Oncology Care First Model: Informal Request for Information

Overview

The Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) is seeking feedback regarding a potential new model for value-based payment to support high-quality oncology care. We appreciate your continued support and engagement with the Innovation Center and the ongoing Oncology Care Model (OCM), and hope to engage you as we develop a new payment and service delivery model that builds on OCM. The Innovation Center is releasing this informal Request for Information (RFI) and holding a public listening session (please refer to page 3 for more details) in order to gather feedback on the design of a potential Oncology Care First (OCF) Model. The Innovation Center welcomes stakeholder input on the ideas included in this informal RFI.

Model Goals

As currently conceptualized, the OCF Model would test whether an innovative approach to prospectively paying for management and drug administration services provided by oncology practitioners, together with a total cost of care accountability, reduces program expenditures while preserving or enhancing the quality of care for Medicare beneficiaries with cancer or a cancer-related diagnosis.¹ The multi-payer aspect of this potential model could also encourage more comprehensive oncology practice transformation and provide the opportunity to improve the quality of care and decrease costs for non-Medicare fee-for-service (FFS) oncology patients. The potential OCF Model would be a new and distinct model from current 5-year OCM, building on lessons learned to date in that model.

Notably, of the roughly 1.75 million people diagnosed with cancer every year in the United States,² approximately half are more than 65 years old and eligible for Medicare.³ The inefficiency and variation in oncology care in the United States is well documented, with avoidable hospitalizations and emergency department (ED) visits occurring frequently, high service utilization at the end of life, and use of high-cost drugs and biologicals (hereafter called "drugs") when lower-cost, clinically equivalent options exist.^{4,5}

As currently conceptualized, OCF Model participants would include both physician group practices (PGPs) and hospital outpatient departments (HOPDs) that provide oncology care. The OCF Model would be designed to align Model participants' financial incentives to eliminate reliance on volume-driven, FFS revenue cycle management while increasing accountability for outcomes in oncology care. The potential OCF Model would test whether holding Model participants accountable for total cost of care and offering them predictable revenue streams through an alternative payment mechanism improves care coordination and management for Medicare beneficiaries with cancer or a cancer-related diagnosis while reducing

¹ Cancer-related would, for example, encompasses patients under active surveillance and/or cancer survivors.

² National Cancer Institute. 2018. Cancer statistics. <u>https://www.cancer.gov/about-cancer/understanding/statistics</u> (accessed August 30, 2019).

³ National Cancer Institute. 2018. SEER Cancer Statistics Review 1975-2016: Age Distribution (%) of Incidence Cases by Site, 2012-2016. <u>https://seer.cancer.gov/csr/1975_2016/browse_csr.php?sectionSEL=1&pageSEL=sect_01_table.10</u> (accessed August 30, 2019).

⁴ Brooks G, Li L, Sharma D. 2013. Regional variation in spending and survival for older adults with advanced cancer. J Natl Cancer Inst 105(9):634-642. Clough JD, Patel K, Riley GF, et al. 2015. Wide variation in payments for Medicare beneficiary oncology services suggests room for practice-level improvement. Health Affairs 34(4):601-608.

⁵ Clough JD, Patel K, Riley GF, et al. 2015. Wide variation in payments for Medicare beneficiary oncology services suggests room for practice-level improvement. Health Affairs 34(4):601-608.

expenditures under the Medicare program. As currently conceptualized, the payment mechanisms for the potential OCF Model would include:

- (1) A prospective, monthly population payment (MPP) for an OCF participant's assigned population of Medicare FFS beneficiaries with cancer or a cancer-related diagnosis that would include payment for Evaluation and Management (E&M) services, "Enhanced Services" required under the terms of the model participation agreement, and drug administration services; and,
- (2) Total cost of care accountability for Medicare costs, including drug costs, incurred during a sixmonth episode of care triggered by a Medicare beneficiary's receipt of a Part B or D chemotherapy drug,⁶ with the opportunity to achieve a performance-based payment (PBP) or owe a repayment to CMS (PBP recoupment), depending on quality performance and costs relative to benchmark and target amounts.

Building on the Current Oncology Care Model

The current OCM continues a FFS framework like many episode payment models, but includes a total cost of care overlay through the performance-based payment. Though OCM is ongoing, early results suggest that the model is having an increasingly positive impact on acute care utilization and quality of care, including at the end of life (e.g., fewer inpatient admissions and Intensive Care Unit (ICU) stays in the last month of life).⁷

Through the potential OCF Model, the Innovation Center aims to build on the lessons learned to date in OCM and incorporate feedback from stakeholders. The Innovation Center remains committed to continuing OCM as a distinct model through the designated model duration. We do not anticipate that the timeline of OCM would be impacted by the potential implementation of the OCF Model. OCM is currently scheduled to end in 2021 (six-month episodes would initiate no later than December 31, 2020, and therefore end no later than June 30, 2021). We anticipate that the OCF Model would start in January 2021, when no new episodes would be initiating in OCM.

Stakeholder Feedback and Engagement

The Innovation Center would like to continue engaging with stakeholders as we further develop the potential OCF Model. Feedback we have received to date on a potential future oncology alternative payment model has been valuable in the development of the model design reflected in this informal RFI. In particular, we greatly appreciate the oncology-related proposals submitted to the Physician-Focused Payment Model Technical Advisory Committee (PTAC). We are continuing to think of ways to incorporate elements of these proposals submitted to the PTAC as well as PTAC's recommendations and comments. We hope that the potential OCF Model will represent an outgrowth of robust stakeholder feedback.

We will accept written feedback on this informal RFI for fifteen business days after the posting of the informal RFI to the Innovation Center website; as such, the feedback period will close on Monday, November 25, 2019. Written feedback can be sent to <u>OCF@cms.hhs.gov</u>, until the close of the feedback period.

⁶ As identified by either the date of service listed on a Part B chemotherapy claim with a cancer diagnosis, or the fill date of a Part D chemotherapy claim with a corresponding Part B claim with a diagnosis code for cancer on the day of, or the 59 days preceding, the fill date on the Part D drug claim.

⁷ Evaluation of the Oncology Care Model: Performance Period One, available via: <u>https://innovation.cms.gov/Files/reports/ocm-</u> secondannualeval-pp1.pdf

Public Listening Session on the Informal RFI for the Potential OCF Model

The Innovation Center will hold a public listening session on the informal RFI for the potential OCF Model. The Innovation Center believes this public input will strengthen and enhance the potential OCF Model. The public listening session is scheduled for November 4, 2019 in Washington, D.C. More information regarding the public listening session, including both in-person and virtual registration, can be accessed here: <u>https://innovation.cms.gov/resources/oncology-listening-session.html</u>

Potential Model Design Elements

Model Timing and Duration

We are currently anticipating that the OCF Model would be a voluntary, five-year model that would be tested throughout the United States from January 2021 to December 2025.

Potential Model Beneficiaries

Assigned Beneficiaries Included in the Monthly Population Payment (MPP)

To be inclusive of an OCF participant's patient population, simplify beneficiary assignment, and promote predictable payments for OCF participants, the population of assigned beneficiaries for the purposes of calculating the OCF participant's MPP would be broadly defined as all Medicare FFS beneficiaries (that are eligible for Part A and enrolled in Part B with Medicare as his/her primary payer) who receive an E&M service at the OCF PGP with a cancer or cancer-related diagnosis designated on the Medicare claim. Once the E&M service with a cancer or cancer-related diagnosis is furnished at the OCF PGP, any service included in the MPP that is provided at the HOPD would also result in the beneficiaries included in the MPP as "assigned beneficiaries," and for purposes of the performance-based payment (PBP), we refer to beneficiaries included in an episode as "attributed beneficiaries." In cases where an assigned beneficiary receives E&M services with a cancer or cancer-related diagnosis designated on the Medicare to beneficiaries included in an episode as "attributed beneficiaries." In cases where an assigned beneficiary receives E&M services with a cancer or cancer-related diagnosis designated on the Medicare claim at two OCF participants, the beneficiary would be assigned to both for the purpose of the MPP calculation.

Notably, this population of assigned beneficiaries would include beneficiaries with cancer who receive chemotherapy, those who receive hormonal therapy only, and also those who are not receiving any cancer-related drugs, such as those under active surveillance or cancer survivors who are still undergoing care management from their oncologist. This would be a broader population of beneficiaries than in OCM, which limits the Monthly Enhanced Oncology Services (MEOS)⁸ payments for beneficiaries who receive chemotherapy. Our intent would be to support oncology practice improvements designed to benefit a practice's broader cancer population.

Attributed Beneficiaries Included in Performance-based Payment (PBP) Episodes

In contrast to the broadly defined Medicare beneficiary population that would be assigned to a participant in the potential OCF for the purposes of the MPP, the population of beneficiaries eligible to initiate an episode would be defined more narrowly as only Medicare FFS beneficiaries receiving Part B or D chemotherapy—not including hormonal therapy—for a cancer diagnosis of any stage.⁹ A Medicare

⁸ The Monthly Enhanced Oncology Services (MEOS) payments are OCM payments for Enhanced Services. The MEOS payment assists participating OCM practices in effectively managing and coordinating care for oncology patients during episodes of care.
⁹ The Innovation Center would release a preliminary list of Part B and D chemotherapy drugs that would trigger an episode under

the potential OCF Model

beneficiary would need to meet all of the following criteria for an episode to be defined and attributed to a PGP:

- Beneficiary is eligible for Medicare Part A and enrolled in Medicare Part B;
- Beneficiary receives an included chemotherapy drug for cancer;
- Beneficiary does not receive the Medicare end-stage renal disease benefit, as identified through the Medicare Enrollment Database;
- Beneficiary has Medicare as their primary payer;
- Beneficiary is not covered under Medicare Advantage or any other group health program; and,
- Beneficiary has at least one E&M visit during the episode with a cancer diagnosis billed by a PGP with at least one oncologist in the performance period.

OCF Model Participants

A potential OCF model might include both PGP participants (identified by a Taxable Identification Number [TIN]) and HOPDs participants (identified by a CMS Certification Number [CCN]) that provide oncology care. Only HOPDs paid under the outpatient prospective payment system, as defined in section 42 CFR 419.20, would be eligible to participate in the model.¹⁰ PGP participants would include both community- and hospital-based PGPs.

For the purposes of the MPP and its included services, we would define OCF practitioners as the subset of Medicare-enrolled physicians and non-physician practitioners billing under the TIN or CCN of the PGP or HOPD participant who provide chemotherapy or chemotherapy-related services (e.g., E&M services related to chemotherapy) to cancer patients; this would allow non-oncologists at multi-specialty practices and academic medical centers to continue billing and receiving payment for drug administration and E&M services as they currently do.

PGP Participants

PGP participants would include Medicare-enrolled PGPs that are identified by a TIN and composed of one or more physicians and non-physician practitioners who treat Medicare beneficiaries receiving chemotherapy or chemotherapy-related services for a cancer diagnosis and who have reassigned to the PGP the right to receive Medicare payments. PGP participants would receive the MPP rather than receiving separate payment for claims for drug administration and E&M services for their assigned beneficiaries. PGP participants would be responsible for the management of OCF beneficiaries' care, including the implementation of the PGP participant redesign activities, and accountable for the total cost of care for 6-month episodes.

Pooling of PGP Participants

Pooled PGP participants would consist of two or more PGP participants who have joined together for the purposes of setting benchmark prices and calculating PBP and PBP recoupment amounts. We would require mandatory pooling in cases of significant OCF practitioner overlap between PGP participants, and we would allow voluntary pooling in other cases.

¹⁰ PPS-exempt cancer hospitals (PCHs), critical access hospitals (CAHs), Rural Health Centers (RHCs), and Federally Qualified Health Centers (FQHCs) would not be eligible to participate in the model.

HOPD Participants

Any HOPD that provides chemotherapy or chemotherapy services for 25 percent or more of a PGP participant's attributed episodes would need to voluntarily participate in the potential OCF Model in a grouping with the PGP participant, in order for the PGP to be eligible to participate in the model. HOPD participants would receive the MPP rather than separate Medicare FFS payments for claims for drug administration and E&M services for HOPD assigned beneficiaries. Both the PGP and HOPD participants would enter into participation agreements with CMS and participate in the model as a grouping. HOPD participants would not be responsible for the implementation of the PGP participant redesign activities or accountable for episodes' total cost of care.

Any HOPD that provides chemotherapy or chemotherapy services for less than 25 percent of a PGP participant's attributed Medicare episodes would not need to join the model for the PGP to be eligible to participate, though the HOPD could choose to do so.

Multi-Payer Participation

The Innovation Center is conceptualizing the potential OCF Model as a multi-payer model, similar to OCM, where we would invite commercial payers and state Medicaid agencies to partner with the Innovation Center by signing a Memorandum of Understanding (MOU), thereby aligning their oncology value-based payment models with the OCF Model in certain key ways. The main goal of multi-payer alignment would be to promote a consistent approach across payers. Incorporation of multi-payer alignment within the OCF Model would be expected to reduce costs and improve the quality of care for Medicare beneficiaries through improved ability to leverage whole practice transformation, reduce administrative burden, and align incentives across a participating practice's patient population, rather than having different approaches for their Medicare FFS population compared to their other patients.

Care Transformation

The potential OCF Model would require PGP participants to implement seven PGP participant redesign activities, five of which would be defined as Enhanced Services,¹¹ for all assigned OCF beneficiaries, which are as follows: 1) offer beneficiaries 24/7 access to a clinician with real-time access to their medical records; 2) provide the core functions of patient navigation;¹² 3) document a care plan for beneficiaries that contains the 13 components of the Institute of Medicine's (IOM) Care Management Plan;¹³ 4) treat beneficiaries with therapies consistent with nationally recognized clinical guidelines, 5) use Certified Electronic Health Record Technology (CEHRT) as specified in regulation (42 C.F.R. 414.1415(a)); 6) utilize data for continuous quality improvement; and 7) gradually implement electronic patient-reported outcomes (ePROs). The first six of these activities are currently required in OCM, and based on OCM experience to date; we believe that they continue to be critical for high-quality care. We wish to continue supporting and building on the practice transformation work from OCM participants.

¹¹ Enhanced Services refer to five of the seven required OCF PGP participant redesign activities; use of Certified EHR technology and utilizing data for continuous quality improvement would not be considered Enhanced Services.
¹² Please refer to this link for more information about patient navigation: <u>https://www.cancer.gov/about-nci/organization/crchd/disparities-research/pnrp#PNRP-Overview.</u>

¹³ Please refer to Section 3, Pg. 3-23 Box 3-3, for information on the 13 components of the IOM Care Management Plan available here: <u>http://nationalacademies.org/HMD/Reports/2013/Delivering-High-Quality-Cancer-Care-Charting-a-New-Course-for-a-System-in-Crisis.aspx</u>.

The seventh PGP participant redesign activity, gradual implementation of ePROs, is intended to enhance care coordination. Information from ePRO systems can be used for monitoring patient symptoms in clinical care and identifying high-risk patients for complications or utilization of emergency services. Several recent publications have highlighted the value of ePROs in helping clinicians to stay aware of patients' clinical status, translating to improved survival outcomes.^{14,15}

Potential Payment Methodology

Overview

The potential OCF Model payment methodology is designed to test alternatives to Medicare FFS payment for oncology care in two ways, as described below in Table 1. Under the OCF Model, beneficiary cost sharing would continue to be the same as under FFS, as it would be absent the Model (e.g., the beneficiary cost sharing payments for the services included in the MPP would be based on the FFS payment rate for each individual services). Payer partners would be encouraged to align their payment approaches, to the extent feasible.

Payment Element	Monthly Population Payment (MPP)	Performance-based Payment (PBP)
Main Features	Prospective payment includes a Management Component (Enhanced Services, E&Ms) and an Administration Component (drug administration services, E&M payments to HOPDs where applicable)	Total episode expenditures reconciled against a benchmark or target amount, with possibility of receiving a PBP or owing a PBP recoupment
Overview of Calculation	Based on median national historical Medicare payments during a fixed, historical baseline period with a participant-specific adjustment and an Enhanced Services payment; overall the MPP would be calculated prospectively using the historical payments trended forward based on nonparticipants and applied to volume and case mix in the most recently available population data.	Benchmark amount calculated based on historical episode payments, trended forward, risk adjusted, and adjusted for participant-specific experience and use of new drugs. Target amount is the benchmark amount discounted to provide savings for Medicare.

Monthly Population Payment (MPP)

The first aspect of the potential OCF Model's payment methodology would be to pay OCF participants a prospective MPP, calculated partly based on median Medicare expenditures during a historical baseline period for E&M services and drug administration services for an assigned population of Medicare FFS beneficiaries. Beneficiaries would be assigned based on receiving an E&M service with a cancer or cancer-related diagnosis designated on the Medicare claim with a date of service that occurred during a six-month population period of either January-June or July-December. An Enhanced Services payment

¹⁴ Basch E, Deal AM, Dueck AC, et al. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring during Routine Cancer Treatment. JAMA 2017; 318(2):197-198.

¹⁵ Denis F, Basch E, Septans A-L, et al. Two-Year Survival Comparing Web-Based Symptom monitoring vs Routine Surveillance Following Treatment for Lung Cancer. JAMA 2019; 321(3):306-307.

(described below) would then be added to the MPP. Participants would not need to submit a claim in order to receive this payment.

In conjunction with the services described above that would represent the MPP, we are considering the inclusion of additional services in the MPP, such as imaging or lab services, and seek feedback on adding these or other services to the MPP.

Population Definition

As described above, the population of assigned beneficiaries for the purposes of the OCF PGPs' MPP would be broadly defined as all Medicare FFS beneficiaries (that are eligible for Part A and enrolled in Part B with Medicare as his/her primary payer) who receive an E&M service with a cancer or cancer-related diagnosis designated on the Medicare claim with a date of service that occurred during a sixmonth population period of either January-June or July-December. Beneficiaries assigned to an OCF HOPD would be a subset of the beneficiaries assigned to the OCF PGP in the grouping with the OCF HOPD. We believe our MPP assignment policy would promote real-time assignment predictability.

Risk Stratification

Since the MPP is primarily intended to represent predicted median spending on E&M visits and drug administration services over a given six-month population period across an OCF participant's assigned beneficiary population, the MPP calculation process would be designed to take into account an OCF participant's patient volume and case mix. In order to determine the MPP amount for a given OCF participant, median historical spending during a baseline period across all OCF-eligible PGPs and HOPDs nationally would be calculated after stratifying Medicare FFS patients based on cancer type and whether or not the patient received chemotherapy or hormonal therapy over each historical six-month population period. The median spending amounts would then be trended forward based on Medicare payments to non-OCF participants so that they reflect changes in oncology practice patterns that are not primarily driven by OCF.

A subset of cancers (i.e., breast, bladder, and prostate) would be divided into high- and low-risk categories,¹⁶ in recognition that spending patterns are significantly different between patients receiving chemotherapy for high-risk versions of these cancer types and those receiving select hormonal therapy only for low-risk versions of these cancer types. The resulting patient risk strata would be grouped into three risk tiers: (1) high risk (i.e., receiving chemotherapy) stratified by cancer type; (2) low risk (i.e., receiving hormonal therapy only) stratified by breast, bladder, or prostate cancer; and (3) no hormonal therapy or chemotherapy for any cancer type. A separate MPP amount would be calculated, as described in the previous paragraph, for each risk stratum.

Enhanced Services Portion of the MPP

The Enhanced Services portion of the MPP in the OCF Model would represent payment for providing assigned beneficiaries the five enhanced services described above in the Care Transformation section. In the OCF Model, we would create three different tiers for the Enhanced Services payment based on the risk strata of the OCF participant's MPP population, as described above in the Risk Stratification section, with the highest payment for the high risk tier and lowest payment for the no hormonal or chemotherapy tier.

¹⁶ We note that this terminology generally fits these categories, though there may be some high-risk patients who may receive hormonal therapy only.

Management and Administration Components of the MPP

Given the heterogeneity in practice settings and structures, the MPP design would be flexible to ensure that community- and hospital-based PGPs are able to participate in the OCF Model. We are envisioning that we would split the MPP into a Management Component (i.e., Enhanced Services, E&M services) and an Administration Component (i.e., drug administration services and E&M payments to HOPDS where applicable) in recognition that while the former set of services could only be billed by a PGP, the latter set of services could be billed by either a PGP participant or an HOPD participant. For the portion of a PGP participant's assigned population that receives chemotherapy in a community-based practice, the PGP participant would be paid both the Management and Administration Components of the MPP. For the portion of the PGP participant's assigned population (if any) that receives chemotherapy in an HOPD, the PGP would receive the Management Component of the MPP and the HOPD would receive the Administration Component of the MPP.

Calculation and Payment of the MPP

Over the course of the model, the MPP would be calculated prospectively for each six-month population period. The MPP amount would be based on median national historical Medicare payments during a fixed, historical baseline period with a participant-specific adjustment and an Enhanced Services payment added based on the risk tiers described above. Historical payments would be trended forward based on nonparticipants' Medicare payments to account for changes in oncology practice patterns not directly related to participation in OCF. Because we would be calculating the MPP on a prospective basis, prior to each population period, we would estimate the volume and case mix of patients that we expect to be assigned to the OCF participant using the most recently available data. For the portion of a PGP participant's assigned population that receives chemotherapy in a community-based practice, the MPP would include both the Management and Administration Components. For the portion of the PGP participant's assigned population (if any) that receives chemotherapy in an HOPD, the PGP's MPP would include the Management Component only, while the HOPD MPP would include the Administration Component only. In those cases, although the MPP for PGP participants and HOPD participants would each incorporate a different set of services, the calculation methodology would otherwise be the same.

MPP Reconciliation

After each six-month population period, we would retrospectively reconcile the MPP by repeating the calculation process for the prospective MPP, with two changes. First, we would trend the participantspecific historical payment rate forward based on Medicare payments to non-OCF PGPs and HOPDs for the same set of services using the most recently available claims data, in order to account for changes in oncology practice patterns that occurred during the performance period. Then, we would apply the forward-trended participant-specific payment rates to the actual assigned population for that population period. If the MPP calculated retrospectively based on the actual assigned population and forward-trended participant-specific payment rates exceeded the prospectively paid MPP due to higher than predicted patient volume or a more complex case mix, CMS would pay the difference to the OCF participant. If it was less than the prospectively paid MPP due to lower than predicted patient volume or less complex case mix, the OCF participant would owe a repayment of the difference, referred to as an MPP recoupment, to CMS. While CMS would adjust the previously paid MPP for changes to the patient volume and case mix originally calculated from the reference population, as well as trends in Medicare payments to non-OCF PGPs and HOPDs during the performance period, it would not make adjustments to the MPP based on changes to the volume and intensity of services provided by the OCF participant during the population period.

Performance-based Payment (PBP)

The second aspect of the potential OCF Model's payment methodology would be to provide PGP participants, including pooled PGP participants,¹⁷ with the opportunity to achieve a performance-based payment (PBP) by reducing episode expenditures for six-month episodes of care for patients on chemotherapy below a target amount.

Episode Definition

For purposes of the PBP in the OCF Model, episodes would begin with a Medicare beneficiary's receipt of chemotherapy.¹⁸ Hormonal therapy would not qualify as an episode trigger. As a result, beneficiaries who trigger an episode would be a subset of those assigned to an OCF participant for purposes of the MPP calculation. Episodes would last six months after receipt of the episode-initiating chemotherapy; with the possibility for new, subsequent episodes to initiate if a beneficiary continues to receive chemotherapy after completing the first episode. A performance period is the six-month period of time in which episodes are attributed to an OCF participant; for example, Performance Period 1 would include any episodes that initiated between January 1, 2021, and June 30, 2021.¹⁹

Episode Attribution

In order to be attributed to a PGP participant for purposes of the PBP calculation, episodes would need to include at least one cancer-related E&M service for an eligible beneficiary with a cancer diagnosis. If multiple PGP participants bill cancer-related E&M services after a beneficiary receives episode-initiating chemotherapy, the episode would be attributed to the PGP participant that provides the episode-initiating chemotherapy, as long as that PGP participant also billed at least 25% of the cancer-related E&M services associated with the episode.²⁰ While episodes would be retrospectively attributed during PBP reconciliation, this approach to attribution would provide more predictability regarding episode attribution as compared to attributing based on plurality of E&M services.

Episode Benchmark and Target Price Calculation

Episode benchmark prices would be based on a combination of PGP participant-specific, regional, and national historical Medicare payments during episodes from the baseline period. Baseline episode Medicare payments would include all Part A and Part B services, including Part B chemotherapy and supportive care drugs, and certain Part D expenditures (the Low-Income Cost Sharing Subsidy amount, and 80 percent of the Gross Drug Cost above the Catastrophic threshold), which would be Winsorized²¹ to minimize the impact of outlier cases and then risk-adjusted using a regression model based on a national set of baseline episodes and using clinical data submitted by PGP participants.

¹⁷ The PBP payment methodology would generally be the same for pooled PGP participants as for individual PGP participants, except that pooled participants would have all of their episodes pooled together for PBP calculations.

¹⁸ The receipt of chemotherapy would be identified by either the date of service listed on a Part B chemotherapy claim with a cancer diagnosis, or the fill date of a Part D chemotherapy claim with a corresponding Part B claim with a diagnosis code for cancer on the day of, or the 59 days preceding, the fill date on the Part D drug claim.

¹⁹ Performance period is a separate concept from the population period. The population period is the six-month period (of either January-June or July-December) in which the MPP is provided to OCF participants.

²⁰ If the PGP participant that provided the episode-initiating chemotherapy did not bill at least 25% of cancer-related E&M services during the episode, or if the episode-initiating chemotherapy was provided at an HOPD, then episode attribution would default to a plurality approach, with the episode attributed to the PGP participant that bills a plurality of cancer-related E&M services furnished to a beneficiary with a cancer diagnosis during the course of the six-month episode.

²¹ Winsorization refers to the process in which there is a limitation on extreme values in the statistical data to reduce the effect of possibly spurious outliers.

We would apply a trend factor to create the episode benchmark prices. In order to account for changes in non-OCF oncology spending patterns for specific cancer types, we are considering calculating the trend factor separately for each cancer type with sufficient volume.

CMS would apply an adjustment for use of new drugs to the trended, risk-adjusted baseline episode price to account for situations where a PGP participant has a higher proportion of expenditures for approved uses of newly Food and Drug Administration (FDA) approved oncology drugs than non-OCF PGPs. We are considering making the novel therapies adjustment at the cancer type level rather than the participant level as is done in OCM.

After calculating the episode benchmark prices, CMS would create episode target prices by applying a discount meant to result in savings for CMS. In the OCF Model, we might expect to set the discount within a range of 3% to 4% of the benchmark price.

Episode Expenditures

Episode expenditures would include the same categories of costs included in the episode benchmark price, including MPP amounts for population period months that overlap with the six months of the episode, given that such MPP amounts replace FFS payments for E&M services, drug administration services, and E&M payments to HOPDs, if applicable.

PBP Risk Tracks

The potential OCF Model would have three risk tracks for purposes of the PBP reconciliation, including a one-sided risk track (i.e., upside financial risk only) available for the first two performance periods of the OCF Model, and two tracks with two-sided risk (i.e., upside and downside financial risk). To allow some participants the time to familiarize themselves with the requirements of an oncology-focused model, we are considering whether PGP participants that did not participate in OCM might be given the option of no downside risk for a limited time. We envision the first of the two-sided risk tracks as being less aggressive ("Track A"), while the second risk track may be more aggressive ("Track B"). Risk would be defined as a percent of the PGP participant's episode benchmark amount. The potential OCF Model would require all PGP participants that participated in OCM to be in two-sided risk for the full duration of their participation in the OCF Model.

PBP Reconciliation Process

The PBP reconciliation process would occur on a semiannual basis, after all episodes initiated during the performance period have ended and allowing for one month of claim run out. We plan to do one subsequent reconciliation (or "true up") per performance period one year after the initial reconciliation.

At PBP reconciliation, the benchmark prices and target prices for all of a PGP participant's attributed episodes would be aggregated, resulting in a total episode benchmark amount and a total episode target amount. If the PGP participant's episode expenditures were lower than the target amount, the PBP would be calculated based on the difference between the episode expenditures and the target amount, adjusted based on the PGP participant's (or pooled PGP participants') performance on quality measures. If the episode expenditures were higher than the benchmark amount, the PGP participant would owe a PBP recoupment amount, which would be based on the difference between the episode expenditures and the benchmark amount, adjusted for performance on quality measures. The final PBP payment or recoupment amount would depend on the risk track chosen by the PGP participant.

Quality Strategy

The potential OCF Model would include quality measures that are tied to payment to ensure that the incentive to reduce costs is balanced with an incentive to maintain or improve care quality. The amount of the PBP that PGP participants would be eligible to receive, and the amount of any repayment that PGP participants would be based, in part, on their performance on each of the measures in the potential OCF Quality Measure Set. The Innovation Center anticipates that the OCF Model Quality Measure Set could be the same as the measures currently used in OCM.²² These existing measures have room for further improvement (e.g., they are not "topped out"), and we believe that this measure set continues to represent the best way to assess high-quality care in oncology today.

As currently conceptualized, quality performance would be linked to payment under the model through a performance multiplier. The performance multiplier would be based on summing together each PGP participant's scores, or pooled PGP participants' scores, on the quality measures and then cross-walking the aggregate quality score to a performance multiplier. The resulting performance multiplier would be applied to the potential PBP or PBP recoupment amount, so that PGP participants with better quality performance would get higher PBPs and owe lower PBP recoupment amounts than those with poorer quality performance.

Data Sharing and Collection Strategy

The potential OCF Model would draw on the data sharing and collection strategy used in OCM, focused on continuous quality improvement. OCF participants would be able to request the specific types of claims data they would need to perform certain healthcare operations.

Advanced APM and Merit-based Incentive Payment System (MIPS) Status

Advanced APM Status

As currently conceptualized, both of the OCF two-sided risk tracks would qualify as Advanced APMs under the Quality Payment Program (QPP) because both of the two-sided risk tracks are expected to (1) satisfy the Certified Electronic Health Record (CEHRT) criterion in 42 CFR 414.1415(a), (2) satisfy the criterion for payment based on quality measures in 42 CFR 414.1415(b), and (3) satisfy the financial risk criterion based on meeting the generally applicable financial risk and nominal amount standards.

MIPS APM Status

We anticipate that the one-sided risk track and both of the two-sided risk tracks would be MIPS APMs starting on January 1, 2021.

²² OCM Measure List, Version 1.5, (Effective July 1 2019) available here:

 $[\]underline{https://www.healthcarecommunities.org/DesktopModules/Bring2mind/DMX/Download.aspx?portalid=3\&EntryId=134224.www.healthcarecommunities.org/DesktopModules/Bring2mind/DMX/Download.aspx?portalid=3&EntryId=134224.www.healthcarecommunities.org/DesktopModules/Bring2mind/DMX/Download.aspx?portalid=3&EntryId=134224.www.healthcarecommunities.org/DesktopModules/Bring2mind/DMX/Download.aspx?portalid=3&EntryId=134224.www.healthcarecommunities.org/DesktopModules/Bring2mind/DMX/Download.aspx?portalid=3&EntryId=134224.www.healthcarecommunities.www.healthcarecommunities.org/DesktopModules/Bring2mind/DMX/Download.aspx?portalid=3&EntryId=134224.www.healthcarecommunities.wwww$

Potential Overlap with Other Payment Models

As in OCM, we would develop methodologies to account for overlap and interaction between current or new CMS programs or initiatives and OCF participants, practitioners, and beneficiaries.

Application Process and Selection

As currently conceptualized, the OCF Model would be voluntary and would include an application process for potential participants to complete in order to be considered for participation in the Model.

Targeted Topics for the Public Listening Session and Written Feedback

At the Public Listening Session and in submitted written feedback, we hope to gather stakeholder input on the following targeted topics:

- 1. The potential OCF Model would seek to improve health outcomes and quality of care for Medicare beneficiaries with cancer. How could the potential model support participants' care transformation through practice redesign activities? Specifically, how could the potential model build on lessons learned from the implementation of the practice redesign activities included in the Oncology Care Model (OCM)? What revisions or additions should be made to the OCM practice redesign activities in the potential model?
- 2. We welcome feedback on the potential payment methodology, including the structure and design of the monthly population payment and the performance-based payment. We are considering the inclusion of additional services in the monthly population payment, such as imaging or lab services, and seek feedback on adding these or other services to the monthly population payment.
- 3. We encourage feedback on the conceptualized risk arrangements, in particular, how a downside risk arrangement might be best constructed in terms of the level of risk.
- 4. We invite feedback on the interest of physician group practices (PGPs) and hospital outpatient departments (HOPDs) in participating in a potential OCF Model. We are particularly interested in hearing from PGPs and HOPDs about the conceptualized participation eligibility parameters (e.g., the grouping concept), and whether they think that meeting those parameters would be feasible. We also invite feedback from potential payer partners, including commercial payers and state Medicaid agencies. We welcome suggestions about the model concept that would better incentivize participation in the potential model.

We will accept written feedback on the informal RFI until Monday, November 25, 2019. Written feedback can be sent to <u>OCF@cms.hhs.gov</u>, until the close of the feedback period. More information regarding the public listening session can be accessed here: <u>https://innovation.cms.gov/</u>resources/oncology-listening-session.html