payers would have flexibility to decide whether to discontinue CMP and PIP payments to these practices or extend the deadline based on their own business interests.
- In the proposal, the submitter indicated the potential for inclusion of radiation and surgical oncology services under a consolidated payment, where potential savings could be garnered. However, the submitter clarified that such inclusion would only be feasible through an additional component of an accountable care organization comprised of multiple specialties, which is not part of this proposed PCOP model.[32] Meanwhile, it is unclear to what extent one of the PCOP model's other unique features, the inclusion of CMPs for active monitoring patients, will reduce costs.
- It is not clear that some aspects of the PCOP model are sufficiently different that they could not be tested under current CMMI models, particularly with regard to Track 1. For example, beneficiary alignment is ongoing in the PCOP model as long as a patient is being treated (with a 12-month limit for claiming the CMP for active monitoring patients); however, although the OCM is episodic, OCM patients can trigger new six-

[32] Source: ASCO's 4-28-2020 response to Additional Questions Received from the Preliminary Review Team.

month episodes if they are still receiving chemotherapy. Similarly, the PCOP model's New Patient and Cancer Treatment CMPs are similar to the OCM Monthly Enhanced Oncology Services (MEOS) payment, which is risk adjusted to factor in, among other things, whether a patient has received chemotherapy during the previous two years.

- PCOP's proposed community led, multi-payer, practice, and stakeholder model may be difficult to implement in practice. Prior multi-payer models such as CPC+ and SIM (state innovation models) had low participation from private payers, and OCM has 10 participating payers. Additionally, some aspects of the model's proposed collaboration between participating payers may raise potential legal issues that would need to be further explored.
- The flexibility for PCOP communities to vary the performance methodology weighting for non-Medicare payers may result in increased administrative complexity.
- The proposed PCOP CMP amounts for new patients and cancer treatment are two to three times higher than payments for current E&M services and also higher than OCM's MEOS payment, which is $160 per month and is typically guaranteed for the entire six months. The proposed PCOP CMPs are also not case-mix or risk-adjusted.
- Drug costs, which are included in the Track 1 PIP and Track 2 CPOC payments, may be very difficult to predict, which may make the proposed model challenging to implement and manage for PCOP communities and practices.
- The submitter has indicated that participating payers will have discretion relating to applying the incentives that are designed to encourage practices to transition to Track 2, including flexibility to extend the deadline. Without such a transition, the model's potential to reduce costs would be considerably reduced.
- The proposed cancer cohorts (A-D) used to group all cancers for purposes of all three payment components in the PCOP proposal may not be granular enough given the variation in treatment for various types of cancer, rapid changes in cancer treatment, and absence of clinical information in claims used to develop the cohorts.

Summary of Rating:

The PRT unanimously believes that the proposed PFPM does not meet the criterion. Although the proposed payment methodology includes some innovative components, some of the proposed model's features that have the greatest potential to reduce costs are optional; it is unclear to what extent the proposed model is likely to be able to achieve net savings; and it is not clear that some aspects of the proposed model could not be tested under current payment methodologies. Finally, some aspects of the proposed model, such as clinical pathways and the performance methodology weighting for non-Medicare payers, may vary by community and payer and could lead to disparate results.

Criterion 4. Value over Volume

The proposal is anticipated to provide incentives to practitioners to deliver high-quality health care.

PRT Qualitative Rating: Meets Criterion

Strengths:

- The PCOP model uses financial incentives to encourage participating hematology/oncology practices and physicians to deliver higher-value care. For example, the performance incentive payments are based on adherence to clinical treatment pathways, providing care consistent with quality standards, and accountability for cost-of-care metrics.
- The proposed model also uses non-financial incentives to encourage hematology/oncology practices and physicians to deliver higher-value care. These non-financial incentives include the OMH care model, which has been shown to improve quality, and the associated 22 care delivery requirements. For example, PCOP requires adherence to clinical pathways and care delivery requirements that include specific activities and services, as well as the patient safety standards.
- The PCOP model's proposed use of geographically-based, multi-payer stakeholder communities, led by OSCs, and use of clinical pathways could strengthen efforts to reduce disparities in care or address other unique needs of rural and urban communities.
- PCOP communities and practices advancing to Track 2 would have additional financial and non-financial incentives to deliver high-quality health care – including additional care coordination requirements, and having 10 percent of the bundled CPOC subject to a performance adjustment.

Weaknesses:

- Although the proposed model states that "practices that elect Track 1 are expected to advance to Track 2 within two years or else be subject to discontinuation of care management and performance incentive payments," the submitter has indicated that participating payers would have flexibility in determining whether to discontinue these payments, or extend the deadline for advancing to Track 2. This could potentially affect participating practices' incentives to deliver higher-value care.

Summary of Rating:

The PRT unanimously believes that the proposed PFPM meets the criterion. The proposed model includes financial and non-financial incentives to encourage participating practices to deliver higher-value care.

Criterion 5. Flexibility

Provide the flexibility needed for practitioners to deliver high-quality health care.

PRT Qualitative Rating: Meets Criterion

Strengths:

- The proposed model calls for the creation of PCOP communities comprised of multiple payers, employers, hematology/oncology practices, and other stakeholders in a geographic region, which would each be led by an OSC. The OSCs would select clinical pathways and quality measures that are most relevant to their patient populations. Each PCOP community would also have flexibility regarding a variety of other decisions relating to the model, such as which additional services should be included in the bundle for Track 2, whether and how to alter the performance methodology weighting for non-Medicare, and when to transition providers to Track 2. The community component of the PCOP model would support flexibility.
- The PCOP model's inclusion of Track 1 and Track 2 is designed to allow participating payers to meet practices where they are while engaging them in value-based care. For example, smaller and medium-sized practices, with less OMH capacity, or those with less experience with APMs may elect to participate in Track 1. Those that are larger, have more OMH capacity, and more experience with APMs may elect to participate in Track 2.
- The PCOP model emphasizes the use of and adherence to clinical pathways. However, the submitter has indicated that the proposed model would allow participating providers to justify off-pathway treatment by documenting the rationale in the pathway decision support system and/or medical record.

Weaknesses:

- The required adherence to clinical pathways may be somewhat restrictive to some of the model's participants. Although the submitter has noted that providers can select off-pathways treatment when appropriate and documented, to the extent that off-pathways treatments are included in the calculation of the measure for purposes of the model's payment methodology components (e.g., PIP and CPOC), there may be a potential for gaming the system, dropping patients who express a preference for off-pathway care or develop problems that require changes in care by providers.

Summary of Rating:

The PRT unanimously believes that the proposed PFPM meets the criterion. The proposed two-track model and the ability of the individual PCOP communities and their associated OSCs to make various decisions, such as selecting the clinical pathways and quality measures most relevant to their particular population, promotes flexibility at the community and practice participation levels.

Criterion 6. Ability to Be Evaluated

Have evaluable goals for quality of care, cost, and any other goals of the PFPM.

PRT Qualitative Rating: Does Not Meet the Criterion

Strengths:

- The proposed model could potentially serve a large number of Medicare beneficiaries, and it would be feasible to obtain claims data on these beneficiaries and a comparison group. If Medicare were the dominant payer participating in the model, this would allow for an evaluation that covers a significant portion of patients served in the model.
- The proposed model would require participating practices to submit data to regional HIEs and APCDs, which would potentially provide a rich set of data to inform the evaluation.

Weaknesses:

- ASCO's proposal would include individual PCOP communities that would each select their own clinical pathways and quality measures for measuring performance. Additionally, the submitter has indicated that the proposed model would give PCOP communities flexibility to change the performance measure weighting for non-Medicare payers. Without uniformity of measures and consistent weighting of performance metrics, evaluation of the model as a whole would be challenging.
- An independent evaluator would not be likely to get data from a comparison group on adherence to clinical pathways, as this data is not available in claims.
- There may not be a sufficient number of participants to evaluate the proposed model's impact on TCOC.
- The availability and sophistication of HIEs and APCDs vary by state, so not all participants will have sufficiently robust data from these sources to inform the evaluation.
- The proposed PCOP model is intended to be a multi-payer model, and it would potentially be challenging to obtain data for Medicaid and private payers.

Summary of Rating:

The PRT unanimously believes that the proposed PFPM does not meet the criterion. The challenges associated with conducting a comprehensive assessment of performance when individual participating PCOP communities are selecting their own measures for clinical pathways adherence and quality, the potential for differences in the weighting of performance measures for private payers, and obtaining sufficient numbers of practices to estimate impacts are likely to complicate the evaluation of the proposed model. The evaluation could also potentially be affected by insufficient data, including inconsistent reporting to HIEs and APCDs; the inability to obtain clinical pathways data from a comparison group; and uncertain access to clinical and claims data from private payers.

Criterion 7. Integration and Care Coordination

Encourage greater integration and care coordination among practitioners and across settings where multiple practitioners or settings are relevant to delivering care to the population treated under the PFPM.

PRT Qualitative Rating: Meets Criterion

Strengths:

- The proposed model encourages care coordination through its care delivery requirement for comprehensive team-based care. Track 1 and Track 2 include specific care delivery requirements that facilitate integration and care management.
- The proposed model would encourage the use of common, high-quality clinical pathways and quality metrics for all participating payers, which could also improve care coordination.
- The proposed model promotes community case conferences to bring together providers from multiple specialties, as well as researchers, to determine care plans.
- The monthly CMPs would help participating practices to invest in resources to support care management.

Weaknesses:

- PCOP communities would be free to develop their own methods for ensuring compliance with all care delivery standards, rather than using the Quality Oncology Practice Initiative (QOPI®) Certification Program as long as other methods do not violate the submitter's exclusive right to utilize the standards for a certification program. The submitter has also indicated that it is unaware of an equivalent certification program.[33]
- The submitter has indicated that many of the specific PCOP Care Delivery Requirements are in the public domain and can be used without restriction or cost. However, there are two or three care delivery requirement areas where practices may need to use proprietary pathways and standards that result in a cost to the practice, including:
    - Symptom management pathways/guidelines.
    - Quality Oncology Practice Initiative (QOPI®) safety standards for the administration of chemotherapy.
    - Evidence-based treatment pathways; measures and reports on physician compliance with pathways; and required documentation for off-pathway treatment.[34]
- The cost of these Care Delivery Requirement programs to participating hematology/oncology practices is difficult to estimate, because fees vary by the alternative chosen and other factors such size as practice size.[35]

[33] Source: ASCO's 4-28-2020 response to Additional Questions Received from the Preliminary Review Team.
[34] Source: ASCO's 4-28-2020 response to Additional Questions Received from the Preliminary Review Team.
[35] Source: ASCO's 4-28-2020 response to Additional Questions Received from the Preliminary Review Team.

- The PCOP model focuses on clinical pathways for hematology/oncology and chemotherapy related care. The submitter has indicated that PCOP is designed to address the services and phase of care managed by the medical oncologist. Therefore, while the model may promote more integration and care coordination among hematology/oncology care providers, the model does not provide incentives for greater integration and coordination across all oncology sub-specialties (including radiation and surgical oncology services).

Summary of Rating:

The PRT unanimously believes that the proposed PFPM meets the criterion. The proposal promotes greater integration and care coordination for hematology/oncology through team-based care and other participating practice care delivery requirements.

The potential requirement to use proprietary methods for ensuring compliance with care delivery standards or pathways and standards to meet some delivery requirements should be noted, however, as the Secretary has previously expressed concerns about the use of proprietary tools/materials. Additionally, developing an alternative to the Quality Oncology Practice Initiative (QOPI®) Certification Program and potentially related OMH certification program to ensure compliance with all care delivery standards, may be challenging and costly to communities.

Finally, there are limitations in the model's ability to promote integration and care coordination across oncology sub-specialties.

Criterion 8. Patient Choice

Encourage greater attention to the health of the population served while also supporting the unique needs and preference of individual patients.

PRT Qualitative Rating: Meets Criterion

Strengths:

- The proposed model includes a local community focus, allowing the PCOP communities' OSCs to select clinical pathways and quality metrics that can take into consideration the care needs of their specific patient populations.
- The PCOP model's clinical pathways criteria would consider efficacy, toxicity, and cost, in that order, in an effort to encourage value-based decision-making.[36]
- The proposed model's clinical pathway adherence benchmarks are set such that some individual providers and/or their patients can choose off-pathway care when necessary or preferred, such as when patients are in clinical trials, without undue or high risk of such a choice negatively impacting the practice's overall performance.

[36] Source: ASCO's 7-24-2020 Response to Questions Received from the Preliminary Review Team, specifically question 9.

- The proposal includes fielding patient satisfaction surveys, developing family advisory councils, and other mechanisms for enabling participating practices to get patient input.
- The optional ability for PCOP communities to develop an Oncology Research Collaborative to help to ensure equal access to clinical trials could also increase patient choice.

Weaknesses:

- There is concern in the oncology community that adherence to clinical pathways may inhibit the use of more expensive antineoplastic medications and could interfere with a patient-centered approach despite the ability for providers to deviate from the pathway as necessary to address individual patient needs.
- The proposal does not explicitly include use of shared decision-making tools or patient reported outcomes that may better support the unique needs and preferences of individual patients and the quality of care that they receive.
- If the proposed model's clinical pathway benchmark is set too low, or there are too many accepted reasons for off-pathway treatment, the proposed model may be less likely to hold providers accountable for delivering evidence-based care and achieving the intended quality improvement and cost reduction effects. In order to avoid these potential unintended consequences, the benchmark level and exemptions may need to be revisited and revised over time so that provider flexibility is better balanced with provider accountability for pathway adherence.

Summary of Rating:

The PRT unanimously believes that the proposed PFPM meets the criterion. The proposal's flexibility in allowing PCOP communities to select the clinical pathways and quality measures most relevant to their local populations supports patient choice. The clinical pathway adherence performance metric also is set at a level that would allow some individual providers and/or their patients to choose off-pathway care when necessary or preferred without undue or high risk of financial penalty to the practice, though it will be necessary to better balance provider and patient flexibility with provider accountability.

Criterion 9. Patient Safety

How well does the proposal aim to maintain or improve standards of patient safety?

PRT Qualitative Rating: Meets Criterion

Strengths:

- The proposal requires compliance with QOPI® safety standards for chemotherapy administration under its care delivery requirements. The standards were developed by ASCO and the Oncology Nursing Society and span four specified domains (related to creating a safe environment; treatment planning, patient consent, and education; ordering, preparing, dispensing, and administering chemotherapy; and monitoring after

chemotherapy is given). The submitter has indicated that these standards are open access and available to all practices via its website.

- The PCOP care delivery requirements include requirements related to comprehensive team-based care and safety.
- The proposed PIP utilizes robust quality measures and patient experience of care measures.

Weaknesses:

- The bundling of the value of Medicare FFS payments for oncology-related professional services and drug administration and costs under Track 2 would be subject to performance adjustments based on their aggregate performance score (relating to pathway compliance, quality of care, and cost-of-care). In spite of the PCOP model's care delivery requirements, this could raise concerns about the potential for stinting on necessary care.
- Because each PCOP community's OSC would have flexibility in selecting the quality metrics that would be measured for each performance period, ensuring patient safety within the proposed PCOP model assumes that the various OSCs would develop and select metrics that are safety-focused.

Summary of Rating:

The PRT unanimously believes that the proposed PFPM meets the criterion. The proposal includes requirements to adhere to QOPI® safety standards for chemotherapy, as well as other care delivery requirements. However, it will be important for participating PCOP communities to select quality metrics that are safety-focused in order to ensure that patients are receiving necessary care.

Criterion 10. Health Information Technology

Encourage use of health information technology to inform care.

PRT Qualitative Rating: Meets Criterion

Strengths:

- As part of the care delivery requirements, the PCOP model would require participating practices in Track 1 and Track 2 to use CEHRT.
- The PCOP model would also require practices to participate in regional HIE efforts, and payer submission of oncology claims to an APCD to facilitate information sharing.
- The submitter has noted that providers share data with multiple entities through a myriad of disjointed ways, creating significant administrative burden on providers to interchange with multiple entities, as well as limits on the availability of complete data sets for measurement and analysis of quality and cost. The proposed PCOP model may result in a shared, and more streamlined, approach that reduces practice burden and results in more complete data at the community level.

Weaknesses:

- The lack of interoperability across health information technology (HIT) systems and state-level differences in HIE and APCD requirements could complicate data sharing within the PCOP model.
- The data management activities that are necessary for managing performance data, governance, and transparency would practically limit participation in the PCOP model to communities that already have in place, or are committed to developing, regional HIE and APCD capabilities.
- Some information technology (IT), and related software and tools, are proprietary and would result in additional costs for participating communities and practices. ASCO has acknowledged that the QOPI® Reporting Registry costs $495 per provider per year to integrate with their practice's EHR systems. There may be additional interface or licensing fees depending on the EHR system.
- The PCOP model does not propose the collection and use of clinical data that complement claims data for the purpose of developing stronger APMs. While there is stated interest from CMS in models that can be developed and implemented using only claims data, timely collection of clinical data on a large enough sample of Medicare beneficiaries may be necessary for developing better cancer APMs.

Summary of Rating:

The PRT unanimously believes that the proposed PFPM meets the criterion. It promotes the implementation of CEHRT and meaningful information exchange across data sources, despite potential costs associated with required data management capabilities and potential limitations associated with the use of proprietary technology.

E. PRT Comments

The proposed PCOP model is a thoughtful response to the potential for and challenges of incorporating the principles of alternative payment models into cancer care delivery and payment. The PRT found a number of aspects of the proposal conceptually appealing, including:

- the community-level, multi-payer approach;
- the OMH care model, particularly efforts to improve quality and greater adherence to high-quality clinical pathways;
- a balanced performance payment methodology that provides financial incentives for adherence to clinical pathways, other quality and safety improvements, and targeted cost metrics (which may vary by payer);
- a "life cycle"-based approach to cancer care and related care management services, particularly the addition of New Patient and Active Monitoring phases that may result in greater adherence to clinical pathways and support for other key decisions before and after chemotherapy treatment; and

- The Track 2, which includes CMPs worth 3 percent of TCOC, a PIP up to 3 percent of TCOC, and a bundled CPOC payment for Medicare FFS professional and services and drug administration and costs, and their greater potential for cost savings relative to Track 1.

The PRT believes that these aspects of the proposed PCOP model represent potential improvements on the currently operational OCM and warrant consideration as other cancer models are developed. The submitter made strong arguments about the need for more local, multi-payer efforts; greater private payer participation; and a more balanced payment methodology that may allow more oncology practices, particularly smaller ones to participate. Additionally, a cancer model, and related CMPs, that addresses the entire care continuum (rather than just chemotherapy) while holding participating practices accountable for only quality and cost is appealing.

Despite the PRT's agreement with the submitter as to the potential attractiveness of these concepts, the PRT has significant concerns about several aspects of the proposed model. Most notably, the proposed model does not appear to meaningfully expand the portfolio of APMs available for the hematologist/oncologist. Core aspects of the model are similar to OCM, which is also undergoing potential revisions, and several other oncology-related CMMI models are in development (e.g., OCF). The PRT's other major concern is that while the model has the potential to improve quality, there may not be sufficient reductions in TCOC to achieve cost neutrality or savings. The proposed model includes start-up costs for the PCOP communities that have not been quantified, as well as proposed CMPs that are substantially higher than those in CMMI's OCM program, and gives participating payers discretion relating to applying the incentives that are designed to encourage practices to transition to Track 2, which has greater potential to reduce cost, and is optional. Additionally, it is unclear whether, and how, the participating hematology/oncology practices could further reduce current rates of inpatient admissions, ED visits, and observation stays to produce net savings.

We understand that CMMI is continually reviewing OCM for potential revision, and is reviewing the potential OCF model, as well as a proposed APM for radiation oncology. Preceded by Hackensack Meridian Health and Cota Inc.'s "Oncology Bundled Payment Program Using CNA-Guided Care" and Innovative Oncology Business Solutions Inc.'s "MASON—Making Accountable Sustainable Oncology Networks" proposals, the proposed PCOP model represents another thoughtful proposal that has been reviewed by PTAC relating to value-based oncology care. The submitter has thought carefully about several perceived weaknesses in OCM, and the proposed model would provide an opportunity to test some other alternative oncology care delivery and payment model approaches or features that seek to improve quality and hold costs neutral while making it more feasible for more hematology/oncology practices (including small to medium-sized ones) to participate in an APM, particularly through participation in Track 1.