

# Physician-Focused Payment Model Technical Advisory Committee

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November 19, 2020

Alex M. Azar II, Secretary

U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Azar:

On behalf of the Physician-Focused Payment Model Technical Advisory Committee (PTAC), I am pleased to submit PTAC's comments and recommendation to you on a physician-focused payment model (PFPM), *Patient-Centered Oncology Payment Model (PCOP)*, submitted by the American Society of Clinical Oncology (ASCO). These comments and recommendation are required by section 1868(c) of the Social Security Act, which directs PTAC to: 1) review PFPM models submitted to PTAC by individuals and stakeholder entities; 2) prepare comments and recommendations regarding whether such models meet criteria established by the Secretary of Health and Human Services (HHS); and 3) submit these comments and recommendations to the Secretary.

With the assistance of HHS' Office of the Assistant Secretary for Planning and Evaluation (ASPE), PTAC's members carefully reviewed the *PCOP* proposal (submitted to PTAC and found to have met the Committee's administrative requirements on January 14, 2020); additional information on the model, which was provided by the submitter in response to questions from a PTAC Preliminary Review Team; and other information. PTAC also reviewed supplemental information on the model provided by the submitter and considered issues in payment and care delivery, as well as relevant research findings. At a public meeting of PTAC held on September 15, 2020, the Committee deliberated on the extent to which this proposal meets the criteria established by the Secretary in regulations at 42 CFR §414.1465 and whether it should be recommended.

PTAC refers ASCO's proposal for other attention as specified in PTAC comments. Additionally, the Committee requests that the referral of this proposal be given high priority consideration by HHS due to the importance of the issues that are addressed in the proposal. The Committee finds that the proposal meets six of the Secretary's 10 criteria for PFPMs; the Committee finds that the proposal does not meet the other four criteria, including the three high-priority criteria of scope, quality and cost, and payment methodology.

Committee members believe that the proposed *PCOP* model includes a number of innovative features that would be beneficial for HHS to consider as new oncology care models are being developed. PTAC concludes that the proposed *PCOP* model, which seeks to transform cancer care delivery and reimbursement

while promoting high-quality, well-coordinated, and high-value cancer care, provides valuable mechanisms for addressing important issues in oncology care. The Committee agrees that the proposal addresses gaps in current cancer models by expanding the focus beyond the cost of cancer drugs, promoting adherence to clinical pathways that improve quality and reduce disparities, and facilitating engagement of more practices and payers through the development of geographically-based communities.

The Committee recognizes that one of the most crucial issues in oncology is to ensure that cancer care and decisions pertaining to drug therapies are driven by clinical indication and current best practices rather than drug costs. The proposed *PCOP* model presents a thoughtful approach to addressing this issue through its focus on adherence to evidence-based pathways, which are supported by the literature and could address disparities in care by reducing undertreatment. Additionally, the Committee acknowledges that the proposed *PCOP* communities provide a valuable framework for community engagement in care delivery. PTAC believes that the Oncology Steering Committees (OSCs), which provide oversight of *PCOP* communities, offer an opportunity for including multiple stakeholders, including employers, who have been underrepresented in multi-payer models to date. *PCOP* communities may enable the engagement of smaller practices and broaden the spectrum of participating providers and patients served. The Committee also agrees that holding providers accountable for costs and utilization beyond drug payments, such as emergency department visits, is a valuable contribution.

PTAC appreciates the framework and several elements of the *PCOP* proposal but shares some concerns about the model. First, the Committee concludes that *PCOP's* proposed cancer care delivery model and payment model do not expand the portfolio of alternative payment models (APMs) available to the hematologist/oncologist community, due to similarities with the Oncology Care Model (OCM) and requirements that may make it challenging for some communities and practices to participate. Secondly, the Committee believes that despite its potential, it is not clear that the proposed model would ultimately increase the participation of hematology/oncology practices in value-based care. Third, the Committee is concerned that there may not be sufficient reductions in total cost of care under the proposed *PCOP* model to achieve cost neutrality or net savings, because the features of the proposed model with the greatest potential to reduce costs are optional, and any savings may be offset by care management and performance incentive payments to practices. Finally, PTAC recognizes that without uniformity of measures and consistent weighting of performance metrics, quality may not be adequately captured, and evaluation of the proposed model as a whole would be challenging.

The members of PTAC appreciate your support of our shared goal of improving the Medicare program for both beneficiaries and the physicians who care for them. The Committee looks forward to your detailed response.

Sincerely,

//Jeffrey Bailet//

Jeffrey Bailet, MD

Chair

Attachments

# REPORT TO THE SECRETARY OF HEALTH AND HUMAN SERVICES

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Comments and Recommendation on  
*Patient-Centered Oncology Payment Model (PCOP)*

November 19, 2020

## **About This Report**

The Physician-Focused Payment Model Technical Advisory Committee (PTAC) was established by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to: 1) review physician-focused payment models (PFPMs) submitted by individuals and stakeholder entities; 2) prepare comments and recommendations regarding whether such models meet criteria established by the Secretary of Health and Human Services (HHS); and 3) submit these comments and recommendations to the Secretary. PTAC reviews submitted proposals using criteria established by the Secretary in regulations at 42 CFR §414.1465.

This report contains PTAC's comments and recommendation on the PFPM proposal *Patient-Centered Oncology Payment (PCOP) Model*. This report also includes: 1) a summary of PTAC's review of the proposal; 2) a summary of the proposed model; 3) PTAC's comments on the proposed model and its recommendation to the Secretary; and 4) PTAC's evaluation of the proposed PFPM against each of the Secretary's criteria for PFPMs. The appendices to this report include a record of the voting by PTAC on this proposal, the proposal submitted by the American Society for Clinical Oncology (ASCO), and additional information on the proposal submitted subsequent to the initial proposal submission.

## SUMMARY STATEMENT

PTAC refers ASCO's proposal for other attention as specified in PTAC comments. Additionally, the Committee requests that the referral of this proposal be given high priority consideration by the Secretary of Health and Human Services (HHS) due to the importance of the issues that are addressed in the proposal. The Committee finds that the proposal meets six of the Secretary's 10 criteria for physician-focused payment models (PFPMs); the Committee finds that the proposal does not meet the other four criteria, including the three high-priority criteria of scope, quality and cost, and payment methodology.

Committee members believe that the proposed *Patient-Centered Oncology Payment Model (PCOP)* includes a number of innovative features that would be beneficial for HHS to consider as new oncology care models are being developed. PTAC concludes that the proposed *PCOP* model, which seeks to transform cancer care delivery and reimbursement while promoting high-quality, well-coordinated, and high-value cancer care, provides valuable mechanisms for addressing important issues in oncology care. The Committee agrees that the proposal addresses gaps in current cancer models by expanding the focus beyond the cost of cancer drugs, promoting adherence to clinical pathways that improve quality and reduce disparities, and facilitating engagement of more practices and payers through the development of geographically-based communities.

The Committee recognizes that one of the most crucial issues in oncology is to ensure that cancer care and decisions pertaining to drug therapies are driven by clinical indication and current best practices rather than drug cost. The proposed *PCOP* model presents a thoughtful approach to addressing this issue through its focus on adherence to evidence-based pathways, which are supported by the literature and could address disparities in care by reducing undertreatment. Additionally, the Committee acknowledges that the proposed *PCOP* model provides a valuable framework for community engagement in care delivery. PTAC believes that the Oncology Steering Committees (OSCs), which provide oversight of such communities, offer an opportunity for including multiple stakeholders, including employers, who have been underrepresented in multi-payer models to date. *PCOP* communities may enable the engagement of smaller practices and broaden the spectrum of providers participating and patients served. The Committee also agrees that holding providers accountable for costs and utilization beyond drug payments, such as emergency department (ED) visits, is a valuable contribution.

PTAC appreciates the framework and several elements of *PCOP* but shares some concerns about the model. First, the Committee concludes that *PCOP's* proposed cancer care delivery model and payment model do not expand the portfolio of alternative payment models (APMs) available to the hematologist/oncologist community, due to similarities with the Oncology Care Model (OCM) and requirements that may make it challenging for some communities and

practices to participate. Secondly, the Committee believes that despite its potential, it is not clear that the proposed model would ultimately increase the participation of hematology/oncology<sup>1</sup> practices in value-based care. Third, the Committee is concerned that there may not be sufficient reductions in total cost of care under the proposed *PCOP* model to achieve cost neutrality or net savings, because the features of the proposed model with the greatest potential to reduce costs are optional, and any savings may be offset by care management and performance incentive payments to practices. Finally, PTAC recognizes that without uniformity of measures and consistent weighting of performance metrics, quality may not be adequately captured and evaluation of the proposed model as a whole would be challenging.

## **PTAC REVIEW OF THE PROPOSAL**

The *PCOP* proposal was submitted to PTAC and found to have met the Committee's administrative requirements on January 14, 2020. The proposal was first reviewed by a Preliminary Review Team (PRT) composed of three PTAC members (Jennifer Wiler, MD, MBA; Paul Casale, MD, MPH; and Charles DeShazer, MD). The PRT conducted its review of the proposal between February 2, 2020, and August 11, 2020. The proposal was also posted for public comment. The PRT's findings were documented in the PRT Report to PTAC on the *PCOP* proposal dated August 11, 2020, with an erratum published on August 21, 2020. The submitter provided a written response to the PRT Report on August 31, 2020. At a public meeting held on September 15, 2020, PTAC deliberated on the extent to which the proposal meets the criteria established by the Secretary in regulations at 42 CFR §414.1465 and whether it should be recommended to the Secretary for implementation.<sup>2</sup> The submitter and members of the public were given an opportunity to make statements to the Committee at the public meeting. Remaining sections of this report provide a summary of the proposal, PTAC's comments and recommendation to the Secretary on the proposal, and the results of PTAC's evaluation of the proposal using the Secretary's criteria for PFPMs.

## **PROPOSAL SUMMARY**

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

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<sup>1</sup> The terms hematology/oncology and hematologist/oncologist are used throughout this report and include medical oncology and hematologic oncology practices and physicians.

<sup>2</sup> PTAC member Kavita Patel, MD MSHS was not in attendance and recused herself from deliberation and voting on this proposal.

*Participating Communities.* The proposal calls for the creation of “PCOP communities” comprised of multiple payers, employers, hematology/oncology practices, and other stakeholders in a geographic region that could represent a single metropolitan area, a single state, or multiple states. Each PCOP community would be led by an OSC that would select high-quality clinical pathways, focusing on the use of chemotherapy/biologic therapy pathways,<sup>3</sup> 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 proposed 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 proposed *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 proposed *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 QOPI® program to efficiently collect, integrate, and report quality and cost metrics.<sup>4</sup> The submitter has also identified the states of Maine, Maryland, and Washington as promising communities for initial implementation of the proposed *PCOP* model due to their strong HIEs, APCDs, and regional health care improvement organizations.

Although the proposed *PCOP* model is designed to be multi-payer, the proposal does not specify a minimum threshold for the number of payers or covered patients participating, 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 APMs.

*Provider and Patient Eligibility.* The proposed *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

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<sup>3</sup> ASCO’s 7-24-2020 response to Questions Received from the Preliminary Review Team.

<sup>4</sup> ASCO’s 3-16-2020 response to Questions Received from the Preliminary Review Team.

participate. The practices would serve as the APM entity for purposes of provider assignment, patient and episode attribution, and performance measurement.

There are no restrictions on the type of oncology practices (e.g., free-standing, hospital-based) that can participate in the proposed *PCOP* model. However, the submitter notes that participants in the proposed 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 proposed model.<sup>5</sup>

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 that the submitter has grouped into four cohorts (A through D).<sup>6</sup> 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.<sup>7</sup> Patients would be eligible to participate in the proposed *PCOP* model as soon as they are diagnosed, during chemotherapy treatment, and up to 12 months after they complete their chemotherapy treatment.

*Payment Model.* The *PCOP* proposal includes two payment tracks ("Track 1" and "Track 2") for participating hematology/oncology practices and associated physicians, both with monthly payments and performance-based adjustments. Distinct from Track 1, Track 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 for their beneficiaries (i.e., "physician services, inpatient stays, diagnostics, provided drugs, and other claims received by Medicare," not specific to cancer diagnoses). Providers in Track 2 practices would receive 3 percent of TCOC.<sup>8</sup> 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

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<sup>5</sup> ASCO's 3-16-2020 response to Questions Received from the Preliminary Review Team.

<sup>6</sup> Additional details on the four cohorts are provided in Table 1 (page 5) in the PRT Report available at <https://aspe.hhs.gov/system/files/pdf/261881/PRTReportASCO.pdf>.

<sup>7</sup> ACCO's 7-24-2020 response to Questions Received from the Preliminary Review Team.

<sup>8</sup> ASCO Proposal, page 12, and ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically question 1.



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.<sup>9</sup>

Proposed *PCOP* provider payments would also include a Performance Incentive Payment (PIP) for meeting quality metrics, adhering to clinical pathways, and reducing cost-of-care. The Aggregate Performance Score (APS) would 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) would contribute equally to the APS, which would determine the PIP amount. However, the submitter has indicated that *PCOP* communities would have flexibility to adjust the weighting for non-Medicare payers.<sup>10</sup> Providers in Track 1 practices would be eligible for PIPs worth up to 2 percent of TCOC, and providers in Track 2 practices could receive up to 3 percent of TCOC.

Quality metric adherence would be based on criteria for a subset of six quality measures selected by the *PCOP* community's OSC. Clinical pathways are intended to ensure that patients receive appropriate care and that treatment decisions are not driven by motivations to undertreat and save money or overtreat and gain profit. Because clinical pathway adherence rates vary by cancer type, a provider's total adherence score would be weighted by the proportion of treatments by cancer type.<sup>11</sup> The cost-of-care portion of the performance methodology includes three utilization and spending metrics: unplanned acute care hospital admissions, unplanned emergency and observation care visits, and supportive and maintenance drug costs. National trends would be used to establish the benchmarks for the cost-of-care metrics and would be updated annually. Cost-of-care measures would 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.<sup>12</sup> 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.

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<sup>9</sup> ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team

<sup>10</sup> ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically questions 2b and 3a.

<sup>11</sup> ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically questions 9c-e and 2b.

<sup>12</sup> ASCO's 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically question 7a.

The proposal describes a potential timeline for implementation of the proposed five-year model, including a start-up year.<sup>13</sup> 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 could 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.<sup>14</sup> 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.<sup>15</sup> The proposal states that beginning in Year 3, model funding, including funding for the CMP and PIP amounts, would come from an agreed-upon percentage of savings that have been generated. Thus, funds available for the CMPs and PIPs could be positively or negatively adjusted depending on whether and how much savings have been generated.

While Track 1 practices would receive regular Medicare FFS payments plus the CMP, practices that elect Track 2 would participate in Consolidated Payments for Oncology Care (CPOC) that require them to elect to bundle either 50 percent or 100 percent of Medicare FFS payments for hematology/oncology-specific professional services, as well as drug costs.<sup>16</sup> The CPOC would vary by the specific segment of cancer care the patient falls into (New Patient, Cancer Treatment, or Active Monitoring), and would also be adjusted using the four proposed cancer cohorts (A-D). 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.<sup>17</sup>

The proposal states that practices that elect Track 1 would be 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

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<sup>13</sup> ASCO Proposal, pages 22-24.

<sup>14</sup> ASCO’s 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically question 5a

<sup>15</sup> ASCO’s 7-24-2020 response to Questions Received from the Preliminary Review Team, specifically question 5b.

<sup>16</sup> ASCO Proposal page 14.

<sup>17</sup> Additional details on the performance incentive payment measures and two-track payment model provisions are provided in Table 2 and Table 3 (pages 7-8 and 10-11) in the PRT Report available at <https://aspe.hhs.gov/system/files/pdf/261881/PRTReportASCO.pdf>.

in the proposed *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.<sup>18</sup>

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 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 Accountable Care Organization (ACO), which is not part of the proposed *PCOP* model.<sup>19</sup> The submitter has also stated that a community could potentially apply multiple models for cancer patients, including surgical episodes, radiation, and the proposed *PCOP* model. However, no additional details were provided; therefore, it is unclear how multiple models might work in a community.<sup>20</sup>

*Care Model.* The proposed care model builds on the OMH model concept that has been developed over the past decade. The proposed *PCOP* model, which was originally developed in 2015, features team-based care led by a hematologist/oncologist. Practices must meet 22 “*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 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.<sup>21</sup>

The submitter states that the *PCOP* proposal’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 Center for Medicare & Medicaid

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<sup>18</sup> 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.

<sup>19</sup> 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*.

<sup>20</sup> ASCO’s 7-24-2020 response to Additional Questions Received from the Preliminary Review Team, specifically question 10.

<sup>21</sup> Additional details on the care delivery requirements are provided in Table 4 (page 12) in the PRT Report available at <https://aspe.hhs.gov/system/files/pdf/261881/PRTReportASCO.pdf>.

Innovation's (CMMI's) OCM or private payer pilots may gravitate toward Track 1, as it would give them time to implement new practice transformations throughout the proposed model. Those who have already participated in CMMI's OCM or applied an OMH model may choose Track 2.<sup>22</sup>

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, which could be available by the end of 2020. As an alternative to certification, payer participants could conduct periodic audits to encourage practice compliance with requirements.<sup>23</sup>

*Data Management Requirements.* In order to implement the proposed model, PCOP communities would 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 would have to 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 would 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 APCD for oncology. All participating data contributors would be required to ensure that participating providers and payers would be given access to all available data for their patient populations and that aggregated performance data in all three categories would be shared publicly after reconciliation.

## **RECOMMENDATION AND COMMENTS TO THE SECRETARY**

PTAC refers ASCO's proposal for other attention as specified in PTAC comments. Additionally, the Committee requests that the referral of this proposal be given high-priority consideration by HHS due to the importance of the issues that are addressed in the proposal. PTAC commends the submitter for thoughtfully addressing one of the crucial issues in the current payment system and oncology care: avoiding undertreatment and overtreatment relating to chemotherapy treatment, by promoting high-quality, well-coordinated, and high-value cancer care. The Committee especially appreciates the proposed model's focus on adherence to evidence-based clinical pathways to ensure that cancer care and decisions pertaining to drug therapies are driven by clinical indication and current best practices rather than cost. The use of evidence-based pathways is supported by the literature and could help to address disparities in

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<sup>22</sup> ASCO's 7-24-2020 Response to Questions Received from the Preliminary Review Team, specifically question 8.

<sup>23</sup> ASCO's 3-16-2020 response to Questions Received from the Preliminary Review Team.

care by reducing undertreatment. The Committee also notes the importance of promoting flexibility to reevaluate the clinical pathways to ensure that they are consistent with the most recent clinical innovations. Additionally, the Committee believes that the proposed *PCOP* model provides a valuable framework for community engagement in care delivery through the use of PCOP communities. The OSCs that would provide oversight of those communities would offer an opportunity for including multiple stakeholders, including employers, who have been underrepresented in multi-payer models to date. The PCOP communities and other aspects of the proposed model may facilitate the engagement of smaller practices and broaden the spectrum of providers participating and patients served. For example, the Committee believes that the *PCOP* proposal's emphasis on holding participating practices responsible for the costs and utilization over which they have the most control, including ED visits and supportive drug costs, may be attractive to providers. Committee members also believe that the data-sharing infrastructure that would be developed to support the calculation of the proposed model's payment methodology (including the calculation of the performance incentive payments) could also be beneficial for future payment models.

However, PTAC believes that the proposal as written has weaknesses that will limit its ability to achieve the proposed model's objectives as described by the submitter. Core aspects of the proposed model are similar to the OCM and other oncology-related CMMI models in development (e.g., Oncology Care First [OCF]). Therefore, while it includes innovative features, the *PCOP* proposal does not expand the portfolio of APMs available to the hematologist/oncologist community and does not encourage integration with the larger "medical neighborhood" of other oncologists (such as radiation and surgical oncologists). Additionally, certain aspects of the proposed model – most notably the data-sharing requirements – may limit the potential number of communities, payers, and practices that may be able to participate.

The Committee also believes that although the proposed model has the potential to improve quality of care, there may not be sufficient reductions in total cost of care to achieve cost neutrality or produce net savings. Additionally, there could be variations in the proposed model's impact on quality across the various PCOP communities. For example, there is a risk that quality measures and clinical pathway adherence may "top out," and no guarantee that PCOP communities would replace these measures to ensure continuous quality improvement. It is unclear whether, and how, the participating hematology/oncology practices could further reduce current rates of inpatient admissions, ED visits and observation stays, and drug costs to offset the costs of the CMPs and PIPs. The most recent evaluation of OCM covering its first two years found no statistically significant declines in total episode payments (TEPs), and the combined Monthly Enhanced Oncology Services (MEOS) payment and Performance-Based Payment (PBP) were greater than the small overall reduction in TEP, resulting in net losses to Medicare. The *PCOP* proposal provides a glide path that is designed to encourage more

hematology/oncology practices to participate in value-based care models requiring increased financial risk, such as exists in Track 2. However, it is not evident that the proposed model would ensure a guaranteed transition to Track 2, which has the greatest potential for achieving cost-savings, since it could potentially be optional or delayed.

Finally, PTAC recognizes that, without uniformity of quality measures and pathways or consistent weighting of performance metrics, evaluation of the proposed *PCOP* model as a whole would be challenging. The ability to evaluate the proposed model would also be complicated if providers in the comparison group are not participating in HIEs or APCDs, or tracking data on adherence to clinical pathways.

In spite of the proposed model's shortcomings, Committee members believe that the *PCOP* model includes a number of innovative features that would be beneficial for HHS to consider as new oncology care models are being developed. In particular, PTAC wishes to highlight the proposal's use of value-based clinical pathways as a potential way of addressing quality and cost, as well as addressing undertreatment and disparities; the expansion of the definition of drug costs to also include Part D drugs; the emphasis on costs that participating practices can control; the use of multi-stakeholder *PCOP* communities and OSCs as a way of increasing community engagement; and the potential benefits of building the proposed data-sharing infrastructure for the implementation of additional APMs in the future.

## EVALUATION OF PROPOSAL USING SECRETARY’S CRITERIA

### PTAC Rating of Proposal by Secretarial Criteria

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

#### Criterion 1. Scope (High-Priority Criterion)

*Aim 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.*

#### Rating: Does Not Meet Criterion

PTAC concludes that the proposed model does not meet this criterion. While the proposal seeks to provide a comprehensive and innovative approach to delivering and paying for high-quality cancer care, which is an important clinical area for the Medicare program, it is unclear how the proposed *PCOP* model would significantly broaden the Centers for Medicare & Medicaid Services (CMS) APM portfolio available to the hematologist/oncologist community due to its similarities with OCM and new CMMI models in development (e.g., OCF). Additionally, certain aspects of the proposed model may limit the potential number of communities, payers, and practices (particularly smaller practices) that may be able to participate, and could complicate the integration of the model into larger health care systems. However, the Committee believes that the proposed *PCOP* model’s proposed inclusion of a multi-stakeholder group (e.g., the *PCOP* communities and OSC) as a key component of the proposed model emphasizes the value of community engagement in care delivery models and warrants further exploration.

The proposed *PCOP* model could potentially provide an opportunity to test some innovative alternative approaches to value-based oncology care. For example, the proposed 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 *PCOP* proposal presents a valuable model for community engagement in care delivery, and the proposed OSCs provide an opportunity for including multiple stakeholders, such as employers, who have not been represented in multi-payer models to date. While there may be potential challenges associated with creating such entities, the Committee believes that the OSC concept deserves potential consideration by CMS as it explores new multi-payer models.

Some of the proposed model's other innovative features include its "life-cycle-based" approach to cancer care, providing CMPs for patients in the Cancer Treatment phase, as well as New Patients and patients in the Active Monitoring phase; performance-based adjustments for Track 2 CPOC would hold hematology/oncology providers responsible for the quality and cost of services that they have control over. The proposed model also builds on the OMH model concept, and the submitter is working with the COA to update the certification standards for providing team-based oncology care.

The proposed *PCOP* model also has the potential to expand medical and hematology oncologists' opportunity to participate in an APM, including small practices. Approximately 5 percent<sup>24</sup> of the nation's hematology/oncology practices participate in CMMI's OCM, and those participating practices are relatively large.<sup>25</sup> Small practices, such as those with fewer than six medical and hematology oncologists, treat three-quarters of Medicare FFS beneficiaries<sup>26</sup> and may be more willing and able to participate in the proposed *PCOP* model due to its inclusion of features that are designed to increase participation, such as stakeholder participation in the OSCs and community-specific flexibility in the selection of clinical pathways and metrics. Additionally, the proposed model's two tracks are 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

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<sup>24</sup> 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 that was prepared for the ASCO PRT (available at <https://aspe.hhs.gov/system/files/pdf/226776/PRTDataRequestASCO.PDF>), 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.

<sup>25</sup> The OCM Evaluation Report states that 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.

<sup>26</sup> ASCO *PCOP*: Quantitative Analyses for the PTAC Preliminary Review Team, 2020. Accessed here: <https://aspe.hhs.gov/system/files/pdf/226776/PRTDataRequestASCO.PDF>.



participate in Track 1, while practices that are larger or have more OMH capacity and more experience with APMs may elect to participate in Track 2.

However, the CMS portfolio already includes an APM that addresses the proposal's clinical area (cancer) and target providers (hematology/oncology), the OCM. The proposed *PCOP* model has some similarities with CMMI's OCM, which is scheduled to end in June 2022,<sup>27</sup> and CMS is reportedly working on possible revisions to the model. Additionally, the proposed *PCOP* model's focus on the high cost of cancer drug therapies, and its inclusion of supportive and maintenance care drug costs as a performance metric, are consistent with CMMI's potential Oncology Care First Model's emphasis on accountability for drug costs. Committee members also express a concern regarding whether the proposed *PCOP* model could be appropriately integrated with the larger "medical neighborhood" of other oncologists involved in care coordination (such as radiation and surgical oncologists), and whether the proposed model's payment methodology would encourage innovation. The submitter has stated that participation in Track 2 will provide additional opportunities for participating practices to innovate by developing additional strategies that could potentially help to reduce ED utilization (such as psycho-oncology, palliative care, or urgent care after-hours programs).

Although the proposed model could encourage the engagement of smaller practices, there may still be obstacles that could inhibit their adoption of the model, such as incurring start-up costs associated with establishing *PCOP* communities and OSCs and paying practices' CMP and PIP amounts during the initial years; meeting the model's care delivery requirements (including potentially paying licensing fees); building data-sharing capacity; and taking the additional financial risk associated with Track 2.

Additionally, the data management activities that are necessary for managing performance data governance and transparency would practically limit participation in the proposed *PCOP* model to communities that already have in place, or are committed to developing, regional HIE and APCD capacities – such as the 18 regions that are currently participating in the CPC+ model. In light of the difficulties associated with implementing HIEs and APCDs, and developing trust, collaboration, and support between stakeholders (including payers and providers) for increased data-sharing, the submitter was unable to provide an estimate of the amount of time that it would potentially take for a community to develop these capabilities.

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<sup>27</sup> For more information about these similarities, see the comparison table that was prepared for the PRT, which can be accessed at <https://aspe.hhs.gov/system/files/pdf/226776/AddlInformationorAnalysesASCO.PDF>.

## Criterion 2. Quality and Cost (High-Priority Criterion)

*Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.*

### Rating: Does Not Meet Criterion

PTAC concludes that the proposed model does not meet this criterion. Although the proposed model has a potential to improve quality of cancer care, there may not be sufficient reductions in TCOC to achieve cost neutrality or net savings. Additionally, there could be variations in the proposed model's impact on quality across the various PCOP communities.

The proposed *PCOP* model could help to address existing issues relating to the quality of oncology care by improving adherence to high-quality evidence-based clinical pathways; improving and increasing the consistency of care coordination requirements; and reducing variation and disparities in cancer treatment and outcomes by enabling greater access to services regardless of practice size, sociodemographic characteristics, and geography. The proposed *PCOP* model, which builds on the OMH concept, emphasizes quality improvement through practice transformation and would allow some flexibility so that each PCOP community can address quality issues that are most salient to them through the selection of quality metrics and clinical pathways. The OMH concept and the proposed model's care delivery requirements, including adherence to safety standards and its high-quality clinical pathways, have been shown to improve quality and safety and have the potential to reduce costs. The proposed model would also require participating practices to collect and analyze patient satisfaction data, and use this information in quality improvement activities.

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 quality metrics that it selects. Additionally, while the proposed model includes financial incentives that are related to performance on quality metrics and clinical pathway adherence (which would affect PIPs for practices in Track 1 and Track 2 and the CPOC performance adjustment for practices in Track 2), each OSC would have some discretion regarding the weighting of the performance metrics for non-Medicare payers. There is a lack of specificity and standardization in how clinical pathway adherence and quality metrics are measured and evaluated, and how this might impact quality improvement in the proposed model. The submitter has acknowledged that due to the proposed model's quartile scoring methodology for quality metrics and clinical pathway adherence, there is a risk of having "topped out" measures in which the majority of participating practices score 100 percent. In this case, each OSC would have discretion regarding whether to select new measures or to continue scoring the participating practices at 100 percent, which could adversely affect future quality improvement.

There is a risk that any quality improvements that are achieved under the proposed model may not correspond with sufficient reductions in TCOC to achieve net savings or cost neutrality. 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. Although the submitter and recent trend data suggest that there may still be an opportunity to further reduce hospitalizations, ED visits, and observation stays, the potential reductions in these rates and associated TCOC may be smaller than assumed and insufficient to offset implementation costs. Additionally, the *PCOP* model's proposed CMP payment amounts for New Patients and Cancer Treatment payments were at least double the 2017 mean payment amounts for E&M visits for oncology patients.

There is emerging evidence from recent CMMI OCM evaluations that care management payments are not resulting in significant reductions in Medicare expenditures or TCOC, or in net cost savings to Medicare. The most recent CMMI OCM evaluation of the first two years of the program found no statistically significant reductions in cost, and found that when MEOS payments were included, the program produced net losses to Medicare.<sup>28</sup>

### Criterion 3. Payment Methodology (High-Priority Criterion)

*Pay APM Entities with a payment methodology designed 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.*

#### Rating: Does Not Meet Criterion

PTAC concludes that the proposed model does not meet this criterion. While the proposed model includes some innovative components, some of the proposed model's features that have the greatest potential to reduce costs are optional. It is also 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 model could not be tested under current payment methodologies. The *PCOP* proposal provides a glide path that is designed to encourage more hematology/oncology practices to participate in value-based care models requiring increased financial risk, such as exists in Track 2. However, it is not evident that the proposed model would ensure a guaranteed transition to Track 2, which has the greatest potential for achieving cost-savings, since it could potentially be optional or delayed.

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<sup>28</sup> Abt Associates. Evaluation of the Oncology Care Model: Performance Periods 1-3. <https://innovation.cms.gov/data-and-reports/2020/ocm-evaluation-annual-report-2>. Published May 2020. Accessed October 2020.

The proposed payment methodology includes several innovative components, including opportunities to test several alternative approaches that differ from CMMI's current OCM. The proposed *PCOP* model would provide financial support for clinical practice transformation through CMPs for practices in Track 1 and Track 2 for patients who are receiving chemotherapy treatment, as well as those who are newly diagnosed patients and those who are in the Active Monitoring phase. The proposed *PCOP* model would also provide an opportunity for participating practices to receive bundled payments in Track 2 through CPOC that bundle 50 percent or 100 percent of Medicare FFS payments for hematology/oncology-specific professional services and drug costs, and financial incentives related to quality and cost-of-care (through monthly PIPs for practices in Track 1 and Track 2, and a CPOC performance adjustment for practices in Track 2). These components are designed to facilitate transitioning more hematology/oncology practices from FFS to more accountability and value-based payment. For example, Track 2 of the proposed model seeks to increase the potential for cost savings by introducing financial risk through the CPOC, using a bundle that would be adjusted prospectively based on performance, which would allow participating practices to know their expected revenue for the next period. Participating practices would face up to 10 percent downside risk and 4 percent upside risk of previous Medicare FFS amounts, depending on their aggregate performance score.

In addition to the required use of clinical pathways to ensure clinically-relevant treatment regimens, as opposed to an approach that is primarily focused on costs, another innovative feature of the *PCOP* proposed model relates to its inclusion of both Medicare Part B and Part D drugs in its definition of total cost of care, which helps to reduce incentives to use a more expensive Part D drug in place of a less expensive Part B drug. Additionally, the proposed model's focus on supportive drug costs could help to ensure that the most appropriate drug is used, and reduce unnecessary spending.

Additionally, the submitter has indicated that for purposes of participation in the Medicare program, the proposed model would also weight participating practices' performance on quality metrics, cost-of-care metrics, and clinical pathway adherence equally. This may make it easier for more practices, particularly small to medium-sized ones, to participate because they would have less financial risk due to common cause variation.

However, several features of the proposed model 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

has clarified that such inclusion would be feasible only through an additional component of an ACO comprised of multiple specialties, which is not part of this proposed *PCOP* model.

Drug costs, which are included in the cost metrics that affect Track 1 and Track 2 monthly PIP payments, as well as in the Track 2 CPOC and the cost metrics that affect the CPOC performance-based adjustment, may be very difficult to predict, which may make the proposed model challenging to implement and manage. The proposed *PCOP* CMP amounts for New Patients and Cancer Treatment are two to three times higher than payments for current E&M services, are also higher than the OCM's MEOS payment, and would not be case-mix- or risk-adjusted.

Finally, some aspects of the proposed payment model, such as determinations related to adherence to clinical pathways and the performance methodology weighting for non-Medicare payers, may vary by *PCOP* community and payer and could lead to disparate results. Additionally, *PCOP*'s proposed community-led, multi-payer, multi-stakeholder model may be difficult to implement in practice, and some aspects of the model's proposed collaboration between participating payers may raise potential legal issues that would need to be further explored.

#### Criterion 4. Value over Volume

*Provide incentives to practitioners to deliver high-quality health care.*

#### **Rating: Meets Criterion**

PTAC concludes that the proposed model meets this criterion. The proposed model includes financial and non-financial incentives to encourage participating hematology/oncology practices to deliver higher-value care.

For example, the proposed model's monthly PIP payments (Track 1 and Track 2) are based on adherence to clinical treatment pathways, providing care consistent with quality standards, and accountability for cost-of-care metrics. The proposed model's non-financial incentives include the use of the OMH care model, which has been shown to improve quality, and the associated 22 *PCOP* care delivery requirements. For example, the *PCOP* proposal requires adherence to clinical pathways and care delivery requirements that include specific activities and services related to encouraging the provision of value-based care, as well as the QOPI® patient safety standards.

The proposed model's 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. Additionally, *PCOP* communities and practices advancing to Track 2 would have additional financial incentives to deliver high-

quality health care, having 10 percent of the bundled CPOC subject to a performance-based adjustment, along with additional care coordination requirements.

However, although the proposed model states that “practices that elect Track 1 are expected to advance to Track 2 within two years,” the submitter has indicated that participating payers would have flexibility in determining whether to discontinue CMP and PIP payments, or extend the deadline for advancing to Track 2. This could potentially affect participating practices’ incentives to deliver higher-value care.

## Criterion 5. Flexibility

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

### Rating: Meets Criterion

PTAC concludes that the proposed model meets this 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, promote flexibility at the community and practice participation levels.

The proposed model calls for the creation of geographically-based PCOP communities that are comprised of multiple stakeholders, which would each be led by an OSC that would select clinical pathways and quality measures that are most relevant to their patient populations, and have flexibility regarding a variety of other decisions relating to the model. The proposed 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. While the proposed model emphasizes the use of clinical pathways, the submitter has indicated that it would allow participating providers to justify off-pathway treatment.

However, the required adherence to clinical pathways may be somewhat restrictive to some of the proposed model’s participants to the extent that off-pathway treatments are included in the calculation of clinical pathway adherence measures for purposes of the model’s payment components (e.g., monthly PIP payments and CPOC). There may be a potential for unintended consequences related to dropping patients who express a preference for off-pathway care or develop problems that require changes in care by providers. The submitter has indicated that the proposed model would allow participating providers to justify off-pathway treatment, with an estimate that 10 to 30 percent of patients may go off-pathway depending on a range of clinical or patient preferences. However, it is unclear what oversight mechanisms would serve to monitor and ensure appropriateness of off-pathway decision-making.

## Criterion 6. Ability to Be Evaluated

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

### Rating: Does Not Meet Criterion

PTAC concludes that the proposed model does not meet this criterion. 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. Additionally, the proposed model would require participating practices to submit data to regional HIEs and APCDs, which would potentially provide a rich set of data. However, 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 are likely to complicate the evaluation of the proposed model. Additionally, the potential for differences in the weighting of performance measures for non-Medicare payers, and the risk of not obtaining sufficient numbers of practices to estimate impacts could impede the evaluation.

The evaluation could also potentially be affected by insufficient data, including availability and sophistication of HIEs and APCDs by state; 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 Medicaid and private payers. Without uniformity of measures and consistent weights of performance metrics across PCOP communities, evaluation of the proposed model as a whole would be challenging.

## 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.*

### Rating: Meets Criterion

PTAC concludes that the proposed model meets this criterion. The proposal promotes greater integration and care coordination for hematology/oncology through its care delivery requirement for comprehensive team-based care and other participating practice 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's monthly CMPs would help participating practices to invest in care management resources.

However, while the submitter has indicated that many of the proposed model's specific PCOP Care Delivery Requirements are in the public domain and can be used without restriction or cost, there are two or three areas where participating practices may need to use proprietary

pathways and standards that result in a cost to the practice (e.g., symptom management pathways/guidelines and QOPI® safety standards for the administration of chemotherapy). 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, as the Secretary has previously expressed concerns about the use of proprietary tools/materials. While PCOP communities would be free to develop their own methods for ensuring compliance with all of the proposed model's care delivery standards, developing an alternative to the QOPI® Certification Program and potentially related OMH certification program to ensure compliance with all care delivery standards, may be challenging and costly to PCOP communities.

Finally, while the proposed model may promote integration and care coordination among hematology/oncology care providers, the model as currently written does not provide incentives for greater integration and care coordination across all oncology sub-specialties (including radiation and surgical oncology services) because its primary focus is on hematology/oncology.

#### Criterion 8. Patient Choice

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

#### **Rating: Meets Criterion**

PTAC concludes that the proposed model meets this criterion. The proposal's flexibility in allowing PCOP communities' OSCs to select the clinical pathways and quality measures most relevant to the care needs of their local patient populations supports patient choice. The proposed model's clinical pathways requirement would consider efficacy, toxicity, and cost in that order, in an effort to encourage value-based decision-making. The proposed model's clinical pathway adherence performance metric is also 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. The proposed model also includes fielding patient satisfaction surveys, developing family advisory councils, and providing other mechanisms for getting patient input.

There remains a 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. However, the submitter has indicated that there are several successful commercial clinical pathways companies, and the best-designed evidence-based clinical pathways incorporate information about emerging evidence. The Committee emphasizes the importance of evolving and flexible pathways, which can remain open to innovations in care and technology, and improve patient choice.



Additionally, the proposed model does not explicitly include use of shared decision-making tools or patient-reported outcomes that may better address the unique needs and preferences of individual patients and the quality of care that they receive. Finally, there may be a need to monitor the proposed model's clinical pathway benchmark thresholds and exemptions to ensure that there is an appropriate balance between provider flexibility and accountability for pathway adherence. If the 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 achieve the intended quality improvement and cost reduction effects. The submitter has indicated that depending on the clinical pathway, average adherence may range from 70 to 90 percent, depending on the degree of flexibility or choice in a given pathway, while the remaining 10 to 30 percent of patients may go off-pathway depending on a range of clinical or patient preferences. In order to avoid potential unintended consequences, the benchmark level and exemptions may need to be revisited and revised over time.

## Criterion 9. Patient Safety

*Aim to maintain or improve standards of patient safety.*

### Rating: Meets Criterion

PTAC concludes that the proposed model meets this criterion. The proposal includes requirements to adhere to QOPI® safety standards for chemotherapy administration under its care delivery requirements. These 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 indicated that these standards are open access and available to all practices via its website. The proposed PCOP model also includes care delivery requirements related to comprehensive team-based care and safety.

PTAC believes that the proposed model's emphasis on the use of evidence-based clinical treatment pathways that specify what treatments are appropriate based on both effectiveness and cost can provide protections against stinting of treatment and disparities in care. The proposed PCOP model also includes financial incentives that ensure that participating practices' performance on clinical pathway adherence affects a portion of their monthly PIP payments (Track 1 and Track 2) and the CPOC (Track 2). The proposed model's use of evidence-based medicine through the use of evidence-based clinical treatment pathways that consider individual patient characteristics and molecular subtype can help to ensure that cancer care and treatment are neither stinted on nor a source of excessive profit, and therefore help to prevent overtreatment or undertreatment in vulnerable populations.

However, it is important to note that each PCOP community's OSC would have flexibility in selecting the evidence-based clinical pathways that would be used for its population. Additionally, since each PCOP community's OSC would have flexibility in selecting the quality metrics that will be measured for each performance period, it will be important for each OSC to select quality metrics that are safety-focused in order to ensure that patients are receiving necessary care. Additionally, the bundling of the value of Medicare FFS payment for oncology-related professional services and drug costs under Track 2 would be subject to performance adjustments based on the aggregate performance score (relating to equally weighted scores for pathway compliance, quality of care, and cost-of-care), which might raise concerns about the potential for stinting on necessary care.

## Criterion 10. Health Information Technology

*Encourage use of health information technology to inform care.*

### Rating: Meets Criterion

PTAC concludes that the proposed model meets this criterion. The proposed model's data management requirements relating to the use of CEHRT in Track 1 and Track 2, participation in regional HIE efforts, and payer submission of oncology claims to APCDs may result in a more streamlined approach to data-sharing that reduces burden on providers, and results in more complete data sets for measurement and evaluation at the community level.

However, 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 proposed model. Additionally, the data management activities that are necessary for managing performance data, governance, and transparency would practically limit participation in the proposed model to communities with robust HIEs and APCDs. Moreover, some IT and related software and tools are proprietary and would result in additional costs for participating communities and practices.<sup>29</sup> In spite of these potential challenges, PTAC believes that the PCOP model's proposal to establish the infrastructure to promote meaningful information exchange across data sources could also be beneficial for future payment models.

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<sup>29</sup> 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.

## APPENDIX 1. COMMITTEE MEMBERS AND TERMS

**Jeffrey Bailet, MD, Chair**

**Grace Terrell, MD, MMM, Vice Chair**

Term Expires October 2020

**Grace Terrell, MD, MMM**

*Eventus WholeHealth*

Concord, NC

Term Expires October 2021

**Jeffrey Bailet, MD**

*Altais*

San Francisco, CA

**Kavita Patel, MD, MSHS**

*Johns Hopkins Health System*

Baltimore, MD

**Angelo Sinopoli, MD**

*Prisma Health*

Greenville, SC

**Jennifer Wiler, MD, MBA**

*UHealth and University of*

*Colorado School of Medicine*

Aurora, CO

Term Expires October 2022

**Paul N. Casale, MD, MPH**

*NewYork Quality Care*

*NewYork-Presbyterian, Columbia University College of*

*Physicians and Surgeons, Weill Cornell Medicine*

New York, NY

**Bruce Steinwald, MBA**

*Independent Consultant*

Washington, DC

Term Expires October 2023

**Jay S. Feldstein, DO**

*Philadelphia College of Osteopathic Medicine*

Philadelphia, PA

**Joshua M. Liao, MD, MSc**

*University of Washington School of*

*Medicine*

Seattle, WA

**Lauran Hardin, MSN, FAAN**

*National Center for Complex Health and Social Needs,*

*Camden Coalition of Healthcare Providers*

Camden, NJ

## APPENDIX 2. PFPM CRITERIA ESTABLISHED BY THE SECRETARY

### PFPM CRITERIA ESTABLISHED BY THE SECRETARY

- 1. Scope.** Aim 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.
- 2. Quality and Cost.** Are anticipated to improve health care quality at no additional cost, maintain health care quality while decreasing cost, or both improve health care quality and decrease cost.
- 3. Payment Methodology.** Pay APM Entities with a payment methodology designed 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 Physician-Focused Payment Model cannot be tested under current payment methodologies.
- 4. Value over Volume.** Provide incentives to practitioners to deliver high-quality health care.
- 5. Flexibility.** Provide the flexibility needed for practitioners to deliver high-quality health care.
- 6. Ability to Be Evaluated.** Have evaluable goals for quality of care, cost, and any other goals of the PFPM.
- 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.
- 8. Patient Choice.** Encourage greater attention to the health of the population served while also supporting the unique needs and preferences of individual patients.
- 9. Patient Safety.** Aim to maintain or improve standards of patient safety.
- 10. Health Information Technology.** Encourage use of health information technology to inform care.

**APPENDIX 3. DISTRIBUTION OF MEMBER VOTES ON EXTENT TO WHICH PROPOSAL MEETS CRITERIA<sup>30 31</sup>**

Criteria Specified by the Secretary (at 42 CFR §414.1465)	Not Applicable	Does Not Meet Criterion		Meets Criterion		Priority Consideration		Rating
	*	1	2	3	4	5	6	
1. Scope (High Priority)	0	0	5	3	0	1	0	Does Not Meet Criterion
2. Quality and Cost (High Priority)	0	0	6	2	0	1	0	Does Not Meet Criterion
3. Payment Methodology (High Priority)	0	0	7	1	0	1	0	Does Not Meet Criterion
4. Value over Volume	0	0	0	5	3	1	0	Meets Criterion
5. Flexibility	0	0	0	3	6	0	0	Meets Criterion
6. Ability to Be Evaluated	0	1	6	1	1	0	0	Does Not Meet Criterion
7. Integration and Care Coordination	0	0	0	7	2	0	0	Meets Criterion
8. Patient Choice	0	0	0	3	6	0	0	Meets Criterion
9. Patient Safety	0	0	0	1	5	3	0	Meets Criterion
10. Health Information Technology	0	0	0	3	6	0	0	Meets Criterion

\* Indicates a vote that was not in any of the other categories for this criterion

<sup>30</sup> Criteria designated as “high priority” are those PTAC believes are of greatest importance in the overall review of the payment model proposal.

<sup>31</sup> PTAC member Kavita Patel, MD MSHS was not in attendance and recused herself from deliberation and voting on this proposal.

## APPENDIX 4. DISTRIBUTION OF MEMBER VOTES ON OVERALL RECOMMENDATION<sup>32</sup>

### Recommendation Vote: Part 1 of 2<sup>33</sup>

Not Recommended for Implementation as a PFPM	Recommended	Referred for Other Attention by HHS	Result
0	0	9	Referred for Other Attention by HHS

### Recommendation Vote: Part 2 of 2 (if applicable)

Proposal substantially meets Secretary's criteria for PFPMs. PTAC recommends implementing proposal as a payment model.	PTAC recommends further developing and implementing the proposal as a payment model as specified in PTAC comments.	PTAC recommends testing the proposal as specified in PTAC comments to inform payment model development.	PTAC recommends implementing the proposal as part of an existing or planned CMMI model.	Result
N/A	N/A	N/A	N/A	N/A

**Final recommendation to Secretary: PTAC recommends the proposal be referred for other attention by HHS as specified in PTAC comments.**

<sup>32</sup> PTAC member Kavita Patel, MD MSHS was not in attendance and recused herself from deliberation and voting on this proposal.

<sup>33</sup> In 2018, PTAC adopted new voting categories, used first at its December 2018 public meeting. First, PTAC votes on the three categories listed above as Part 1 of 2. PTAC must achieve a two-thirds majority for one of these categories. If a two-thirds majority votes to not recommend the proposal for implementation as a PFPM or to refer the proposal for other attention by HHS, that category is the Committee's final recommendation to the Secretary. If the two-thirds majority votes to recommend the proposal, the Committee proceeds to Part 2 of 2 to determine the final, overall recommendation for the Secretary. The second vote uses the four subcategories listed above. A two-thirds majority must be achieved for one of these four categories.