



The Enhancing Oncology Model (EOM)

Request for Applications

June 27, 2022

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW: This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law

Table of Contents

I.	Authority	5
A.	Authority to Test the Model	5
B.	Authority to Waive Medicare Program Requirements	7
C.	Fraud and Abuse Law Waivers and Safe Harbor Authority	7
II.	Model Scope and Participation	7
A.	Model Timing and Duration	7
B.	EOM Participants and EOM Payers	7
III.	Application Process	11
A.	Application	12
B.	Screening	12
C.	Withdrawal of Application	13
IV.	Health Equity Strategy	13
V.	Model Design Elements	17
A.	Model Episodes	18
B.	Care Transformation	23
C.	Payment Methodology	34
D.	Extreme and Uncontrollable Circumstances Policy	46
E.	Overlap Adjustments	46
F.	Quality Strategy	52
G.	Dispute Resolution Process	56
VI.	Advanced APM And Merit-Based Incentive Payment System (MIPS) Status	57
A.	Advanced APM Status	58
B.	MIPS APM Status	58
C.	Changes in Advanced APM or MIPS APM Status	59

VII.	Benefit Enhancements, Financial Arrangements, and Patient Incentives	59
A.	Benefit Enhancements.....	59
B.	Financial Arrangements.....	62
C.	Patient Incentives	64
VIII.	Data Sharing and Health IT Strategy.....	65
A.	EOM Participant-Reported Data Collection Strategy	65
B.	CMS Data Sharing with EOM PGPs and Collection Platform	66
IX.	CMS Monitoring.....	68
X.	Remedial Actions	69
XI.	Evaluation	70
XII.	Information Resources for Beneficiaries and Health Care Providers.....	71
XIII.	Learning System.....	71
XIV.	Termination	72
XV.	Amendment.....	72
XVI.	Appendices	74
	Appendix A: Comparison of OCM to EOM by Select Model Features	74
	Appendix B: Health Equity Strategy Overview Examples.....	77
	Appendix C: Core Functions of Patient Navigation for Cancer Patients	79
	Appendix D: Components of the Institute of Medicine Care Management Plan	80
	Appendix E. Application Templates	81

Background and Introduction

The purpose of the new Enhancing Oncology Model (EOM) is to drive transformation in oncology care by preserving or enhancing the quality of care furnished to beneficiaries undergoing treatment for cancer while reducing program spending under Medicare fee-for-service (FFS). Under the Medicare FFS program, Medicare generally makes a separate payment to providers and suppliers for each item or service furnished to a beneficiary during the course of treatment. The amount of payments received by a provider or supplier for such items and services varies with the volume and value of items and services furnished to a beneficiary. As a result, some providers and suppliers may be financially incentivized to inappropriately increase the volume of items and services, and the Average Sales Prices (ASP)-based payment approach for Part B drugs may lead to prescribing higher-cost drugs, resulting in unnecessary or duplicative care and expenditures. In addition, under Medicare FFS, the incentives to manage care and costs across the spectrum of services a beneficiary might receive across multiple providers and suppliers are limited, which can result in fragmented care, including for cancer patients.

Under EOM, which builds on lessons learned to date from the Oncology Care Model (OCM), participating physician practices will take on financial and performance accountability for episodes of care surrounding chemotherapy administration to cancer patients (by way of a potential lump-sum performance-based payment or performance-based recoupment) and will have the opportunity to submit claims for a Monthly Enhanced Oncology Services (MEOS) payment for Enhanced Services furnished to EOM beneficiaries (defined as Medicare FFS beneficiaries who meet the eligibility criteria outlined in Section V.A.i and are in an episode attributed to the EOM participant). We envision that this 5-year voluntary model will improve quality and reduce costs because its payment methodology is aligned with care quality, and because EOM participants will have significant opportunities to redesign care and improve the quality of care furnished to beneficiaries receiving care for certain cancers. Specifically, EOM participants will be required to implement participant redesign activities—such as a gradual implementation of electronic Patient Reported Outcomes (ePROs)—as well as activities that promote health equity.

Reports indicate positive practice transformation is happening among OCM practices,^{1,2,3} and quality of care is improving for OCM beneficiaries. This ranges from more informative education at treatment initiation, to better symptom management and psychosocial care during chemotherapy treatment and survivorship. Based on our experience testing OCM, we also expect that the beneficiary experience under EOM will reflect increased shared decision making around the goals of treatment, reduced financial toxicity, better adoption of evidence-based treatment guidelines and high-value therapies, increased medication adherence, improved symptom management and reduced acute care utilization, improved transitions between care settings (including better communication with the primary care provider), improved psychosocial outcomes, incorporation of palliative

¹Pittman A.T., Rossi W., Pini T.M. (2019). Three benefits to the Oncology Care Model and four recommendations to advance it. Health Affairs blog <https://www.healthaffairs.org/doi/10.1377/hblog20190417.733414/full/> (accessed May 3, 2019)

² Participants' perspective evaluation report (2021), retrieved from: <https://innovation.cms.gov/initiatives/oncology-care/>

³ Kline R.M., Blau S., Buescher N.R. et al (2021): Secret sauce: How diverse practices succeed in Centers for Medicare & Medicaid Services Oncology Care Model. *JCO Oncology Practice* 12: 734-743.

care throughout the course of treatment, and increased use of hospice at the end of life.

Moreover, CMS is committed to addressing affordability through the inclusion of drug expenditures in the calculation of the performance-based payment (PBP) and performance-based recoupment (PBR) under EOM, which we expect to support higher-value drug prescribing by EOM participants, such as a shift to biosimilars and generics, where possible. Value-based payment models like OCM have motivated clinicians to focus on supportive care therapies,⁴ and high-value prescribing, such as the adoption of biosimilars, as increasing numbers of biosimilars have come to market. For example, the increased adoption of biosimilars in an OCM practice led to a significant reduction in typical drug costs.⁵

Like OCM, EOM will be a multi-payer model. Private payers, Medicare Advantage plans, and state Medicaid agencies are invited to apply for the model and to enter into a Memorandum of Understanding (MOU) with CMS to align their oncology value-based payment models with EOM in key areas (e.g., commitment to health equity, and alignment on payment approach, episode definition and attribution, performance periods, practice redesign activities and accountability, quality measurement, and data sharing with EOM participants and CMS). The main goal of multi-payer alignment under EOM will be to promote a consistent approach across payers and their patient population.

There will be two parts of EOM: one operated by CMS for Medicare FFS (“EOM FFS”), and another operated by EOM payers (“EOM Other Payer”) that will apply to patients of an EOM participant who are insured by an EOM payer (“EOM Other Payer Beneficiaries”). EOM is expected to reduce costs and improve the quality of care for both EOM FFS beneficiaries and EOM Other Payer Beneficiaries through improved ability to leverage whole practice transformation, reduce administrative burden, and align financial incentives across a participating practice’s patient population, rather than having different approaches for their Medicare FFS population compared to their other patients. This alignment is expected to promote flexibility and competition among payers; for example, while EOM payers will commit to provide their aligned participant a payment for Enhanced Services furnished to EOM Other Payer Beneficiaries, CMS will not dictate the frequency, amount, method, or basis for this payment.

I. Authority

A. Authority to Test the Model

Section 1115A of the Social Security Act (the Act) (added by Section 3021 of the Affordable Care Act) (42 USC § 1315a) established the Innovation Center to test innovative payment and service delivery models that have the

⁴ Abt Associates. 2021. Evaluation of the Oncology Care Model Performance Periods 1 – 6. Retrieved from: <https://innovation.cms.gov/data-and-reports/2021/ocm-ar4-eval-payment-impacts>

⁵ Wilfong L., Dave N., Garey J.S., et al (2021). A successful model of biosimilar adoption in a community oncology practice. Presented at: ASCO 2021: June 3-7, 2021. Abstract 6514.

potential to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of beneficiaries' care.

Section 1115A(b)(2) of the Act requires the Secretary to select models to be tested where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The statute also provides a non-exhaustive list of examples of models that the Secretary may select to test, which includes models under which the Innovation Center contracts directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment (see section 1115A(b)(2)(B)(ii) of the Act).

As described above, under traditional Medicare fee-for-service (FFS), oncology providers and suppliers generally receive separate payments for each item or service furnished to a beneficiary during the course of their cancer treatment. This creates a financial incentive for some providers and suppliers to increase the volume of items and services (sometimes inappropriately) or prescribe high-cost, but not necessarily higher value drugs, which may result in unnecessary or duplicative services that may adversely affect the beneficiary with cancer and the Medicare program.

EOM addresses a defined population (Medicare FFS beneficiaries undergoing certain chemotherapy treatment for certain cancers) for which there are potentially avoidable expenditures (arising from less than optimal care coordination and the provision of unnecessary or duplicative services, or low-value drugs). EOM presents an opportunity to test whether appropriately aligned financial incentives and practice transformation requirements improve care coordination for beneficiaries receiving chemotherapy treatment for certain cancers, resulting in better health outcomes, and better quality of care while reducing Medicare expenditures. Both risk arrangement options, Risk Arrangement 1 and Risk Arrangement 2 (as discussed in section V.C.iii.9), available under EOM are expected to increase beneficiaries' access to innovative, affordable care while ensuring beneficiaries maintain all original Medicare benefits. The information gained from testing EOM will allow CMS to more comprehensively evaluate the impact of episode-based payment methodologies with total cost of care accountability and adjustments based on quality, as well as the implementation of Practice Redesign Activities, on both cost and quality.

EOM's design is also innovative. While EOM builds on previous OCM experiences and stakeholder feedback, EOM differs from OCM in several ways, including a focus on health equity, the requirement for gradual implementation of ePROs, a lower per-beneficiary per-month Monthly Enhanced Oncology Services (MEOS) payment, a cancer-type specific approach to calculating benchmarks, and required downside risk. In addition, while EOM will include Medicare FFS beneficiaries receiving Part B or Part D chemotherapy for a cancer diagnosis, we will limit the model to beneficiaries receiving systemic chemotherapy (not beneficiaries receiving hormonal therapy only) for seven cancer types, most of which have shown savings in OCM: breast cancer, chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer. See Appendix A for additional details comparing the key differences in design elements between OCM and EOM.

B. Authority to Waive Medicare Program Requirements

The authority for EOM is section 1115A of the Act. Under section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII of the Act and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and certain provisions of section 1934 of the Act as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b).

C. Fraud and Abuse Law Waivers and Safe Harbor Authority

Consistent with the authority under section 1115A(d)(1) of the Act, the Secretary may consider issuing waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act. No fraud or abuse waivers are being issued in this document; fraud and abuse waivers, if any, will be set forth in separately issued documentation. Any such waiver will apply solely to EOM and could differ in scope or design from waivers granted for other programs or models.

In addition to or in lieu of a waiver of certain fraud and abuse provisions in sections 1128A and 1128B of the Act, CMS may determine that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR §1001.952(ii)) is available to protect remuneration exchanged pursuant to certain financial arrangements or patient incentives permitted under EOM participation documentation. No such determination is being issued in this document. Such determination, if any, will be set forth in documentation separately issued by CMS.

Notwithstanding any provision of this RFA, providers and suppliers must comply with all applicable laws and regulations, except as explicitly provided for EOM in a separately documented waiver issued pursuant to section 1115A(d)(1) of the Act specifically for EOM. We note that the applicable law will include the CMS-sponsored model safe harbor to the extent CMS determines that it is applicable for this model.

II. Model Scope and Participation

A. Model Timing and Duration

EOM will be a voluntary 5-year model test that will be national in scope. The model performance period will begin in July 2023, and end in June 2028. This RFA is for applications to begin participation in EOM on July 1, 2023. Section II.B below describes the eligible model participants and section III describes the application process.

B. EOM Participants and EOM Payers

This section describes the requirements an entity must meet to be eligible to participate in EOM as an EOM participant or to partner with CMS in EOM as an EOM payer. CMS notes that sufficient participation in the model by EOM participants will be necessary in order for CMS to be able to detect a meaningful change in Medicare's expenditures as a result of the model test. PGP's that apply and are selected to participate in EOM will become an EOM participant upon signing the participation agreement with CMS. Similarly, payers that apply and are selected to align their payment methodology with CMS under EOM will become an EOM payer

upon signing an EOM Payer Memorandum of Understanding (MOU) with CMS.

i. EOM Participants

EOM participants will be required to implement certain Participant Redesign Activities (PRAs) and will have the option to bill a MEOS payment and will be financially responsible for episodes' total cost of care through the EOM performance-based payment (PBP) or performance-based recoupment (PBR). To be eligible for participation in EOM as an EOM participant, an applicant must be a Medicare-enrolled oncology PGP identifiable by a unique federal taxpayer identification number (TIN). Entities eligible to participate in EOM as "EOM participants" include PGPs with at least one EOM practitioner (as defined below in this section), and at least one of the EOM practitioners must be an oncology practitioner (as defined below in this section). Medicare-enrolled oncology PGPs that routinely refer beneficiaries to PPS-Exempt Cancer Hospitals (PCHs) for chemotherapy services are not eligible to participate in EOM. The PGP must also be a legal entity formed under applicable state, federal, or tribal law, and authorized to conduct business in each state in which it operates.

To participate in EOM as an EOM participant, an applicant must demonstrate compliance with all applicable state licensure requirements regarding risk-bearing entities. Each state has unique regulatory systems for health care delivery, the practice of medicine, fraud and abuse, and insurance, but CMS understands that states may not have laws that specifically address health care providers bearing substantial financial risk or distributing savings. Therefore, depending on the particular state laws and the discretion of state authorities, EOM participants may be subject to insurer or third-party administrator (TPA) licensure requirements. It is an EOM participant's responsibility to determine and meet all applicable state licensure requirements. EOM does not alter state law requirements, but CMS intends to engage with relevant state agencies to promote an understanding of EOM's features and requirements.

ii. EOM Practitioners

As noted above, to be eligible to participate in EOM as an EOM participant, a PGP must be composed of at least one "EOM practitioner," defined as a Medicare-enrolled physician or non-physician practitioner (e.g., nurse practitioner or physician assistant) identified by an individual National Provider Identifier (NPI), who furnishes Evaluation and Management (E&M) services to Medicare beneficiaries receiving chemotherapy for a cancer diagnosis, bills under the TIN of the PGP for such services, has reassigned his or her right to receive Medicare payments to the PGP, and appears on the PGP's EOM Practitioner List. The EOM Practitioner List means the list of EOM practitioners that are approved by CMS for participation in EOM. Further, for the oncology PGP to be eligible for participation in EOM, at least one of the EOM practitioners at the PGP must be an "oncology practitioner", defined as a Medicare-enrolled physician identified by an individual NPI with a specialty code of Hematology/Oncology or Medical Oncology. Each EOM participant will be required to ensure that its EOM practitioners comply with all applicable laws and regulations, as well as all applicable EOM participation requirements. Note that PGP applicants must submit a list of practitioners the PGP applicant proposes to satisfy the definition of an "EOM practitioner" as part of their application, as described in Appendix E.

We have found in our experience with OCM that some oncology PGPs, including both OCM practices and non-

OCM practices, employ practitioners who bill for services under the TIN of another entity, but do so at a minimal capacity (e.g., one or two practitioners who manage care for patients at another oncology PGP once or twice a month as an example). Therefore, for EOM, unlike OCM, we plan to have participation requirements that allow a limited degree of flexibility for EOM practitioners simultaneously billing under the TIN of the EOM participant and the TIN of another PGP, while still preserving program integrity. For example, an EOM practitioner may furnish care predominantly in an urban or suburban area and travel to and provide care in a rural area on an infrequent but recurring basis. As a result, in EOM, we will allow limited⁶ billing by EOM practitioners for outpatient cancer-related E&M services under the TIN of another PGP other than the EOM participant, without restriction on the outpatient site of service (e.g., a PGP based in a critical access hospital and federally qualified health center will be allowable). This will ensure that EOM participation does not impede access to oncology care in areas with underserved communities.⁷ However, we recognize that there are program integrity concerns related to the potential for EOM participants to move high-cost patients into a non-participating oncology PGP that employs the same practitioners (a practice known as “lemon-dropping”) or to encourage their EOM practitioners to move low-cost patients from the non-participating oncology PGP to the EOM participant (a practice known as “cherry-picking”). Therefore, CMS will establish a mandatory pooling threshold, such that EOM participants whose EOM practitioners bill a high volume of outpatient cancer-related E&M services under the TIN of another PGP will be required to enter into a pooling arrangement with that other PGP as a condition of their participation in EOM. We will also carefully monitor for any systematic movement of certain types of patients to (or from) non-EOM oncology PGPs and CMS will reserve the right to take remedial action in the event such a practice is discovered.

iii. Pooling of EOM Participants

Like OCM, EOM will also allow pooling of two or more EOM participants for purposes of the semi-annual reconciliation calculations described in section V.C.iii. Pooling in EOM will mean that the episode expenditures for two or more EOM participants are considered together for the reconciliation calculations, both to set the benchmark prices and to determine PBP or PBR amounts. EOM participants will be allowed to voluntarily form a pooling relationship with one or more other EOM participants should they so wish. As described above, in cases of limited billing overlap in which an EOM participant’s EOM practitioner bills under the TIN of an oncology PGP that is not participating in the model, that non-EOM oncology PGP will not be required to participate in the model or to form a mandatory pooling relationship with the EOM participant. Similarly, if there is limited billing overlap between two or more EOM participants, they will not be required to form a mandatory pooling relationship with one another. However, we will require mandatory pooling in cases of significant billing overlap

⁶ Details on the threshold set for the limited percentage are still being considered; further information will be made public in advance of the model start date.

⁷ In alignment with Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and the CMMI Strategy Refresh, “underserved communities” is defined for purposes of EOM as: populations sharing a particular characteristic, as well as geographic communities, that have been systemically denied a full opportunity to participate in aspects of economic, social, and civic life, as exemplified by the list in the definition of “equity” in EO 13985.

between EOM participants. Moreover, if billing overlap occurs to a substantial degree with a non-EOM oncology PGP and the EOM participant cannot cease or reduce the billing overlap, either the EOM participant will be required to terminate its participation in EOM or the non-EOM oncology PGP will need to apply to become an EOM participant, execute a participation agreement with CMS, and participate in the model in a mandatory pooling arrangement. If one or more EOM participants in a mandatory pooling relationship want to terminate the participation agreement, then CMS will terminate the participation agreements for all EOM participants in the pool unless the reason for their mandatory pooling is eliminated.

iv. Care Partners

EOM participants may elect to enter into financial arrangements with certain individuals or entities called “Care Partners”. For purposes of EOM, the term “Care Partner” means any Medicare-enrolled provider or supplier that engages in at least one of the PRAs during a performance period; has entered into a Care Partner arrangement with an EOM participant; is identified on the EOM participant’s Care Partner list; and is not an EOM practitioner. If a PGP applicant intends to enter into financial arrangements with Care Partners under EOM it must submit a proposed Care Partner list with its application and, if selected to participate in EOM, must resubmit a proposed Care Partner List on at least a semiannual basis during the model performance period. The Care Partner List is further described in section VII.B. below.

Each EOM participant will be required to ensure that its Care Partners comply with all applicable laws and regulations, as well as all applicable EOM participation requirements.

v. Program Overlap

Oncology PGPs participating in other CMS models and programs that provide health care entities with opportunities to improve care and reduce spending during the model performance period (July 2023-June 2028) will also be eligible to participate in EOM. Participation in these other CMS models and programs include, but may not be limited to the following. These overlap policies may be adjusted by CMS if or when CMS makes changes to existing models/ initiatives or implements new models/initiatives.

1) Medicare Accountable Care Organization (ACO) Initiatives

During the model performance period, EOM participants may simultaneously participate in Medicare ACO initiatives including the Global and Professional Direct Contracting Model (to be renamed the ACO Realizing Equity, Access, and Community Health (REACH) Model beginning in 2023), the Medicare Shared Savings Program (Shared Savings Program), and the three Comprehensive Kidney Care Contracting (CKCC) Options in the Kidney Care Choices (KCC) Model.

2) Other Innovation Center Models

EOM participants may participate in the following Innovation Center Models during the model performance period:

- Radiation Oncology (RO) Model⁸
- Bundled Payments for Care Improvement (BPCI) Advanced Model
- Comprehensive Care for Joint Replacement (CJR) Model
- Primary Care First (PCF) Model
- Maryland Total Cost of Care (TCOC) Model
- Pennsylvania Rural Health Model (PARHM)
- Community Health Access Rural Transformation (CHART) Model

Episode expenditure adjustments and payment adjustments for overlap between these initiatives and EOM are detailed in section V.E.

vi. EOM Payers

EOM will be a multi-payer model. Private payers, Medicare Advantage plans, and state Medicaid agencies are eligible to apply to partner with CMS in the model as EOM other payers. There would be two parts of EOM: one for EOM Medicare FFS (“EOM Medicare FFS”) that would apply to EOM beneficiaries, and another for EOM payers (“EOM other payer”) that would apply to patients of an EOM participant who are insured by an EOM payer (“EOM other payer beneficiaries”).

To be eligible to partner with CMS in EOM as an EOM other payer, a payer will be required to partner with at least one EOM participant (“partner EOM participant”). The EOM other payer’s collaboration with at least one partner EOM participant must be sustained throughout the entirety of the model to remain as an EOM other payer. For example, if an EOM other payer has one partner EOM participant and that partner EOM participant terminates from the model, the EOM other payer will no longer be able to participate in the model unless the EOM other payer is able to partner with a different partner EOM participant that is still participating in the model. CMS will encourage commercial payers that enter into a Memorandum of Understanding (MOU) with CMS to participate in EOM as EOM other payers to include their Medicaid managed care plans to the extent permitted by, and consistent with, the Medicaid managed care plan’s contract with the state. To the extent permitted by law, CMS will provide EOM other payers with aggregated model-level de-identified participant data, opportunities for collaboration and engagement with other payers, learning activities, and informational resources pertaining to EOM, as CMS has done in OCM.

III. Application Process

PGPs and payers that wish to participate in EOM are required to submit an application using the EOM RFA Application Portal. CMS is not soliciting Letters of Intent (LOIs) from potential applicants. An internal committee

⁸ Applicable only to the extent that the RO Model is implemented during the EOM performance period.

will review completed applications. Prior to application approval, CMS will also conduct a program integrity (PI) screening as further described in section III.B. Applications to participate in EOM will be accepted on the basis of completeness, quality of narratives, and the result of a program integrity screening.

A. Application

Applicants may access the application at: <https://app.innovation.cms.gov/EOM>. All EOM applications must be submitted by 11:59 pm Eastern Daylight Time on September 30, 2022. CMS may not review applications submitted after the deadline.

Information regarding EOM application process will be available on the Innovation Center website: <https://innovation.cms.gov/innovation-models/enhancing-oncology-model>.

Questions that arise during the application process may be directed to EOM mailbox: EOM@cms.hhs.gov.

B. Screening

PGP applications will be screened to determine eligibility for further review. Screening for applicant eligibility will include the criteria detailed in this RFA for EOM participants and applicable law and regulations.

In addition, CMS will conduct a PI screening of the PGP applicant and its proposed EOM practitioners and proposed Care Partners. CMS may deny a PGP applicant on the basis of information found during the PI screening. The PI screening may include, but is not limited to, the following:

- Confirmation of current Medicare enrollment status and history of adverse enrollment actions;
- Identification of delinquent Medicare and Medicaid debt;
- Review of performance in, and compliance with the terms of, other CMS models, demonstration programs, and initiatives;
- Review of compliance with Medicare and Medicaid program requirements;
- Review of billing history and any administrative audits, investigations, or other activities conducted regarding suspicious billing or other potential program fraud and abuse; and
- Review of any administrative, civil, or criminal actions related to program integrity or other factors relevant to participation in an initiative involving Federal funds.

To support the PI screening, PGP applicants will be required to disclose the following with respect to the PGP applicant and with respect to individuals and entities the PGP applicant proposes to be EOM practitioners and Care Partners: (i) any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed under an Innovation Center model, or to any agency of the federal government; (iv) whether any such individuals or entities are on a government suspension, debarment or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy. Failure to disclose any of the information described above could be grounds for

application denial or, if selected for participation in EOM, immediate termination from the model.

For reference, enforcement actions include criminal, civil or administrative legal actions relating to fraud and other alleged violations of law, initiated or investigated by the HHS Office of Inspector General and its law enforcement partners.

C. Withdrawal of Application

PGP and payer applicants seeking to withdraw a completed application must submit an electronic withdrawal request to CMS via email to the EOM mailbox (EOM@cms.hhs.gov) prior to signing the participation agreement or EOM Payer MOU, as applicable. The request must be submitted as a PDF on the organization's letterhead and signed by an official authorized to act on behalf of the organization. It should include the applicant organization's legal name; the organization's primary point of contact; the full address of the organization; and a description of the reason for the withdrawal.

IV. Health Equity Strategy

EOM seeks to improve quality of care and equitable health outcomes for all EOM beneficiaries. Research has highlighted differential cancer prevention, screening, diagnosis, treatment, and health outcomes by sociodemographic factors such as race, ethnicity, socioeconomic status (SES), and geography.^{9,10,11,12,13,14} For example, across all cancers combined, African Americans have a higher overall cancer incidence and death rate than all other racial and ethnic minorities in the U.S.¹⁵ In addition to race and ethnicity, socioeconomic status (SES) and geographic disparities influence mortality and survival rates. One study found that those with more education are less likely to die prematurely from colorectal cancer than those with less education, regardless of

⁹ Morris, A.M., Rhoads, K.F., Stain, S.C., Birkmeyer, J.D. (2010). Understanding Racial disparities in cancer treatment and outcomes. *Journal of the American College of Surgeons*. Retrieved from:

<https://www.sciencedirect.com/science/article/pii/S1072751510001857?via%3Dihub>

¹⁰ Green, A.K., Aviki, E.M., Matsoukas, K., Patil, S., Korenstein, D., & Blinder, V. (2018). Racial Disparities in Chemotherapy Administration for Early-Stage Breast Cancer: A Systematic Review and Meta-Analysis. *Breast Cancer Research and Treatment*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6958704/>

¹¹ AACR Cancer Disparities Progress Report. (2020). American Association for Cancer Research. Retrieved from: https://cancerprogressreport.aacr.org/wp-content/uploads/sites/2/2020/09/AACR_CDPR_2020.pdf

¹² Blake, K.D., Moss, J.L, Gaysynsky, A., Srinivasan, S., & Croyle, R.T. (2017). Making the case for investment in rural cancer control: An analysis of rural cancer incidence, mortality and funding trends. *Cancer Epidemiol Biomarkers Prev*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5500425/>

¹³ Yabroff, K.R., Han, Z., Zhao, J., Nogueira, L., & Jemal, A. (2020). Rural Cancer Disparities in the United States: A multilevel framework to improve access to care and patient outcomes. *JCO Oncology Practice*. /

¹⁴ National Cancer Institute. GIS Portal for Cancer Research. Rural-Urban Disparities in Cancer. Retrieved from: <https://gis.cancer.gov/mapstory/rural-urban/index.html>

¹⁵ American Association for Cancer Research, "AACR Cancer Disparities Progress Report 2020," accessed via: https://cancerprogressreport.aacr.org/wp-content/uploads/sites/2/2020/09/AACR_CDPR_2020.pdf

race/ethnicity.¹⁶ Another study discovered racial disparities in receipt of chemotherapy for colorectal cancer patients in urban settings, and general disparities in receipt of treatment for rural patients, holding race constant.¹⁷

Health disparities, defined here, are the preventable differences in the burden of disease, injury, violence, or opportunities that allow an individual to achieve optimal health, health quality, or health outcomes.¹⁸ According to the Office of Disease Prevention and Health Promotion's Healthy People 2020 Report, "health disparities adversely affect groups of people who have systematically experienced greater social or economic obstacles to health based on their racial or ethnic group, religion, socioeconomic -status, gender, age, or mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion."¹⁹ Examples of disparities in cancer care include, but are not limited to, delays in initiation of chemotherapy, more advanced stage of diagnosis, underrepresentation and access to clinical trials, decreased medication adherence, more frequent hospitalizations and ICU admissions near the end of life, and lower enrollment in hospice.^{20,21,22,23} Particular cancers, such as breast, colorectal, lung and prostate cancer, show increased incidence and mortality among certain minority and at-risk populations, contributing to cancer disparities and widening the health equity gap.²⁴

Reducing health disparities and advancing health equity requires addressing the underlying health-related social needs (HRSNs), such as challenges in obtaining proper nutrition during chemotherapy treatment, access to transportation for infusion appointments, and financial toxicity in chemotherapy cost, that impact the health

¹⁶ Jemal, A., Siegal, R.L., Ma, J., Islami, F., DeSantis, c., Sauer, A.G., Simard, E.P., Ward, E.M. (2015). Inequalities in Premature Death from Colorectal Cancer by State. *Journal of Clinical Oncology*.

¹⁷ Hao, Y., Landrine, H., Jemal., A. et al., (2011). Race, neighborhood characteristics and disparities in chemotherapy for colorectal cancer. *Journal of Epidemiology & Community Health*. Retrieved from: <https://jech.bmj.com/content/65/3/211.full>

¹⁸ CDC. Health Disparities. Retrieved from: <https://www.cdc.gov/aging/disparities/index.htm>

¹⁹ Healthy People 2020. Disparities. Retrieved from: <https://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities>

²⁰ Green, A.K., Aviki, E.M., Matsoukas, K., Patil, S., Korenstein, D., & Blinder, V. (2018). Racial disparities in chemotherapy administration for early-stage breast cancer: a systematic review and meta-analysis. *Breast Cancer Research and Treatment*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6958704/>

²¹ Smith., A.K., Earle, C.C., & McCarthy, E.P. (2008). Racial and Ethnic Differences in End-of-Life Care in Fee-for-Service Medicare Beneficiaries with Advanced Cancer. *Journal of the American Geriatrics Society*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2948958/>

²² Ajewole, V.B. et al., (2021). Cancer disparities and black American representation in clinical trials leading to the approval of oral chemotherapy drugs in the United States between 2009 to 2019. *JCO Oncology Practice*. Retrieved from: <https://ascopubs.org/doi/full/10.1200/OP.20.01108>

²³ AACR Cancer Disparities Progress Report. (2020). American Association for Cancer Research. Retrieved from: https://cancerprogressreport.aacr.org/wp-content/uploads/sites/2/2020/09/AACR_CDPR_2020.pdf

²⁴ NIH (2021). Cancer Disparities. Retrieved from: <https://www.cancer.gov/about-cancer/understanding/disparities>

and well-being of many Medicare beneficiaries with cancer. Social needs contribute to and often exacerbate health disparities if not identified and mitigated, for example through referrals and other patient navigation efforts.^{25,26} We believe there are additional opportunities to reduce health disparities in oncology care. In an evaluation of OCM,²⁷ CMS found modest and statistically significant impacts on unplanned readmissions, adherence to medication, and patient-reported care experiences that differed by race and ethnicity. To improve the quality of care and outcomes for all EOM beneficiaries, EOM *must* test new ways to address these health inequities. In alignment with CMS’s commitment to reducing health disparities and achieving health equity in CMS quality programs and within Innovation Center models,^{28,29} EOM is designed to advance health equity within all stages of model implementation and evaluation.³⁰

Equitable care³¹ is one of the six domains of health care quality developed by the Institute of Medicine (IOM) and promoted by the Agency for Healthcare Research and Quality (AHRQ), which is defined as providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, or socioeconomic status.^{32,33} Advancing health equity is a key Innovation Center strategic objective and necessary to achieve the Innovation Center’s goal of a health system that achieves equitable outcomes through

²⁵ AACR Cancer Disparities Progress Report. (2020). American Association for Cancer Research. Retrieved from: https://cancerprogressreport.aacr.org/wp-content/uploads/sites/2/2020/09/AACR_CDPR_2020.pdf

²⁶ Anderson, J.K.E., Jain, P., Wade, A., Morris, A.M, Slaboda, J.C., Norman, G.J. (2020). Indicators of Potential Health-Related Social Needs and the Association with Perceived Health and Well-Being Outcomes Among Community-Dwelling Medicare Beneficiaries. *Quality of Life Research*.

²⁷ Evaluation of the Oncology Care Model: Performance periods 1-5. (2021). Retrieved from: <https://innovation.cms.gov/data-and-reports/2021/ocm-evaluation-pp1-5>

²⁸ Brooks-LaSure, C., Fowler, E., Seshamani, M. & Tsai, D. (2021). Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years. *Health Affairs*. Retrieved from: <https://www.healthaffairs.org/doi/10.1377/hblog20210812.211558/full/>

²⁹ Centers for Medicare & Medicaid Services, Office of Minority Health (2021). Paving the Way to Equity: A Progress Report. Retrieved from: <https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf>

³⁰ Centers for Medicare & Medicaid Services, Office of Minority Health (2021). Paving the Way to Equity: A Progress Report. Retrieved from: <https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf>

³¹ In the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, (Executive Order 13985), “equity” is defined as “the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.”

³² Institute of Medicine (IOM). (2001). *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, D.C: National Academy Press: Retrieved from: <https://www.ncbi.nlm.nih.gov/books/NBK222274/>

³³ Agency for Healthcare Research and Quality. Six Domains of Health Care Quality. Retrieved from: <https://www.ahrq.gov/talkingquality/measures/six-domains.html>

high quality, affordable, person-centered care and is therefore critical to EOM's success.³⁴ CMS defines health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. CMS is working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive.³⁵ As such, EOM is introducing a number of policies to promote health equity.

First, EOM participants will be required to collect beneficiary-level sociodemographic data (e.g., race, ethnicity, language preference, disability status, sexual orientation, gender identity) from EOM beneficiaries willing to share this information, and report data collected to CMS. The sociodemographic data reported to CMS will be used for purposes of CMS's monitoring and evaluation activities, as described in detail in section VIII. CMS may also use the data to inform feedback reports sent to EOM participants and CMS's model dashboards. Additional information on data sharing in EOM can also be found in section VIII.

Second, EOM participants will also be required to use health-related social needs (HRSN) screening tools to collect HRSN data (e.g., food insecurity, housing instability and transportation concerns) from EOM beneficiaries to identify and address potential health disparities within their beneficiary populations. We believe the identification and subsequent addressing of social needs may be accomplished through a combination of patient navigation and care planning activities—both required Participant Redesign Activities (PRAs) under EOM, as described in section V.B.³⁶ We may require EOM participants to report HRSN data to CMS in later years of the model.

Third, we will require EOM participants to provide patient navigation, as appropriate, to EOM beneficiaries, including but not limited to facilitating linkages to follow-up services and community resources (e.g., make referrals to cancer survivor support groups and community organizations or other third parties that provide child/elder care, transportation, or financial support). Patient navigation bridges other gaps in care to reduce health disparities, such as access to clinical trials and connections to other health specialists or community resources. We will encourage EOM participants to develop relationships with community partners to accomplish this goal.

³⁴ CMS White Paper on CMS Innovation Center's Strategy: [Driving Health System Transformation - A Strategy for the CMS Innovation Center's Second Decade](https://innovation.cms.gov/strategic-direction-whitepaper). (2021). Retrieved from: <https://innovation.cms.gov/strategic-direction-whitepaper>

³⁵ CMS. Health Equity. Retrieved from: <https://www.cms.gov/pillar/health-equity#:~:text=Health%20equity%20means%20the%20attainment,language%2C%20or%20other%20factors%20that>

³⁶ Freund, K.M., Battaglia, T.A., Calhoun, E., Dudley, D.J., Fiscella, K., Paskett, E., Raich, P., & Roetzheim, R.G. (2008). National Cancer Institute Patient Navigation Research Program: methods, protocols and measures. ACS. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2698219/>

Fourth, we aim to include a payment methodology that acknowledges and is responsive to the greater resources that may be needed to care for complex and underserved communities; for example, we plan to adjust our cost benchmarks by dual eligibility and low-income subsidy (LIS) status as proxies for income and social risk.³⁷ More details on the benchmark adjustments can be found in section V.C.iii. Other payment features include Monthly Enhanced Oncology Services (MEOS) payments to EOM participants to support implementation of Enhanced Services, described in section V.B.i. The base MEOS payment will be \$70 per beneficiary per month during the 6-month episode, which will be included in the EOM participant's total cost of care (TCOC) responsibility. To encourage participation from PGPs who engage with underserved communities and to provide additional resources for the more resource intensive care management of complex patients, we will provide an additional MEOS payment of \$30 (for a total of \$100) for dual eligible beneficiaries. The additional MEOS payment of \$30 will not be included in the EOM participant's TCOC responsibility. We believe this adjustment will help mitigate any potential disincentive in a total cost of care model to serve dual eligible beneficiaries who historically account for a disproportionate share of Medicare expenditures and are associated with higher episode expenditures.^{38,39} We hope this adjustment will lead to improved access, treatment, and outcomes for these beneficiaries.

Fifth, to improve access to patient-centered care for EOM beneficiaries, EOM participants will also be required to provide EOM beneficiaries with 24/7 access to a clinician with real-time access to the practice's medical record, as described in section V.B.i.1, and through increased shared-decision making in developing an EOM beneficiary's care plan, as described in section V.B.i.3.

Sixth, EOM participants will be required to establish a health equity plan, as described in section V.B.ii, as part of their use of data for continuous quality improvement (CQI) efforts. We believe it is important for EOM participants to identify and monitor where disparities exist in their EOM beneficiary population and use data to support evidence-based strategies aimed at addressing health disparities identified and advancing health equity.

A more detailed description of our health equity strategy can be found in Appendix B.

V. Model Design Elements

EOM includes a number of key design elements that will allow CMS to test new features in payment and cancer care delivery in Medicare FFS. This section describes the EOM model baseline period, EOM model performance period, episode definition, eligible beneficiaries, included cancer types, initiating cancer therapies, episode,

³⁷ ASPE Second Report to Congress: Social risk factors and performance in Medicare's value-based purchasing program. (2020). Retrieved from: https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195191/Second-IMPACT-SES-Report-to-Congress.pdf

³⁸ Internal analyses of OCM data found that dual eligible beneficiaries are associated with higher episode expenditure in an oncology population.

³⁹ MedPAC. July 2021 Data Book: Health Care Spending and the Medicare Program. (2021). Retrieved from: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/data-book/july2021_medpac_databook_sec.pdf

duration of the model and scope, episode exclusion, and episode, attribution methodology. It also includes a detailed description of the care transformation requirements, the payment methodology, and quality strategy.

A. Model Episodes

EOM’s payment methodology centers around episodes of care for eligible beneficiaries triggered by receipt of an initiating cancer therapy for an included cancer type. EOM baseline episodes include those initiating in one of eight baseline periods. Episodes may initiate during one of the eight baseline periods and during the EOM model performance period.

i. EOM Model Baseline Period

The model baseline period is defined as the period between July 1, 2016 – June 30, 2020,⁴⁰ and is divided into 8 baseline periods. A “baseline period” is defined as the 6-month period of time during the model baseline period during which a given cohort of baseline period episodes begins. EOM performance period episodes will include those initiating in one of nine six-month periods during the model performance period. CMS has defined a baseline period to be 6-months long for consistency with the 6-month duration of EOM performance periods described below. Additional details on baseline period episode initiation dates and baseline period episode end dates are below in table 1.

Table 1. Baseline Period Episode Initiation and End Dates

Baseline Period	Episode Initiation Dates	Episode End Dates
1	07/01/2016 – 12/31/2016	12/31/2016 – 06/29/2017
2	01/01/2017 – 06/30/2017	06/30/2017 – 12/29/2017

⁴⁰ At this time, CMS expects the model baseline period to include episodes initiating from July 1, 2016 through June 30, 2020. Episodes with a COVID-19 diagnosis (fewer than 3% of baseline period episodes in the first six months of calendar year 2020) will be removed from the price prediction models. CMS will continue to monitor utilization patterns, expenditures, and the relative cost profile of COVID-19 episodes in years closer to the model start date in mid-2023. As data from more recent years become available, CMS may consider updating the model baseline period, adding COVID-19 episodes to the baseline period, and/or re-baselining the model after the model start. CMS will establish criteria for any changes to the model baseline period and will state these decision criteria in the EOM participation agreement.

3	07/01/2017 – 12/31/2017	12/31/2017 – 06/29/2018
4	01/01/2018 – 06/30/2018	06/30/2018 – 12/29/2018
5	07/01/2018 – 12/31/2018	12/31/2018 – 06/29/2019
6	01/01/2019 – 06/30/2019	06/30/2019 – 12/29/2019
7	07/01/2019 – 12/31/2019	12/31/2019 – 06/29/2020
8	01/01/2020 – 06/30/2020	06/30/2020 – 12/29/2020

ii. EOM Model Performance Period

The EOM model performance period is defined as the period between July 1, 2023 – December 31, 2027, and consists of 9 performance periods. A “performance period” is the 6-month period during the EOM model performance period during which a cohort of performance period episodes begins. Additional details on performance period episode initiation dates and performance period episode end dates are below in table 2.

Table 2. Performance Period Episode Initiation and End Dates

Performance Period	Episode Initiation Dates	Episode End Dates
1	07/01/2023 – 12/31/2023	12/31/2023 – 06/29/2024
2	01/01/2024 – 06/30/2024	06/30/2024 – 12/29/2024
3	07/01/2024 – 12/31/2024	12/31/2024 – 06/29/2025
4	01/01/2025 – 06/30/2025	06/30/2025 – 12/29/2025
5	07/01/2025 – 12/31/2025	12/31/2025 – 06/29/2026
6	01/01/2026 – 06/30/2026	06/30/2026 – 12/29/2026
7	07/01/2026 – 12/31/2026	12/31/2026 – 06/29/2027
8	01/01/2027 – 06/30/2027	06/30/2027 – 12/29/2027
9	07/01/2027 – 12/31/2027	12/31/2027 – 6/29/2028

i. Eligible Beneficiaries

CMS will include a Medicare FFS beneficiary in EOM in the event that they are an eligible beneficiary. Note that an EOM beneficiary is an eligible beneficiary that satisfies the below criteria and is in an episode attributed to an EOM participant. CMS also attributes eligible beneficiaries' episodes to non-EOM oncology PGPs for purposes of the EOM reconciliation calculations. Additional details regarding episode attribution and EOM reconciliation are described below in section V.A.v. and section V.C.iii, respectively. To be an eligible beneficiary, an individual must meet the following criteria:

- Has a diagnosis for an included cancer type;
- Receives an initiating cancer therapy that triggers an episode;
- Receives a qualifying E&M service from an oncology PGP during the episode (i.e., within six months of receipt of the initiating cancer therapy);
- Is eligible for Medicare Part A and enrolled in Medicare Part B for the entirety of the episode;
- Is not enrolled in any Medicare managed care organization, such as Medicare Advantage, at any point during the episode;
- Is not eligible for Medicare on the basis of an End Stage Renal Disease (ESRD) diagnosis at any point during the episode; and
- Has Medicare as his or her primary payer for the entirety of the episode.

CMS will include only those Medicare beneficiaries who have a diagnosis for an included cancer type, receive an initiating cancer therapy that will trigger an episode, and receive qualifying E&M services from an oncology PGP, for consistency with the scope and duration of EOM episodes (see section V.A.iv), as well as the methodology for defining and attributing those episodes to oncology PGPs, including EOM participants and non-EOM oncology PGPs (see section V.A.vi). CMS will limit the population of beneficiaries included in the model to those with Medicare Parts A and B given that EOM is focused on program spending in Medicare FFS.

Note that a beneficiary participating in a clinical trial for which Medicare pays routine costs may be considered an eligible beneficiary, provided that such beneficiary meets all of the beneficiary eligibility criteria. We will consider routine costs of a clinical trial to be all items and services that are otherwise generally available to Medicare beneficiaries (that are provided in either the experimental or the control arms of a clinical trial). Medicare pays routine costs by way of FFS payments, making it appropriate to include beneficiaries who participate in a clinical trial in EOM. However, as described in section V.A.iv an episode is triggered based on a beneficiary's receipt of an included cancer therapy, which is determined based on certain Medicare claims. Therefore, a beneficiary in a clinical trial in which all cancer therapies are provided at no cost to Medicare, and there is no associated paid Medicare claim (for any cancer therapy), will not be an eligible beneficiary because they will not be in an episode.

ii. Included Cancer Types

Subject to certain exceptions, seven cancer types will be included in EOM. These include breast cancer, chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer. These cancer types were selected because they are all prevalent cancer types treated in the United States and all have sufficient Medicare claims data for CMS to calculate benchmark prices for episodes among the Medicare

FFS population for purposes of EOM. In addition, these seven cancers are all commonly treated with systemic chemotherapy,⁴¹ and only systemic chemotherapy would have the potential to trigger an episode for purposes of EOM.

EOM's design, unlike that of OCM, will have certain cancer type exclusions that are expected to increase the likelihood of model savings. Specifically, low-risk breast cancer and low-intensity prostate cancer will be excluded from EOM because episodes for these cancer types are not achieving savings in OCM. The inclusion of beneficiaries with low-risk breast and low-intensity prostate cancer may jeopardize any potential savings under EOM.⁴² We also believe that a focus on the most common higher-risk and higher-intensity cancers in EOM will allow EOM participants to focus their care management and coordination efforts more effectively.

Each episode will be assigned a cancer type for monitoring, benchmarking, and reconciliation purposes. CMS will review the claims for qualifying E&M services with dates of service that occurred during an episode, and then assign a cancer type to the episode based on the plurality of ICD-10 cancer diagnosis codes included on those claims.

iii. Initiating Cancer Therapies

The receipt of an initiating cancer therapy by an eligible beneficiary for an included cancer type will trigger the start of an episode, as long as the beneficiary receives a qualifying E&M service during the episode (as described in section V.A.iv below). CMS will maintain a list of initiating cancer therapies. CMS will update this list of initiating therapies with EOM participants prior to the start of the performance period to which it will apply. CMS will include a chemotherapy drug on this list of initiating cancer therapies if we determine the chemotherapy drug is a systemic chemotherapy commonly used to treat beneficiaries undergoing active treatment of an included cancer type.

iv. Episode Duration and Scope

Each episode will begin with a beneficiary's receipt of an initiating cancer therapy (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 in the 59 days preceding, the fill date on the Part D drug claim) and must include a qualifying E&M service during the 6-month period that follows the receipt of the initiating cancer therapy.

⁴¹ According to the National Cancer Institute, systemic chemotherapy is treatment with anticancer drugs that travel through the blood to cells all over the body. National Cancer Institute <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/systemic-chemotherapy>.

⁴² For the purposes of EOM, low-risk breast cancer is defined as breast cancer treated with only long-term oral endocrine chemotherapy; and low-intensity prostate cancer is defined as prostate cancer treated with either androgen deprivation and/or anti-androgen therapy without any other chemotherapy.

For the purposes of EOM, a qualifying E&M service means the evaluation and management of a new or established patient, furnished to an eligible beneficiary with an included cancer type and with a Current Procedural Terminology (CPT®)⁴³ code in the ranges 99201-99205 or 99211-99215.

Episodes will last for 6 months. A CMS analysis of Medicare claims data indicates that 6-month episodes appropriately captured the majority of chemotherapy treatment and cancer-related expenditures. The fraction of beneficiaries who continue to receive chemotherapy steeply declines during the 6-month period following initiation of cancer therapy before leveling off. If a beneficiary continues to receive chemotherapy after completing the 6-month episode, a new episode of care will begin. If the beneficiary entered hospice or died during the 6-month episode, the episode will still continue for the full 6 months, and it will include hospice costs or claims for care that occurred around the time of death but were not processed until after the beneficiary's death.

v. Episode Exclusions

An episode during which a beneficiary is treated with a chimeric antigen receptor t-cell therapy (CAR T-cell therapy) will be removed from the baseline periods and the performance periods because these therapies are associated with a single (or very few) potentially extremely high-cost infusion(s). MEOS billed for these episodes will be recouped as detailed in section V.C.ii.3.

Additionally, for purposes of establishing baseline period episodes, CMS will remove episodes that initiated during the model baseline period (mid-2016 – June 30, 2020) that include an inpatient or outpatient claim with a COVID-19 diagnosis. CMS will also consider removing episodes with a COVID-19 diagnosis that initiated during the EOM model performance period from the model's reconciliation calculations if the care for such beneficiaries remains extremely costly as more recent data become available.

vi. Episode Attribution

CMS will attribute episodes to oncology PGPs, including both EOM participants and non-EOM oncology PGPs, on a retrospective basis for each baseline period and performance period. For each baseline period, baseline period episodes will be attributed to non-EOM oncology PGPs, as episodes attributed to non-EOM oncology PGPs will be used for purposes of the cancer type-specific price prediction models and the experience adjuster described in sections V.C.iii.3(a) and V.C.iii.3(b), respectively. For each performance period, episodes attributed to non-EOM oncology PGPs will be used for the calculation of the trend factor and novel therapy adjustment as described in section V.C.iii.3(b).

For both the baseline periods and performance periods, CMS will attribute an episode to an oncology PGP through a series of steps. First, we will determine if an EOM participant or a non-EOM oncology PGP is eligible for episode attribution. For either an EOM participant or a non-EOM oncology PGP to be eligible to be attributed an episode, at least one qualifying E&M service must be billed by an oncology practitioner with a

⁴³ Current Procedural Terminology (CPT®) is a registered trademark of the American Medical Association.

Hematology/Oncology or Medical Oncology specialty code under the TIN of the oncology PGP during the period in which the episodes initiated.

Second, after determining whether an EOM participant or a non-EOM oncology PGP is eligible for episode attribution, we will attribute an episode to the eligible EOM participant or non-EOM oncology PGP that provided the first qualifying E&M service after the EOM beneficiary received the initiating cancer therapy (called the initiating oncology PGP), as long as that PGP also provided at least 25 percent of the qualifying E&M services during the episode. We will prioritize attributing episodes to oncology PGPs that meet both of these criteria to strike a balance between attributing an episode to the initial oncology PGP that started the care pattern for the beneficiary and ensuring that the episode is not attributed to an oncology PGP that provided care only at the beginning of an episode. In comparison to OCM, in which attribution is based purely on plurality of care, this attribution method is expected to promote predictability of performance period episode attribution in real time, so that EOM participants can more accurately predict during the episode which episodes of care will ultimately be attributed to them at reconciliation. If the initiating oncology PGP did not bill at least 25 percent of cancer-related E&M services during the episode, then episode attribution will default to a plurality approach, with the episode attributed to the oncology PGP that billed the plurality of cancer-related E&M services furnished to the beneficiary.

Performance period episodes will be defined and attributed in the same way as baseline period episodes, as detailed above. For each performance period, we will identify the national set of episodes meeting EOM criteria and attribute each episode to an EOM participant or a non-EOM oncology PGP. The performance period episodes attributed to each EOM participant will make up the beneficiary population for that practice for that performance period. The EOM participant will be accountable for the actual Medicare FFS expenditures incurred for the episodes attributed to them for each performance period.

B. Care Transformation

Under the terms of the participation agreement, EOM participants will be required to implement eight participant redesign activities (PRAs), a key element of the quality strategy, described in section V.B. While most of the PRAs were components of OCM's practice redesign activities, EOM participants will be required to implement two additional activities in EOM: identifying EOM beneficiary social needs using a health-related social needs (HRSN) screening tool, described in section V.B.i.5; and gradually implementing electronic Patient Reported Outcomes (ePROs), described in section V.B.i.6. The complete list of EOM PRAs includes:

- 1) Provide beneficiaries 24/7 access to an appropriate clinician with real-time access to the EOM participant's medical records;
- 2) Provide patient navigation, as appropriate, to EOM beneficiaries. Further details on minimum standards of patient navigation can be found in Appendix C;
- 3) Document a care plan for each EOM beneficiary that contains the 13 components of the Institute of Medicine (IOM) Care Management Plan, as applicable to the EOM beneficiary. Further details on the 13 IOM care plan elements can be found in Appendix D;
- 4) Treat beneficiaries with therapies in a manner consistent with nationally recognized clinical guidelines;

- 5) Identify EOM beneficiary health-related social needs (HRSN) using a health-related social needs screening tool;
- 6) Gradual implementation of electronic Patient Reported Outcomes (ePROs);
- 7) Utilize data for continuous quality improvement (CQI);
- 8) Use Certified EHR Technology (CEHRT) as specified in 42 CFR § 414.1415(a).

The first six participant redesign activities are defined as Enhanced Services when furnished to a beneficiary during the period that begins 30 days prior to the start of an episode and ends 30 days after the last day of the episode. As described in section V.C.ii, EOM participants will have the option to bill for the MEOS payment to support the investments necessary for providing Enhanced Services to EOM beneficiaries during episodes under EOM. EOM participants will have a 90-day period from the participant's start date to implement the first five enhanced services, as described in section V.B.i., with the sixth enhanced service, ePROs, being gradually implemented, as described in section V.B.i.6. However, EOM participants will only be allowed to bill for MEOS once they furnish Enhanced Services to EOM beneficiaries.⁴⁴ EOM participants will also have a 90-day period from the EOM participant's start date to begin to use data for continuous quality improvement (CQI), another PRA, as described in section V.B.ii. The requirements for CEHRT use and attestation are described in section V.B.iii.

The first four EOM participant redesign activities, as well as CEHRT use and CQI, are all required practice redesign elements within OCM. OCM evaluation reports^{45,46} noted that OCM practices reported process improvements as a result of implementing the practice redesign activities, such as, but not limited to:

- OCM practices reported using care plans to improve information sharing with patients;
- Many OCM practices reported increasing access to same-day appointments and urgent care;
- OCM practices reported working to enhance shared decision making and communication; and
- OCM practices reported enhancing many care processes to better manage patients' symptoms in the outpatient setting by streamlining triage of patient phone calls and addressing chemotherapy toxicity in an effort to prevent ED visits and hospitalizations, and to improve end-of-life (EOL) care.

The OCM evaluation reports noted that oncologists and other clinicians in OCM practices believe that OCM's practice redesign activities improve patient care and that patients have better information about their treatment because of the practice's participation in OCM. While OCM quantitative evaluation results have not shown a measurable impact of OCM practice transformation requirements on hospital or outpatient service

⁴⁴ This applies to the first five Enhanced Services, during the initial 90-day period from the EOM participant's start date. EOM participants must adhere to the implementation timeline for the sixth Enhanced Service, ePROs, as described in section V.B.i.6.

⁴⁵ Evaluation of the Oncology Care Model: Performance periods 1-3. (2020). Retrieved from: <https://innovation.cms.gov/data-and-reports/2020/ocm-evaluation-annual-report-2>

⁴⁶ Evaluation of the Oncology Care Model: Performance periods 1-5. (2021). Retrieved from: <https://innovation.cms.gov/data-and-reports/2021/ocm-evaluation-pp1-5>

utilization, there are a number of positive care transformations reported by OCM practices and outlined in recent OCM evaluation reports that highlight the role of practice redesign activities in improving patient care and the patient care experience. We believe that these practice transformation activities take time to produce measurable results, and we are encouraged by early qualitative findings. We believe that by incorporating best practices from the OCM experience, EOM can build upon initial OCM experiences. We believe these practice redesign activities are relevant, evidence-based, and critical for high-quality care in oncology.

Further, many of these PRA requirements are in alignment with the goals of other organizations also seeking to improve cancer care (e.g., the Commission on Cancer); and, therefore, in combination with CMS, there is a possibility to achieve the broad adoption of these important components of cancer care. Many OCM practices have told CMS they provide these practice redesign activities for all their patients since total practice transformation is both ethically more satisfying and operationally easier than having different workflows for patients with different payers. In EOM, we plan to continue encouraging participants to implement changes to their workflows and clinical care for all of their patients.

i. Enhanced Services

1) Provide EOM beneficiaries 24/7 access to an appropriate clinician who has real-time access to the EOM participant's medical records.

We believe this Enhanced Service will broaden access to care for EOM beneficiaries while allowing EOM participants flexibility to select approaches for efficient care coordination and leveraging the EOM participants' existing systems. We believe this requirement promotes patient safety while avoiding inappropriate acute care utilization. As many cancer patients have complex medical needs that may change over the course of treatment, we believe continuous availability of patient-provider communication in real-time, as well as access to the most up-to-date record of care for the cancer treatment regimen, are fundamental to EOM. We believe this requirement will improve the quality of care furnished to the EOM beneficiary, and reduce care fragmentation that can result in avoidable hospitalizations and ED visits.

We believe access to care extends beyond access to insurance; for example, there are inequities in access to timely receipt of care that when mitigated can improve the care experience and reduce avoidable acute care utilization.^{47,48} We will encourage EOM participants to assess their protocols to promote equity, including, but not limited to, identifying health equity goals and identifying potential barriers to access to care (e.g., waiting times, cultural competencies, health literacy, transportation).⁴⁹

⁴⁷ Institute of Medicine (1993). Access to Health Care in America. *NASEM*. Retrieved from: <https://www.ncbi.nlm.nih.gov/books/NBK235882/>

⁴⁸Daly, B., Michelis, L.C., Sprandio, J.D., Kapke, J.T., Narra, R.K., Malosh, E., Zervoudakis, A., Holland, J., & Zabolocki, M. (2020). From theory to practice: Implementation of strategies to reduce acute care visits in patients with cancer. American Society of Clinical Oncology Educational Book.

⁴⁹ Derose, K.P, Gresenz, C.R., & Ringel, J.S. (2011). Understanding Disparities in Health Care Access – And Reducing Them – Through a Focus on Public Health. *Health Affairs*.

2) Provide patient navigation, as appropriate, to EOM beneficiaries

EOM participants will be required to provide the core functions of patient navigation, as appropriate, to all EOM beneficiaries who request and/or need these services. While not every EOM beneficiary may need patient navigation services, these services should be available to all EOM beneficiaries. We believe that patient navigation and care planning (as described below) are key elements of identifying and addressing health disparities.⁵⁰ We believe patient navigation will allow EOM participants to offer support and guidance to EOM beneficiaries with the goal of overcoming barriers to timely, quality care.⁵¹ Minimum requirements for patient navigation are included in Appendix C. The list of the patient navigation services was selected based on the review of National Cancer Institute (NCI) Patient Navigation Research Program patient navigation examples⁵² and the experience of OCM practices. While the patient navigation services listed are not an exhaustive list of all possible patient navigation services EOM participants may offer to EOM beneficiaries, we believe offering, at a minimum, each activity listed in Appendix C will allow EOM participants to provide high-quality care and facilitate care coordination and practice care transformation for EOM beneficiaries. Examples of additional patient navigation activities conducted by OCM practices include assessing and facilitating referrals to address whole-person health needs (e.g., social worker, psychologist), and establishing interdisciplinary care teams composed of clinical and/or lay navigators to provide services or support.

3) Document a care plan for each EOM beneficiary that contains the 13 components in the Institute of Medicine (IOM) Care Management Plan applicable to the EOM beneficiary.

We believe documenting care plans to be an integral component to providing high-quality care. Care plans facilitate communication between health care providers and their patients while simultaneously allowing for shared-decision making in navigating cancer care.⁵³ Shared decision-making factors into the decision to initiate chemotherapy and subsequent cancer therapies as well as in the development of the required care plans. Actively engaging beneficiaries and gathering beneficiary-level data has been associated with better health outcomes, and in combination with patient navigation, is a key element of EOM's health equity strategy, described in section IV.⁵⁴ We recognize and aim to highlight the importance of beneficiary involvement and engagement in the care planning process. As such, the EOM participant will be required to document a comprehensive cancer care plan for the EOM beneficiary, and the EOM participant will be required to engage

⁵⁰ Freund, K.M., Battaglia, T.A., Calhoun, E., Dudley, D.J., Fiscella, K., Paskett, E., Raich, P., & Roetzheim, R.G. (2008). National Cancer Institute Patient Navigation Research Program: methods, protocols and measures. *ACS*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2698219/>

⁵¹ The EOM definition of patient navigation is modified from the National Cancer Institute (NCI), Patient Navigation Research Program. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2698219/>

⁵² Freund, K.M., Battaglia, T.A., Calhoun, E., Dudley, D.J., Fiscella, K., Paskett, E., Raich, P., & Roetzheim, R.G. (2008). National Cancer Institute Patient Navigation Research Program: methods, protocols and measures. *ACS*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2698219/>

⁵³ Please see the IOM'S Delivering high-quality cancer care: Charting a new course for a system in crisis. Retrieved from: <https://www.ncbi.nlm.nih.gov/books/NBK202148/>

⁵⁴ Hibbard, J.H. & Greene, J. (2013). What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs. *Health Affairs*.

the EOM beneficiary in the development of the care plan. We will encourage EOM participants to share a physical and/or electronic copy of the care plan with the EOM beneficiary for discussion and review of prognosis and treatment goals on an ongoing basis.

The care plan must include EOM beneficiary information from the 13 elements identified in the Institute of Medicine Report, *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*, to the extent relevant and applicable to that beneficiary.⁵⁵ These 13 elements are included in Appendix D. The IOM report and 13 elements of the care plan serves as a blueprint for delivering high-quality, patient-centered care.

Two elements within the IOM care plan directly promote health equity. The first is addressing a patient's psychosocial health needs.⁵⁶ For example, stress, untreated mental illness and social factors such as social isolation, can contribute to emotional distress and affect a patient's adherence to treatment and quality of life.⁵⁷ Social risk factors and their accompanying HRSNs can contribute to health disparities.⁵⁸ The second is estimating total and out-of-pocket costs for cancer treatment for the period of each EOM episode, for each EOM beneficiary. Many people diagnosed with cancer in the United States experience a significant financial burden associated with their treatment.⁵⁹ Economic stability, inclusive of expenses, debt, and medical bills, has been identified as a key social determinant of health (SDOH).⁶⁰ Financial distress, also known as financial toxicity, can impact the mental, physical and emotional health of a cancer patient and is an important consideration in providing whole-person care.⁶¹

4) Treat EOM beneficiaries with therapies in a manner consistent with nationally recognized guidelines.

We will require EOM participants to treat EOM beneficiaries with therapies consistent with CMS-approved clinical guidelines, except as contraindicated by clinical decision-making for a given EOM beneficiary. For purposes of this requirement, CMS will approve only those clinical guidelines that are:

- Nationally recognized;
- Developed by clinicians with relevant disease expertise;

⁵⁵ Please refer to Section 3, Pg. 3-23 Box 3-3, for information on the 13 components of the IOM Care Management Plan. The full report can be found here: <https://www.ncbi.nlm.nih.gov/books/NBK202148/>

⁵⁶ This IOM care plan element "addressing a patient's psychosocial health needs" includes psychological, vocational, disability, legal, or financial concerns and their management.

⁵⁷ IOM. (2008). *Cancer Care for the Whole Patient: Meeting psychosocial health needs*. NASEM. Retrieved from: <https://www.ncbi.nlm.nih.gov/books/NBK4015/>

⁵⁸ Accounting for Social Risk Factors in Medicare Payment (2017). NASEM. Retrieved from: <https://www.ncbi.nlm.nih.gov/books/NBK395663/>

⁵⁹ Zafar S. Y. (2015). Financial Toxicity of Cancer Care: It's Time to Intervene. *Journal of the National Cancer Institute*, 108(5), djv370. Retrieved from: [Financial Toxicity of Cancer Care: It's Time to Intervene \(silverchair.com\)](https://doi.org/10.1093/jnci/kjv370).

⁶⁰ Artiga, S, & Hinton, E. (2018). Beyond Health Care: The role of social determinants in in promoting health and health equity. KFF.

⁶¹ National Cancer Institute. Financial Toxicity (Financial Distress) and Cancer Treatment (PDQ®)-Patient Version. Retrieved from: <https://www.cancer.gov/about-cancer/managing-care/track-care-costs/financial-toxicity-pdq>.

- Evidence-based with links to supporting literature; and
- Patient-focused, with alternative treatment options that account for patient variability, preferences, and comorbidities.

Examples of clinical guidelines that satisfy these criteria include those published by the American Society of Clinical Oncology (ASCO®) and the National Comprehensive Cancer Network (NCCN®).

Clinical guidelines are evidence-based recommendations for clinical practice that are used to determine appropriate treatments and care,⁶² including genomic testing, when appropriate. We believe that treating EOM beneficiaries with therapies consistent with recognized clinical guidelines will improve the quality of care furnished to EOM beneficiaries by decreasing unnecessary practice variation and increasing the use of proven, beneficial research into clinical practice. EOM participants will generally be required to use nationally recognized clinical guidelines in selecting therapies for EOM beneficiaries due to the rigor and review required to develop these guidelines. EOM participants may utilize pathways programs to satisfy this requirement, as long as the pathways are based on clinical guidelines approved by CMS. We encourage EOM participants to use a health equity lens when utilizing clinical guidelines. We believe adhering to guidelines may help address disparities in care. One study exploring rural/urban differences in survival outcomes found that differences in outcomes may be due, in part, to inadequate receipt of guideline-concordant care; suggesting the importance of guideline-concordant cancer care in mitigating health disparities.⁶³ However, we believe it is important for care to remain individualized and that EOM participants should deliver culturally competent care.

5) Identify EOM beneficiary social needs using a health-related social needs screening tool

EOM participants will be required to identify and will be encouraged to address disparities in care, specifically related to beneficiary HRSNs and SDOH. HRSNs are the adverse social conditions that negatively impact a person's health or health care.⁶⁴ Where SDOH are the structural and contextual factors that shape a person's life, HRSNs are individual level factors, such as, challenges in obtaining proper nutrition during chemotherapy treatment, access to transportation for infusion appointment, and financial toxicity from chemotherapy costs. HRSNs impact the health and well-being of many Medicare beneficiaries with cancer and pose a risk of exacerbating health disparities if not identified and mitigated, for example, referrals and other patient

⁶² Melnyk, M.B. (2015). Important Information About Clinical Practice Guidelines: Key Tools for Improving Quality of Care and Patient Outcomes. *Worldviews on Evidence-Based Nursing*.

⁶³ Geographic Distribution and Survival Outcomes for Rural Patients with Cancer Treated in Clinical Trials
<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2696871>

⁶⁴ A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. (2021). Retrieved from: <https://innovation.cms.gov/media/document/ahcm-screeningtool-companion>

navigation efforts.^{65,66} Evidence shows that identifying and addressing SDOH is essential to reducing health disparities and promoting health and health equity.⁶⁷ A number of OCM practices began to incorporate tools to screen for distress and psychosocial needs such as transportation, social support, and nutrition to address disparities in care, and we believe there is room for improvement to standardize screening across all EOM participants.⁶⁸

Examples of free and non-proprietary screening tools include, but are not limited to the NCCN Distress Thermometer and Problem List, the Accountable Health Communities (AHC) Screening Tool, and the Protocol for Responding to and Assessing Patients' Assets, Risks and Experiences (PRAPARE) Tool.^{69,70, 71} The HRSN screening tools included here are examples only and do not constitute an endorsement by CMS or CMS affiliates, and EOM participants will have flexibility to use other HRSN screening tools. In addition, CMS is currently working to create a Fast Healthcare Interoperability Resources (FHIR)-based application programming interface (API) that will be available for EOM participants to use as an HRSN screening tool. Where appropriate, we encourage EOM participants to use this API, but will allow for flexibility if an EOM participant is using another HRSN screening tool that meets the unique needs of its beneficiary population. EOM participants will be required to screen EOM beneficiaries at a minimum for HRSNs in the following domains: food insecurity, transportation, and housing. We will encourage EOM participants to screen for additional HRSNs to meet the needs of their unique patient population, including, but not limited to social isolation, emotional distress, interpersonal safety, and financial toxicity. As additional standards are developed, CMS may require that EOM participants report HRSN data to CMS, beginning in later performance periods.

6) Gradual implementation of electronic Patient Reported Outcomes (ePROs)

⁶⁵ AACR Cancer Disparities Progress Report. (2020). American Association for Cancer Research. Retrieved from:

https://cancerprogressreport.aacr.org/wp-content/uploads/sites/2/2020/09/AACR_CDPR_2020.pdf

⁶⁶ Anderson, J.K.E., Jain, P., Wade, A., Morris, A.M, Slaboda, J.C., Norman, G.J. (2020). Indicators of Potential Health-Related Social Needs and the Association with Perceived Health and Well-Being Outcomes Among Community-Dwelling Medicare Beneficiaries. Quality of Life Research.

⁶⁷ Artiga, S, & Hinton, E. (2018). Beyond Health Care: The role of social determinants in promoting health and health equity. KFF.

⁶⁸ Evaluation of the Oncology Care Model: Performance periods 1-5. (2021). Retrieved from:

<https://innovation.cms.gov/data-and-reports/2021/ocm-evaluation-pp1-5>

⁶⁹ Please refer to this link for the National Comprehensive Cancer Network®, NCCN Distress Thermometer and Problem List: https://www.nccn.org/docs/default-source/patient-resources/nccn_distress_thermometer.pdf?sfvrsn=ef1df1a2_4

⁷⁰ CMS has secured permissions from the original authors of the questions for model participants to use, copy, modify, publish, and distribute the questions for the Accountable Health Communities (AHC) Model and other CMS initiatives only. However, the license agreement does not extend to third parties who contract with model participants to perform services related to the model. Third parties who contract with model participants will require a separate license agreement to use this screening tool. For more information and a link to the screening tool please see here:

<https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf>.

⁷¹ Please refer to this link for more about the PRAPARE screening tool: <https://prapare.org/the-prapare-screening-tool/>

The sixth enhanced service is the gradual implementation of ePROs. Patient Reported Outcomes (PROs) are measurements based on a report that comes directly from the patient, without amendment or interpretation of the patient's response;⁷² ePROs are the electronic capture of this data.⁷³ The use of ePROs has been shown to lead to improved survival, sometimes exceeding the benefits of oncology drugs.^{74,75} Using ePROs tools in oncology settings can lead to better identification of patients' needs, improved patient-provider communication, care management, patient satisfaction, and advances in cancer outcomes, such as decreased ED visits and increased survival from certain cancers.^{76,77} Furthermore, ePROs can aid both process and outcome quality improvements, including clinician awareness of concerning changes in a patient's clinical status on a timely basis, translating to improved survival outcomes when part of oncology treatment.^{78,79} While ePROs have seen relatively limited adoption to date, the COVID-19 public health emergency has emphasized the need for additional data provided by patients outside of in-person visits in cancer clinical practice, as demonstrated by the increased utilization of telehealth and remote communication technologies that have allowed health care

⁷² BEST (Biomarkers, Endpoints, and other Tools) Resource. (2016). Glossary. Retrieved from <https://www.ncbi.nlm.nih.gov/books/NBK338448/#IX-P>

⁷³ Jensen, R. E., Snyder, C. F., Abernethy, A. P., Basch, E., Potosky, A. L., Roberts, A. C., Loeffler, D. R., & Reeve, B. B. (2014). Review of electronic patient-reported outcomes systems used in cancer clinical care. *Journal of oncology practice*, 10(4), e215–e222. Retrieved from: <https://doi.org/10.1200/JOP.2013.001067>

⁷⁴ Basch E, Deal AM, Dueck AC, et al. (2017) Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. *JAMA*. 318(2):197–198. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5817466/>

⁷⁵ Ladanie, A., Schmitt, A.M., Speich, B. (2020). Clinical trial evidence supporting US Food and Drug Administration approval of novel cancer therapies between 2000 and 2016. *JAMA*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7656288/>

⁷⁶ Chen, J., Ou, L., & Hollis, S.J. (2013). A systematic review of the impact of routine collection of patient reported outcome measures on patients, providers and health organizations in an oncologic setting. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3700832/>

⁷⁷ Basch E., Deal, A. M., Kris, M.G., Scher, H.L., Hudis, C.A., Sabbatini, P., Rogak, L., Bennett, A.V., Dueck, A. C., Atkinson, T.M. Chou, J.F., Dulko, D., Sit, L., Barx, A., Novotny, P., Fruscione, M., Sloan, J.A., & Schrag, D. (2016). Symptom monitoring with patient-reported outcomes during routine cancer treatment: A randomized controlled trial. *Journal of Clinical Oncology*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4872028/>

⁷⁸ Basch E., Deal A.M., Dueck A.C., et al. (2017) Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring during Routine Cancer Treatment. 318(2):197-198. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5817466>

⁷⁹ Denis F., Basch E., Septans A.L., et al. (2019) Two-Year Survival Comparing Web-Based Symptom monitoring vs Routine Surveillance Following Treatment for Lung Cancer. *JAMA*. 321(3) 306-307. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6439676/>

providers to deliver care to patients, safely, within their homes.^{80,81,82,83,84} We believe the adoption of ePROs technology by EOM participants will improve the quality of care delivered to EOM beneficiaries.

(a) ePROs Tool Standard Domains

Because there are several ePROs tools available, we are not requiring the use of a specific ePROs tool in order to encourage ePROs uptake and to avoid limiting innovation in this field. However, we believe outlining defined domains and standards for use of ePROs under the model will ensure the use of high-quality tools and help meet EOM's goal of improved care quality. We believe defining domains will preserve flexibility and allow for new ePROs development, as well as the use of existing ePROs tools that may already be utilized by EOM participants prior to the start of EOM. First, EOM participants will be required to use ePROs tools that capture, where applicable, outcomes for each of the following domains:

- Symptoms and/or toxicity (e.g., frequency, severity, activity interference, presence/absence);
- Functioning (e.g., physical functioning, role functioning);
- Behavioral health (e.g., psychosocial functioning, anxiety, depression, other behavioral health conditions);
- Health-related social needs (e.g., financial toxicity, transportation, food insecurity)⁸⁵

These domains represent areas for potential quality improvement in oncology service delivery. We encourage the use of non-proprietary ePROs as a way to further transparency and consistency across CMS programs. In line with CMS' focus on achieving health equity, we encourage EOM participants to consider ePROs tools and communication methods that are valid and reliable for diverse populations.

(b) Integration of ePROs with electronic health records (EHR)

EOM participants will be required to integrate ePROs data into electronic health records (EHRs). The EOM participant and its EOM practitioners must be able to access ePROs data integrated with the electronic health records. Integration of clinically meaningful PRO data in an EHR has shown to be an effective way to leverage

⁸⁰ Denis F., Basch E., Septans A.L., et al. (2019) Two-Year Survival Comparing Web-Based Symptom monitoring vs Routine Surveillance Following Treatment for Lung Cancer. *JAMA*. 321(3) 306-307. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6439676/>

⁸¹ H.R. 6074 – Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. Retrieved from: <https://www.congress.gov/bill/116th-congress/house-bill/6074/text>

⁸² Telehealth: Delivering Care Safely During COVID-19; retrieved from: <https://www.hhs.gov/coronavirus/telehealth/index.html>

⁸³ Verma, S. (2020). Early Impact of CMS Expansion of Medicare Telehealth During COVID-19. *Health Affairs*.

⁸⁴ Marandino, L., Necchi, A., Aglietta, M., & Di Maio, M. (2020). COVID-19 Emergency and the Need to Speed Up Adoption of Electronic Patient-Reported Outcomes in Cancer Clinical Practice. *JCO oncology practice*, 16(6), 295–298.

⁸⁵ We will encourage EOM participants to screen EOM beneficiaries through ePROs; however, we will allow for additional flexibility, should an EOM participant choose to screen for HRSNs outside of ePROs to satisfy the HRSN screening enhanced service requirement. Should participants choose not to implement ePROs at the model start, they will still need to screen for HRSNs.

data, improve patient-provider communications, and deliver care.⁸⁶ We acknowledge logistical challenges, such as technical design and workflow configuration, and are sensitive to potential costs associated with an ePROs integration requirement. However, we believe that data that are readily available, integrated into the workflow, and easy to view are more actionable and lead to better patient outcomes. Furthermore, integrating PROs within EHRs has facilitated symptom reporting, automated triage, and referral for psychosocial and supportive care as well as improvements in standardized care and workflow.^{87,88} We believe that there are strong benefits to the integration of clinical data that outweigh the burden associated with this approach.

Acknowledging the current diversity in ePROs tools available, lack of standards, and the varying degree to which oncology PGPs have implemented these tools to date, we will not require EOM participants to transmit ePROs data to CMS. However, as the ePROs field progresses, and CMS assesses the implementation of ePROs under EOM, we may require that EOM participants report ePROs data to CMS beginning in later performance periods.

(c) [Frequency of ePROs Administration](#)

The first step to utilize ePROs is through integration in EOM participant workflows, as assessed by engagement between the EOM participant and EOM beneficiaries. We will require the EOM participant to obtain ePROs data from each EOM beneficiary a minimum of once before each visit where one or more qualifying E&M services are furnished to the EOM beneficiary by the EOM participant during an episode, with the exception of the beneficiary's first visit with the EOM participant. We do not expect ePROs to be furnished in advance of the first visit or during the first visit. We hope EOM participants will use this first visit to introduce and set up ePROs with the EOM beneficiary, and believe this policy will provide the needed flexibility to do so. The ePROs may be administered at any point prior to the qualifying E&M service via an electronic format, including, but not limited to, interactive voice response systems (telephone), screen-based reporting devices, SMS text systems, and in the waiting room immediately before the appointment. In order to reduce EOM beneficiary burden, ePROs should be short, for example no longer than a few minutes per assessment. EOM participants will be required to review EOM beneficiary ePROs responses with the EOM beneficiary at each visit during which a qualifying E&M service is furnished.

(d) [ePROs Implementation Timeline](#)

EOM participants will implement ePROs capabilities in a stepwise manner over the course of the model. First, model year 1 (PP1 and PP2) and model year 2 (PP3 and PP4) will be optional pre-implementation years, during which EOM participants who so choose will develop the capabilities necessary to successfully implement ePROs

⁸⁶ Zhang, R., Burgess, E.R., Reddy, M.C., Rothrock, N.E., Bhatt, S., Rasmussen, L.V., Butt, Z., Starren, J.B. (2019). Provider Perspectives on the Integration of Patient-Reported Outcomes in an Electronic Health Record. *JAMIA Open*.

⁸⁷ Wagner, L.I., Schink, J., Bass, M., Patel, S., Diaz, M.V., Rothrock, N., Pearman, T., Gershon, R., Penedo, F.J., Rosen, S. Cella, D. (2015). Bringing PROMIS to Practice: Brief and Precise Symptom Screening in Ambulatory Cancer Care. *Cancer*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4352124/>

⁸⁸ Chung, A.E., & Basch, E.M. (2015). Incorporating the Patient's Voice into Electronic Health Records through Patient-Reported Outcomes as the "Review of Systems." *Journal of the American Medical Informatics Association*. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5009898/>

in a manner consistent with the standard domains and implementation requirements. We believe it is important to remain flexible so EOM participants can prepare themselves in a way that is appropriate for their practice needs. Beginning in model year 3 (PP5 & PP6), we will require the gradual implementation of ePROs by all EOM participants. We will require EOM participants to obtain standardized beneficiary-level ePROs response data from a percentage of beneficiaries that increases each model year, beginning with model year 3 (e.g., 35%, 50%, 70%).

We believe that a gradual implementation approach from optional to required will provide flexibility for EOM participants with and without experience with ePROs and allow the necessary time to adjust workflows and technology in order to integrate this important enhanced service into clinical care delivery. Feedback from the Oncology Care First (OCF) Model Informal Request for Information (RFI) showed support for incorporating ePROs in EOM, highlighting the value and need for specific, real-time, beneficiary-informed data to improve the quality of cancer care for Medicare beneficiaries. However, this feedback also identified several limitations to the immediate implementation of ePROs technology by all EOM participants, including that ePROs technology is still evolving and that implementation of ePROs technology is resource-intensive, requiring dedicated staff for implementation, rollout, and maintenance.⁸⁹ CMS also received feedback that patient responses from ePROs should be integrated into triage processes and workflows, which may require process changes to ensure information is received and acted upon appropriately and timely. We believe that ePROs will improve each EOM participant's ability to engage with EOM beneficiaries and incorporate EOM beneficiaries' responses in order to deliver patient-centered care as part of the care plan development and throughout the treatment course. We will encourage EOM participants to document what action is taken in response to ePROs data, as necessary and applicable, to address EOM beneficiary needs.

ii. Continuous Quality Improvement

While using data for CQI will not be an Enhanced Service, EOM participants will be required to use data for CQI as a PRA. We believe use of data for CQI will positively enhance an EOM participant's ability to improve their performance and achieve the goals of EOM. Using data includes the collection and reporting of certain data to CMS, and utilizing data provided by CMS to EOM participants (e.g., feedback and reconciliation reports, described in section VIII) to inform CQI efforts.

As part of advancing use of data for CQI and in line with our equity strategy, as described in section IV., EOM participants will be required to develop and submit a health equity plan that identifies where health disparities may currently exist in their care or patient population and describes strategies they will explore to address these disparities. We believe it is important for model participants to develop strategies for how they will achieve health equity within EOM and to update these goals throughout the model performance period. We believe this will prove helpful to EOM participants as they work to implement initiatives that meet the needs of their underserved communities and improve care for all their beneficiaries. We note that health equity strategies

⁸⁹ Oncology Care First Model: Informal Request for Information. Retrieved from: <https://innovation.cms.gov/files/x/ocf-informalrfi.pdf>

must be supported by specific data or other information demonstrating a need for the identified strategy and a relationship between disparities and the action the EOM participant intends to take. We will ask participants to demonstrate a close fit between the specific problem identified and the solution proposed to address the identified concern, citing data or other information about the cause of the disparity, and/or information indicating that other solutions will not address the problem. We plan to review EOM participant’s health equity plans.⁹⁰

iii. Use of Certified Electronic Health Record Technology (CEHRT)

While the use of CEHRT will not be an Enhanced Service under EOM, EOM participants will be required to implement CEHRT as a PRA. We believe the use of CEHRT will facilitate the delivery of Enhanced Services in EOM; CEHRT use is also a requirement for a model, or a track of a model, to qualify as an Advanced APM, as described in section VI.A. The EOM participant and its EOM practitioners will be required to use CEHRT, as defined in 42 CFR § 414.1305, in a manner sufficient to meet the applicable requirements set forth in 42 CFR § 414.1415(a)(1)(i).⁹¹ Section V.C.iii describes what the CEHRT use requirements will be for EOM further.

C. Payment Methodology

i. Overview

We will implement a two-part payment structure for EOM participants to incentivize the provision of Enhanced Services while creating incentives to reduce avoidable costs and utilization and improve care quality. EOM participants⁹² will be responsible for the total cost of care during a 6-month episode. Depending on total episode expenditures and quality performance (see section V.F), EOM participants or pools have the potential to earn a PBP or owe CMS a PBR. EOM participants or pools will select one of two possible two-sided risk arrangements that will determine: the EOM discount used to determine the target amount as a percentage of the benchmark amount (see section V.C.iii.4); the maximum PBP that may be earned (stop-gain); and the maximum PBR that may be owed (stop-loss). PBP and PBR amounts will be adjusted based on actual quality performance, as described in section V.F.

EOM participants will also have the option to bill a Monthly Enhanced Oncology Services (MEOS) payment per beneficiary per month for the provision of Enhanced Services (described in section V.B.i) to EOM beneficiaries

⁹⁰ Health equity plans would not be used for determinations within EOM, but rather as a tool for EOM participants to develop evidence-based strategies to advance health equity within their EOM beneficiary population for purposes of continuous quality improvement.

⁹¹ 42 CFR § 414.1415(a)(1)(i) requires use of CEHRT by the APM Entity — the EOM participant — as one part of eligibility requirements necessary to achieve QP status.

⁹² EOM participants that have entered into a pooling arrangement will be collectively responsible for the total cost of care for all episodes attributed to the participants in their pool. Pooled EOM participants will identify a single participant to be designated as the “pooled payee” that will receive PBPs or pay PBRs on behalf of the pool. The pooled payee will distribute PBPs or collect PBRs pursuant to the pooling arrangement. Further information regarding pooling, PBP distribution, and PBR collection among pooled EOM participants will be included in the participation agreement.

during each 6-month episode.

ii. Monthly Enhanced Oncology Services (MEOS) Payment

An EOM participant may bill Medicare for up to six MEOS payments for each 6-month episode attributed to them (as described in section V.A.vi), subject to certain exclusions. EOM participants can bill for MEOS payments either in real time or within 12 months following the date of service. Permissible dates of service for MEOS claims will range from 30 days prior to the start of the episode to 30 days after the end of the episode as it may be challenging for EOM participants to identify the exact start and end dates of an episode in real time. No more than six MEOS payments can be billed per episode, and each payment must be associated with a single month during the episode or the 30 days immediately preceding the start of the episode and following the end of the episode.

1) Prohibited MEOS Payments

MEOS payments will be prohibited in certain situations to be detailed in the participation agreement. For instance, MEOS payments will be prohibited if CMS determines: (1) the beneficiary was not in an episode attributed to the EOM participant or in the 30 days immediately before or after such episode; (2) MEOS was billed with a date of service after the date on which an EOM beneficiary elected hospice or died; (3) multiple MEOS payments were made for the same beneficiary with a date of service in the same calendar month; (4) more than six MEOS payments were billed for the same beneficiary for a single episode; (5) the EOM participant failed to make Enhanced Services available and accessible to EOM beneficiaries;⁹³ (6) MEOS was billed with a date of service after the EOM participant terminated from the model or under a legacy TIN (i.e., a TIN that an EOM participant used for billing Medicare Parts A and B for qualifying E&M services but no longer uses to bill for those services); (7) the beneficiary was treated with CAR T-cell therapy during the episode; or (8) the EOM participant billed Medicare for Chronic Care Management (CCM) services or certain other care coordination services for a given EOM beneficiary with a date of service during the same calendar month as the date of service on a claim for a MEOS payment for that beneficiary submitted by the EOM participant. MEOS payments received under prohibited circumstances will be recouped as detailed below in section V.C.ii.3.

An EOM participant and its EOM practitioners will be prohibited from collecting beneficiary cost-sharing for the MEOS payment. CMS will instead use its waiver authority under section 1115A(d)(1) of the Act as necessary to allow CMS to pay the full amount of the MEOS payment to EOM participants.

2) MEOS Payment Amount

The base MEOS payment amount will be \$70 per EOM beneficiary per month. For episodes involving a beneficiary who is dually eligible for Medicare and Medicaid, CMS will pay an additional \$30 per dually eligible beneficiary per month, for a total MEOS payment of \$100 per beneficiary per month. The additional \$30 per dually eligible beneficiary per month will not count toward the EOM participant's total cost of care

⁹³ The provision of Enhanced Services will be a model requirement under the terms of the participation agreement, but it is possible that an EOM beneficiary may decline to receive one or more Enhanced Services (e.g., patient navigation). In such instances, CMS will not recoup MEOS payments, provided that the EOM participant made the Enhanced Services available and accessible to the beneficiary as required in the participation agreement.

responsibility; only the base MEOS payment of \$70 per beneficiary per month will be included in episode expenditures. The higher MEOS amount for dually eligible beneficiaries is meant to facilitate the delivery of high-quality care to a beneficiary population that is likely to have complex needs.

The MEOS payment amount in EOM will be lower than the OCM MEOS payment amount of \$160 per beneficiary per month. The EOM MEOS payment amount is intended to provide sufficient resources to support the provision of Enhanced Services while making it more feasible for EOM participants to bill MEOS payments and still achieve the savings required to earn a PBP in this total cost of care model requiring downside risk for all participants.

3) MEOS Payment Recoupment Report

If CMS determines that an EOM participant received one or more MEOS payments under any prohibited circumstance(s) detailed in the Participation Agreement, the EOM participant will owe CMS a recoupment for the prohibited MEOS payment(s). After the end of each performance period, CMS will issue a MEOS payment recoupment report to the EOM participant detailing any MEOS payments to be recouped. This report will be issued twice for each performance period: first as an initial MEOS payment recoupment report, and then as a true-up MEOS payment recoupment report. The initial MEOS payment recoupment report will specify MEOS payment recoupments for the performance period using at least one month of claims run out. The true-up MEOS payment recoupment report will allow for an additional 12 months of claims run-out to ensure that EOM beneficiaries' episodes are correctly attributed to EOM participants and that all MEOS payments have been appropriately billed. EOM participants will have the opportunity to review and contest suspected errors in each MEOS payment recoupment report before the report becomes final and the amounts owed become due.

iii. Performance-Based Payment (PBP) and Performance-Based Recoupment (PBR)

EOM participants will have the opportunity to earn a performance-based payment (PBP) by reducing total expenditures for attributed 6-month episodes of care below a calculated target amount, while providing high-quality care. EOM participants will owe CMS a performance-based recoupment (PBR) if total expenditures for attributed episodes exceed a calculated threshold for recoupment. EOM participants owing CMS a PBR may have their recoupment amount reduced by performing well on quality measures. The calculation of the episode expenditures, target amount, threshold for recoupment, PBP (if applicable), and PBR (if applicable) is described in the following sections. We discuss the EOM quality strategy below in section V.F.

1) EOM Episode Expenditure Inclusions

EOM is a total cost of care model, meaning that episode expenditures will include Medicare expenditures for all items and services provided during the episode to the EOM beneficiary by any Medicare providers or suppliers – including the EOM participant, its EOM practitioners and Care Partners, non-EOM oncology PGPs, and non-oncology providers and suppliers – subject to certain exclusions.

Episode expenditures will include all non-excluded Medicare Part A and Part B FFS expenditures, certain Part D expenditures (i.e., the Low-Income Cost-Sharing Subsidy amount (if any) and 80 percent of the Gross Drug Cost above the Out-of-Pocket Threshold (if any)), and payments (if any) from overlapping participation in other CMS

initiatives as detailed in section V.E. Additionally, episode expenditures for a performance period episode will include the base amount (\$70) of each MEOS payment billed for the episode.

2) EOM Episode Expenditure Exclusions

For both baseline period episodes and performance period episodes, episode expenditures will exclude specific MS-DRGs and any Part D expenditures not specifically included as episode expenditures (described in section V.C.iii.1.). For performance period episodes involving a dually eligible beneficiary, the additional MEOS payment of \$30 PBPM will be excluded from episode expenditures.

While the model baseline period (episodes initiating July 1, 2016 – June 30, 2020) occurred concurrently with certain OCM performance periods, MEOS payments and PBPs paid to OCM participants under OCM will be excluded from EOM baseline period episode expenditures; this approach is described in greater detail in section V.E. on overlap adjustments.

3) Benchmark Amount

The benchmark amount for an EOM participant that is not in a pool is the projected cost of all episodes attributed to the EOM participant for a given performance period. The benchmark amount for a pool is the projected cost of all episodes attributed to all EOM participants who are in the pool. For each performance period, CMS will determine a benchmark amount for each EOM participant or pool by calculating a benchmark price for every episode and then totaling the benchmark prices for all episodes attributed to the EOM participant (or to all EOM participants in the pool, as applicable).

The process to determine the benchmark price for each performance period episode is described in the following sections (V.C.iii.3(a) — V.C.iii.3(d)). Separately for each included cancer type, CMS will create a model predicting the cost of a 6-month episode of care based on beneficiary characteristics and clinical variables. CMS will create these models using baseline period episodes (episodes initiating from July 1, 2016 through June 30, 2020) and will use these models to establish the predicted expenditures for performance period episodes. CMS will then apply a set of adjustments (described in section V.C.iii.3(b) and section V.C.iii.3(c)) to the predicted expenditures for each performance period episode in order to obtain a benchmark price for each performance period episode.

(a) Creation of the Price Prediction Model for Each Included Cancer Type

First, episodes that initiated during the model baseline period will be grouped into baseline periods lasting 6 months each (BP1 — BP8). As noted in section V.A.xi, baseline period episodes will include those attributed to EOM participants and those attributed to non-EOM oncology PGPs.

Second, CMS will calculate expenditures for each baseline period episode. After summing included expenditures for each episode (as described above in section V.C.iii.1), and removing any excluded expenditures, CMS will apply a series of adjustments. These adjustments will include:

- An adjustment to account for EOM beneficiary alignment or attribution to participants in other CMS models or initiatives (see section V.E.)

- An adjustment to bring expenditures to the level that would have occurred in the absence of sequestration (if sequestration was in effect during the relevant baseline period)
- A cancer type-specific trend adjustment capturing changes in inflation and broad changes in the price of cancer care during the baseline periods (making expenditures from BP1 — BP7 comparable to expenditures in BP8)
- An adjustment limiting the impact of outliers (extremely high or low values) on average baseline period episode expenditures

Next, CMS will use baseline period episodes to create a separate price prediction model for each included cancer type. These models will predict the national average expenditures per baseline period episode, based on a set of beneficiary and episode characteristics. The beneficiary and episode characteristics included in these models are factors that vary systematically among practitioners, are likely to affect the cost of oncology care, and are generally beyond a practitioner’s control. Examples of these characteristics include:

- age
- sex ⁹⁴
- dual eligibility for Medicare and Medicaid
- eligibility for a Part D low-income subsidy (LIS)
- selected non-cancer comorbidities (e.g., obesity, chronic obstructive pulmonary disease (COPD), hypertension, heart disease)
- receipt of selected cancer-directed treatments (surgeries, bone marrow transplant, radiation therapy)
- institutional status
- participation in a clinical trial
- history of prior chemotherapy use
- episode length in days

This is not an exhaustive list; additional details will be provided in the participation agreement and the EOM payment methodology document.

After creating a price prediction model for each included cancer type, CMS will use these models to establish the predicted expenditures for each baseline period episode and each performance period episode.

CMS will apply a series of adjustments to the predicted expenditures for each performance period episode: an experience adjuster, the applicable clinical adjuster(s) (for certain cancer types), a retrospective trend factor, and an adjustment for use of novel therapies (if applicable). The creation and purpose of each of these adjusters is described in the following sections.

⁹⁴ It is necessary to include sex as a covariate in order to determine valid benchmarks, due to established patterns of expenditures and utilization for cancer care that differ by sex.

(b) Calculation of Experience Adjuster

The experience adjuster reflects a blend of national, regional, and EOM participant-specific episode spending patterns during the model baseline period. The purpose of the experience adjuster is to account for regional and participant-specific variation in the cost of oncology care that is not otherwise accounted for in the price prediction models.

First, CMS will calculate the ratio of actual expenditures to predicted expenditures for baseline period episodes, separately by included cancer type and at three levels of aggregation:

- National: the national set of baseline period episodes of the included cancer type
- Regional: for each of 9 census divisions, the set of baseline period episodes of the included cancer type that are attributed to oncology PGPs located within that division
- EOM participant-specific: for each EOM participant, the set of baseline period episodes of the included cancer type that are attributed to that EOM participant

This process will result in 21 separate ratios per EOM participant.

CMS will calculate the experience adjuster for each EOM participant as the weighted average of these ratios. The weights applied to each ratio will depend on the number of baseline period episodes attributed to the EOM participant and the distribution of included cancer types among the EOM participant's attributed baseline period episodes:

- Participant-specific ratios will be weighted more heavily for EOM participants with more attributed baseline period episodes, whereas regional ratios will be weighted more heavily for EOM participants with fewer attributed baseline period episodes.
- For EOM participants with fewer than 50 attributed baseline period episodes, the experience adjuster will be based on only national and regional ratios for each included cancer type.
- Included cancer types that were more common among an EOM participant's attributed baseline period episodes will contribute more heavily to the EOM participant's experience adjuster than included cancer types that were less common among the EOM participant's attributed baseline period episodes.

(c) Calculation of Clinical Adjusters, Trend Factors, and Novel Therapy Adjustments

CMS will calculate clinical risk adjusters for certain cancer types based on the following clinical and staging data submitted by EOM participants to CMS:

- Ever-metastatic status (breast cancer, lung cancer, and small intestine/colorectal cancer)
- Human epidermal growth factor receptor 2 (HER2) status (breast cancer).

The collection of these clinical and staging data is described in section VIII.A.

The trend factor adjusts for changes over time in expenditures across the oncology field as a whole. The purpose of this adjustment is to ensure that EOM participants and pools are not held financially responsible for changes

in spending patterns or treatment standards occurring after the model baseline period that would have occurred even in the absence of EOM. Therefore, CMS will calculate trend factors solely from episodes attributed to non-EOM oncology PGPs in the model baseline period and episodes attributed to non-EOM oncology PGPs for the relevant performance period. Trend factors will be calculated separately by included cancer type for each performance period, and will capture changes in spending patterns for that specific cancer type between the model baseline period and the relevant performance period.

The novel therapy adjustment will increase the benchmark price for performance period episodes attributed to those EOM participants and pools with a high share of expenditures for newly FDA-approved oncology drugs, many of which are substantially more expensive than existing therapies when they first enter the market. The purpose of this adjustment is to avoid financially disincentivizing EOM participants and pools who are early adopters of new chemotherapies, provided that these novel therapies are used in a manner consistent with the FDA-approved indications. The novel therapy adjustment may result in a higher benchmark price for a performance period episode, but will never result in a lower benchmark price for the episode. Novel therapy adjustments will be calculated and applied separately by included cancer type. (For instance, an EOM participant or pool might receive an upward adjustment for their attributed lung cancer episodes, but not for their attributed breast cancer episodes, if their use of novel therapies differs across included cancer types.)

(d) [Calculation of Baseline Price, Benchmark Price, and Benchmark Amount](#)

CMS will multiply the predicted expenditures for each performance period episode (described in section V.C.iii.3.(a)) by the experience adjuster and any applicable clinical adjuster(s) to obtain the baseline price for each episode. CMS will multiply the baseline price for each performance period episode by the relevant trend factor and novel therapy adjustment (if applicable) to obtain the benchmark price for each episode.

Finally, CMS will determine the benchmark amount for each EOM participant or pool. For each EOM participant that is not in a pool, CMS will sum the benchmark prices for all episodes attributed to the participant for a given performance period. For each pool, CMS will sum the benchmark prices for all performance period episodes attributed to all EOM participants in the pool. The resulting benchmark amount represents total projected Medicare expenditures for all episodes attributed to an EOM participant (or for all episodes attributed to the EOM participants in a pool) for a given performance period.

Table 3 below summarizes the steps involved in calculating the benchmark amount for each EOM participant or pool.

Table 3. Summary of Steps to Calculate Benchmark Amounts for EOM Participants or Pools for a Given Performance Period

1	Establish predicted expenditures for each performance period episode, using cancer type-specific price prediction models created from baseline period episodes
2	Apply EOM participant's experience adjuster

3	Apply clinical risk adjustments (for certain cancer types)
4	Apply cancer type-specific trend factor to obtain the baseline price for each performance period episode
5	Adjust for EOM participant's or pool's cancer type-specific use of novel therapies (if applicable) to obtain benchmark price for each performance period episode
6a	<i>For EOM participants not in a pool:</i> Sum benchmark prices for all performance period episodes attributed to the EOM participant to calculate the benchmark amount for the EOM participant
6b	<i>For pools:</i> Sum benchmark prices for all performance period episodes attributed to all EOM participants in the pool to calculate the benchmark amount for the pool.

As described below in section V.C.iii.6., CMS will use the benchmark amount to determine each EOM participant's or pool's target amount, threshold for recoupment, neutral zone, stop-gain, and stop-loss for a given performance period. Any PBP earned or PBR owed by the EOM participant or pool will be calculated as a percentage of this benchmark amount.

4) Target Amount

The target amount will equal the EOM participant's or pool's benchmark amount reduced by the EOM discount under the risk arrangement they have selected (see section V.C.iii.6 for more details about the risk arrangements).

In order to earn a PBP for a given performance period, an EOM participant's or pool's total expenditures for all episodes attributed to them for the performance period must be lower than the target amount.

5) Calculation of Actual Expenditures

CMS will sum included expenditures for each performance period episode detailed in section V.C.iii.1, subject to the expenditure exclusions detailed in section V.C.iii.2. To finalize the actual performance period episode expenditures, CMS will apply adjustments similar to those made to the baseline period expenditures: adjustments to account for overlap with other CMS initiatives during the episode (see section V.E), an adjustment to remove the effect of sequestration from any included expenditures to which sequestration was applied, and an adjustment limiting the influence of outliers.

For each performance period, CMS will calculate actual expenditures for each EOM participant that is not in a pool by summing the non-excluded expenditures for each of their attributed episodes; CMS will calculate each pool's actual expenditures by summing the non-excluded expenditures for all episodes attributed to each EOM participant in the pool.

6) Risk Arrangements and Calculation of PBP and PBR

EOM participants will be in a two-sided risk arrangement for the full duration of their participation in EOM. EOM participants will be required to choose between two different risk arrangements: risk arrangement 1 (RA1) and risk arrangement 2 (RA2). Participants in a pooling arrangement must select a single risk arrangement for the pool. By default, EOM participants and pools will be in RA1 unless they request to be in RA2. Participants and pools will have the opportunity to move from one risk arrangement to the other risk arrangement on a semi-annual basis prior to the start of the next performance period.

RA1 has an EOM discount of 4% of the benchmark amount. The target amount (the benchmark amount less the EOM discount) in RA1 will therefore be 96% of the benchmark amount. The downside risk (or stop-loss) will be 2% of the benchmark amount and the upside risk (or stop-gain) will be 4% of the benchmark amount.

RA2 has an EOM discount of 3% of the benchmark amount. The target amount (the benchmark amount less the EOM discount) in RA2 will therefore be 97% of the benchmark amount. The downside risk (or stop-loss) will be 6% percent of the benchmark amount and the upside risk (or stop-gain) will be 12% of the benchmark amount.

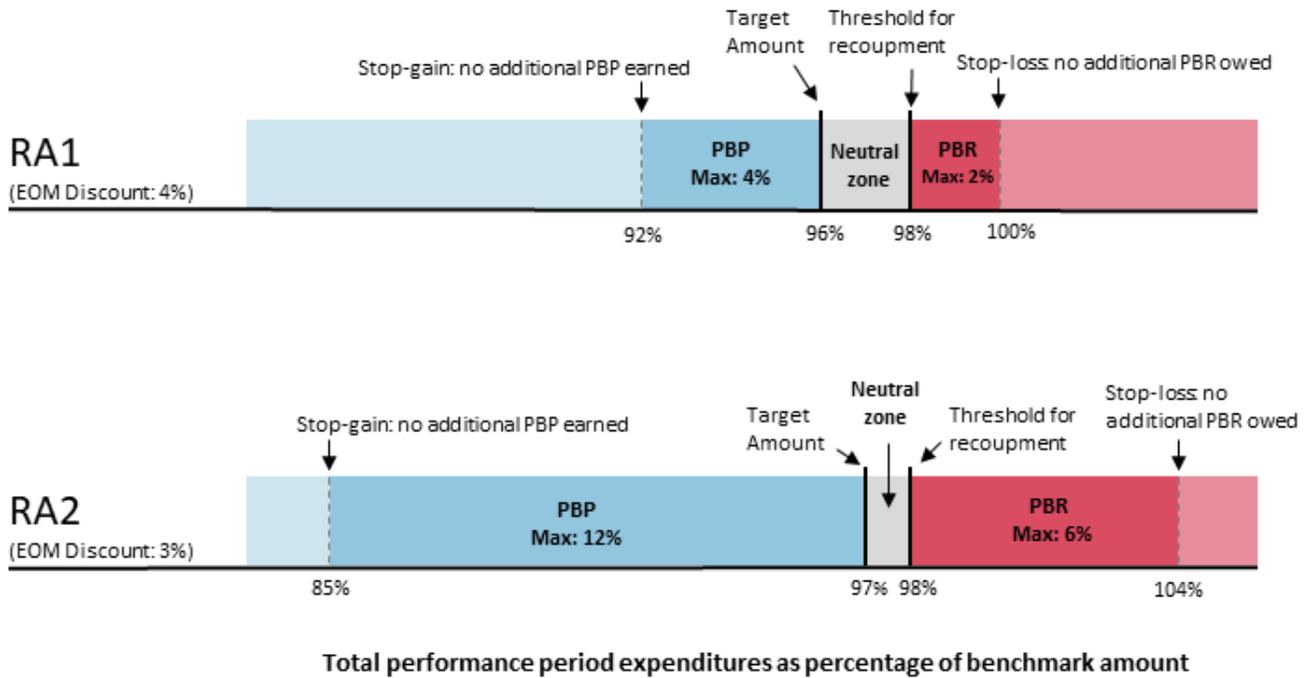
In both risk arrangements, the threshold for recoupment will be 98% of the benchmark amount. That is, EOM participants and pools whose performance period expenditures are greater than 98% of the benchmark amount will owe a PBR.

There will be a neutral zone policy in EOM: if an EOM participant's or pool's performance period expenditures are above the target amount and below or equal to the threshold for recoupment, the participant or pool will not earn a PBP or owe a PBR. Both risk arrangements will have a neutral zone:

- Neutral zone in RA1: performance period expenditures greater than the target amount (96% of the benchmark amount) and less than or equal to the threshold for recoupment (98% of the benchmark amount)
- Neutral zone in RA2: performance period expenditures greater than the target amount (97% of the benchmark amount) and less than or equal to the threshold for recoupment (98% of the benchmark amount)

Figure 1 below illustrates the maximum PBP and PBR amounts (as a percentage of the benchmark amount) that EOM participants or pools may potentially earn or owe under each risk arrangement and the placement of the corresponding target amount, threshold for recoupment, neutral zone, stop-gain, and stop-loss.

Figure 1. Risk Arrangement Options in EOM



Under the terms of the participation agreement, EOM participants will be required to comply with the CEHRT requirements described in section V.B.iii. We expect that both risk arrangements will qualify as MIPS APMs, and that RA2, which requires the EOM participant to take on increased downside risk, will qualify as an Advanced APM (as further detailed in section VI.A.)

Table 4 below outlines the details of the two risk arrangements in EOM.

Table 4: Risk Arrangement Options in EOM

Risk Arrangement	Downside Risk (Stop-Loss)	Upside Risk (Stop-Gain)	EOM Discount	MIPS APM	Advanced APM
RA1	2% of benchmark	4% of benchmark	4% of benchmark	Yes	No
RA2	6% of benchmark	12% of benchmark	3% of benchmark	Yes	Yes

Table 5 below provides an example of the PBP calculation process for a potential EOM participant in RA1. CMS will compare the EOM participant’s or pool’s performance period expenditures to the target amount and threshold for recoupment to determine whether the EOM participant or pool potentially: (1) earned a PBP; (2) owes CMS a PBR; or (3) falls in the neutral zone and neither earned a PBP nor owes CMS a PBR.

Table 5. RA 1 Example⁹⁵

	Example A (PBP with Stop-Gain)	Example B (PBP)	Example C (Neutral Zone)	Example D (PBR)	Example E (PBR with Stop-Loss)
Benchmark Amount	\$1,000,000				
Target Amount (96% of Benchmark amount)	\$960,000				
Threshold for Recoup (98% of Benchmark amount)	\$980,000				
Neutral Zone	\$960,000 - \$980,000				
Stop-Gain (4% of Benchmark Amount)	\$40,000 (PBP maximum if performance period episode expenditures are below \$920,000)				
Stop-Loss (2% of benchmark amount)	\$20,000 (PBR maximum if performance period episode expenditures are above \$1,000,000)				
Performance Period Expenditures	\$800,000	\$925,000	\$975,000	\$990,000	\$1,045,000
Amount Participant Earns (PBP) or Owes (PBR)	\$40,000 (PBP with Stop-Gain)	\$35,000 (PBP)	\$0 (Neutral Zone)	\$10,000 (PBR)	\$20,000 (PBR with StopLoss)

Table 6 below provides an example of the PBP calculation process for a potential EOM participant in RA2.

Table 6. RA 2 Example

	Example A (PBP with Stop-Gain)	Example B (PBP)	Example C (Neutral Zone)	Example D (PBR)	Example E (PBR with Stop-Loss)
Benchmark Amount	\$1,000,000				
Target amount (97% of Benchmark Amount)	\$970,000				

⁹⁵ Tables 5 and 6 provide an example of the potential amount owed or earned under RA1 and RA2 respectively, as the calculations are prior to the application of the Aggregate Quality Score (AQS) detailed in section V.F.

Threshold for Recoup (98% of Benchmark Amount)	\$980,000				
Neutral Zone	\$970,000 - \$980,000				
Stop-Gain (12% of benchmark amount)	\$120,000 (PBP maximum if performance period episode expenditures are below \$850,000)				
Stop-Loss (6% of benchmark amount)	\$60,000 (PBR minimum if performance period episode expenditures are above \$1,040,000)				
Performance Period Expenditures	\$800,000	\$925,000	\$975,000	\$990,000	\$1,045,000
Amount Participant Earns (PBP) or Owes (PBR)	\$120,000 (PBP with Stop-Gain)	\$45,000 (PBP)	\$0 (Neutral Zone)	\$10,000 (PBR)	\$60,000 (PBR with Stop Loss)

7) PBP Reconciliation Process

During reconciliation for each performance period, CMS will compare the EOM participant’s or pool’s total expenditures to the target amount and threshold for recoupment to determine whether the EOM participant or pool potentially: (1) earned a PBP; (2) owes CMS a PBR; or (3) falls in the neutral zone and neither earned a PBP nor owes CMS a PBR. The amount of the PBP or PBR, if any, will be adjusted based on the EOM participant’s or pool’s aggregate quality score (AQS), as described in section V.F.

The EOM PBP reconciliation process will take place on a semi-annual basis, following the end of each performance period. CMS will ensure a minimum of one month of claims run-out for each performance period before conducting the initial PBP reconciliation for that performance period. The first PBP reconciliation will happen during the model year 2 of EOM, since the last episodes to begin during the first performance period (July 1, 2023 – December 31, 2023) will not be complete until the end of the second performance period (January 1, 2024 – June 30, 2024).

CMS will conduct only one subsequent reconciliation (or “true-up”) per performance period, rather than the two subsequent reconciliations performed in OCM, because episode expenditures tend to be highly concentrated toward the beginning of an episode and CMS expects that most claims will be submitted on a timely basis. The true-up will be conducted one year after the initial reconciliation and will include an additional twelve months (thirteen months total) of claims run-out.

(a) PBP Reconciliation Report

Each EOM participant or pool will receive a PBP reconciliation report for both the initial PBP reconciliation and the true-up PBP reconciliation for each performance period. CMS will issue the true-up PBP reconciliation report for a performance period simultaneously with the initial PBP reconciliation report for a subsequent performance period. The PBP amounts and/or PBR amounts specified in the simultaneously issued reconciliation reports may be netted together, resulting in a single payment to the EOM participant or pool or demand (as applicable), the amount of which may differ from the PBP or PBR amounts specified in the individual reconciliation reports for each of the two performance periods. The EOM participant or pool will have the opportunity to review and contest suspected errors in the initial PBP reconciliation report and in the true-up PBP reconciliation report. Following each contestation period, CMS will finalize the reconciliation report and pay or collect any amounts owed.

(b) PBP Eligibility

An EOM participant or pool who has earned a PBP as described in section V.C.iii.6. will not receive a PBP from CMS unless the EOM participant (or in the case of a pool, every EOM participant in the pool) satisfied all of the PBP eligibility requirements throughout the performance period, including but not limited to:

- Achieving an aggregate quality score (AQS) that meets or exceeds the minimum performance threshold as described in section V.F
- Accurately, completely, and timely submitting data in the time and manner specified by CMS on all of the required data elements as described in section VIII.A.
- Implementing the required PRAs during the relevant performance period, including furnishing Enhanced Services to EOM beneficiaries and using CEHRT and data for CQI, as further detailed in section V.B.

D. Extreme and Uncontrollable Circumstances Policy

The nation, its communities, and its health care providers, on certain occasions, are forced to confront extreme and uncontrollable circumstances outside of their control that impact their ability to operate in the ordinary course of business for short-term, or sometimes even extended periods. These events may include public health emergencies (such as COVID-19), and large-scale natural disasters (such as but not limited to, hurricanes, tornadoes, and wildfires) as well as other extreme and uncontrollable circumstances. To prepare for the possibility that situations such as these may arise during the model performance period of EOM, CMS will have the flexibility under the participation agreement to provide payment and reporting flexibilities to ensure that participation in EOM does not further strain EOM participants' capacity, so they can focus on delivering safe and efficient health care. CMS will have the flexibility to offer payment and reporting flexibilities to EOM participants located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has issued a waiver under section 1135(g) of the Act, and for EOM participants in a county, parish, or tribal government designated in a major disaster declaration or emergency declaration under the Stafford Act.

E. Overlap Adjustments

For baseline period episodes, CMS will make certain adjustments to the baseline period episode expenditures to account for overlap when a beneficiary in a baseline period episode was aligned with another payment model being tested by CMS or other CMS initiatives as detailed in section V.E.i. Additionally, CMS expects that there will be situations where an EOM beneficiary in a performance period episode attributed to an EOM participant will also be attributed to or aligned to, a participant in another payment model being tested by CMS or a CMS initiative during the performance period. CMS will make certain adjustments to the performance period episode expenditures to account for overlaps in beneficiaries and participants between EOM and these other CMS initiatives as detailed in section V.E.ii and referenced in section V.C.iii.5. These overlap policies may be adjusted by CMS if or when CMS makes changes to existing models or initiatives or implements new models or initiatives.

i. Accounting for Overlap in the Model Baseline Period

1) Adjustments for Payments to Medicare ACOs in the Model Baseline Period

When calculating the baseline period episode expenditures, CMS will determine whether the beneficiaries in those episodes were also aligned to ACOs participating in the Next Generation ACO Model or the Vermont Medicare ACO Initiative during the model baseline period. For those Next Generation ACOs or Vermont ACOs participating in All-Inclusive Population Based Payment (AIPBP) or Population-Based Payment (PBP), CMS makes a monthly payment to the ACO based on an estimate of total annual expenditures for care furnished to beneficiaries aligned to the ACO by AIPBP- or PBP-participating providers and suppliers. Medicare then makes a corresponding reduction in Medicare FFS payments to these providers and suppliers. To avoid any artificial reduction in spending due to the reduction in Medicare FFS payments to AIPBP- and PBP- participating providers and suppliers, CMS will adjust the paid amount on claims, as necessary, to reflect the amount that would have been paid by Medicare in the absence of such fee reductions. To avoid double counting these payment amounts, CMS will not include the portion of the monthly AIPBP or PBP payments made to Next Generation ACOs or Vermont ACOs attributable to beneficiaries aligned to the relevant Next Generation ACO or Vermont ACO in the baseline period episode expenditures under EOM.

2) Inclusion of Payments from Bundled Payments for Care Improvement (BPCI), BPCI Advanced, Comprehensive Care for Joint Replacement (CJR), and Medicare Care Choices Model (MCCM) in the Model Baseline Period

In the baseline period episode expenditures, payments resulting from beneficiary attribution to participants in other CMS initiatives, specifically payments from the Bundled Payments for Care Improvement (BPCI) and BPCI Advanced Models, the Comprehensive Joint Replacement (CJR) Model, and the Medicare Care Choices Model (MCCM) will be included. To avoid double counting episode expenditures across episode payment models, if CMS finds that a beneficiary in an EOM episode was attributed to a participant in BPCI or BPCI Advanced or was a CJR beneficiary (as defined in 42 CFR § 510.2) during the model baseline period, CMS will calculate the portion of the BPCI/BPCI Advanced reconciliation or CJR reconciliation amount (Net Payment Reconciliation Amount or Repayment Amount) was paid for an BPCI/BPCI Advanced or CJR episode, as applicable, that overlapped with the relevant baseline period episode under EOM by prorating the BPCI/BPCI Advanced or CJR reconciliation amount. This prorated BPCI/BPCI Advanced or CJR reconciliation amount will be included as an expenditure for

that beneficiary's baseline period episode established for purposes of EOM.

In the event that beneficiaries in EOM baseline period episodes were enrolled in MCCM, the per beneficiary per month (PBPM) payments paid by Medicare to MCCM participants during the model baseline period will be included as part of the baseline period episode expenditures. Of note, the payments associated with MCCM are reflected directly in standardized claims so no additional accounting for overlap is needed when calculating baseline period episode expenditures.

3) Exclusion of Payments from the Oncology Care Model (OCM) in the Model Baseline Period

Payments from OCM will be excluded from expenditures for baseline period episodes. That is, any OCM MEOS payments or OCM PBPs received and any OCM MEOS recoupments or OCM PBP recoupments paid during the model baseline period (i.e., during any of the eight 6-month baseline periods during the period of July 1, 2016 – June 30, 2020) will not be included as expenditures for baseline period episodes. OCM MEOS and OCM PBP will be excluded from the baseline period episode expenditures to level-set cancer care-related spending across all EOM participants and to not advantage previous OCM participants by the inclusion of OCM-specific payments in their baseline period expenditures. Additionally, an EOM participant's previous OCM recoupments will not lower their baseline period episode expenditures, so as to avoid disadvantaging prior OCM participants since this was an OCM-specific recoupment not applicable to non-OCM participants.

4) Adjustments for Payments from the Comprehensive Primary Care Plus (CPC+) Model Baseline Period

When calculating the EOM baseline period episode expenditures, CMS will determine whether the beneficiaries in those episodes were also attributed to a practice participating in the Comprehensive Primary Care Plus (CPC+) Model during the model baseline period.

There were two tracks in the CPC+ Model: in Track 1, participating primary care practices were paid a care management fee (CMF) and a performance based-incentive payment (PBIP). In Track 2, participating primary care practices were paid a CMF, a PBIP, and a capitated payment (Comprehensive Primary Care Payments (CPCPs)) which partially replaced FFS payments for certain E&M services. If a practice participating in Track 2 of the CPC+ Model billed for those E&M services, they received a CPCP and a proportionally reduced FFS payment. To account for any potential overlap in beneficiaries that were attributed to a practice participating in the CPC+ Model during the model baseline period, CMS will include prorated CMFs in the calculation of the baseline period episode expenditures, but will exclude the PBIPs because the PBIPs were not beneficiary-specific. CMS will also exclude the CPCPs made to Track 2 CPC+ participants from the baseline period episode expenditures. Instead of the CPCPs, CMS will include in the baseline period episode expenditures the standardized paid amounts for FFS claims that Track 2 CPC+ participants would have received for certain E&M services in the absence of the CPCPs and reduced FFS amounts under the CPC+ Model.

5) Adjustments for Payments from the Maryland Total Cost of Care (TCOC) Model and Pennsylvania Rural Health Model (PARHM) in the Model Baseline Period

CMS expects there will be beneficiaries in baseline period episodes included in the Maryland Total Cost of Care (TCOC) Model and the Pennsylvania Rural Health Model (PARHM) during the model baseline period.

The Maryland TCOC Model includes three programs: (1) the Hospital Payment Program, (2) the Care Redesign Program (CRP) and (3) the Maryland Primary Care Program (MDPCP). In the Hospital Payment Program, participating hospitals receive a global budget that they must stay within when they bill Medicare FFS claims— a form of capitation. To account for the total cost of care for beneficiaries in the Maryland TCOC Model, CMS will utilize the Medicare FFS claims submitted by regulated Maryland hospitals to Medicare FFS using the standardized paid amount to reflect what the actual Medicare payment amount would have been in the absence of the Maryland TCOC Model when calculating baseline period episode expenditures under EOM.

Hospital Payment Program participant hospitals may also participate in the Care Redesign Program under the Maryland TCOC Model. The Care Redesign Program (CRP) tests whether allowing Maryland hospitals to incent nonhospital providers and suppliers to engage in care redesign activities that support state-wide efforts to reduce the growth in total cost of care for Medicare beneficiaries will create meaningful partnerships that improve the quality of care and reduce potentially avoidable hospitalizations. Under the CRP, participating hospitals may enter into financial arrangements with Care Partners, that is, enrolled Medicare providers or suppliers which are mostly physician group practices. The participating hospitals may pay Care Partners incentive payments or non-monetary remuneration for performing certain care redesign interventions. The CRP does not involve payment of Medicare dollars and thus is not relevant to EOM payment methodology.

The third Maryland TCOC Model program, the MDPCP, currently offers two tracks. Track 1 provides participating primary care providers a care management fee (CMF) and a performance based-incentive payment (PBIP) and participating practices continue to bill for items and services using the conventional FFS structure. In Track 2, participating practices were paid a CMF, a PBIP, and a capitated payment (Comprehensive Primary Care Payments (CPCPs)), which partially replaced FFS payments for certain E&M services. If a practice participating in Track 2 of MDPCP billed for those E&M services, they received a CPCP and a proportionally reduced FFS payment. To account for any potential overlap in beneficiaries that were attributed to a practice participating in the MDPCP program, CMS will include prorated CMFs in the calculation of the baseline period episode expenditures, but will exclude the PBIP because the PBIP is not beneficiary-specific. CMS will also exclude the CPCPs made to Track 2 participants from the baseline period episode expenditures. Instead of the CPCPs, CMS will include in the baseline period episode expenditures the standardized paid amounts for FFS claims that Track 2 MDPCP participants would have received for certain E&M services in the absence of the CPCPs and reduced FFS amounts under the MDPCP.

Under the PARHM, participating rural hospitals are paid by CMS and other participating payers under a global budget that is set in advance to cover all inpatient and hospital-based outpatient services. CMS makes biweekly payments equivalent to 1/26 of the approved Medicare FFS portion of each hospital's global budget. Participating hospitals continue to submit Medicare FFS claims for services covered by the global budget which are processed as no-pay claims. CMS will exclude the global budget payments and instead use the Medicare FFS

claims submitted by participating hospitals to calculate the baseline period episode expenditures under EOM.

ii. Accounting for Overlap in the Model Performance Period

1) *The Radiation Oncology (RO) Model⁸ in the Model Performance Period*

As EOM and the RO Model are both designed to include care for patients with a cancer diagnosis who receive radiation therapy (RT) services, CMS expects that there would be beneficiaries who qualify to be in both an episode under EOM and an episode under the RO Model. CMS plans to align the EOM overlap methodology to parallel the OCM overlap approach with respect to the RO Model, specifically as described in the Specialty Care Models to Improve Quality of Care and Reduce Expenditures final rule.⁹⁶

If a 6-month EOM episode includes an entire RO Model episode (90 days of RT services) then the EOM performance period episode expenditures will include the associated RO Model payments for RT services. In addition, to account for the savings generated by the RO Model discount and withhold amounts, the RO Model's discount and withhold amounts will be added to the total cost of the EOM performance period episode during the reconciliation process to ensure that there is no double counting of savings between the two models.

In those cases where a RO Model episode occurs partially within an EOM episode and partially before or after the EOM episode, CMS will allocate the RO Model payments for RT services and the RO Model discount and withhold amounts to the EOM episode on a prorated basis, based on the number of days of overlap. In this case, the prorated portion of the payment under the RO Model, based on the number of days of overlap with the EOM episode, will be included in the EOM performance period episode's expenditures as well as the prorated portion of the dollar amount that represents the RO Model discount and withhold amounts, again based on the number of days of overlap with the EOM episode.

2) *ACO Initiatives in the Model Performance Period*

The Global and Professional Direct Contracting Model (to be renamed the ACO Realizing Equity, Access, and Community Health (REACH) Model beginning in 2023), the Shared Savings Program, and the three Comprehensive Kidney Care Contracting (CKCC) Options in the Kidney Care Choices (KCC) Model are ACO initiatives. In addition, CMS will treat overlap between EOM and the Kidney Care First (KCF) Option of the KCC Model in the same manner as overlap between EOM and ACO initiatives. Of note, as described in section V.A.i., beneficiaries diagnosed with End Stage Renal Disease (ESRD) will be excluded from EOM. Moreover, CMS will exclude kidney transplant bonus payments in all four options of the KCC Model and the Performance Based Adjustments (PBAs) from the KCF Option from EOM performance period expenditures for any shared beneficiaries.

In all of the EOM performance period episode expenditure calculations, CMS will account for any reductions in FFS payments for services furnished to EOM beneficiaries who are also aligned to Medicare ACOs or other

⁹⁶ 85 FR 61260 through 61262 (September 29, 2020).

similar entities that are participating in population-based payments by adjusting the paid amount on claims, as necessary, to reflect the amount that would have been paid in the absence of population based-payments. To avoid double counting these payment amounts, CMS will not include the portion of the monthly capitation payment to an ACO or similar entity that has elected population-based payments that is attributable to EOM beneficiaries aligned to that ACO or similar entity in actual episode expenditure calculations under EOM. Non-claims-based payments and recoupments received under the Shared Savings Program, other ACO initiatives, or the KCF option would not be included in the EOM performance period expenditures for overlapping beneficiaries. If a portion of the EOM discount is paid out as shared savings to an ACO or similar entity that includes a health care provider or supplier who bills under the same TIN as an EOM participant, and if the EOM participant has a PBP calculated for a time period that overlaps with the period for which shared savings were calculated, CMS will generally recover that portion of the PBP that corresponds to the overlapping period from the EOM participant. However, if the ACO initiative uses retrospective growth rates which reflect concurrent, actual growth in expenditures between the benchmark and performance year, such as in the case of the Shared Savings Program, CMS will not recover the overlapping EOM PBP as the earned EOM PBP would not be viewed as an overpayment. The retrospective growth rate would capture the impact of the EOM participant's performance in EOM insofar as any reduction in actual expenditures at the EOM participant would reduce the actual expenditures used in the numerator of the growth rate, effectively dampening the growth rate and setting a lower benchmark for the Shared Savings Program.

3) BPCI Advanced and Comprehensive Care for Joint Replacement (CJR) Model in the Model Performance Period

An EOM beneficiary's performance period episode may be simultaneously attributed to both an EOM participant and a participant in either the BPCI Advanced Model or the CJR Model. When a BPCI Advanced or CJR Model episode overlaps with an EOM episode, any reductions or increases in expenditures will first accrue to the BPCI Advanced or CJR Model episode. After BPCI Advanced or the CJR Model performs its reconciliation calculations, CMS will prorate the BPCI Advanced or CJR Model reconciliation amount, a non-claims-based payment or recoupment, by the portion of the BPCI Advanced or CJR episode(s) included in the reconciliation calculations that overlapped with the EOM episode. This prorated BPCI Advanced or CJR Model reconciliation amount will be included in the EOM participant's performance period episode expenditures.

4) Primary Care First (PCF) Model in the Model Performance Period

CMS will account for any overlap if an EOM participant is also participating in the PCF Model or if the beneficiary in the episode is also attributed to a participant in the PCF Model. The model payments in the PCF Model include a professional population-based payment (PCF PBP) and a flat visit fee (FVF), both of which are subject to adjustments based on performance through the Performance-Based Adjustment (PBA).

The PCF PBP is designed to partially replace Medicare FFS practice revenue for primary care services. In all of the EOM performance period episode expenditure calculations, CMS will account for any reductions in FFS payments for services furnished to EOM beneficiaries who are also attributed to a PCF practice by adjusting the

paid amount on claims, as necessary, to reflect the amount that would have been paid in the absence of the PCF PBP, and including that amount in the EOM performance period episode expenditure calculations. To avoid double counting these payment amounts, CMS will not include the portion of the monthly capitation payment to a PCF participant that is attributable to EOM beneficiaries aligned to that PCF participant in actual episode expenditure calculations under EOM. To avoid increasing Medicare expenditures and to accurately account for the total cost of care for EOM beneficiaries, CMS will adjust any PCF FVF payments received by an EOM participant during the episode to reflect what the actual Medicare FFS payment amount would have been in the absence of participation in the PCF Model for purposes of calculating performance period episode expenditures. We will also include the actual Medicare FFS payment amount for FVF services in the EOM performance period expenditures for EOM beneficiaries who are also attributed to a PCF practice.

5) *Maryland TCOC Model and PARHM in the Model Performance Period*

CMS will adjust for payments from the Maryland TCOC Model and PARHM in the calculation of the performance period episode expenditures for EOM in the same way the adjustments are described in the calculation of the total expenditures for EOM baseline period episodes as described in further detail in section V.E.i.4.

Additionally, the Health Equity Advancement Resource and Transformation (HEART) payment, paid to participating MDPCP Track 1 and Track 2 practices as part of the MDPCP CMF, would be excluded in the performance period episode expenditures under EOM as to not disadvantage EOM participants from serving high-risk beneficiaries who reside in areas with a high area deprivation index (ADI).

6) *Community Health Access Rural Transformation (CHART) Model in the Model Performance Period*

The CHART Model aims to test whether upfront investments, predictable capitated payments, and operational and regulatory flexibilities will enable rural health care providers to improve access to high-quality care while reducing health care costs. CHART participants may participate in CHART through the Community Transformation Track. In the event there is an overlap between attributed EOM episodes and attributed beneficiaries in the CHART Community Transformation Track, CMS will include any Medicare FFS claims associated with CHART in the EOM performance period episode expenditures for shared beneficiaries. The included Medicare FFS claim will be adjusted to reflect what the actual Medicare payment amount would have been in the absence of the EOM participant's participation in the CHART Community Transformation Track.

F. Quality Strategy

In EOM, we believe EOM participants will be incentivized to improve quality of care in three ways. First, EOM participants will implement PRAs that we believe will result in beneficiaries receiving higher quality care, as described in section V.B. Second, we will assess the performance of EOM participants on quality measures tied to payment. An EOM participant's or pool's performance on these quality measures will be used to determine an EOM participant's or pool's aggregate quality score (AQS), which will impact the amount of an EOM participant's or pool's PBP earned or PBR owed to CMS, if applicable. In the case of pooled EOM participants,

the EOM participants that are part of a pool will have all their episodes treated as if they are a single EOM participant for the purposes of quality scoring. To calculate the pool's AQS, we would sum the numerators and denominators for each participant in the pool before calculating a pooled performance rate for each measure. Each EOM participant in a pool must report their quality measures in order for the pool to be eligible to obtain a PBP, if earned. Third, EOM participants will identify and address opportunities to eliminate health disparities and advance health equity for EOM beneficiaries, as described in section IV and in Appendix B. We believe these three facets combine to create a person-centered, accountable, and equitable quality strategy. The following section focuses on quality measures and clinical data elements.

The EOM Quality Measures set will include valid, reliable, and meaningful measures in the following three categories: EOM participant-reported, claims-based, and patient experience survey quality measures. Each of these types of measures are key for CMS to verify clinical improvements, assess patient health outcomes and EOM participant care coordination activities, and ensure continued quality of care for beneficiaries. The EOM quality strategy will focus on the following domains: patient experience, avoidable acute care utilization, management of symptoms toxicity, management of psychosocial health, and management of end of life care. In selecting specific measures, we will prioritize measures that reflect national priorities for quality improvement and patient-centered care consistent with Section 1890(b)(7)(B) of the Act, as well as outcomes-based measures. Outcomes-based measures, including those collected from patients, minimize EOM participant burden where possible, and align with CMS and Innovation Center quality strategy. The measures set will be similar to measures included in OCM and we will continue to explore opportunities to update the quality measure set over time in alignment with the principles and domains outlined above as new measures emerge, including those that promote equity.⁹⁷

In addition, as noted above, each EOM participant's performance on quality measures will be tied to payment. We believe that tying payment to quality measures helps to ensure that the incentive to reduce costs is balanced with the incentive to maintain or improve quality. The amount of PBP that an EOM participant or pool may receive, or the amount of any PBR that an EOM participant or pool may owe, will be based, in part, on their performance on each of the measures. From the start of the model, payment for all of the quality measures will be considered pay-for-performance and therefore payment will be directly linked to how each EOM participant performs on each measure. Benchmarks for the claims-based measures will be based on national claims data from the model baseline period, benchmarks for EOM participant-reported measures will be based on MIPS data, where such benchmarks are available, and benchmarks for the patient experience survey measure will be based on data collected during OCM.⁹⁸

Quality performance will be linked to payment in one of two ways. For an EOM participant or pool that earns a high AQS, the EOM participant or pool will either: 1) maximize their PBP, if the EOM participant or pool has

⁹⁷ With the exception of patient experience survey measure(s), generally quality measures will not be risk adjusted for sociodemographic factors to avoid masking meaningful differences in the quality of care and to promote high-quality, equitable care for all. We would consider risk adjustment for social risk, if appropriate.

⁹⁸ We may use EOM data for purposes of benchmarking if we see any meaningful differences in quality measure reporting or data trends, beginning in later performance periods.

earned and is eligible to receive a PBP; or 2) reduce the amount of PBR owed to CMS, if the EOM participant or pool's performance period expenditures exceed the threshold for recoupment (98 percent of the benchmark amount). Alternatively, for an EOM participant or pool that earns a low AQS, the EOM participant or pool will either: 1) reduce their PBP, if the EOM participant or pool has earned and is eligible to receive a PBP; or 2) have no impact on the amount of PBR owed to CMS, if the EOM participant or pool's performance period expenditures exceed the threshold for recoupment (98 percent of the benchmark amounts).

To calculate quality performance, we will (1) compare an EOM participant's or pool's performance on each measure to the measure's benchmarks; (2) calculate the EOM participant's or pool's AQS; and lastly (3) cross-walk the EOM participants' or pool's AQS to the PBP performance multiplier (if the EOM participant or pool earned a PBP), as shown in Table 7, or the PBR performance multiplier (if the EOM participant or pool owes a PBR), as shown in Table 8. For purposes of calculating the AQS as described the second step, each measure will be weighted equally. Additionally, CMS will apply a minimum episode threshold when scoring each quality measure to ensure the score is meaningful. For example, if an EOM participant has less than 20 episodes for a given quality measure, CMS will disregard the measure from both the numerator and denominator in the AQS, and readjust the AQS denominator accordingly. The minimum episode thresholds will also be applied to the total number of attributed episodes for the pool.

Table 7. Example AQS Translated into PBP Performance Multiplier

AQS (% of maximum points)	PBP Performance Multiplier
≥75% to 100%	100%
≥50% and <75%	75%
≥30% and <50%	50%
Less than 30%	0%

The resulting PBP performance multiplier will be applied as part of the PBP calculation, so that eligible EOM participants or pools with better quality scores will earn a higher PBP under EOM. The PBP performance multiplier will only decrease or maintain the amount of the PBP a given EOM participant or pool could earn; it will not be possible for the PBP performance multiplier to increase the EOM participant's or pool's PBP beyond the total difference between the target price and actual episode expenditures. For example, if an EOM participant's actual performance period expenditures were lower than its target amount for that performance period by \$10,000 and the EOM participant has a score that falls between 75-100 percent of the total possible AQS, the EOM participant would earn a PBP payment of \$10,000 (the maximum possible amount for that performance period).

EOM will also link performance on quality measures to payment through a reduction applied to an EOM participant's or pool's PBR for EOM participants or pools who performed well on their quality measures but who owe CMS a PBR for a given performance period. We believe this method will incentivize EOM participants to

provide high-quality care, even if they owe a PBR. The potential reduction in PBR will be determined based on the EOM participant’s or pool’s AQS, translated into a PBR performance multiplier. CMS will cross-walk the AQS to the PBR performance multiplier, as shown in Table 8. The PBR performance multiplier will then be used to either decrease or maintain the amount of the PBR an EOM participant or pool owes to CMS. For example, if an EOM participant’s actual performance period expenditures exceed the threshold for recoupment by \$10,000 and the EOM participant has a score that falls between 75-100 percent of the total possible AQS, the EOM participant would owe CMS a PBR of \$9,000, a 10% reduction (90% x \$10,000).

Table 8. Example AQS Translated into PBR Performance Multiplier

AQS Range (% of maximum points)	PBR Performance Multiplier
≥75% to 100%	90%
≥50% and <75%	95%
≥30% and <50%	100%
Less than 30%	100%

The PBR performance multiplier will not increase the amount of the PBR; it will only decrease the amount of PBR owed by an EOM participant or pool.

Clinical Data Elements

EOM participants will also be required to collect and submit to CMS certain beneficiary-level, clinical data elements not available in claims or captured in the quality measures on a semiannual basis. Pursuant to 42 CFR § 403.1110(b), EOM participants will be required to collect and report this data to CMS for CMS’s model monitoring and evaluation purposes in order for CMS to assess the cost and quality of care under the model and to ensure that participants are not stinting on care. CMS will also use specified clinical data for CMS’s payment purposes pursuant to HIPAA Privacy Rule requirements at 45 CFR § 164.506(c)(3) and the definition of “payment” under 45 CFR § 164.501; specifically, we will also use specified clinical data reported by EOM participants to inform risk adjustment used in calculating episode baseline prices, as described in section VIII. As described in section V.C. iii.3(b), CMS will calculate risk adjustments for both ever-metastatic status and HER2 positive status for the applicable included cancer type(s) using EOM beneficiary-level clinical and staging data submitted by the EOM participant. While the ever-metastatic risk adjustment was not applied in OCM, analyses by CMS demonstrated the value of including metastatic disease at any point prior to the episode’s end in order to be reflective of a beneficiary’s care during the entirety of the episode. Additionally, internal analyses of OCM registry data have shown that HER2 positive status is statistically significantly associated with higher average performance period expenditures than what would be predicted with the cancer-type specific price prediction model for breast cancer. EOM participants may be required to report on data elements other than ever-metastatic status and HER2 status as noted in section VIII. CMS will notify EOM participants of the reporting requirements for clinical data elements prior to the model’s start, and of any updates to such reporting requirements prior to the start of each performance period. CMS will require that EOM participants report the clinical data elements to CMS on at least a minimum of 90 percent of attributed episodes in a given performance

period.

G. Dispute Resolution Process

Under EOM's dispute resolution process, EOM participants will have the opportunity to contest an error in the calculation of the PBP, PBR, neutral zone, or MEOS Payment recoupment. This process will ensure that individuals involved in adjudicating these disputes will be familiar with EOM and its unique payment methodology and that these issues are resolved in an efficient manner by individuals with such knowledge. Also, under an additional EOM dispute resolution process, the EOM participant will have the opportunity to contest certain remedial actions taken by CMS under the terms of the participation agreement.

The participation agreement will describe the processes the EOM participant and CMS must follow.

- i. Dispute resolution process for calculation of the PBP, PBR, neutral zone, and MEOS payment recoupment.

The EOM participant will have 30 calendar days from the date the reconciliation report or MEOS payment recoupment report (as discussed in section V.G.) is issued to provide to CMS with written notice of a suspected error in the calculation of the PBP, the PBR, the neutral zone, and MEOS payment recoupment. If CMS receives a timely notice of error, CMS will respond in writing to the EOM participant within 30 calendar days of the written notice of suspected error to either confirm or refute the notice of error submitted by the EOM participant, although CMS may extend the deadline for its response if necessary. The participation agreement will provide additional details about the dispute resolution process, including the process for an EOM participant to request a reconsideration of CMS' refutation of the notice of error.

Following a refutation of a notice of error from CMS, EOM participants will be able to submit a request to CMS for reconsideration. The reconsideration request must include a detailed, written explanation of the basis for the dispute, including supporting documentation. Further, as will be detailed in the participation agreement, the reconsideration request must be submitted in writing within 10 calendar days of the date of CMS's refutation of the notice of error.

CMS will then contact the EOM participant within 15 calendar days of receiving a reconsideration request, to provide the review procedures and a briefing schedule that permits each party to submit written briefs, including any evidence, for consideration by the reconsideration official in support of each position. After review of the written briefs and evidence, the reconsideration official will issue to CMS and to the EOM participant a written notification of the reconsideration determination. Absent extenuating circumstances, this written notification will be issued within 60 days of receipt of timely filed written briefs and supporting documentation. The determination of the reconsideration official will be considered final and binding.

- ii. Dispute resolution process following certain remedial actions

If CMS finds that terms of the participation agreement are violated, or that an EOM participant, EOM practitioner, or Care Partner, has past or present program integrity issues, CMS may take remedial actions as discussed in section X.

CMS will describe in the participation agreement the specific remedial actions that may be contested by an EOM participant.

If an EOM participant wishes to contest the remedial action taken by CMS, the EOM participant will have 15 calendar days from the date of the remedial action to provide to CMS a written contestation of the remedial action. The contestation of the remedial action must include a detailed, written explanation of the basis for the contestation, including supporting documentation. CMS will contact the EOM participant within 15 calendar days of receiving the contestation acknowledging the receipt of the contestation of the remedial action. CMS will provide the EOM participant with the review procedures and a briefing schedule that permits each party to submit written briefs, including any evidence, for consideration by the reconsideration official in support of each position.

After review of the written briefs and evidence, the reconsideration official will issue to CMS and to the EOM participant a written notification of determination. Absent extenuating circumstances, this written notification will be issued within 60 days of receipt of timely filed written briefs and supporting documentation. The determination of the reconsideration official will be considered final and binding.

iii. Waiver of requirements of section 1869 of the Act

CMS will waive requirements of section 1869 of the Act specific to claims appeals to the extent otherwise applicable. CMS will issue this waiver so that EOM participants may utilize the dispute resolution processes specific to EOM. This waiver is necessary for purposes of testing EOM because the payment methodology for EOM is unique and as such, we have developed a separate timely error notice and reconsideration request process that EOM participants may use in lieu of the claims appeals process under section 1869 of the Act for model-specific disputes. During their participation in EOM, EOM participants may continue to use the standard CMS claims appeals procedures under section 1869 of the Act for Medicare claims issues that occur outside the scope of EOM.

VI. Advanced APM And Merit-Based Incentive Payment System (MIPS) Status

Beginning in Performance Period 1 (July 1, 2023), we expect Risk Arrangement 2 of EOM will meet the criteria under 42 CFR § 414.1415 to be an Advanced Alternative Payment Model (Advanced APM), and we expect both Risk Arrangement 1 and Risk Arrangement 2 of EOM will meet the criteria to be a Merit-based Incentive Payment System (MIPS) APM under the Quality Payment Program (QPP). Please refer to section V.C.iii.6 for additional details on the risk arrangements.

A. Advanced APM Status

A model (or track within a model) must meet three specific criteria to be an Advanced APM. The first criterion to be an Advanced APM is the CEHRT use criterion at 42 CFR § 414.1415(a). All EOM participants will be required to use CEHRT, and ensure that their EOM practitioners use CEHRT, in a manner sufficient to meet the requirements at 42 CFR § 414.1415(a). Each EOM participant will also be required to annually certify their use of CEHRT as specified at 42 CFR § 414.1415(a) and in a form and manner specified by CMS.

The second criterion to be an Advanced APM is that payment must be based on MIPS-comparable quality measures as specified at 42 CFR § 414.1415(b). This criterion will be satisfied by the quality reporting, assessment, and payment adjustment requirements for EOM. An AQS will be calculated based on the EOM participant's or pool's performance on the EOM quality measure set, and the AQS will contribute to the determination of the EOM participant's or pool's total PBP or PBR amount, if applicable. For an EOM participant or pool that earns a sufficiently high AQS, the EOM participant or pool will either maximize their PBP, if the EOM participant or pool met the cost target necessary to earn a PBP; or reduce the amount of their PBR owed to CMS, if the EOM participant or pool's performance period expenditures exceed the threshold for recoupment (98 percent of the benchmark amount). Please see sections V.F. for more detail on how quality measure performance ties to the PBP or PBR. Therefore, CMS will adjust payment to EOM participants based on quality measure performance. In addition, in alignment with 42 CFR § 414.1415(b)(2), we plan to select claims-based quality measures that are based on measures endorsed by the National Quality Forum (NQF), a consensus-based entity, and that are outcomes-based measures, consistent with 42 CFR § 414.1415(b)(3).

The third criterion to be an Advanced APM is the financial risk requirement at 42 CFR § 414.1415(c). Risk Arrangement 2 of EOM (see section V.C.iii.6. for additional information on the risk arrangements in EOM) will meet the generally applicable financial risk standard at 42 CFR § 414.1415(c)(1)(iii), because it requires the EOM participant to potentially owe payments to CMS in the form of a PBR, if applicable. Risk Arrangement 2 of EOM will also meet the generally applicable nominal amount standard at 42 CFR § 414.1415(c)(3)(i)(B), because the total amount that an EOM participant potentially owes CMS may equal more than 3 percent of the expected expenditures for which the EOM participant is responsible under EOM. Specifically, Risk Arrangement 2 will have maximum downside risk (or stop-loss) of 6 percent of the benchmark amount, maximum upside risk (or stop-gain) of 12 percent of the benchmark amount, and an EOM discount (representing Medicare savings) of 3 percent of the benchmark amount.

B. MIPS APM Status

Beginning in Performance Period 1 (July 1, 2023), we expect that EOM will also be considered a MIPS APM as defined at 42 CFR § 414.1305. Any MIPS eligible clinician who is included on the EOM participant's Practitioner List (see section II.B.ii. for details on EOM practitioners and the Practitioner List) will be eligible for voluntary scoring under the Advanced Performance Pathway (APP) as described at 42 CFR § 414.1367 as part of an APM Entity. This will apply to both Risk Arrangement 1, and to any individual clinician that will participate through an EOM participant that elects Risk Arrangement 2 but who fails to meet the QP thresholds required to become a

QP based on participation in an Advanced APM.

Because Risk Arrangement 1 will not meet the generally applicable financial risk standard described above (specifically the stop-loss in RA1 does not meet the generally applicable nominal amount standard), we expect that any EOM participant in Risk Arrangement 1 with individuals listed on the Practitioner List during the relevant QPP performance year will not be participating in an Advanced APM, but that they will still be considered MIPS APM participants for purposes of the QPP.

Under 42 CFR § 414.1367(b)(1), in order to be a MIPS APM, APM entities must participate in the APM under an agreement with CMS or through a law or regulation. Because EOM will be a voluntary model governed by a participation agreement, any individual who is an EOM practitioner (as defined in section II.B.ii.) for the applicable QPP performance year, will be participating in an APM under an agreement with CMS.

Under 42 CFR § 414.1367(b)(2), the APM must base payment on quality measures and cost/utilization. EOM participants will be required to report quality measures as described in section V.F., and EOM will meet the quality measure and cost/utilization requirement through the application of the AQS and the PBP performance multiplier or PBR performance multiplier, if applicable, and through the total cost of care responsibility to reduce expenditures and utilization for attributed episodes under the model.

C. Changes in Advanced APM or MIPS APM Status

MIPS eligible clinicians who will be identified on a Practitioner List for the performance period of an APM Entity participating in a MIPS APM have unique reporting options under MIPS. CMS anticipates certain circumstances may arise whereby it may be necessary to add or remove individual clinicians from an EOM participant's Practitioner List. In all such circumstances, CMS will report the necessary updates to QPP for the next relevant snapshot. It may be necessary to remove one or more individuals from such Practitioner Lists used for internal tracking. CMS will only remove one or more individuals from the Practitioner List when an EOM participant or EOM practitioner has failed to comply with EOM requirements, such as quality reporting or use of CEHRT, or for program integrity concerns.

VII. Benefit Enhancements, Financial Arrangements, and Patient Incentives

A. Benefit Enhancements

In order to emphasize high-value services and support the ability of EOM participants to manage the care of beneficiaries, we believe it is necessary to utilize the authority under section 1115A(d)(1) of the Act to conditionally waive certain Medicare payment requirements as part of testing certain benefit enhancements under EOM. The three benefit enhancements that will be made available to EOM participants at the start of the EOM model performance period include a telehealth benefit enhancement, a post-discharge home visits benefit enhancement, and a care management home visits benefit enhancement. While these three benefit enhancements will be made available at the start of EOM, CMS may consider offering future additional benefit enhancements.

Implementation of benefit enhancements by EOM participants will be optional and acceptance into EOM would not be contingent upon an EOM participant selecting to implement any particular benefit enhancement. EOM participants will be required to select the optional benefit enhancement(s) they wish to offer and to submit an implementation plan to CMS for each such benefit enhancement. CMS must approve the EOM participant's selection to participate in a given benefit enhancement before the EOM participant may implement the benefit enhancement. We reiterate that benefit enhancements are optional, so an EOM participant may choose not to implement any of them. If an EOM participant does not submit an implementation plan, they may not utilize the benefit enhancements.

EOM participants will be required to include specific information in the implementation plan, such as: (1) descriptions of the EOM participant's planned strategic use of the benefit enhancement; and (2) self-monitoring plans reflecting meaningful safeguards to prevent unintended consequences. If CMS approves the EOM participant's selection to implement any such benefit enhancement, the EOM participant, its EOM practitioners, and its Care Partners could furnish services pursuant to the benefit enhancement subject to the terms of the participation agreement.

Since episode attribution in EOM will be retrospective after the end of each performance period, we understand that it may be difficult for an EOM participant to identify EOM beneficiaries in real-time during the relevant performance period for purposes of utilizing a given benefit enhancement. CMS would mitigate this issue by permitting EOM participants to provide the given benefit enhancement to any Medicare beneficiary that is an eligible beneficiary (defined in section V.A.i).

CMS will incorporate a variety of program integrity safeguards in the participation agreement to ensure that these benefit enhancements do not result in program integrity issues or patient abuse. For example, an EOM participant that has received CMS approval to offer a given benefit enhancement(s) will be required to submit the benefit enhancement implementation plan to CMS on an annual basis to allow CMS to review the benefit enhancement(s) selected by EOM participant, and determine if adjustments to the implementation plan are needed based on the EOM participant's prior use of benefit enhancement(s).

i. Telehealth Benefit Enhancement

CMS will make available to EOM participants conditional waivers of (1) the originating site requirements at section 1834(m)(4)(C) of the Act and 42 CFR § 410.78(b)(3)–(4) with respect to telehealth services furnished to eligible beneficiaries; (2) the originating site requirement in the eligible telehealth individual provision at section 1834(m)(4)(B) of the Act with respect to that telehealth services being “furnished at an originating site”; and (3) the originating site facility fee provision in section 1834(m)(2)(B) of the Act and 42 CFR § 414.65(b) with respect to telehealth services furnished to a eligible beneficiary at his/her home or place of residence.

These waivers will allow EOM participants, EOM practitioners, and Care Partners to provide telehealth services⁹⁹ to eligible beneficiaries via telehealth outside of rural areas, including in the beneficiaries' homes, and allow EOM participants, EOM practitioners, or Care Partners to conduct telehealth visits that are not limited to the sites referenced in section 1834(m)(4)(C)(ii) of the Act. Additionally, these waivers will also allow EOM participants, EOM practitioners and Care Partners to use telemedicine to improve access and efficiency of care for eligible beneficiaries by allowing eligible beneficiaries with limited mobility or transportation barriers to access telehealth services more easily as well as allowing eligible beneficiaries to receive telehealth services wherever they are located, including at their home or place of residence. Like other CMMI models that provide the telehealth benefit enhancement, CMS will not pay a facility fee when the originating site is the beneficiary's home or place of residence. Generally, the facility fee provides for reimbursement of administrative duties of the facility, and since the facility in this instance is the beneficiary's home or place of residence there are no additional costs associated.

ii. Post-Discharge Home Visits Benefit Enhancement

Under 42 CFR § 410.26(b), Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner). CMS will make available to EOM participants a conditional waiver of 42 CFR § 410.26(b)(5), to allow payment for certain home visits furnished to eligible beneficiaries by auxiliary personnel (as defined in 42 CFR § 410.26(a)(1)) under general supervision, rather than direct supervision of the physician or other practitioner.

In order to be eligible to submit claims for services furnished to eligible beneficiaries pursuant to the post-discharge home visit benefit enhancement, the physician or other practitioner must be an EOM practitioner or Care Partner and permitted under Medicare rules to submit claims for "incident to" services as defined in Chapter 15, Section 60 of the Medicare Benefit Policy Manual.

Under the post-discharge home visit benefit enhancement, an eligible beneficiary is may receive up to nine post-discharge home visits within 90 days following discharge. The nine home visit services do not accumulate across multiple discharges; if the beneficiary is readmitted within 90 days of the initial discharge and before receiving nine home visits, the beneficiary may receive only nine home visits in connection with the subsequent discharge.

EOM participants approved to offer this benefit enhancement will be required to comply with additional requirements set in forth in the participation agreement. Specifically, Medicare payment will be made for these home visits only when they are furnished following an eligible beneficiary's discharge from an acute inpatient hospital, inpatient psychiatric facility, inpatient rehabilitation facility, long-term care hospital, or skilled nursing facility. Further, the eligible beneficiary must not qualify for Medicare coverage of home health services (or qualify for Medicare coverage of home health services on the sole basis of living in a medically underserved

⁹⁹ List of telehealth services payable under the Medicare Physician Fee Schedule when furnished via telehealth is available at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>

area). Also, the EOM participant must ensure that post-discharge home visits are not used to prevent or deter a beneficiary from seeking or receiving other medically necessary care, and that the services are furnished in accordance with all other applicable state and Federal laws and all other Medicare coverage and payment criteria, including the remaining provisions of 42 CFR § 410.26(b).

iii. Care Management Home Visits Benefit Enhancement

CMS will make available to EOM participants a conditional waiver of 42 CFR § 410.26(b)(5) to allow for payment for certain home visits that are furnished to eligible beneficiaries by auxiliary personnel (as defined in 42 CFR § 410.26(a)(1)) under the general supervision of a physician or other practitioner proactively and in advance of potential hospitalization. The items and services provided as part of these home visits are those that would be covered under Medicare Part B as “incident to” the services of a physician or other practitioner, and would be furnished by auxiliary personnel (as defined in 42 CFR § 410.26(a)(1)) under general supervision, rather than direct supervision. These care management home visits are intended to supplement, rather than substitute for, visits to physician or other practitioner in a traditional routine outpatient health care setting. As such, these home visits are not intended to be performed on an ongoing basis, nor to serve as a substitute for the Medicare home health benefit or as the primary mechanism to meet beneficiaries’ care needs.

In order to be eligible to submit claims for services furnished to eligible beneficiaries pursuant to the care management home visit benefit enhancement, the physician or other practitioner must be an EOM practitioner or Care Partner and permitted under Medicare rules to submit claims for “incident to” services as defined in Chapter 15, Section 60 of the Medicare Benefit Policy Manual.

EOM participants approved to offer this benefit enhancement will be required to comply with additional requirements set in forth in the participation agreement. Specifically, an eligible beneficiary is permitted to receive up to 10 care management home visits within a performance period. Further, the beneficiary must be determined to be at risk of hospitalization; the beneficiary must not qualify for Medicare coverage of home health services (unless the sole basis for qualification is living in a medically underserved area); and the services must be furnished in the beneficiary’s home by auxiliary personnel under the general supervision of an EOM practitioner or Care Partner.

Also, the EOM participant must ensure the home visits services are not used to prevent or deter a beneficiary from seeking or receiving other medically necessary care, and that the services are furnished in accordance with all other applicable state and Federal laws and all other Medicare coverage and payment criteria, including the remaining provisions of 42 CFR § 410.26(b).

B. Financial Arrangements

i. Care Partner Arrangements

EOM participants may want to enter into financial arrangements with one or more Care Partner(s) who contribute to the EOM participant’s episode performance under EOM. Under such Care Partner arrangements,

an EOM participant may share all or some of the PBPs they receive from CMS with its Care Partners. Likewise, under such arrangements EOM participants and their Care Partners may share the responsibility for repaying PBRs to CMS.

As described above, the term “Care Partner” means a Medicare-enrolled provider or supplier that engages in at least one of the PRAs during a performance period; has entered into a Care Partner arrangement with an EOM participant; is identified on the EOM participant’s Care Partner List; and is not an EOM practitioner. We believe that requiring Care Partners to be involved in at least one PRA (as discussed in section V.B.i) during a performance period helps, engage the Care Partner to assist EOM participants with improving care quality and reducing costs under EOM.

The participation agreement will set forth the requirements for Care Partner arrangements. For example, CMS will require the EOM participant to comply the following requirements and to impose such requirements on each of its Care Partners:

1. The EOM participant and Care Partner must reasonably determine that the Care Partner arrangement will advance one or more goals of EOM.
2. The Care Partner arrangement must not induce the EOM participant, Care Partner, or other providers or suppliers to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient;
3. The EOM participant and Care Partner must not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of EOM;
4. The EOM participant and Care Partner in advance of or contemporaneous with the commencement of the Care Partner arrangement must set forth the terms of the Care Partner arrangement in a signed writing. The writing must specify at a minimum the activities to be undertaken by the EOM participant and Care Partner and the nature of the remuneration to be exchanged under the Care Partner arrangement; and
5. The Care Partner arrangement must satisfy such programmatic requirements as outlined in the participation agreement.

If an Applicant wishes to enter into a Care Partner arrangement, it must submit a proposed Care Partner List during the application process. In addition, EOM participants will be required to submit a proposed Care Partner List to CMS on at least a bi-annual basis during the model performance period of EOM. The Care Partner List must include specific information for each Care Partner, including a Medicare-enrolled identifier such as a TIN or NPI; the name of the Care Partner; and provider/supplier type of the Care Partner, for example a hospital or post-acute care provider. The participation agreement will set forth directions and guidelines for EOM participants to remove or add Care Partners to their Care Partner List throughout the model performance period. The participation agreement will also set forth the circumstances in which CMS will remove a Care Partner from an EOM participant’s Care Partner list.

CMS will conduct a program integrity screening of each Care Partner, similar to the screening conducted for EOM participants and EOM practitioners, as discussed in section IX., to determine if the individual or entity satisfies the definition of Care Partner and is appropriate for inclusion on the Care Partner List. The program integrity screening will be administered during the application process and model performance period.

ii. Pooling Arrangement

As discussed in section II.B.iii., EOM will involve voluntary and mandatory pooling relationships between EOM participants. In these relationships, the EOM participant will enter into a financial arrangement with one or more other EOM participants, where one EOM participant is designated as the pooled payee. The pooled payee will receive PBPs or be responsible for the PBR on behalf of the pool. The “pooling arrangement” will permit each EOM participant party to the pooling arrangement to distribute PBPs to, or collect the PBRs from, other EOM participants in the pooling arrangement. The participation agreement will outline the requirements for a pooling arrangement under EOM. For example, CMS will require EOM participants in a pooling arrangement to comply with the following requirements:

1. The parties to the pooling arrangement must be EOM participants in a mandatory or voluntary pooling relationship;
2. The EOM participants must reasonably determine that the pooling arrangement will advance one or more goals of EOM;
3. The pooling arrangement must not induce EOM participants, or other providers or suppliers, to furnish medically unnecessary items or services, or reduce or limit medically necessary items or services furnished to any patient;
4. The EOM participants must not offer, pay, solicit, or receive remuneration in return for, or to induce or reward, any Federal health care program referrals or other Federal health care program business generated outside of EOM;
5. The EOM participants in advance of or contemporaneous with the commencement of the pooling arrangement must set forth the terms of the pooling arrangement in a signed writing that must specify at a minimum the activities to be undertaken by EOM participants and the nature of the remuneration to be exchanged under the pooling arrangement; and
6. The pooling arrangement must satisfy such programmatic requirements as outlined in the participation agreement.

C. Patient Incentives

We believe that beneficiary engagement is an important part of encouraging more active participation by beneficiaries in their health care. Beneficiary engagement and coordination of care could be enhanced by providing certain in-kind patient incentives to beneficiaries. Specifically, EOM participants, EOM practitioners, and Care Partners will be permitted to provide in-kind items or services to EOM beneficiaries, subject to compliance with all applicable laws and regulations and the terms of the participation agreement, if the following conditions

are satisfied:

1. The item or service would advance one or more goals of EOM (as set forth below);
2. The item or service has a direct connection to the EOM beneficiary's health care;
3. The item or service is furnished by an EOM participant, EOM practitioner, or a Care Partner (or by an agent acting under the direction and control of the EOM participant, EOM practitioner, or Care Partner);
4. The item or service is not tied to the receipt of items or services outside the episode;
5. The availability of the item or service is not advertised or promoted, except that an EOM beneficiary may be made aware of the availability of the item or service at the time the beneficiary could reasonably benefit from it;
6. The cost of the item or service is not shifted to Medicare or another federal health care program;
7. The EOM participant maintains, and requires its Care Partners to maintain, contemporaneous documentation of the following for items or services that exceed \$25 in retail value: (i) the date the item or service was provided; (ii) the identity of the EOM beneficiary to whom the item or service was provided; and (iii) the retail value of the item or service.; and
8. The item or service is furnished in a manner consistent with any other programmatic requirements imposed by CMS in the participation agreement.

For purposes of the first criterion, the goals of EOM include advancing clinical goals for EOM beneficiaries' oncology care, such as adherence to a drug regimen or care plan related to cancer, or otherwise improving management of the EOM beneficiary's cancer diagnosis.

VIII. Data Sharing and Health IT Strategy

A. EOM Participant-Reported Data Collection Strategy

CMS will provide an electronically enabled mechanism for EOM participants to report to CMS various model-related data abstracted from the EOM participant's own health IT. EOM participants will report three types of data to CMS: 1) quality measure data, 2) clinical and staging data, and 3) beneficiary-level sociodemographic data.

EOM participants will collect and report the quality measure as well as clinical and staging data to CMS pursuant to 42 CFR § 403.1110 (b), as necessary for CMS' model monitoring and evaluation purposes. CMS currently lacks the robust sociodemographic data on Medicare and Medicaid beneficiaries necessary to evaluate the impact of the models across sub-populations of such beneficiaries. As such, we believe it will be necessary to require model participants to collect and submit sociodemographic data on the beneficiaries they will be serving to CMS so that CMS can evaluate the impact of EOM and assess the generalizability of model results, as described in section XI. Further, to ensure that model participants will not commit any acts or omissions, nor adopt any policies, that will inhibit beneficiaries from obtaining the general rights and guarantees available under their Medicare or Medicaid coverage, we believe it will be necessary to require model participants to

collect and submit sociodemographic data to CMS for purposes of model monitoring activities to ensure equitable access and treatment is provided to all applicable sub-populations of beneficiaries in EOM, in line with our current monitoring strategy, described in section IX. This will help to ensure that evaluation results are generalizable and will provide additional data points to assist CMS in making informed decisions about possible expansion of the scope and duration of a model under section 1115A(c) of the Act. The quality measure data will inform CMS' assessment of participants' performance on quality measures. Additionally, CMS will use the clinical data for our payment purposes, pursuant to HIPAA Privacy Rule provisions at 45 CFR §§ 164.506(c)(3) and 164.501, to inform adjustments in calculating episodes' benchmark prices in order to account for the clinical case mix management by participants. More information on the quality and clinical data can be found in section V.F.

CMS may also use data collected from EOM participants to support learning events and materials to encourage model participants to support reductions in identified health disparities. For example, as noted above, CMS may also use the data to inform feedback reports and dashboards that would be shared with EOM participants.

While CMS believes in the importance of collecting complete and accurate sociodemographic data to inform our model monitoring and evaluation activities, to avoid discouraging beneficiaries from accessing care from EOM participants, EOM beneficiaries will not be required to share such data with EOM participants or CMS. As such, EOM participants will not be required to report to CMS sociodemographic data for any EOM beneficiary who chooses to not provide such data. Examples of sociodemographic data we may require EOM participants to collect and report, if available, include but are not limited to: race, ethnicity, and language. Collecting standardized patient demographic and language data across care settings is an important first step towards improving population health.¹⁰⁰

EOM participants will be required to report the data described above to CMS, at a time and manner specified by CMS, but no more than once per performance period. EOM will enhance functionality already in use by various other Innovation Center models to support collection of these data, possibly allowing EOM participants to choose from more than one option to submit data (e.g., manual submission via an Excel template upload, or potentially sent from a participant's EHR via a Fast Healthcare Interoperability Resources (FHIR)-based application programming interface (API)).

B. CMS Data Sharing with EOM PGPs and Collection Platform

On an annual basis, CMS will provide EOM participants with the opportunity to request certain data reports from CMS. CMS will make these data available by request by the EOM participant for the EOM participant's quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines; to develop and implement activities related to coordinating care and improving the quality and

¹⁰⁰ OMH. Inventory of Resources for Standardized Demographic and Language Data Collection. Retrieved from: <https://www.cms.gov/about-cms/agency-information/omh/downloads/data-collection-resources.pdf>

efficiency of care for EOM beneficiaries; and to conduct population-based activities relating to improving health or reducing health care costs, as specified in the first two paragraphs of the definition of “health care operations” at 45 CFR § 164.501. CMS will share requested data with a given EOM participant only after the EOM participant signs and submits a Data Sharing Agreement (DSA) to CMS, as described in section VIII.B.iv.

The data reports CMS will make available upon request to EOM participants will include, but not be limited to, quarterly de-identified feedback reports and dashboards, semiannual reconciliation reports (MEOS payment recoupment, PBP, PBR, and the neutral zone), beneficiary-identifiable attribution reports, beneficiary-identifiable episode-level files, and beneficiary-identifiable claims data. These reports will not include any substance use disorder data subject to the confidentiality requirements in 42 C.F.R. part 2. Examples of the information CMS may include in these reports are described below.

i. Quarterly feedback reports and dashboards

CMS believes feedback reports and dashboards will provide EOM participants with beneficiary information useful for care coordination and continuous quality improvement (CQI). The feedback reports and dashboards will be de-identified, while associated claims data will be beneficiary-identifiable, as discussed below. The quarterly feedback reports and dashboards will provide associated utilization and expenditure patterns for EOM participants’ eligible beneficiaries, broken out into included cancer types, in order to enable EOM participants to conduct quality assessment and improvement activities and conduct population-based activities relating to improving health or reducing health care costs. The initial quarterly feedback reports and dashboards will include historical data to help EOM participants understand their beneficiary populations’ health needs as necessary to conduct quality assessment and improvement activities, and population-based activities related to improving health or reducing health costs. EOM participants will be able to compare their utilization and expenditures data with de-identified data for other EOM participants and non-EOM oncology PGPs.

ii. Semiannual reconciliation reports, attribution lists, and episode-level files

Semiannual reconciliation reports (including MEOS payment recoupment, PBP, PBR and the neutral zone) and attribution lists will provide EOM participants with a list of attributed episodes for the relevant performance period, including aggregate quality scores. CMS believes episode attribution lists and the reconciliation reports are necessary for EOM participants to conduct quality assessment and improvement activities, care coordination, and population-based activities to improve health or reduce health care costs. For instance, episode attribution lists will provide insight to EOM participants to help them reduce health care costs, target care, and ensure that Enhanced Services are provided. EOM reconciliation reports will identify the EOM participant’s, or pool’s, PBP amount or PBR amount, if applicable, and contain detailed information on the reconciliation calculation for the relevant performance period. Along with the reconciliation reports, EOM participants also will have the opportunity to request episode-level files and associated claims data for the purposes of patient identification to implement PRAs focused on developing and implementing population-based activities relating to improving health or reducing health care cost, care coordination, and quality improvement.

iii. Monthly associated claims data

EOM participants will be able to request claims data regarding EOM beneficiaries on a monthly or quarterly basis. We anticipate that the claims data will assist EOM participants in identifying areas where they may need to change their care practice patterns, conduct quality assessment and improvement activities, including outcomes evaluation, patient safety activities, population-based activities relating to improving health or reducing health care costs, case management, and care coordination. In addition, we believe that the availability of as often as monthly updated beneficiary-identifiable claims data will enable EOM participants to monitor their cost and quality of care and to identify beneficiaries who are likely to be in episodes and attributed to the EOM participant. CMS believes that sharing data on an up to monthly basis will allow EOM participants to rapidly access this data to inform their care management and efforts to improve their health care operations. CMS believes that providing this data to EOM participants will assist each EOM participant in improving its performance and achieving the goals of EOM.

All EOM participants will be required to provide EOM beneficiaries with information about how to modify their data sharing preferences and opt out of claims data sharing of beneficiary-identifiable information for care coordination and quality improvement purposes. As noted previously in this section, EOM beneficiaries will not be required to share sociodemographic data with EOM participants, and as such, EOM participants will not be required to report sociodemographic data to CMS for any beneficiary who chooses not to provide such data. CMS will provide EOM beneficiaries who inquire about or wish to modify their preferences regarding claims data sharing with information about how to modify their data sharing preferences via 1-800-MEDICARE. EOM participants will be required to allow EOM beneficiaries to reverse a claims data sharing preference at any time via 1-800-MEDICARE. Reports containing individually identifiable data will not include individually identifiable data regarding beneficiaries who opt out of claims data sharing. Aggregate reports will incorporate de-identified data from EOM beneficiaries who have opted out of data sharing.

To facilitate sharing and collection of data between CMS and EOM participants, CMS anticipates utilizing Innovation Center-wide IT platforms while potentially also utilizing CMS APIs designed for seamlessly sharing data. CMS expects that these data platforms will allow EOM participants to easily interact with a user-friendly user interface (UI), allowing for easy downloading of CMS-provided data and permitting EOM participant-reported data submission via both manual and bulk upload.

iv. Data Sharing Agreement

As used in other payment models, including OCM, CMS will use a Data Sharing Agreement (DSA) for EOM. Through the data request and DSA process, eligible EOM participants will be able to request specific types of data needed to perform certain health care operations activities (listed in paragraph (1) or (2) of the definition of "Health care operations" in 45 CFR § 164.501) related to EOM, and will attest that the data requested are the minimum necessary to perform those activities, consistent with HIPAA regulations.

IX. CMS Monitoring

As part of testing EOM, CMS will implement a monitoring plan designed to protect beneficiaries and identify potential program integrity risks. CMS will employ a range of methods to monitor and assess compliance by EOM participants, EOM practitioners, and Care Partners with the terms of the participation agreement, including, but not limited to:

- Claims analyses to identify fraudulent behavior or program integrity risks such as inappropriate reductions in care (e.g., through claims-based utilization, inappropriate changes in case-mix or quality measures), efforts to manipulate risk adjustments or attributed beneficiaries, overutilization, and cost-shifting to other payers or populations;
- Interviews with any individual or entity participating in PRAs, including members of the EOM participant leadership and management, EOM practitioners, and Care Partners;
- Interviews with EOM beneficiaries, eligible beneficiaries, and their caregivers, particularly related to beneficiaries with complex care conditions in addition to undergoing chemotherapy for a cancer diagnosis (e.g., those with behavioral health needs); interviews will provide an opportunity for CMS to examine care coordination and ensure that cherry-picking, lemon-dropping, and stinting of care are not issues;
- Audits of charts, medical records, implementation plans, and other data from the EOM participants, EOM practitioners, and Care Partners;
- Site visits to EOM participants and Care Partners; and
- Documentation requests to the EOM participants, EOM practitioners and/or Care Partners, including surveys and questionnaires.

CMS will conduct comprehensive annual audits related to compliance with the participation agreement and to identify potential program integrity risks, with more limited targeted or ad-hoc audits as necessary. This includes requiring and auditing EOM participant financial disclosures to ensure the solvency of the EOM participant as applicable, and monitoring EOM participants for compliance with the participation agreement. Finally, CMS will maintain an email inbox for inquiries related to EOM at EOM@cms.hhs.gov.

X. Remedial Actions

Noncompliance with the terms of the participation agreement will trigger appropriate actions based on the type of issue, degree of severity, and the EOM participant's compliance record while in the model. If CMS determines that any provision of the participation agreement may have been violated, CMS may take one or more of the following actions:

- Notify the EOM participant, and, if appropriate, associated EOM practitioners, Care Partners, or EOM payers of the violation;
- Require the EOM participant to provide additional information to CMS or its designees;
- Conduct on-site visits, interview beneficiaries, or take other actions to gather information;
- Place the EOM participant on a monitoring and/or auditing plan developed by CMS;

- Request a corrective action plan (CAP) from the EOM participant that is acceptable to CMS, and to implement the CAP by a deadline established by CMS;
- Require the EOM participant to remove an EOM practitioner from the EOM participant’s Practitioner List and to terminate its arrangement, immediately or within a timeframe specified by CMS, with such EOM practitioner with respect to this model;
- Require the EOM participant to remove the Care Partner from the Care Partner List and to terminate its arrangement, immediately or within a timeframe specified by CMS, with such Care Partner with respect to this model;
- Require the EOM participant to terminate its relationship with any other individual or entity performing functions or services related to PRAs;
- Discontinue the provision of data sharing to the EOM participant;
- Prohibit the EOM participant from distributing PBPs or collecting funds to repay PBRs;
- Withhold, deny, or recoup PBPs or MEOS payments;
- Prohibit the EOM participant from accessing any or all waivers of existing law made pursuant to section 1115A(d)(1) of the Act;
- Amend the participation agreement without the consent of the EOM Participant to deny the use of one or more benefit enhancements by an EOM practitioner or Care Partner and to require that the EOM participant terminate any agreements effectuating such benefit enhancements by a date specified by CMS;
- Prohibit the EOM participant from furnishing any in-kind items and services under the terms of the participation agreement;
- Terminate the EOM participant from the model.

XI. Evaluation

All EOM participants will be required under 42 CFR § 403.1110(b) and the participation agreement to cooperate with efforts to conduct an independent, federally funded evaluation of the model by CMS and/or its designees. The evaluation may require EOM participants to participate in surveys; interviews; site visits; and other activities that CMS determines necessary to conduct a comprehensive formative and summative evaluation.¹⁰¹ The evaluation will assess the impact of the EOM on the goals of better health, better health care, lower program expenditures, and equitable care. The evaluation will be used to inform policymakers about the effect of the EOM’s policies. To do so, the evaluation will seek to understand the behaviors of health care providers and beneficiaries, the impacts of increased financial risk, the effects of various payment arrangements and benefit enhancements, the impact of the model on beneficiary engagement and experience, and other factors associated

¹⁰¹ In accordance with 42 CFR § 403.1110(b), “Any State or other entity participating in the testing of a model under section 1115A of the Act must collect and report such information, including ‘protected health information’ as that term is defined at 45 CFR § 160.103, as the Secretary determines is necessary to monitor and evaluate such model. Such data must be produced to the Secretary at the time and in the form and manner specified by the Secretary.”

with patterns of results. Each EOM participant must require its EOM practitioners and other staff, as well as the EOM participant's Care Partners, to participate and cooperate in any such independent evaluation activities conducted by CMS and/or its designees. If an EOM participant does not provide the data necessary for CMS and/or its designees to complete the evaluation, upon request, CMS may take remedial action.

XII. Information Resources for Beneficiaries and Health Care Providers

The primary resource for beneficiaries with questions about EOM will be 1-800-MEDICARE. CMS has developed scripts for customer service representatives (CSRs) that will answer anticipated questions related to the model. Questions that CSRs cannot answer will be triaged to the model support help desk and key model personnel. EOM participants will also be required to establish processes to answer beneficiary queries. Finally, CMS will maintain an email inbox for inquiries related to EOM at EOM@cms.hhs.gov.

XIII. Learning System

CMS intends to operate a learning system for EOM participants to facilitate the achievement of EOM's strategic goals and aims described in section I. The EOM Learning System will utilize improvement science methods and will connect EOM participants along the capability continuum through learning events, with a focus on peer-to-peer sharing. A learning needs assessment and annual survey will be distributed to EOM participants to help CMS assess EOM participants' learning priorities and needs, understand EOM participants' capabilities and strategies implemented to meet model requirements, and improve care furnished to EOM beneficiaries. Health equity will be embedded in the learning system – including, but not limited to, one of the domains within the learning needs assessment and annual survey, and as an underlying element of improvement work and model drivers. EOM learning supports will also build on lessons learned from the OCM Learning System, which has been able to successfully connect practice-peers and payer-peers in targeted work. This includes fostering more proactive and integrated palliative care and pain management, increasing hospice utilization, reducing avoidable ER visits and admissions, integrating value-based drug prescribing approaches for efficacy and cost-control, utilizing patient navigation and care plan strategies to address barriers and social determinants of health (SDOH), and building robust data analysis approaches to identify opportunity areas and high-needs patients.

The EOM Learning System will be based on novel aspects of EOM, and will also build upon pertinent learnings from OCM, including OCM evaluation results and qualitative feedback from OCM practices. EOM learning system activities will focus on improving the quality of oncology care, reducing costs, and improving the patient experience of care. We believe this will be achieved by supporting EOM participants as they work to reduce inefficiency and variation in oncology care by improving workflows and staffing approaches, developing strategic plans for use of revenue and comprehensive coordinated care approaches and building their skills as “learning organizations” as they use data for continuous quality improvement (CQI) to implement targeted, effective tests of change.

The EOM Learning System will support the achievement of the model's strategic goals in three main ways: (1) identification and packaging of resources related to new knowledge and practices; (2) leveraging CMS and EOM participant data, as well as EOM participant input and feedback; and (3) building learning communities and

networks to share and spread new knowledge and best practices. Information and work will occur through three channels of communication: (1) from EOM participant to EOM participant, (2) from CMS to EOM participants, and (3) from EOM participants to CMS. Active flows in all of these streams will allow EOM participants to work together for success, help EOM participants understand technical aspects and requirements of EOM implementation, and assist CMS in understanding what is (or is not) working in EOM. The EOM Learning System curriculum will be built on an assessment of EOM participant needs and priorities. The EOM Learning System activities will include direct engagement with EOM participants, written resources and tools for EOM participants to use, and virtual learning events and online platforms for information dissemination and collaboration.

CMS will also have a voluntary payer workgroup aimed at supporting EOM payers' implementation of oncology value-based payment models that align with EOM, which will be open to the broader community of payers contracting with EOM participants but not necessarily participating in the model as EOM payers. This voluntary payer workgroup will provide an informal forum for payers to interact, share challenges and lessons learned, and work toward alignment, following CMS's lead. CMS aims to maintain a competitive environment while providing an opportunity for payer participation, and nothing in this RFA shall be deemed as a guidance to supersede or suspend any applicable antitrust laws or regulations.

XIV. Termination

CMS may terminate an EOM participant's participation agreement at any point during the EOM model performance period for reasons associated with poor performance, non-compliance with the terms and conditions of the participation agreement, or as otherwise specified in the participation agreement.

An EOM participant may terminate its participation agreement at any point during the model performance period provided that the EOM participant provides advanced written notice to CMS in a form and manner specified by CMS. At CMS' request, the EOM participant will be required to provide feedback regarding its decision to terminate the participation agreement and its experience as it relates to the implementation of PRAs and other model requirements.

An EOM payer may terminate their participation in EOM at any point during the model performance period. CMS requests that the EOM payer provide advanced written notice of their intent to terminate to CMS. CMS may request that the EOM payer provide feedback regarding its decision to terminate and its experience in EOM.

XV. Amendment

CMS may modify the terms of EOM for a variety of reasons, including to respond to stakeholder input, to reflect the agency's experience with the model, or as may be required under section 1115A of the Act or any other applicable provision of law. The terms of EOM as set forth in this Request for Applications may differ from the terms of the model as set forth in the participation agreement between CMS and the EOM participant. Unless

otherwise specified in the participation agreement, the terms of the participation agreement, as amended from time to time, shall constitute the terms of EOM.

XVI. Appendices

Appendix A: Comparison of OCM to EOM by Select Model Features

Description	OCM	EOM
Included Beneficiary Population	Beneficiaries with a cancer diagnosis receiving chemotherapy (including hormonal therapies)	Beneficiaries with a cancer diagnosis for an included cancer type (breast cancer, lung cancer, lymphoma, multiple myeloma, small intestine/colorectal, prostate cancer, and chronic leukemia) receiving systemic chemotherapy (not including exclusively hormonal therapies)
Required Practice/Participant Redesign Activities	Six cross-cutting requirements that provide for broad improvements in cancer care including documenting a care plan that includes the 13 element Institute of Medicine Care Management Plan	Same as OCM with the addition of two participant redesign activities: the gradual implementation of electronically submitted patient reported outcomes and screening EOM beneficiary social needs using a health-related social needs screening tool Added health equity planning requirement under use of data for CQI
Data Sharing and Collection	Participants were not required to collect any sociodemographic data; CMS did not stratify data based on sociodemographic data within feedback reports or reconciliation reports	Required submission of sociodemographic data, if available, as a part of EOM health equity strategy; CMS may share with EOM participants certain aggregate, de-identified data, for example, aggregate utilization data, stratified by sociodemographic metrics (e.g., dual status, LIS eligibility, and race and ethnicity)
PBPM	Monthly Enhanced Oncology Services (MEOS) payment amount = \$160 PBPM for each OCM beneficiary; the entire \$160 is included as episode expenditures	Monthly Enhanced Oncology Services (MEOS) payment amount = \$70 PBPM (beneficiary not dually eligible for Medicaid and Medicare); or \$100 PBPM (beneficiary dually eligible for Medicaid and Medicare) of which \$70 will be included as episode expenditures in reconciliation calculation
Drug Payment	No change from FFS Medicare: payment is typically ASP+6%; total cost of care responsibility that includes Part B drug payment and certain Part D expenditures	No change from OCM

Attribution Methodology for MEOS and Performance-Based Payment	Plurality of E&M claims with a cancer diagnosis on the service line during a six-month episode	Attribute to the eligible oncology PGP that provides the first qualifying E&M service after the initiating chemotherapy, provided that the PGP has at least 25% of the cancer-related E&M services during the episode; if the initiating oncology PGP does not did not bill at least 25% of cancer-related E&M services during the episode, then attribute based on plurality of cancer-related E&M services at an oncology PGP
Novel Therapies Adjustment for Performance-Based Payment	Calculated in aggregate across all cancer types	Calculated separately for each of the seven included cancer types
Risk Adjustment for Performance-Based Payment	All cancer types included in one price prediction model; clinical data used in final five performance periods, where participating practice-reported metastatic status is included in risk adjustment	Included cancer type-specific price prediction models; a more robust use of EOM participant-reported clinical and staging data in risk adjustment, to include ever-metastatic status and HER2 status
Risk Arrangements for Performance-Based Payment	<p>One-sided risk in PP1, followed by the option for one- or two-sided risk in PP2—PP7</p> <p>Participants earning a performance-based payment by the initial reconciliation of PP4 have the option to stay in one-sided risk in PP8—PP11; other participants must either accept two-sided risk in PP8—PP11 or be terminated from the model</p> <p>1) Original two-sided risk arrangement: Discount=2.75% of benchmark amount</p>	<p>Two downside risk arrangement options:</p> <p>1) Less aggressive two-sided risk arrangement option (RA1) will include minimal downside risk (below the generally applicable nominal amount standard for RA1 to qualify as an Advanced APM): Discount=4% of benchmark amount Stop-gain=4% of benchmark amount Stop-loss=2% of benchmark amount</p> <p>2) More aggressive two-sided risk arrangement option (RA2) (expected to meet the generally applicable nominal amount standard for RA2 to qualify as an Advanced APM): Discount=3% of benchmark amount Stop-gain=12% of benchmark amount Stop-loss=6% of benchmark amount</p> <p>Across both risk arrangements, if the EOM</p>

	<p>Stop-gain/stop-loss=20% of benchmark amount</p> <p>2) Alternative two-sided risk arrangement (less aggressive): Discount=2.5% of benchmark amount Minimum threshold for recoupment=2.5% of benchmark amount Stop-gain=16% of total Part B revenue for the practice* Stop-loss=8% of total Part B revenue for the practice*</p>	<p>participant's performance period episode expenditures are greater than 98% of the benchmark they will owe a PBR; if the EOM participant's performance period episode expenditures are less than the target amount then they are eligible to earn a PBP (actual payment of PBP is dependent upon the EOM participant satisfying the PBP eligibility requirements); if the EOM participant's performance period episode expenditures are between the target amount and 98% of the benchmark amount, they are in the neutral zone and neither earn a PBP nor owe a PBR.</p>
--	---	---

*Total Part B revenue for the practice is defined as the sum of:

- (1) Total Part B revenue for services billed under the OCM practice's TIN during the 12-month time period that begins on the earliest date on which an episode that terminates during a performance period could initiate and ends on the last day of the Performance Period (i.e., the four calendar quarters that cover initiation through termination for all episodes that terminate during a performance period); plus
- (2) Any additional Part B chemotherapy administration and drug payments for all Episodes attributed to the Practice that terminate during that Performance Period.

Appendix B: Health Equity Strategy Overview Examples

Strategy Domain	Action Plan
<p>Incentivize care for underserved communities</p>	<ul style="list-style-type: none"> • Differential Monthly Enhanced Oncology Services (MEOS) payment <ul style="list-style-type: none"> ○ Base MEOS payment = \$70 per beneficiary per month (PBPM), included in total cost of care (TCOC) accountability for attributed episodes ○ Additional MEOS payment for duals = \$30 PBPM (not included in total cost of care accountability for attributed episodes); total MEOS payment for duals = \$100 • MEOS payments support the implementation of Enhanced Services (e.g., use of a health-related social needs (HRSN) screening tool, care planning, patient navigation) • TCOC benchmark will be risk adjusted for multiple factors, including dual status and low-income subsidy status as proxies for income and social risk, presence of selected non-cancer comorbidities, and clinical case mix • With the exception of the patient experience survey measures(s), generally quality measures will not be risk adjusted for sociodemographic factors to avoid masking meaningful differences in the quality of care and to promote high-quality, equitable care for all. We would consider risk adjustment for social risk, if appropriate.
<p>Collect key beneficiary-level sociodemographic data</p>	<ul style="list-style-type: none"> • Require EOM participants' collection and reporting of beneficiary-level sociodemographic data to CMS to be used in monitoring and evaluation
<p>Identification and action to address health-related social needs (HRSNs)</p>	<ul style="list-style-type: none"> • EOM participants will be required to use screening tools, e.g., the NCCN Distress Thermometer, the Accountable Health Communities Screening Tool • EOM participants will be required to collect electronic patient-reported outcomes (ePROs) data from patients, including an HRSN domain • EOM participants will be required to screen for, at a minimum, three HRSN domains: transportation, food insecurity and housing instability • EOM participants will be required to provide the core functions of patient navigation to all EOM beneficiaries • CMS will encourage EOM participants to develop community partnerships to address identified needs
<p>Better access to care</p>	<ul style="list-style-type: none"> • EOM participants will be required to provide 24/7 access to a clinician with real-time access to the practice's medical record

Improved shared decision-making and care planning	<ul style="list-style-type: none"> • EOM participants will be required to develop a care plan with the patient, including discussion of prognosis and treatment goals, a plan for addressing psychosocial health needs, and estimated out-of-pocket costs
Oncology practice continuous quality improvement	<ul style="list-style-type: none"> • Feedback reports for EOM participants will stratify aggregate de-identified data by sociodemographic variables so EOM participants can identify and address disparities • Require EOM participants to develop a health equity plan as part of using data for CQI
Evaluate the impact of models on subpopulations	<ul style="list-style-type: none"> • The Innovation Center’s evaluation team is planning to examine outcomes for subpopulations as feasible, depending on data availability and sample size considerations

Appendix C: Core Functions of Patient Navigation for Cancer Patients¹⁰²

1. Coordinating appointments with health care providers to ensure timely delivery of diagnostic and treatment services;
2. Maintaining communication with EOM beneficiaries, families, and the health care providers to monitor EOM beneficiary satisfaction with the cancer care experience and provide health education;
3. Ensuring that appropriate medical records are available at scheduled appointments;
4. Providing language translation or interpretation services in accordance with federal law and policy;
5. Facilitating linkages to follow-up services and community resources (e.g., make referrals to cancer survivor support groups and community organizations or other third parties that provide child/elder care, transportation, or financial support); and
6. Providing access to clinical trials as medically appropriate.

¹⁰² Patient navigation must be provided in a manner that is compliant with all applicable laws and regulations.

Appendix D: Components of the Institute of Medicine Care Management Plan¹⁰³

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

¹⁰³ Retrieved from the Institute of Medicine Report, *Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis*.

Appendix E. Application Templates

Enhancing Oncology Model (EOM) Physician Group Practice (PGP) Application Template

Instructions

Thank you for your interest in participating in the CMS Innovation Center’s Enhancing Oncology Model (EOM). This application template is intended for use by Physician Group Practice (PGP) applicants.

The PDF version of this application is for reference only. Applicants interested in submitting an application are required to submit their application using the EOM RFA Application Portal. A link to the application can be found here: <https://app.innovation.cms.gov/EOM>. Submission of the PDF version of this application will not be accepted.

All EOM applications must be submitted by 11:59 pm Eastern Daylight Time on September 30, 2022. CMS may not review applications submitted after the deadline.

Refer to the Request for Applications (RFA) on the Innovation Center website <https://innovation.cms.gov/innovation-models/enhancing-oncology-model> for further details regarding participation requirements and application submission criteria. Applications will be reviewed for completion of all required fields and a signed and dated application certification.

CMS will safeguard the information provided in accordance with the Privacy Act of 1974, as amended (5 U.S.C. § 552a). For more information, please see the CMS Privacy Policy at https://www.cms.gov/AboutWebsite/02_Privacy-Policy.asp.

CMS provides no opinion on the legality of any contractual or financial arrangement that the applicant may disclose, propose, or document in this application. The receipt by CMS of any such information in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules, or regulations, and will not preclude CMS, HHS, the HHS Office of Inspector General, a law enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules, and regulations.

For questions regarding the EOM or the EOM application process, email EOM@cms.hhs.gov.

Physician Group Practice (PGP) Application Template

Applicant PGP Information

Applicant Physician Group Practice (PGP) Legal Name:

The legal entity identified here as the applicant must be the same legal entity that would execute a participation agreement with CMS upon acceptance into the model.

Doing Business As (DBA) Name(s) (if different from PGP Legal Name):

Where is your PGP located?

Provide street address, city, and state for all locations where Evaluation and Management (E&M) services related to chemotherapy billed under the TIN of your PGP are furnished.

Taxpayer Identification Number (TIN):

Provide the TIN under which your PGP expects to bill Medicare under EOM.

Provider Transaction Access Number (PTAN):

Contact Information

Primary Point of Contact (POC)

Name:

POC Title:

POC Street Address:

POC City:

POC State:

POC ZIP Code^{TM,104}

POC Phone:

Extension:

POC Email:

¹⁰⁴ ZIP Code is a registered trademark of the United States Postal Service.



Secondary POC

Name:

POC Title:

POC Street Address:

POC City:

POC State:

POC ZIP Code:

POC Phone:

Extension:

POC Email:

Tertiary POC

Name:

POC Title:

POC Street Address:

POC City:

POC State:

POC ZIP Code:

POC Phone:

Extension:

POC Email:

PGP Profile Information

Provide the following information regarding your PGP:

1. Does your PGP contain organizational National Provider Identifiers (NPIs) that bill under your TIN?
[YES/NO]
2. If yes, please list all organizational NPIs:
3. Please provide a brief description of your PGP's organizational structure (e.g., hospital-based or community-based):
[TEXT BOX]
4. How long has your PGP been in existence? Specifically, when was the PGP that would be participating in EOM incorporated under state, federal, or tribal law?

5. Please provide a brief description of your PGP’s areas of medical specialty (e.g., oncology-specific, multi-specialty):

[TEXT BOX]

6. Has your PGP been restructured in any way since July 1, 2016 (the start of the model baseline period), including any TIN changes or changes in control such as a merger or acquisition?

[YES/NO]

If yes, please provide a brief explanation of the restructuring. Include all legal names, including all DBA names, and TINs in use during calendar years 2016-2022:

[TEXT BOX]

PGP Information

Please provide a brief summary about the geographic area where your PGP provides care, including where most of the PGP’s Medicare fee-for-service beneficiaries reside; if the service area encompasses urban, suburban, and/or rural locations; and if the area is a health professional shortage area designated by the Secretary pursuant to section 332 of the Public Health Service Act (42 USC § 254e) and its implementing regulations (42 CFR part 5).

[TEXT BOX]

In the table below, please provide the NPI, name, and specialty code for each practitioner who currently provides cancer E&M services to Medicare fee-for-service beneficiaries receiving chemotherapy for an included cancer type*, has reassigned his or her right to receive Medicare payments to the TIN of the PGP, and is proposed to participate in EOM as an EOM practitioner (as defined in section II.B.ii. of the RFA).

**As described in section V.A.ii of the RFA, the included cancer types are breast cancer (excluding low-risk breast cancer), chronic leukemia, small intestine/colorectal cancer, lung cancer, lymphoma, multiple myeloma, and prostate cancer (excluding low-intensity prostate cancer).*

NPI	Name	Specialty Code

After CMS reviews historical data on Medicare billing for cancer-related E&Ms outside of your PGP’s TIN by practitioners that also bill Medicare for cancer-related E&Ms under your TIN, CMS may require your

PGP to enter into a mandatory pooling arrangement with another PGP as a condition of participation in EOM. Refer to the next section on pooling for more information on pooling and pooling arrangements.

Pooling with EOM Participants

Pooling means that two or more EOM participants are treated together for reconciliation calculations, meaning that their performance for each performance period will be aggregated to determine whether the pool, if eligible, has earned a performance-based payment (PBP) or owes CMS a performance-based recoupment (PBR). Participation in a pool under EOM may be voluntary or mandatory. The financial relationship among pooled participants will be governed by a pooling arrangement. The terms for such pooling arrangements will be set forth in the participation agreement.

Are you planning to participate in a voluntary pooling arrangement under EOM?

[YES/NO]

Please list the EOM PGP applicant(s) with which you wish to enter into a pooling arrangement:

**Please note that any PGP with which you plan to enter into a pooling arrangement must also submit an Enhancing Oncology Model (EOM) Physician Group Practice (PGP) Application.*

Pooling PGP Applicant 1: Legal Name, TIN, Primary POC, contact information

Pooling PGP Applicant 2: Legal Name, TIN, Primary POC, contact information

Pooling PGP Applicant 3: Legal Name, TIN, Primary POC, contact information

Care Partner Information

CMS may approve Medicare-enrolled providers or suppliers to be Care Partners as discussed in Section IX.B. CMS will collect Care Partner Lists on at least an annual basis during each calendar year of EOM.

In the table below, please provide information regarding each individual and entity you propose will serve as a Care Partner.

NPI/CCN/TIN (Medicare-enrolled identifier)	Name of Individual or Entity	Nature or Category of proposed Care Partner (e.g., NPP; Hospital; Post-acute care entity)

Incorporation and Licensure

1. Please attach a copy of a certificate of incorporation or other documentation demonstrating that the PGP applicant is recognized as a legal entity by the state in which it is located or under federal or tribal law.
2. Please attach documentation demonstrating that the PGP applicant has been licensed as a risk-bearing entity under applicable state, federal, or tribal law, or that it is exempt from such licensure and/or other such requirements, as follows:
 - i. If the PGP applicant has been licensed as a risk-bearing entity, upload a copy of the appropriate certification or documentation.
 - ii. If the PGP applicant is required to obtain licensure as a risk-bearing entity under applicable state, federal, or tribal law, but the PGP is not yet currently licensed as a risk-bearing entity under one or more such laws, please describe the progress the PGP applicant has made toward obtaining such licensure.
 - iii. If the applicable state, federal, or tribal laws do not have a licensure requirement for risk-bearing entities, or if the PGP applicant does not meet the applicable definitions established by such laws, please upload an attestation made by an individual authorized to act on behalf of the PGP applicant indicating that this is so.

Disclosure

Please disclose the following with respect to the PGP applicant, and with respect to each individual and entity the PGP applicant proposes will be EOM practitioners or Care Partners: (i) any sanctions or corrective action imposed under Medicare, Medicaid, or licensure authorities within the last five years (including corporate integrity agreements); (ii) any fraud investigations or enforcement actions initiated, conducted, or resolved within the last five years; (iii) any outstanding debts owed to a Federal health care program, including any debts owed under an Innovation Center model, or to any agency of the federal government; (iv) whether any individuals employed by, or entities engaged by, the PGP are on a government suspension, debarment, or exclusion list relating to procurements or non-procurements; (v) any instances of criminal conduct; and (vi) any instances of bankruptcy.

Individual or entity	Federal, State, or Tribal Agency or Licensing Body	Description of Infraction (including date)	Resolution Status (including date)

For reference, enforcement actions include criminal, civil, or administrative legal actions relating to fraud and other alleged violations of law, initiated or investigated by the Health and Human Services Office of Inspector

General and its law enforcement partners.

Failure to disclose any of the information described above could be grounds for application denial or, if selected for participation in EOM, immediate termination from the model.

Narratives

Implementation Plan (limit 2500 words): The Implementation Plan should describe your PGP’s plans to implement EOM participation requirements and achieve EOM objectives, based on current practice capabilities and any changes that might be necessary.

Include in the implementation plan:

- A clear, realistic plan to implement the EOM participant redesign activities (PRAs) within the required timelines, as specified in section V.B of the RFA. Include any necessary changes in workflow, creation of new collaborations with other entities (e.g., primary care practices, other specialty physician practices, community-based organizations, etc.), hiring and training of appropriate personnel, extending hours of access to care, etc.
- Description of plans to provide person-centered, equitable care (e.g., ensuring patient/caregiver engagement and shared decision-making, developing community partnerships, screening for health-related social needs).
- Description of your PGP’s planned approach to quality improvement and plan to achieve the highest possible Aggregate Quality Score (AQS), as described in section V.F of the RFA.
- Description of how the proposed implementation plan may promote cost savings (please describe how savings generated at your PGP could promote savings to Medicare and for beneficiaries).
- If your PGP plans to utilize one or more Benefit Enhancements described in section VII.A., include descriptions of your PGP’s planned strategic use of each such Benefit Enhancement and self-monitoring plans reflecting meaningful safeguards to prevent unintended consequences.

Financial Plan (limit 2500 words): The Financial Plan should demonstrate your PGP’s financial stability and soundness, as well as present a realistic, sound financial plan for EOM based on expected financial resources to support the implementation plan.

Include in the financial plan:

- Description of any known or expected changes to your PGP’s revenue or revenue model during the performance period of EOM (e.g., revenue increases or decreases due to changes in patient population, practice patterns, mergers or acquisitions, use of different chemotherapy drugs, etc.). If no changes are expected, please indicate why in your demonstration of your PGP’s financial stability and soundness.
- Full description of your PGP’s financial plan to support the implementation plan for EOM, including but not limited to:

- EOM Monthly Enhanced Oncology Services (MEOS) payments: If the PGP intends to bill CMS for MEOS payments, include a description of how these payments will be used to support the implementation plan, including practice transformation and meeting the EOM requirements.
- Expected EOM Performance-Based Payment (PBP): Realistic assessment of expected PBP based on current practice capabilities and expected changes in order to achieve the EOM objectives. (If you intend to enter into a pooling arrangement under EOM, provide this assessment for both your PGP and for each PGP in your intended pool.)
- Preparedness for an EOM Performance-Based Recoupment (PBR): Description of your PGP’s financial readiness in the event that your PGP owes CMS an PBR. (If you intend to enter into a pooling arrangement under EOM, provide this assessment for both your PGP and each PGP in your intended pool.)
- Other sources of revenue: Description of how other sources of revenue (i.e., payment from other programs or sources) will be used to support your PGP’s implementation plan, if applicable.

APPLICATION CERTIFICATION:

I certify that all information and statements provided in this application are true, complete, and accurate to the best of my knowledge, information, and belief. I certify that I am qualified to make the assertions contained herein as an agent of the applicant. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.

Practice Name: _____

Certifying Individual (Please Print): _____ Title: _____

Signature: _____ Date: _____

Enhancing Oncology Model (EOM) Payer Application Template

Instructions

Thank you for your interest in partnering with CMS for the CMS Innovation Center’s Enhancing Oncology Model (EOM). This application template is intended for use by Payer applicants.

The PDF version of this application is for reference only. Applicants interested in submitting an application are required to submit their application using the EOM RFA Application Portal. A link to the application can be found here: <https://app.innovation.cms.gov/EOM>. Submission of the PDF version of this application will not be accepted.

All EOM applications must be submitted by 11:59 pm Eastern Daylight Time on September 30, 2022. CMS may not review applications submitted after the deadline.

Refer to the Request for Applications (RFA) on the Innovation Center website <https://innovation.cms.gov/innovation-models/enhancing-oncology-model> for further details regarding participation requirements and application submission criteria. Applications will be reviewed for completion of all required fields and a signed and dated application certification.

For questions regarding the EOM or the EOM application process, email EOM@cms.hhs.gov.

Payer Application Template

Contact Information

Please provide information for the primary address of the payer that seeks to align with EOM and sign a Memorandum of Understanding with CMS in EOM.

Payer Legal Name:

Doing Business As (DBA) Name(s):

Payer Street Address:

Payer City:

Payer State:

Payer ZIP Code^{TM,105}:

Payer State of Incorporation:

Primary Point of Contact (POC)

Name:

POC Title:

POC Street Address:

POC City:

POC State:

POC ZIP Code:

POC Phone:

Extension:

POC Email:

Secondary POC

¹⁰⁵ ZIP Code is a registered trademark of the United States Postal Service.



Name:

POC Title:

POC Street Address:

POC City:

POC State:

POC ZIP Code:

POC Phone:

Extension:

POC Email:

Tertiary POC

Name:

POC Title:

POC Street Address:

POC City:

POC State:

POC ZIP Code:

POC Phone:

Extension:

POC Email:

Payer Information

1. In the table below, indicate your line(s) of business, and for each one, whether you intend to include the line of business in an oncology care-focused payment and service delivery model that is aligned with CMS' approach in EOM.

Line of Business	Does your organization have this line of business? Indicate "Yes" or "No"	Does your organization intend to include the line of business in your EOM-aligned model? Indicate "Yes" or "No"
Commercial insurance plan		
Medicare Advantage plan		
Medicaid managed care plan		
Medicaid fee-for-service		
State or federal high-risk pool		
Third-party administrator (TPA)/ Administrative services only (ASO)		
Direct purchaser/business		
Other (specify)		

2. Provide your organization’s state insurance license number(s), or attach other documentation of license to provide insurance in the state(s) in which you propose to develop an EOM-aligned payment and service delivery model for your members. Additionally, please include a point of contact at each state’s licensing authority.

State	State insurance license number	State POC	State POC contact information

3. List the physician group practices (PGPs) with which your organization intends to enter into an arrangement for an EOM-aligned payment and service delivery model.

Payers must enter into an arrangement for an EOM-aligned payment and service delivery model with at least one EOM participant (“partner EOM participant”), but may enter into such arrangements with as many additional EOM participants as they choose, and may add partner EOM participants during the model performance period.

Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____
Practice Legal Name _____	Practice EIN _____

Implementation Plan Narrative

(Overall word limit: 5,000 words)

Model Alignment

1. Describe your organization's interest in and commitment to partnering with CMS for the five-year model performance period. How will your payment and service delivery model align with EOM?
2. The participant redesign activities to be required of EOM participants by CMS are described in section V.B. of the RFA. Payers may adopt these same requirements or may adopt similar or additional requirements. Describe your plans to align with EOM participant redesign activities (as described in section V.B. of the RFA) and any additional participation requirements beyond EOM that your organization will include in your model.
3. The Innovation Center's EOM payment methodology is described in section V.C. of the RFA. Payers may use the same payment methodology as the Innovation Center, or develop their own payment methodology that will align with EOM payment methodology as described in section V.C. of the RFA. Describe your organization's proposed EOM-aligned payment methodology. Describe how you plan to make payments to EOM participants that align with the EOM financial incentive structure; that is, providing funding for Enhanced Services (for example, advance payment or PBPM) and for actual performance (for example, retrospective lump sum or increased monthly payments).

EOM Participants

1. Describe your plan to enter into arrangements with EOM participants. How will you identify EOM participants? How many EOM participants do you plan to partner with at the start of your participation in EOM? How long do you anticipate negotiations to take?
2. Will you offer a similar model to non-EOM participants?

Quality Strategy

1. Describe your organization's proposed EOM-aligned quality strategy. Describe the quality metrics, corresponding with the quality domains listed in section V.F. of the RFA, and detail what your organization plans to use to assess the quality performance of partner EOM participants. Include the measure source (e.g., claims, practice-reported, etc.), and note whether you intend to pay partner EOM participants for reporting of the measures (if applicable), performance on the measures, or both.
2. Describe ways your organization has committed to advancing health equity.
3. In addition to the activities included above, describe any other activities your organization plans to implement to support practice transformation and person-centered, equitable care.

Data Sharing

1. Describe your organization’s plan for providing data feedback to partner EOM participants during the model, including cost data, utilization data, and EOM participants’ performance on quality metrics. Provide information about feedback frequency and format (for example, patient-level data, practice-level data, data across practices, etc.).

Monitoring and Evaluation

1. Describe how your organization plans to monitor partner EOM participants’ compliance with the participation requirements under your EOM-aligned payment and service delivery model.
2. Describe how your organization plans to monitor and evaluate partner EOM participants’ achievement and/or improvement on your selected quality metrics. Describe how your organization plans to evaluate the impact of your EOM-aligned model on patients, whether it be through interviews, surveys, etc. and how your organization plans to evaluate outcomes of your EOM-aligned payment and service delivery model.

APPLICATION CERTIFICATION:

I have read the contents of this application. By submitting this application, I certify that I am legally authorized to bind the applicant. I further certify that the information contained herein is true, accurate, and complete, and I authorize the Centers for Medicare & Medicaid Services (CMS) to verify this information. If I become aware that any information in this application is not true, accurate, or complete, I will notify CMS of this fact immediately.

Payer Name: _____

Certifying Individual (Please Print): _____ Title: _____

Signature: _____ Date: _____