Community Oncology Alliance Oncology Care Model 2.0 (OCM 2.0)

Physician-Focused Payment Model Environmental Scan

08/20/2019 *(Updated)*

I. Overview

The purpose of this environmental scan is to provide members of the Physician-Focused Payment Model Technical Advisory Committee (PTAC) with background information and context for the Oncology Care Model 2.0 (OCM 2.0), a physician-focused payment model (PFPM) proposed by the Community Oncology Alliance (COA) on May 29, 2019. OCM 2.0 aims to improve the quality and value of cancer care by focusing on standardized clinical improvements, quality, and costs associated with oncology drugs and related treatments. The submitter states that the proposed model builds on the Center for Medicare and Medicaid Innovation's (CMMI's) Oncology Care Model (OCM), which began in 2016 and runs through 2021. In this section, the environmental scan focuses on the following topics:

- **Epidemiology of cancer,** including overall cancer incidence and costs
- **Issues in oncology payment policy**, including traditional Medicare payment rules, regulations, and other models addressing oncology payment
- **Issues in care delivery**, including an overview of oncology medical home models
- **Results from evaluations of other oncology models,** including select commercial oncology models and CMMI's OCM

Section II presents an annotated bibliography of the sources cited in this scan. Section III provides a summary of the questions, search terms, and annotated sources used to identify the research summarized below. Section IV consists of two appendices on additional oncology value-based payment models and relevant regulations.

Information on the Submitter. COA is a nonprofit membership organization that advocates for independent community oncology practices and their patients. The mission of COA is to ensure that patients with cancer receive the highest quality, most affordable and accessible cancer care in the communities where they live and work. COA's advocacy has included outreach to the Centers for Medicare & Medicaid Services (CMS) to request that the agency address perceived challenges in OCM, such as price prediction, risk adjustment, attribution and monthly enhanced oncology services (MEOS) payment recoupment, and the timeliness of data/information (COA, 2019). COA has multiple ongoing initiatives, including the COA Administrators Network, Community Oncology Pharmacy Association, and the Oncology Care Model Support Network, which the submitter has stated includes 80 percent of CMMI's OCM participants.[1] CMMI reports that there are 176 practices and over 6,500 practitioners participating in CMMI's OCM and that they care for over 150,000 unique Medicare beneficiaries (CMMI, 2019). COA has worked with the American College of Surgeons (ACS) Commission on Cancer (CoC) on Oncology Medical Home (OMH) accreditation standards and related policies.

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[1] Active participants in the Oncology Care Model Support Network include more than 60 percent of the OCM practices (including both independent community oncology practices and hospital systems) and 17 insurers who are participating in the CMMI OCM (https://www.communityoncology.org/ocm/).

- **Epidemiology of Cancer**

Overview of Cancer in Older Adults. Cancer is the second leading cause of death in the United States, accounting for approximately 606,880 expected deaths in 2019 (American Cancer Society, 2019). In 2017, approximately 8 percent of all Medicare fee-for-service (FFS) beneficiaries, 3 percent of those under 65 years old, and about 9 percent of those 65 years and older had claims with cancer diagnosis (CMS, 2017). The most commonly diagnosed types of cancer among populations over 65 years are lung cancer, prostate (male) cancer, colorectal cancer, and breast (female) cancer (National Institutes of Health, 2010; National Institutes of Health, 2015). Medicare is an essential payer of oncology cancer in the United States. As of 2015, nearly 70 percent of lung cancer, 60 percent of prostate cancer, 56 percent of colorectal cancer, and 46 percent of female breast cancer occurred in those age 65 and over (National Institutes of Health, 2015).

Outcomes Associated with Cancer Diagnoses in Older Adults. Older adult cancer patients experience cancer-associated health care utilization and costs, including higher rates of hospitalization and 30-day readmissions, disproportionately compared with those without cancer, after adjusting for demographic variables and other comorbidities (Kedia et al., 2017). Older adults receiving chemotherapy for advanced cancers are at high risk of hospitalization (O'Neill et al., 2016). Moreover, those age 65 years and older have higher rate of cancer-related emergency department (ED) visits compared to other age groups (Rivera et al., 2017).

Medicare accounted for nearly 33 percent of the estimated $87.5 billion spent on cancer treatment in 2012 (Ruiz et al., 2019). For lung and colorectal cancer patients, most spending was on inpatient care in the year of diagnosis, while for breast and prostate cancer patients, most spending was on outpatient care in the year of diagnosis. For all four most commonly diagnosed cancers, inpatient care was the largest source of spending in the year prior to death (Chen et al., 2018).

- **Issues in Oncology Payment Policy**

COA states that OCM 2.0 aims to enhance, transform, and improve quality and value achieved in the CMMI's OCM by incorporating anti-neoplastic prescription drugs (e.g., chemotherapy drugs, immunotherapy) and supportive prescription drugs (e.g., antiemetics) directly into the model. This section provides an overview of other oncology care payment models, including CMMI's OCM, commercial models, and models that have been proposed to PTAC. In addition, this section reviews Medicare payment rules for oncology-related prescription drugs that would be covered under OCM 2.0; the role of the 340B Drug Discount Program; and the seven federal regulations that COA proposes waiving to allow for value-based price negotiations between community oncologists and prescription drug manufacturers, a key component of the proposed model.

Other current and/or pending payment models that address value-based payment in oncology care. CMMI and commercial payers are testing a variety of value-based purchasing (VBP) models that aim to improve oncology care and reduce costs using a range of mechanisms. Alternative payment models (APMs) include episode-based payment, pay for performance, bundled payment, and sharing savings approaches that include both one- and two-sided risk. Appendix A describes 18 existing payment models, including CMMI's OCM, programs from commercial insurers, and two proposals that were proposed to PTAC. This appendix is organized by model type and includes a brief description of the

model, provider payment method, episode triggering event, items and services covered by the model, patient engagement approach, risk-sharing, shared savings calculations, and how savings are generated. All details are not available for every model, particularly savings calculations and justifications for commercial APMs. This section briefly describes key features of existing oncology APMs.

Provider payment method: Existing models use a wide variety of approaches to provider payment beyond FFS, including per-member per-month (PMPM) payments for care management bundled payments, episode-based payments, case rate payments, and bonus payments for adhering to guidelines, meeting quality metrics, or reducing expenditures. In its proposal, COA indicated that Aetna, Cigna, and Priority Health approaches are considered the "best" and most transparent payment approaches by "a focus group of eight administrators that participate in the [CMMI's] OCM and at least one other model," (COA proposal to PTAC, 2019), but little detail is available on the payment models for these commercial APMs in the public domain.

Episode triggering event: Fewer than half of the 18 models provided detailed information on the triggering event for model entry. For the models described in Appendix A, participation in the oncology APM is triggered by a visit to a participating oncologist, submission of a specific claim for reimbursement (an S code for Anthem Cancer Care Quality Program and BCBSNC Medical Oncology Program), a new diagnosis, or receipt of a specific service (e.g., chemotherapy for OCM or radiation for 21st Century Oncology and Humana).

Items and services covered by the model: Most models cover guidelines-based cancer care/primary cancer treatment, with some offering additional coverage of patient navigation and case management. However, for many models, specific details are unavailable. COA indicates that the OCM 2.0 proposal is the first to incorporate an APM for prescription drugs. Among the existing models, many do not specifically mention a prescription drug payment approach. Among those that do, several include payment for prescription drugs "as-is," meaning they do not change current payment structures but instead may encourage substitution of less expensive prescription drugs where appropriate. For example, CMMI's OCM does not alter traditional Medicare payments for Part B drugs but does provide performance-based payments to participating practices if total cancer care episode costs, including prescription drugs, fall below a target episode price. Only two models expressly describe alternative prescription drug payment approaches, and these are based on average sales price (ASP): ASP plus a care-management fee (Priority Health's Michigan OMH Demonstration Project) and ASP plus 2 percent (IOBS).

Patient engagement approach: COA indicates that patient involvement is a central goal of the OCM 2.0 proposal. Other oncology APMs have also emphasized patient engagement, including through shared decision-making, patient education, patient navigators, and patient experience surveys.

Risk-sharing and shared savings: Nine models include risk sharing or shared savings according to publicly available documents. These include CMMI's OCM, MD Anderson and UnitedHealthcare (shared savings only), Advanced Medical Specialties (shared savings only), Priority Health's Michigan OMH Demonstration Project (shared savings only), Cigna Collaborative Care for Oncology (shared savings only), Anthem Cancer Care Quality Program, BCBSNC Medical Oncology Program, IOBS, and HMH-Cota. Shared savings calculations were frequently unavailable, but those with public information were based on total cost of care (CMMI's OCM), actual versus predicted costs (MD Anderson and UnitedHealthcare, HMH-Cota), or national benchmarks (Cigna Collaborative Care for Oncology).

How savings are generated: The COA proposal seeks to reduce Medicare costs in part through value-based prescription drug purchasing. Other models generally seek to reduce costs through better care coordination, lower inpatient costs, lower outpatient costs, decreased ED use, and more appropriate use of prescription drugs. No public documents indicated that other oncology APMs sought to reduce spending through value-based prescription drug purchasing.

Medicare payment rules for anti-neoplastic and supportive prescription drugs under Parts B and D.
Anti-neoplastic drugs to treat cancer come in a variety of forms, including intravenous (IV) drugs, injectables, and oral medications. Medicare Part B pays for any covered prescription drugs administered in an inpatient setting, and Part B also pays for covered prescription drugs administered directly by a physician or other clinician in an outpatient hospital setting or physician office, including intravenous and injectable anti-neoplastic and supportive drugs that are not typically self-administered (CMS, Medicare Coverage of Treatment Services, 2017; MedPAC, 2016; MedPAC, 2017). Part B also includes coverage for certain oral anti-neoplastic drugs when administered in a hospital outpatient setting or physician's office, as long as those drugs are also available in an injectable or IV form (CMS Oncology Care Model Fact Sheet).[2]

Medicare Part D covers anti-neoplastic and supportive prescription drugs that are taken orally and self-administered by the patient (CMS, Medicare Coverage of Treatment Services, 2017). This includes anti-neoplastic drugs for which no injectable or IV form is available (e.g., drugs to treat certain leukemias, such as Imatinib). Increasingly, newly approved cancer drugs are only available in oral form, making them ineligible for Part B coverage (Jung, Feldman, and McBean, 2018). Part D also covers supportive drugs that are taken orally, such as antiemetics and pain medications. For oral antiemetics, Part B covers within 48 hours of physician-administered chemotherapy, whereas Part D provides coverage for all other situations (CMS, 2019). By law, Medicare Part D cannot pay for drugs when they are covered either by Part A or Part B. However, a Part D plan may cover the drug if any money spent on the drug does not count towards a patient's out-of-pocket limit (CMS Medicare Drug Coverage, 2018).

Coverage of orally administered anti-neoplastic drugs has become increasingly important as these drugs have become more integral to cancer care. Increasingly, oral drugs may represent the only treatment option for some patients (Eek et al., 2016, Jung, Feldman, and McBean, 2018), and many anti-neoplastic drugs are available in only one formulation (either oral or IV/injectable) and so are consistently covered by either Part B or Part D (Davidoff et al., 2013; Jung et al., 2017). When both oral and injectable/IV formulations are available, however, beneficiaries are more likely to use Part B drugs (IV or injectable) over Part D (Jung et al., 2017). The increasing availability and use of oral anti-neoplastic drugs is a critical issue for the COA OCM 2.0 proposal, as it envisions price negotiations between prescription drug manufacturers and community oncologists to reduce spending on anti-neoplastic and supportive drugs provided in an office setting by community oncologists (e.g., IV, injectable, and Part B-covered oral chemotherapies).

The 340B drug discount program. The 340B drug discount program (340B) allows for discounts in medications administered by hospital-based providers. In addition, 340B allows a hospital to keep the price differential between the list price and discounted price when insurers and patients pay for the

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[2] Eight oral anticancer drugs that are covered under Part B: ALKERAN® (*melphalan*), HYCAMTIN® (*topotecan hydrochloride*), MYLERAN® (*busulfan*), TEMODAR® (*temozolomide*), XELODA® (*capecitabine*), *cyclophosphamide*, *etoposide*, and *methotrexate* (Avalere, 2010).

treatment at list price (MedPAC, 2015; Conti and Bach, 2013). The program has been criticized as being detrimental to community-based oncologists, who are unable to qualify for the drug discounts and therefore face financial pressure to join or affiliate with hospitals or health systems (Desai and McWilliams, 2018; Conti and Bach, 2013; Pyenson and Fitch, 2011). Beginning in 2018, CMS proposed reducing the payment for drugs purchased through the program; however, it has not yet been implemented (United States District Court, 2019). The COA proposal seeks to provide an oncology care model focused specifically on lowering prescription drug costs for community-based oncologists to partially mitigate these advantages of hospital-based oncologists.

Context and impact of seven regulations proposed for waiver. The submitter proposes waivers for drug companies from seven statutes and regulations, in order to support implementation of the drug-price negotiation portions of OCM 2.0. The submitter describes these seven provisions as barriers to direct negotiation of drug prices between community oncologists and prescription drug manufacturers but does not describe or justify the individual provisions for which a waiver is needed. Appendix B includes the name and link to each regulation. The submitter did not include additional information on the specific nature of the waiver request.

- ## Issues in Care Delivery

This section reviews four aspects of care delivery, including standards for oncology drug treatment and OCM 2.0's proposed care delivery model, called the oncology medical home (OMH) model. These include: clinical delivery standards; the issue of high- and low-value cancer care services; and differences by setting (community-based versus hospital-based oncologists).

Standard of care for cancer drug treatment. Major clinical societies and cancer research organizations, such as the American Society of Clinical Oncology (ASCO, available online [here](#)), the National Comprehensive Cancer Network (available online [here](#)), and an ASCO partner called the European Society for Medical Oncology (available online [here](#)), have compiled diagnosis-specific standards for treating various cancers. The standards include recommendations for drugs, procedures, and chemotherapy safety. COA indicates an intention to use clinical guidelines and pathways in the OCM 2.0 model but does not propose a specific set of guidelines and pathways. In addition, the COA proposal mentions Choosing Wisely, a partnership designed to reduce use of low-value care (see page 8 for further details).

Clinical delivery standards for OMH models. The care delivery component in OCM 2.0 is an OMH model. The COA proposal indicates that all practices will be accredited by the Accreditation Commission for Health Care (ACHC). However, ACHC's [website](#) does not describe an accreditation process specific to the OMH model. OMHs can be accredited through the Commission on Cancer (CoC) of the American College of Surgeons (ACS).[3] CoC has five categories for OMH standards, including: 1) patient engagement, 2) expanded access, 3) evidence-based medicine, 4) comprehensive team-based care, and 5) quality improvement. Exhibit 1 lists the 18 measures that CoC suggests for OMH benchmarking.

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[3] According to its [website](#), the Commission on Cancer is a consortium of professional organizations dedicated to improving survival and quality of life for cancer patients through standard-setting, prevention, research, education, and monitoring of comprehensive quality care.

Exhibit 1. CoC OMH Accreditation Measures List

Area of Care	Measure Description
Patient Care Measures	% of cancer patients that received a treatment plan prior to administration of chemotherapy
	% of cancer patients with documented clinical or pathologic staging prior to initiation of first course of treatment
	% of chemotherapy treatments that have adhered to NCCN guidelines or pathways
	Antiemetic drugs given appropriately with high emetogenic chemotherapy treatments, according to guidelines
	% of cancer patients undergoing treatment with a chemotherapy regimen with a 20% or more risk of developing neutropenia and also received GCSF/white cell growth factor
	% of patients with Stage I or II breast cancer undergoing advanced imaging
	Presence of patient performance status prior to treatment
Resource Utilization	# of emergency room visits per chemotherapy patient per year
	# of hospital admissions per chemotherapy patient per year
Survivorship	% of patients receiving a survivorship plan within 90 days of completion of treatment
	% of patients receiving at least one psychosocial distress screening
	Survivorship
	Survivorship rates of stage I through IV breast cancer patients
	Survivorship rates of stage I through IV colorectal cancer patients
	Survivorship rates of stage I through IV NSC lung cancer patients
End of Life	% of patients with stage IV disease that have had end-of-life care discussions documented
	Average # of days under hospice care (home or inpatient) at time of death
	% of patient deaths where the patient died in an acute care setting
	Chemotherapy given within 30 days of end of life
Other	Patient satisfaction reporting and scoring

Source: Oncology Medical Home, Benchmarking, 18 Oncology Medical Home Measures, available at
http://www.medicalhomeoncology.org/UserFiles/OMHMeasures111015v2.pdf, accessed July 16, 2019.

Costs of CoC accreditation are not publicly available. OMHs also can be recognized through the National Committee for Quality Assurance (NCQA), which costs $660 for a single-site, single clinician practice, according to the NCQA website.

For OCM 2.0, COA selects seven outcome and process measures to validate care delivery and monitor quality of care. Six of the selected measures are consistent with CoC OMH standards, as follows:

- A comprehensive care plan is provided to the patient
- Adherence to recognized pathway and treatment guidelines
- Screening for clinical depression and follow-up plan to screening result
- A survivorship care plan is provided to the patient
- Proportion of patients with cancer receiving chemotherapy in the last 14 days of life
- Proportion of patients with cancer who died but without being admitted to hospice

The submitter proposes an additional measure—pneumococcal vaccination is provided to older adults—which is not a CoC OMH standard but is a measure in Merit-based Incentive Payment System (MIPS) (CMS Quality Payment Program MIPS Overview).

High- and low-value cancer care services. The COA OCM 2.0 proposal indicates that "OCM 2.0 intends to incorporate VBID [Value Based Insurance Design] principles that facilitate providing the correct care for each individual patient. This would be done by removing obstacles to the correct high-value care

while sustaining disincentives for suboptimal low-value care" (COA Proposal to PTAC, 2019). The COA proposal indicates that OCM 2.0 would support Choosing Wisely to further the goals of VBID. This section briefly reviews the Choosing Wisely campaign and its application to cancer care.

The American Society of Clinical Oncologists (ASCO)'s Value in Cancer Care Task Force has devised a framework to assess the value of new cancer therapies, which defines value as "a combination [of] clinical benefit, side effects and improvement in patient symptoms or quality of life in context of cost" (ASCO, 2016). The Cancer Care Task Force joined the Choosing Wisely campaign to develop recommendations for reducing the use of common practices in oncology that have lacked sufficient evidence. Choosing Wisely is intended to facilitate discussions between patients and clinicians about goals and treatment plans (Schnipper et al., 2016; ABIM, 2019). However, progress in adoption of the Choosing Wisely recommendations has been slow,[4] and there is some evidence of limited adherence to the guidelines, including in oncology care (Hahn et al., 2016). To date, Choosing Wisely has only identified five cancer care practices and services as "low-value" or to be avoided (COA Proposal to PTAC, 2019). The COA proposal did not identify sources for clinical guidelines or pathways to support high-value care.

Differences in care delivery and payment issues by setting (community-based versus hospital-based oncologists). The OCM 2.0 proposal is designed to be implemented by community-based oncologists, although hospital-based oncologists are not specifically excluded. The proposal addresses issues specific to community-based oncology practice, including prescription drug prices. Community-based oncology practices report that payers, competition, and staffing are the primary sources of strain and that there have been annual decreases in the number of community-based oncology practices alongside increases in practice size (Kirkwood et al., 2018). Several studies find significantly higher costs for patients treated at hospital-based clinics compared to those treated at community-based clinics, with no increase in care quality (Gordan et al., 2018; Hayes et al., 2015, Sprandio, 2012).

• **Results of Other Oncology Models**

COA describes its model as building on existing oncology value-based care models, particularly CMMI's OCM. This section summarizes evaluations of CMMI's OCM and evaluations of other oncology value-based care models.

Evaluations of CMMI's OCM. The federal evaluation of CMMI's OCM examines practice and patient characteristics, use of services, Medicare spending, quality of care, and patient satisfaction using a difference-in-differences design in their Performance Period One report covering July 2016 to June 2017 (Abt Associates, 2018). When evaluated against comparison practices, both CMMI's OCM and non-OCM practices experienced changes to their practice characteristics, such as increases in practices affiliated with hospitals and/or health systems and practice size through the hiring of nurse practitioners and physician assistants. Additionally, when evaluated against comparison practices, CMMI's OCM and non-OCM practices experienced similar trends in utilization, such as an increase in per-episode Part B chemotherapy use for Part D beneficiaries and consistent use of immunotherapies aligning with U.S. Food and Drug Administration-approved drugs.

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[4] COA included a "Top-Five" infographic for the campaign in the appendix.

The effectiveness of CMMI's OCM depends on the type and severity of the cancer (Baumgardner et al., 2018).[5] When an evaluation adjusted for regional variations in practice styles, the spending effects were similar, and spending per episode decreased with age when evaluated at the mean age. Increases in spending were associated with more advanced disease stages at diagnosis and when accounting for comorbidities.

Evaluations of other oncology models. Appendix A describes 18 existing payment models, including CMMI's OCM, programs from commercial insurers, and two proposals that were proposed to PTAC. This section briefly describes results of the payment models by model type, as organized in Appendix A. Evaluation results are not available for all models, particularly commercial models.

Bundled payment: In addition to CMMI's OCM, there are multiple bundled payment approaches to oncology. In a 2009–2012 pilot project, UnitedHealthcare found statistically significant decreases in hospitalization and therapeutic radiology usage among participants.

Shared savings: Advanced Medical Specialties, which focused on adherence to clinical pathways, resulted in more than 2 percent savings during the first year of operations[6]. Results for Moffitt Cancer Center and Florida Blue and ASCO's PCOP do not have publicly available outcomes or results.

Oncology medical home: Early implementation of OMH models, such as Consultants in Medical Oncology and Hematology (CMOH), demonstrated reductions in unnecessary resource use, lowered ED visits, and reduced length of stay for admitted patients. CMOH resulted in an estimated savings of $1 million per physician per year (Sprandio, 2012). In primary care settings, the OMH model implemented by Cigna and RCCA was associated with reduced outpatient costs, ED visits, and hospital admissions[7].

Payer pathways: Neither Anthem Cancer Care Quality Program nor BCBSNC Medical Oncology Program have publicly available outcomes or results.

Models proposed to PTAC: There are two relevant proposed models, as follows:

- COME HOME by Innovative Business Solutions, Inc. (IOBS), demonstrated reductions in readmission rates, lowered ED visits, and reduced length of stay for admitted patients. COME HOME resulted in a decrease in cost of care (Colligan et al., 2017). IOBS has proposed the Making Accountable Sustainable Oncology Networks (MASON) model, with a bundled fee to cover all expenses related to cancer care.
- HMH-Cota Oncology Bundled Payment Program has proposed a 12-month episode of care, covering payments for medical, radiation, surgical oncology, pharmacy, diagnostic, technical, and inpatient/outpatient fees. Public evaluation results are not available.

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[5] This cohort analysis was of five tumor types: advanced breast cancer, non-small cell lung cancer, renal cell carcinoma, multiple myeloma, and chronic myeloid leukemia.
[6] Berberabe T. *First-Year savings of an oncology accountable care organization.* December 23, 2013. https://www.onclive.com/news/first-year-savings-of-an-oncology-accountable-care-organization
[7] WestMed. *WESTMED medical group continues to improve quality and lower costs through cigna collaborative care program.* October 21, 2015. https://www.cigna.com/newsroom/news-releases/2015/pdf/westmed-medical-group-continues-to-improve-quality-and-lower-costs-through-cigna-collaborative-care-program.pdf

II. Annotated Bibliography

ABIM. Choosing Wisely Initiative. ABIM Foundation. https://abimfoundation.org/what-we-do/choosing-wisely. Accessed July 16, 2019.

> **Subtopic(s):** Issues in care delivery
> **Type of Source:** Website
> **Objective:** To help patients and physicians choose care that is supported by evidence, not duplicative, free from harm, and truly necessary.
> **Main Findings:** N/A
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** N/A
> **Methods:** Over 70 medical specialty societies have published more than 400 recommendations

Abt Associates. Evaluation of the Oncology Care Model: Performance Period One. Center for Medicare and Medicaid Innovation. https://innovation.cms.gov/Files/reports/ocm-secondannualeval-pp1.pdf. Published December 2018. Accessed July 16, 2019.

> **Subtopic(s):** Results of proposed or similar models
> **Type of Source:** Evaluation
> **Objective:** To evaluate the Oncology Care Model (OCM) based on treatment episodes from July 1, 2016, and January 1, 2017, to June 30, 2017.
> **Main Findings:** Cancer care is well coordinated under the OCM 1.0. Unnecessary utilization and total cost of care decreased. There was increased utilization of oncology services, such as round-the-clock patient access and triage, care plans, and pathway adherence. Quality of care and end-of-life services were discussed with patients and their caregivers.
> **Strengths/Limitations:** Limited evaluation time frame and small sample sizes for some population subgroups
> **Generalizability to Medicare Population:** Yes—analysis of Medicare patients and claims data.
> **Methods:** A difference-in-differences matched comparison group and a mixed methods evaluation using claims data to estimate utilization, cost, and clinical treatment outcomes.

AIM Specialty Health. Anthem Cancer Care Quality Program Reimbursement FAQs. https://cancercarequalityprogram.com/pdf/EnhancedReimbursementFAQ.pdf. Accessed July 16, 2019.

> **Subtopic(s):** Issues in payment policy; results of proposed or similar models
> **Type of Source:** Fact sheet
> **Objective:** To determine the reimbursement for Anthem Cancer Care Quality Program.
> **Main Findings:** S-codes 0353 and 0354 trigger a reimbursement of $350 per month, per patient, when using an approved pathway.
> **Strengths/Limitations:** Consultant's website provides a limitation by including bias towards the client.
> **Generalizability to Medicare Population:** Yes
> **Methods:** N/A

AIM Specialty Health. Cancer Care Quality Program. https://cancercarequalityprogram.com/. Accessed July 16, 2019.

> **Subtopic(s):** Issues in payment policy; results of proposed or similar models

Type of Source: Website
Objective: To show the Cancer Care Quality Program's provider portal.
Main Findings: Enhanced reimbursement is available for cancer pathways.
Strengths/Limitations: Consultant's website provides a limitation by including bias towards the client.
Generalizability to Medicare Population: Yes
Methods: N/A

AIM Specialty Health. What is the Medical Oncology Program?
http://www.medicaloncologyprogram.com/AboutTheProgram.html. Accessed July 16, 2019.

Subtopic(s): Issues in payment policy; results of proposed or similar models
Type of Source: Website
Objective: To explain the Medical Oncology Program.
Main Findings: The Medical Oncology Program provides actionable information for cancer treatment pathways and alternate regiments. Enhanced reimbursement is available for both.
Strengths/Limitations: Consultant's website provides a limitation by including bias towards the client.
Generalizability to Medicare Population: Yes
Methods: N/A

American Cancer Society. Cancer Facts & Figures 2019. Atlanta: American Cancer Society; 2019.
https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2019/cancer-facts-and-figures-2019.pdf. Accessed July 29, 2019.

Subtopic(s): Epidemiology
Type of Source: Advocacy report
Objective: To provide descriptive information about cancer in the United States in 2019.
Main Findings: The document includes facts on trends in cancer deaths, estimated number of new cancer cases, selected types of cancer, disparities in cancer, and cancer in older adults.
Strengths/Limitations: Advocacy group website
Generalizability to Medicare Population: Yes
Methods: Specific methods and data source vary, based on the information presented.

American Society of Clinical Oncologist (ASCO). ASCO Value Framework. (2016).
https://www.asco.org/practice-guidelines/cancer-care-initiatives/value-cancer-care. Accessed July 15, 2019.

Subtopic(s): Issues in care delivery
Type of Source: Website
Objective: To provide an overview of the ASCO Value Framework.
Main Findings: The framework aims to assess value of new cancer treatments based on clinical benefit, side effects, and improvements in symptoms or quality of life, with consideration for cost contexts.
Strengths/Limitations: As an advocacy group website, there is inherent bias towards the groups' mission and goals.
Generalizability to Medicare Population: Yes
Methods: N/A

ASCO. Guidelines, Tools, & Resources. ASCO. https://www.asco.org/practice-guidelines/quality-guidelines/guidelines. Accessed July 16, 2019.

> **Subtopic(s):** Issues in care delivery
> **Type of Source:** Website
> **Objective:** To provide clinical practice guidelines, provisional clinical opinions, and guideline endorsements for oncologists.
> **Main Findings:** N/A
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** Yes.
> **Methods:** N/A

ASCO. 2016 Updated American Society of Clinical Oncology/Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. ASCO. https://www.asco.org/practice-guidelines/quality-guidelines/standards/chemotherapy-safety-standards. Published September 13, 2016. Accessed July 16, 2019.

> **Subtopic(s):** Issues in care delivery
> **Type of Source:** Website
> **Objective:** To provide safety standards for chemotherapy and highlight standards for pediatric oncology.
> **Main Findings:** N/A
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** N/A
> **Methods:** The ASCO/ONS Chemotherapy Administration Safety Standards were first published in 2009 and underwent updates in 2011, 2013, and 2016. A joint ASCO/ONS workshop with stakeholder participation was held in 2015 to review the 2013 standards. An extensive literature search and public comments on the revised draft were solicited.

Baumgardner J, Shahabi A, Linthicum M, et al. Greater spending associated with improved survival for some cancers in OCM-defined episodes. *J Manag Care Spec Pharm*. 2018;24(6).

> **Subtopic(s):** Results of proposed or similar models
> **Type of Source:** Journal article
> **Objective:** To use evidence from geographic variations in spending and an individual-level survival analysis to test whether spending within oncology care episodes is associated with survival. Episodes are defined as in CMMI's Oncology Care Model.
> **Main Findings:** The analysis shows significant differences in standardized spending across Hospital Referral Regions (HRRs). The hazard of dying (hazard ratio, or HR) for patients with non-small cell lung cancer (NSCLC) and multiple myeloma (MM) shows a statistically significant decrease by 7% (HR = 0.93, p = 0.006) and 13% (HR = 0.87, p = 0.019), respectively, for a $10,000 increase in standardized spending (in 2013 U.S. dollars). For the three other cancers, spending effects were not statistically significant.
> **Strengths/Limitations:** Includes use of cohorts and regression analyses; while robust, limitations with Surveillance, Epidemiology, and End Results (SEER) data include that it only represents 28% of the US population.
> **Generalizability to Medicare Population:** Strong, sample cohorts are Medicare patients linked to Medicare claims data.

Methods: Retrospective cohort analysis; SEER Program data were linked to HRRs, Medicare enrollment data, and Medicare claims data.

BlueCross BlueShield of North Carolina. Medical Oncology Program. Blue Cross and Blue Shield of North Carolina. https://www.bluecrossnc.com/providers/medical-policies-and-coverage/search-medical-policy/medical-oncology-program. Published June 5, 2017. Accessed July 16, 2019.

> **Subtopic(s):** Issues in payment policy; results of proposed or similar models
> **Type of Source:** Fact sheet
> **Objective:** To explain the details of the Blue Cross NC Medical Oncology Program for patients.
> **Main Findings:** The program, run by AIM Specialty Health, provides coordinated care through clinical pathways and pharmacy benefits for patients receiving outpatient cancer care.
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** Yes
> **Methods:** N/A

Booz Allen Hamilton for Centers for Medicare & Medicaid Services. Oncology Care Model - Key Drivers and Change Package. https://innovation.cms.gov/Files/x/ocm-keydrivers-changepkg.pdf. Published June 1, 2018. Accessed July 16, 2019.

> **Subtopic(s):** Results of proposed or similar models
> **Type of Source:** Report
> **Objective:** To provide a framework for practice redesign, summarizing the essential areas of organizational change, specifically related to structures and processes that drive outcomes and improvement, and suggesting areas of focus for OCM participants.
> **Main Findings:** Drivers include: 1) comprehensive coordinated cancer care; 2) continuous improvement driven by data; 3) strategic use of revenue; and 4) management of appropriate multi-payer structure.
> **Strengths/Limitations:** Purely a body of knowledge or starting point for OCM participants, not a checklist of requirements for success.
> **Generalizability to Medicare Population:** Yes
> **Methods:** Materials were developed through technical discussions and an environmental scan.

Brooks GA, Li L, Sharma DB, et al. Regional variation in spending and survival for older adults with advanced cancer. *J Natl Cancer Inst*. 2013;105(9):634-642. doi:10.1093/jnci/djt025.

> **Subtopic(s):** Issues in payment policy
> **Type of Source:** Journal article
> **Objective:** To evaluate the association between average regional spending and survival in advanced cancer.
> **Main Findings:** From quintile 1 to 5, mean regional spending increased by 32% and 41% in the incident and decedent cohorts (incident cohort: $28,854 to $37,971; decedent cohort: $27,446 to $38,630). The association between spending and survival varied by cancer site and quintile; hazard ratios ranged from 0.92 (95% confidence interval [CI] = 0.82 to 1.04, pancreas cancer quintile 5) to 1.24 (95% CI = 1.11 to 1.39, breast cancer quintile 3). In most cases, differences in survival between quintile 1 and quintiles 2 through 5 were not statistically significant.
> **Strengths/Limitations:** Strengths include use of cohorts; while robust, limitations with SEER data include that it only represents 28% of the US population.

Methods: Survival analysis; spending estimated over a six-month observation period of cohorts selected.

Brooks GA, Li L, Uno H, et al. Acute hospital care is the chief driver of regional spending variation in Medicare patients with advanced cancer. *Health Aff*. 2014;33(10):1793-1800. doi:10.1377/hlthaff.2014.0280.

> **Subtopic(s):** Issues in payment policy
> **Type of Source:** Journal article
> **Objective:** To identify drivers of regional spending variation for Medicare patients with advanced cancer.
> **Main Findings:** Acute hospital care was the largest component of spending and the chief driver of regional spending variation, accounting for 48% of spending and 67% of variation. In contrast, chemotherapy accounted for 16% of spending and 10% of variation. Hospice care constituted 5% of spending. However, variation in hospice spending was fully offset by opposing variation in other categories.
> **Strengths/Limitations:** While robust, limitations with SEER data include that it only represents 28 percent of the U.S. population; study conducted only on advanced cancer patients and should not be generalized to patients with less advanced cancer.
> **Generalizability to Medicare Population:** Strong—study sample is Medicare patients.
> **Methods:** Claims-level spending estimates were aggregated to calculate the mean six-month per capita spending for each HRR, as well as the mean spending for each of the 13 service categories. As a result of differences in cancer case-mix across regions, mean spending was calculated as a weighted average matching the overall distribution of the cancers across SEER areas.

Centers for Medicare & Medicaid Services. Chronic Conditions Dashboard. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CCDashboard.html. Published April 5, 2019. Accessed July 29, 2019.

> **Subtopic(s)**: Epidemiology
> **Type of Source**: Dashboard
> **Objective**: To present statistical information on prevalence, utilization, and spending for Medicare chronic conditions.
> **Main Findings**: N/A
> **Strengths/Limitations**: N/A
> **Generalizability to Medicare Population**: Yes
> **Methods**: N/A

Centers for Medicare & Medicaid Services. Medicare Coverage of Cancer Treatment Services. https://www.medicare.gov/Pubs/pdf/11931-Cancer-Treatment-Services.pdf. Published July 2017. Accessed July 11, 2019.

> **Subtopic(s)**: Issues in payment policy
> **Type of Source**: Informational report published by CMS
> **Objective**: To provide information on the Medicare coverage of cancer treatment services.
> **Main Findings**: Provides a high-level overview of cancer-related services and treatments that are currently covered under Medicare Parts A, B, C, and D. Medicare Part B is a key payer for provider-administered drugs for chemotherapy.

Strengths/Limitations: N/A
Generalizability to Medicare Population: Yes
Methods: N/A

Centers for Medicare & Medicaid Services. Medicare Drug Coverage under Medicare Part A, Part B, Part C & Part D. https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/11315-p.pdf. Published October 2018. Accessed July 11, 2019.

Subtopic(s): Issues in payment policy
Type of Source: Informational report published by CMS
Objective: To provide an overview of drug coverage under Medicare Parts A, B, C, and D.
Main Findings: Medicare Part D offers comprehensive prescription drug coverage to people with Medicare FFS. In general, Part B usually does not cover self-administered drugs, but these drugs may be covered by Medicare Part D under certain circumstances. However, Part D cannot cover any drugs that are paid under Part A or Part B.
Strengths/Limitations: N/A
Generalizability to Medicare Population: Yes
Methods: N/A

Centers for Medicare & Medicaid Services. Oncology Care Model. CMS Innovation Center. https://innovation.cms.gov/initiatives/Oncology-Care. Accessed July 2019.

Subtopic(s): Issues in payment policy
Type of Source: Fact sheet
Objective: To outline OCM implemented with support from CMMI and link to additional information.
Main Findings: The Oncology Care Model is a nationwide program providing enhanced cancer services through improved coordination of care.
Strengths/Limitations: N/A
Generalizability to Medicare Population: Yes
Methods: N/A

Centers for Medicare & Medicaid Services. Oncology Care Model Fact Sheet. CMS Innovation Center. https://www.cms.gov/newsroom/fact-sheets/oncology-care-model. Published June 29, 2016. Accessed July 2019.

Subtopic(s): Issues in payment policy; results of proposed or similar models
Type of Source: Fact sheet
Objective: To give a short outline of OCM.
Main Findings: The OCM is a multi-payer model providing more integrated care through aligned financial incentives. The model focuses on Medicare FFS beneficiaries in six-month episodes, while receiving chemotherapy. CMS uses quality measures and clinical data to verify improvements.
Strengths/Limitations: N/A
Generalizability to Medicare Population: Yes
Methods: N/A

Chen CT, Li L, Brooks G, Hassett M, Schrag D. Medicare spending for breast, prostate, lung, and colorectal cancer patients in the year of diagnosis and year of death. *Health Serv Res*. 2018;53(4):2118-2132. doi:10.1111/1475-6773.12745

> **Subtopic(s):** Epidemiology
> **Type of Source:** Journal
> **Objective:** To characterize spending patterns for Medicare patients with breast, prostate, lung, and colorectal cancer.
> **Main Findings:** Mean spending was $35,849 (breast), $26,295 (prostate), $55,597 (lung), and $63,063 (colorectal), and over the year of death, spending was similar across different cancer types or state at diagnosis.
> **Strengths/Limitations:** Analysis limited to Medicare data.
> **Generalizability to Medicare Population:** Yes
> **Methods:** Calculated per-patient monthly and year mean and median expenditures using 2007–2012 data from SEER Program linked with Medicare FFS claims.

Chino F, Peppercorn JM, Rushing C, et al. Out-of-pocket costs, financial distress, and underinsurance in cancer care. *JAMA Oncol*. 2017;3(11). doi:10.1001/jamaoncol.2016.

> **Subtopic(s):** Issues in payment policy
> **Type of Source:** Journal letters
> **Objective:** To better understand what expectations patients have regarding cancer care costs and how those cost expectations might impact decision-making.
> **Main Findings:** In adjusted analysis, experiencing higher-than-expected financial burden was associated with high or overwhelming financial distress (OR, 4.78; 95% CI, 2.02-11.32; P < .01) and with decreased willingness to pay for cancer care (OR, 0.48; 95% CI, 0.25- 0.95; P = .03).
> **Strengths/Limitations:** Strengths include use of both quantitative and qualitative analyses; limitations include exclusion of shared decision-making analysis and use of convenience sample.
> **Generalizability to Medicare Population:** Somewhat—roughly 35% of sample were covered by Medicare
> **Methods:** Convenience sample; patient survey; multivariable logistic regression.

Colligan EM, Ewald E, Ruiz S, et al. Innovative oncology care models improve end-of-life quality, reduce utilization and spending. *Health Aff*. 2017;36(3):433-440. doi:10.1377/hlthaff.2016.1303.

> **Subtopic(s):** Results
> **Type of Source:** Journal article
> **Objective:** To uncover how three models that received Health Care Innovation Awards from CMS aimed to reduce the cost and use of health care services and improve the quality of care for Medicare beneficiaries with cancer.
> **Main Findings:** The oncology medical home and patient navigation models were associated with decreased costs in the last 90 days of life ($3,346 and $5,824 per person, respectively) and fewer hospitalizations in the last 30 days of life (57 and 40 per 1,000 people, respectively). The patient navigation model was also associated with fewer ED visits in the last 30 days of life and increased hospice enrollment in the last two weeks of life.
> **Strengths/Limitations:** Strengths include retrospective cohort analysis use, with one-year pre-death timeframe applied. Limitations include that the estimates across the three analyzed model are not directly comparable since they all are different in nature of design/intent.
> **Generalizability to Medicare Population:** Strong—Medicare claims used in analysis.

Methods: Retrospective cohort analysis; Medicare claims were primary data source.

Community Oncology Alliance. COA letter to CMMI regarding challenges that need to be addressed in the OCM and future payment reform models. https://www.communityoncology.org/wp-content/uploads/2019/05/COA_CMMI_OCM_5-30-19_FINAL3.pdf Published May 30, 2019. Accessed August 2019.

> **Subtopic(s):** N/A – Submitter Information
> **Type of Source:** Letter to CMMI
> **Objective:** Letter identifies four challenges in CMMI's OCM as identified by COA. The letter requests that the CMMI OCM team address these perceived challenges.
> **Main Findings:** The four perceived challenges are price prediction, risk adjustment, attribution and MEOS payment recoupment, and timeliness of data/information.
> **Strengths/Limitations:** This is an advocacy letter written by the submitter
> **Generalizability to Medicare Population:** N/A
> **Methods:** N/A

Conti RM, Bach PB. Cost consequences of the 340B Drug Discount Program. *JAMA*. 2013;309(19):1995-1996. doi:10.1001/JAMA.2013.4156

> **Subtopic(s):** Issues in payment policy
> **Type of Source:** Perspective article
> **Objective:** Article discusses the effects of the 340B Drug Discount Program on hospitals and other facilities and practices.
> **Main Findings:** Most of the costs of the program are borne by manufacturers; the benefits of the discounts are gained by hospitals, clinics, and physicians. Patients' out-of-pocket costs and total cost of care are being increased.
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** N/A
> **Methods:** N/A

Davidoff AJ, Shaffer T, Erten MZ, et al. Use and spending on antineoplastic therapy for Medicare beneficiaries with cancer: *Medical Care*. 2013;51(4):351-360. doi:10.1097/MLR.0b013e3182726ceb

> **Subtopic(s):** Issues in payment policy
> **Type of Source:** Journal article
> **Objective:** To assess the use and spending on Part B covered and non-Part B (Part D or supplemental insurance) covered anti-neoplastic agents among Medicare beneficiary population with cancer and the impact of supplemental insurance.
> **Main Findings:** Supplemental insurance was associated with anti-neoplastic use. Although the spending on non-Part B covered drugs was less than the spending on Part B covered drugs, the use of non-Part B drugs accounted for a relatively large proportion of beneficiaries with cancer. Given the increase in availability of anticancer therapies, along with the implementation of Medicare Part D, the study noted that it is important to understand the evolving role of non-Part B anticancer drugs. The study also recommended that ongoing research is needed and critical on the role for Medicare Part D.
> **Strengths/Limitations:** Study data included only two years of data after Medicare Part D implementation. It may also include bias due to the endogeneity of supplemental insurance

because people who expect to need health care are more likely to purchase supplemental benefits.

Generalizability to Medicare Population: Yes

Methods: A retrospective, observational study used MCBS data pooled from 1997 to 2007 and consisted of Medicare FFS beneficiaries with cancer who enrolled in both Medicare Part A and Part B. Descriptive statistics was reported to characterize participants' sociodemographics. Logistic regression was performed to estimate receipt of anti-neoplastic therapy.

Desai S, McWilliams M. Consequences of the 340B Drug Pricing Program. *New Eng J Med.* 2018;378:539-548. doi: 10.1056/NEJMsa1706475

    Subtopic(s): Issues in payment policy

    Type of Source: Journal article

    Objective: To assess the impact of the Medicare 340B Drug Pricing Program, with a focus on the financial impacts or gains for participating hospitals.

    Main Findings: The 340B program has been associated with practice consolidation for hematology-oncology specialists, as well as increased hospital-based administration of physician-administered drugs.

    Strengths/Limitations: The study relies on Medicare data. However, there may be large clinical resource investments aimed at low-income groups that would exist outside of Medicare and Medicare data.

    Generalizability to Medicare Population: Yes

    Methods: Quantitative analysis of Medicare claims using a regression-discontinuity design.

Eek D, Krohe M, Mazar I, et al. Patient-reported preferences for oral versus intravenous administration for the treatment of cancer: A review of the literature. *PPA*. 2016;10:1609-1621. doi: 10.2147/PPA.S106629

    Subtopic(s): Issues in payment policy

    Type of Source: Review article

    Objective: To evaluate the administration preference among cancer patients, especially between oral and intravenous treatment, as well as the factors contributing to preference.

    Main Findings: The study concluded that oncology patients prefer oral treatment over IV. Rationale for preference include a number of factors (perception of efficacy, convenience and past experience).

    Strengths/Limitations: Search terms might prevent identification of articles addressing the substantive topics.

    Generalizability to Medicare Population: Potentially weak—age group was not indicated in selected studies.

    Methods: Literature search was performed to identify research in treatment preference (oral vs. IV) among cancer patients. A number of search terms were used to identify peer-reviewed journals, including orals or oral route of drug; intravenous or injection; preference or preferred selection; cancer or oncology; etc. A gray literature search was also conducted as a supplement to address gaps. Content analysis was conducted to inform review of selected articles.

Electronic Code of Federal Regulation. https://gov.ecfr.io/cgi-bin/ECFR. Accessed July 16, 2019.

    Subtopic(s): Issues in payment policy

    Type of Source: Website

Objective: The Electronic Code of Federal Regulation is an updated version of the Code of Federal Regulation. It is an editorial compilation of Federal Register amendments produced by the National Archives and Records Administration's office of the Federal Register.
Main Findings: OCM 2.0 would pursue waivers for drug companies for the following U.S. Code: 1) 42 CFR § 1001.952. Program Integrity – Medicare and State Health Care Programs. Subpart C. Permissive Exclusions. Exceptions; 2) 42 CFR § 447.505. Code of Federal Regulations. Determination of best price; 3) 42 CFR § 414.804. Basis of payment
Strengths/Limitations: N/A
Generalizability to Medicare Population: N/A
Methods: N/A

Ennis RD, Parikh AB, Sanderson M, et al. Interpreting oncology care model data to drive value-based care: A prostate cancer analysis. *J Oncol Pract*. 2019;15(3):e238-e246. doi:10.1200/jop.18.00336.

Subtopic(s): Results of proposed or similar models
Type of Source: Journal article
Objective: To discuss how the OCM can be made more clinically relevant, accurate, and comprehensible to improve quality and value.
Main Findings: Clinical stratification and appropriate risk adjustment within OCM are essential for it to inform and drive meaningful change. Participants must understand the model and its subtleties, especially with regard to how it processes data, to fully realize its potential.
Strengths/Limitations: Only presents a single institution, no comparison to other OCM participants.
Generalizability to Medicare Population: Strong—Medicare population studied.
Methods: The researchers studied OCM data detailing observed and expected expenses for six-month-long episodes of care for patients with prostate cancer. They constructed seven disease state–treatment dyads into which were grouped by episode on the bases of diagnoses, procedures, and medications in OCM claims data. This clinical-administrative stratification model was used to facilitate a comparative cost analysis and evaluate ED, hospital utilization, and drug therapy as potential cost drivers.

Gordan L, Blazer M, Saundankar V, et al. Cost differences associated with oncology care delivered in a community setting versus a hospital setting: A matched-claims analysis of patients with breast, colorectal, and lung cancers. *JOP*. 2018;14(12):e729-e738. doi:10.1200/JOP.17.00040

Subtopic(s): Issues in payment policy
Type of Source: Journal article
Objective: To assess financial and care quality outcomes associated with the shift of cancer care from community-based clinics to hospital-based clinics
Main Findings: Total costs of care were lower across all cancer types studied in the community-based setting compared to the hospital setting. Hospitalization rates 72 hours and 10 days after chemotherapy were similar for patients in both settings; however, patients in the community-based clinics were significantly less likely to go to the ED.
Strengths/Limitations: Results were robust in additional propensity score matching and evaluation of median costs; however, results not generalizable to Medicare population.
Generalizability to Medicare Population: Weak—majority of patients were under 65 and did not include patients with Medicare as sole provider.

Methods: Cost data for patients with breast, lung, or colorectal cancer obtained from IMS LifeLink database; matched patients by specific tumor types, treatments, and other possible confounders.

Greenapple R. Rapid expansion of new oncology care delivery payment models: Results from a payer survey. *Am Heal Drug Benefits*. 2013;6(5):249-256.

> **Subtopic(s):** Issues in payment policy
> **Type of Source:** Journal article
> **Objective:** To determine which payment models and care delivery models payers view as the most viable and the most potentially impactful in managing and reducing the cost of cancer care.
> **Main Findings:** Payers are rapidly moving to implement new reimbursement models to support new care delivery models, including ACOs and PCMHs. Based on the results of this survey, a minority of payers are experimenting with new oncology payment models, but most payers are evaluating various models, including bundled payments, capitation, shared savings, and pay for performance.
> **Strengths/Limitations:** Surveyed commercial, Medicare, and Medicaid payers; small sample size.
> **Generalizability to Medicare Population:** Partially—sample included Medicare enrollees but was a small sample size.
> **Methods:** Online national survey of 49 payers, comprised of approximately 120 questions.

Hahn EE, Munoz-Plaza C, Wang J, et al. Anxiety, culture, and expectations: Oncologist-perceived factors associated with use of nonrecommended serum tumor marker tests for surveillance of early-stage breast cancer. *JOP*. 2016;13(1):e77-e90. doi:10.1200/JOP.2016.014076

> **Subtopic(s):** Issues in care delivery
> **Type of Source:** Journal article
> **Objective:** To examine why physicians continue to use an ineffective practice—serum tumor markers for post-treatment breast cancer surveillance.
> **Main Findings:** Researchers found that, while physicians were aware that surveillance tumor markers are not clinically useful, those that continued to use them often perceived that it helped manage patient and physician anxiety about recurrence and improved patient satisfaction. Those who rarely used tumor markers perceived that the harms outweighed the benefits and emphasized the importance of following clinical guidelines.
> **Strengths/Limitations:** Study took place in an integrated care setting, making it useful for accountable care organizations, patient-centered medical homes, and other bundled-payment models. Study is limited by the low number of physicians interviewed and the absence of the patient perspective.
> **Generalizability to Medicare Population:** Study did not look at treatment in the Medicare population, but results could be reasonably similar.
> **Methods:** Mixed-methods design.

Hayes J, Hoverman RJ, Brow ME, et al. Cost differential by site of service for cancer patients receiving chemotherapy. *Am J Manag Care*. 2015; 21(3):e189-96.

> **Subtopic(s):** Issues in care delivery
> **Type of Source:** Journal article

Objective: To compare treatment costs in community oncology versus hospital outpatient settings

Main Findings: Patients receiving chemotherapy in a community oncology clinic had significantly lower per member per month costs (20% to 39% lower, on average). Cost differential was consistent across cancer type, geographic location, patient age, and number of chemotherapy sessions. Cost categories other than chemotherapy were also higher in the hospital versus community setting.

Strengths/Limitations: Limitations of claims data; however results are corroborated by similar studies.

Generalizability to Medicare Population: Weak—only commercial insurance claims used.

Methods: Analysis of Commercial Claims and Encounters Database to analyze cost. Community-based and hospital-based patients matched according to cancer diagnosis, demographics, and geographic location.

Jung K, Feldman R, McBean AM. The price elasticity of specialty drug use: Evidence from cancer patients in Medicare Part D. *Forum Health Econ Policy*. 2017;20(2):20160007. doi:10.1515/fhep-2016-0007

Subtopic(s): Issues in payment policy

Type of Source: Journal article

Objective: To estimate the price responsiveness of cancer drug use among elderly population using Medicare Part D formulary data linked to patients' claims.

Main Findings: The study reported three key findings, including the limitation in substitutability between Medicare Part B and Part D drugs for cancer treatments. The study also performed the substitution between Part B and Part D for the two cancer drugs, epoetin and filgrastim (available in both route of administration), concluded that beneficiaries are more likely to use Part B drugs over Part D anticancer drugs regardless of the availability of substitutes.

Strengths/Limitations: The utilization rate of cancer drugs in the study sample was quite low.

Generalizability to Medicare Population: Yes

Methods: Study population consisted of a random sample of Medicare enrollees with cancer. The analyzes further restricted to older adult cancer patients (65+), had Medicare Part A and Part B coverage and stayed in the same stand-alone PDP for the entire year. The study noted that many frequently used Part D cancer drugs do not have injectable substitutes; however, some drugs (including epoetin and filgrastim) are available in both route of administration. The author analyzed Part B cancer drug use separately for epoetin and filgrastim.

Kedia SK, Chavan PP, Boop SE, Yu X. Health Care Utilization Among Elderly Medicare Beneficiaries With Coexisting Dementia and Cancer. *Gerontology and Geriatric Medicine*. 2017;3:2333721416689042. doi:10.1177/2333721416689042

Subtopic(s): Epidemiology

Type of Source: Journal article

Objective: To provide insight into the health care utilization among Medicare beneficiaries with diagnoses of dementia and cancer compared to those with dementia or cancer alone, or those with neither diagnosis.

Main Findings: Beneficiaries with diagnoses of cancer and dementia had higher rates of hospitalizations, hospital readmissions within 30 days, intensive care unit use, and ED visits compared to the other populations.

Strengths/Limitations: The study is limited by using administrative data of the Medicare claims, which have no clinical information (i.e., disease severity, symptoms, other health issues).
Generalizability to Medicare Population: Yes.
Methods: Multivariate regression analyses on a population of Medicare enrollees in 2009.

Kirkwood MK, Hanley A, Bruinooge SS, et al. The state of oncology practice in America, 2018: Results of the ASCO Practice Census Survey. *JOP*. 2018;14(7):e412-e420. doi:10.1200/JOP.18.00149

> **Subtopic(s):** Issues in care delivery
> **Type of Source:** Journal article
> **Objective:** To report findings on the state of the oncology practice landscape and factors of operation and care delivery for practices.
> **Main Findings:** Decreases in the number and size of practices. Practices cited payers, competition, and staffing as primary sources of financial strain, though pressures varied by practice setting. Electronic health records were also a burden on practices.
> **Strengths/Limitations:** Report was a survey analysis, so relevant biases such as response bias likely present. Particularly, respondents tended to be larger practices than nonrespondents.
> **Generalizability to Medicare Population:** N/A
> **Methods:** Analysis of the ASCO Oncology Practice Census survey

Kline R, Adelson K, Kirshner JJ, et al. The Oncology Care Model: Perspectives from the Centers for Medicare & Medicaid Services and participating oncology practices in academia and the community. *Am Soc Clin Oncol Educ B*. 2018;(37):460-466. doi:10.1200/edbk_174909.

> **Subtopic(s):** Results from proposed or similar models
> **Type of Source:** Journal article
> **Objective:** To provide an overview of the program from the CMS perspective, as well as perspectives from two practices implementing OCM.
> **Main Findings:** As of March 2017, 190 practices were participating in OCM, with approximately 3,200 oncologists providing care for approximately 150,000 beneficiaries.
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** Strong—developed by CMS.
> **Methods:** N/A

Kline RM, Bazell C, Smith E, et al. Centers for Medicare and Medicaid Services: Using an episode-based payment model to improve oncology care. *J Oncol Pract*. 2015;11(2):114-116. doi:10.1200/jop.2014.002337.

> **Subtopic(s):** Issues in payment policy; results from proposed or similar models
> **Type of Source:** Journal article
> **Objective:** To explain the episode-based payment models developed by CMS.
> **Main Findings:** CMS has designed an episode-based model of oncology care that incorporates elements from several successful model tests. By providing care management and performance-based payments in conjunction with quality metrics and a rapid learning environment, it is hoped that this model will demonstrate how oncology care in the United States can transform into a high-value, high-quality system.
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** Strong—developed by CMS.
> **Methods:** N/A

Kline RM, Muldoon LD, Schumacher HK, et al. Design challenges of an episode-based payment model in oncology: The Centers for Medicare & Medicaid Services Oncology Care Model. *J Oncol Pract*. 2017;13(7):e632-e645. doi:10.1200/JOP.2016.015834.

Subtopic(s): Issues in payment policy; results from proposed or similar models
Type of Source: ReCAP contribution article
Objective: To provide a narrative outlining key problems encountered and rationale for decisions made in the development of Oncology Care Model.
Main Findings: Episode payment models can be complex. They combine into a single benchmark price all payments for services during an episode of illness, many of which may be delivered at different times by different providers in different locations.
Strengths/Limitations: N/A
Generalizability to Medicare Population: N/A
Methods: N/A

McAneny BL. MASON—Making Accountable Sustainable Oncology Networks. 48. https://aspe.hhs.gov/system/files/pdf/255906/ProposalIOBS.pdf.

Subtopic(s): Issues in payment policy; results of proposed or similar models
Type of Source: Proposed model
Objective: To outline the Making Accountable Sustainable Oncology Networks (MASON) proposal.
Main Findings: MASON, proposed after OCM and Community Oncology Medical Home (COME HOME), alleviates problems that practices encountered with those payment models. MASON developed an Oncology Payment Category (OPC) to cover all cancer costs and drug payments at +2% for drug pricing variability. At the end of the episode of care, actual costs are compared to the OPC and there are shared savings if quality measures were met and spending is lower than projected.
Strengths/Limitations: N/A
Generalizability to Medicare Population: Yes.
Methods: N/A

Medicare Payment Advisory Commission. *Report to Congress: Medicare and the Health Care Delivery System (pp 117-149).* http://www.medpac.gov/docs/default-source/reports/chapter-5-medicare-part-b-drug-and-oncology-payment-policy-issues-june-2016-report-.pdf?sfvrsn=0. Published February 2018. Accessed July 16, 2019.

Subtopic(s): Issues in payment policy
Type of Source: Report to Congress
Objective: To provide an overview and update of payment policy issues within Medicare Part B drug and oncology services.
Main Findings: The main recommendation of this report is that the Secretary should reduce the Medicare Part B dispensing and supplying fees to rates similar with other payers.
Strengths/Limitations: N/A
Generalizability to Medicare Population: Yes
Methods: N/A

Medicare Payment Advisory Commission. *Report to Congress: Medicare and the Health Care Delivery System (pp 117-149).* http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf. Published June 2017. Accessed July 16, 2019.

> **Subtopic(s):** Issues in payment policy
> **Type of Source:** Report to Congress
> **Objective:** To provide an overview and update regarding Medicare and the Health Care Delivery System.
> **Main Findings:** The report includes recommendations to the Secretary to implement a prospective payment system (PPS) for post-acute care, lower aggregate payments by 5% and begin aligning setting-specific regulatory requirements, and to revise payments to the current cost of care.
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** Yes.
> **Methods:** N/A

Medicare Payment Advisory Commission. *Report to the Congress: Overview of the 340B Drug Pricing Program (pp 3-34).* http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0. Published May 2015. Accessed July 16, 2019.

> **Subtopic(s):** Issues in payment policy
> **Type of Source:** Report to Congress
> **Objective:** To report to Congress an overview of the 340B Drug Pricing Program as of 2015.
> **Main Findings:** The 340B Drug Pricing Program allows hospital and other covered providers discounted prices on covered outpatient drugs, meaning prescription drugs and biologics (excluding vaccines).
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** Yes
> **Methods:** N/A

Milliman. Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy. Milliman. http://us.milliman.com/insight/health/Site-of-Service-Cost-Differences-for-Medicare-Patients-Receiving-Chemotherapy/. Accessed July 16, 2019.

> **Subtopic(s):** Issues in payment policy; issues in care delivery
> **Type of Source:** Report
> **Objective:** To examine chemotherapy cost differences between community- and hospital-based treatment centers for Medicare patients.
> **Main Findings:** Per patient per month costs were lower for patients receiving chemotherapy in a physician office for most of the most common 10 types of cancer. Annualized, the cost is about $6,500 lower for patients receiving treatment in a community-based setting compared to a hospital.
> **Strengths/Limitations:** Report does not appear to have matched patients on patient characteristics, cancer severity, demographics, geography, etc.
> **Generalizability to Medicare Population:** Strong—though only analyzed Medicare FFS patients so results not generalizable to Medicare Advantage
> **Methods:** Using Medicare Limited Data Set for 2006–2009, compared Medicare FFS beneficiaries who received all chemotherapy treatments at a hospital or at a physician office.

National Institutes of Health on State Cancer Profiles. Incidence Rates Tables.
https://statecancerprofiles.cancer.gov/incidencerates/index.php. Published 2015. Accessed July 29,
2019.

> **Subtopic(s):** Epidemiology
> **Type of Source:** Database
> **Objective:** Provide national cancer statistics.
> **Main Findings:** Incidence rates of cancer in the United States.
> **Strengths/Limitations:** National database.
> **Generalizability to Medicare Population:** Yes.
> **Methods:** N/A

National Institutes of Health on State Cancer Profiles. Death Rates Tables.
https://statecancerprofiles.cancer.gov/deathrates/index.php. Published 2015. Accessed July 29, 2019.

> **Subtopic(s):** Epidemiology
> **Type of Source:** Database
> **Objective:** Provide national cancer statistics.
> **Main Findings:** Death rates of cancer in the United States.
> **Strengths/Limitations:** National database.
> **Generalizability to Medicare Population:** Yes
> **Methods:** N/A

NCCN Clinical Practice Guidelines in Oncology.
https://www.nccn.org/professionals/physician_gls/default.aspx#site. Accessed July 16, 2019.

> **Subtopic(s):** Issues in care delivery
> **Type of Source:** Website
> **Objective:** To provide clinical guidelines for various forms of cancers and patient types
> **Main Findings:** N/A
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** N/A
> **Methods:** N/A

NCQA. The Oncology Medical Home Recognition Process. NCQA.
https://www.ncqa.org/programs/health-care-providers-practices/oncology-medical-home/process-oncology-current/. Accessed July 16, 2019.

> **Subtopic(s):** Issues in care delivery
> **Type of Source:** Website
> **Objective:** Standards and process for Oncology medical home recognition.
> **Main Findings**: N/A
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** N/A
> **Methods:** N/A

Neubauer M. Prepping Oncology Practices for Value-Based Reimbursement. McKesson.
http://www.mckesson.com/blog/oncology-and-value-based-reimbursement/. Accessed July 16, 2019.

Subtopic(s): Issues in care delivery
Type of Source: Perspective article
Objective: Article discusses the future of value-based reimbursement for cancer care.
Main Findings: N/A
Strengths/Limitations: N/A
Generalizability to Medicare Population: N/A
Methods: N/A

Newcomer LN, Gould B, Page RD, et al. Changing physician incentives for affordable, quality cancer care: Results of an episode payment model. *JOP*. 2014;10(5):322-326. doi:10.1200/JOP.2014.001488

Subtopic(s): Issues in payment policy
Type of Source: Journal article
Objective: To outline MD Anderson and United HealthCare's alternative payment model for oncology care and determine the efficacy of episodic payments.
Main Findings: While FFS costs were lower when bundling payments ($98,121,388 as opposed to actual spending of $64,760,116), the model did not account for drug pricing, and the actual price of chemotherapy drugs was three times ($20,979,417) the predicted amount ($7,519,504).
Strengths/Limitations: Cancer types were limited to breast, colon, and lung cancer, which have more treatments available than more advanced cancers that are often more expensive to treat. Only 810 patients were included in the analysis.
Generalizability to Medicare Population: Yes
Methods: Medical oncologists were paid a single fee for their oncology payments using average sales price for drugs.

Office of Inspector General, U.S. Department of Health & Human Services. Compliance Guidance. https://oig.hhs.gov/compliance/compliance-guidance/index.asp. Accessed July 16, 2019.

Subtopic(s): Issues in payment policy
Type of Source: Website
Objective: Office of Inspector General has developed a number of voluntary compliance program guidance documents for various parts of health care industry to encourage the development and use of internal controls to keep track adherence to applicable statutes, regulations and program requirement.
Main Findings: OCM 2.0 would pursue waivers for drug companies for 68 FR 23731.
This Federal Register notice provides the 2003 Compliance Program Guidance for Pharmaceutical Manufacturers developed by the Office of Inspector General (OIG). Through this notice, the OIG posits that there is value compliance programs for pharmaceutical manufacturers to develop and maintain a compliance program. OIG also sets out the elements for an effective compliance program.
Strengths/Limitations: N/A
Generalizability to Medicare Population: N/A
Methods: N/A

Office of the Law Revision Counsel. United States Code. http://uscode.house.gov/. Accessed July 16, 2019.

Subtopic(s): Issues in payment policy
Type of Source: Website

Objective: The United States Code is a consolidation and codification by subject matter of the general and permanent laws of the United States. It is prepared by the Office of the Law Revision Counsel of the United States House of Representatives.
Main Findings: OCM 2.0 would pursue waivers for drug companies for the following U.S. Code: 1) 42 USC § 1320a-7b. Criminal penalties for acts involving Federal health care programs; 2) 42 USC § 1396r–8. Payment for covered outpatient drugs; 3) 42 USC § 1395w–3a. Use of average sales price payment methodology
Strengths/Limitations: N/A
Generalizability to Medicare Population: N/A
Methods: N/A

O'Neill CB, Atoria CL, O'Reilly EM, et al. ReCAP: Hospitalizations in Older Adults With Advanced Cancer: The Role of Chemotherapy. JOP. 2016;12(2):151-152. doi:10.1200/JOP.2015.004812

Subtopic(s): Epidemiology
Type of Source: Journal article
Objective: To review hospital readmissions as a marker for quality of care through reviewing oncology readmissions data.
Main Findings: The study found that a portion of oncology readmissions could have been prevented through improved anticipation of symptoms among high-risk patients, as well as improved communication between patients and providers regarding the symptom burden.
Strengths/Limitations: The approach, while consistent with other previous studies on treatment complications, does not use direct attribution of the hospitalization to a specific cause, which limits the clinical information considered in the analysis.
Generalizability to Medicare Population: Yes.
Methods: The study developed criteria to define preventable and not preventable admissions. Two reviewers independently reviewed sequential nonsurgical oncology readmissions.

ESMO. ESMO Clinical Practice Guidelines. ESMO. https://www.esmo.org/Guidelines. Accessed July 16, 2019.

Subtopic(s): Issues in care delivery
Type of Source: Website
Objective: To provide clinical practice guidelines for oncologists.
Main Findings: N/A
Strengths/Limitations: N/A
Generalizability to Medicare Population: N/A
Methods: N/A

Pecora A. Oncology Bundled Payment Program Using CNA-Guided Care. Proposal for PTAC. https://aspe.hhs.gov/system/files/pdf/255906/OncologyBundledPaymentProgramCNACare.pdf.

Subtopic(s): Issues in payment policy; results of proposed or similar models
Type of Source: Proposed model
Objective: To outline the HMH-COTA Oncology Bundled Payment Program model
Main Findings: The Oncology Bundled Payment Program is a bundle price based on the prospective basis for a 12-month treatment episode of care.
Strengths/Limitations: N/A
Generalizability to Medicare Population: N/A

Methods: Payments are determined by a prospective cohort analysis of patients diagnosed through the CNA classification system. CNA codes allow for grouping and comparison of patients with the same cancer.

Polite BN, Miller HD. Medicare Innovation Center Oncology Care Model: A toe in the water when a plunge is needed. *J Oncol Pract*. 2015;11(2):117-119. doi:10.1200/jop.2014.002899.

    Subtopic(s): Results of proposed or similar models
    Type of Source: Perspective article
    Objective: To highlight criticisms of the OCM 1.0 model.
    Main Findings: There are three main issues with the OCM 1.0: Monthly payments can alleviate the issues in fee-for-service's inflexibility, oncologists cannot control all aspects of spending in cancer care, and oncology care does not fit into three-month episodes.
    Strengths/Limitations: N/A
    Generalizability to Medicare Population: N/A
    Methods: N/A

Pyenseon B, Fitch K. Benefit designs for high cost medical conditions. Milliman. 2011.
http://us.milliman.com/insight/research/health/Benefit-designs-for-high-cost-medical-conditions/

    Subtopic(s): Issues in payment policy
    Type of Source: Paper commissioned by Genentech, Inc.
    Objective: To provide an actuarial perspective on high cost patients and how their associated costs are distributed between the health plan and patient.
    Main Findings: The paper provides the benefit designs that would protect high cost patients.
    Strengths/Limitations: This paper was prepared for Genentech, Inc., and does not provide the degree to which the client may have influenced preparation.
    Generalizability to Medicare Population: Limited.
    Methods: The analysis used Medstat data from 2007 and 2008, selecting patients with drug coverage, not in HMOs or capitated PPOs, and under 70 years old. The actuarial equivalent modeling used the 2010 Milliman Health Cost Guidelines, a proprietary modeling tool.

Rivera DR, Gallicchio L, Brown J, et al. Trends in adult cancer–related emergency department utilization: An analysis of data from the nationwide emergency department sample. *JAMA Oncol*. 2017;3(10):e172450-e172450. doi:10.1001/jamaoncol.2017.2450

    Subtopic(s): Epidemiology
    Type of Source: Journal article
    Objective: To estimate the proportion of ED visits made by adults with a cancer diagnosis.
    Main Findings: The most common cancer diagnoses presenting in the ED were breast, prostate, and lung cancer.
    Strengths/Limitations: Identifier of a cancer-related visit was based on 15 CCS codes within NEDS.
    Generalizability to Medicare Population: Yes
    Methods: Weighted multivariate logistic regression to analyze associations between inpatient admission, demographics, and clinical variables.

Ruiz ES, Seiger K, Mostaghimi A, Schmults C. National cancer expenditure analysis in the United States Medicare population, 2013. *JCO.* 2019;37(15_suppl):6647-6647. doi:10.1200/JCO.2019.37.15_suppl.6647

> **Subtopic(s):** Epidemiology
> **Type of Source:** Journal article
> **Objective:** To provide a comprehensive analysis evaluating total cost of cancer by cancer type and treatment modality.
> **Main Findings:** In 2013, cancer accounted for 5% of Medicare spending, and chemotherapy accounted for approximately one-third of total spending.
> **Strengths/Limitations:** Limited Medicare Data Set
> **Generalizability to Medicare Population:** Yes
> **Methods:** ICD-9 code analysis

RTI International, Actuarial Research Corporation, for Centers for Medicare & Medicaid Services. OCM Performance-Based Payment Methodology. Vol 5.1. https://innovation.cms.gov/Files/x/ocm-pp3beyond-pymmeth.pdf. Published December 17, 2018. Accessed July 16, 2019.

> **Subtopic(s):** Results of similar or proposed models
> **Type of Source:** Report
> **Objective:** To describe the technical details for the methodology that CMS will use to determine a practice's or pool's performance-based payment in OCM.
> **Main Findings:** OCM targets physician group practices that prescribe chemotherapy for cancer and is centered on six-month episodes of care triggered by receipt of chemotherapy. OCM incorporates a two-part payment system for participating practices, composed of a Monthly Enhanced Oncology Services (MEOS) payment and the potential for a retrospective performance-based payment. Practices will be eligible to be paid the MEOS payment monthly for each beneficiary during an episode attributed to them regardless of cancer type, unless the beneficiary enters hospice or dies. Performance-based payments will be made only for higher-volume cancer types for which it is possible to calculate accurate benchmarks.
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** N/A
> **Methods:** Episodic identification methods to trigger six-month period of review.

Schnipper LE, Davidson NE, Wollins DS, et al. Updating the American Society of Clinical Oncology Value Framework: Revisions and reflections in response to comments received. *J Clin Oncol*. 2016;34(24):2925-2934. doi:10.1200/JCO.2016.68.2518

> **Subtopic(s):** Issues in care delivery
> **Type of Source:** Journal article
> **Objective:** The ASCO Value in Cancer Care Task Force is developing a framework for physicians and patients to assess the values of particular treatments. This article documents the Task Force's progress and discusses criticisms and comments received thus far.
> **Main Findings:** The ASCO Value in Cancer Care Task Force developed a framework for assessing treatment value that incorporates information on clinical benefits, toxicity, and symptom palliation. When combined with cost information (provided by the patient/physician, not the tool), the framework produces a "Net Health Benefit" score. While the tool provides a solid basis for facilitating discussions between patients and providers, the tool faces several limitations. Key elements in the framework rely on scientific literature, which isn't always of the highest quality.

More work is needed to assess patient-reported outcomes, such as the convenience of receiving treatment and impact on quality of life, that are important to individuals' decision making.
Strengths/Limitations: Tool incorporates metrics on treatments' clinical benefit, toxicity, and symptom palliation; however, it does not yet address issues of scientific quality and patient reported outcomes.
Generalizability to Medicare Population: N/A
Methods: The ASCO Value in Cancer Care Task Force developed an initial value framework and sought feedback from stakeholders for suggestions on how to strengthen the framework.

Schnipper LE, Smith TJ, Raghavan D, et al. American Society of Clinical Oncology identifies five key opportunities to improve care and reduce costs: The top five list for oncology. *J Clin Oncol*. 2012;30(14):1715-1724. doi:10.1200/jco.2012.42.8375.

Subtopic(s): Issues in care delivery
Type of Source: Journal article
Objective: To explain the five items the American Society of Clinical Oncology to improve care and reduce costs.
Main Findings: 1) Don't use cancer-directed therapy for patients with solid tumors who have specific characteristics; 2) don't perform PET, CT, and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis; 3) don't perform PET, CT, and radionuclide bone scans in the early staging of breach cancer at low risk for metastasis; 4) don't perform surveillance testing or imaging for asymptomatic patients who have been treated for breast cancer with curative intent; and 5) Don't use white cell–stimulating factors for primary prevention of febrile neutropenia for patients with less than 20% risk for this complication.
Strengths/Limitations: N/A
Generalizability to Medicare Population: Strong
Methods: Each participating organization in the American Board of Internal Medicine Foundation's Choosing Wisely initiative was charged with identifying five tests or procedures commonly used in their field whose necessity is not sup- ported by high-level evidence. Each society was free to determine how to create its own list, provided that it used a clear methodology and adhered to a provided set of guidelines.

Sprandio JD. Oncology patient–centered medical home. *J Oncol Pract*. 2012;8(3 Suppl):47s-49s. doi:10.1200/JOP.2012.000590

Subtopic(s): Issues in care delivery; Results of proposed or similar models
Type of Source: Perspective article
Objective: To outline community-based oncology practices and highlight the Oncology Patient-Centered Medical Home.
Main Findings: The Oncology Patient Centered Medical Home coordinates care by having a physician-led care team for disease management, care coordination, standardized evidence base, and direct patient engagement and education. The PCMH led to reductions in ED visits by 68%, hospital admissions for chemo patients by 51%, inpatient admission stays by 21%, and outpatient visits by chemotherapy patients by 12%. Savings are in the range of $1 million per physician, per year.
Strengths/Limitations: Similar results are found when directly compared to the cost and use for national payers.
Generalizability to Medicare Population: Yes

Methods: N/A

Thomson S, Schang L, Chernew ME. Value-based cost sharing in the United States and elsewhere can increase patients' use of high-value goods and services. *Health Aff*. 2013;32(4):704-712. doi:10.1377/hlthaff.2012.0964

> **Subtopic(s):** Issues in care delivery
> **Type of Source:** Journal article
> **Objective:** Article examines efforts of the United States and other members of the Organization for Economic Cooperation and Development to encourage patients to use high-value medications, services, and providers through cost sharing.
> **Main Findings:** Value-based approaches were most commonly used for drug cost sharing. A few countries, including the US, used financial incentives to encourage patients to use preferred providers and preventive services. Cost sharing can be an effective tool to encourage use of high-value services; however, high administrative costs could worsen health inequalities.
> **Strengths/Limitations:** Limited evaluations of value-based cost sharing policies in almost all countries examined.
> **Generalizability to Medicare Population:** Limited discussion of Medicare.
> **Methods:** Information on the US and European countries was found through database searches.

United States District Court for the District of Columbia. Memorandum Opinion: Granting in part Plaintiffs' Motion for Permanent Injunction; Remanding the 2018 and 2019 OPPS Rules to HHS. May 2019.https://images.magnetmail.net/images/clients/AHA_MR1/attach/2019/May/MemorandumOpinionGrantingPartMotionforPermanentInjunction_Remanding2018and2019OPPSRules_HHS_05062019.PDF

> **Subtopic(s):** Issues in payment policy
> **Type of Source:** Legal memorandum opinion
> **Objective:** To describe the Court decision in the American Hospital Association, et al., versus Alex M. Azar II, United States Secretary of Health and Human Services, et al.,
> **Main Findings:** The Court held that the Department of Health and Human Services exceeded its statutory authority by reducing the 2018 Medicare reimbursement rate for certain pharmaceutical drugs as covered by the 340B program.
> **Strengths/Limitations:** N/A
> **Generalizability to Medicare Population:** No, this is a specific court decision.
> **Methods:** N/A

Valuck T, Blaisdell D, Dugan D, et al. Improving Oncology Quality Measurement in Accountable Care. National Pharmaceutical Council; 118. https://www.npcnow.org/system/files/research/download/npc-improving-oncology-quality-measures-final.pdf.

> **Subtopic(s):** Results of proposed or similar models
> **Type of Source:** Report
> **Objective:** To outline alternative payment models that use value-based care to improve oncology care
> **Main Findings:** Accountable care measure sets include a breadth of services not just related to direct cancer care, such as pain quantification, depression screening, and palliative care. Pathways are limited currently, and exist mainly for breast, colorectal, and prostate cancers. There are gaps in measuring quality for cancer treatments, such as biomarker testing, imaging,

pathways, radiation, survival and disease recurrence, and stage and tumor specific data collection.
Strengths/Limitations: N/A
Generalizability to Medicare Population: Yes
Methods: Analysis of 10 cancer types through literature and clinical guidance review and qualitative feedback from participants

Wade JC. Unwanted variation in cancer care: It is time to innovate and change. *JOP*. 2016;13(1):6-8. doi:10.1200/JOP.2016.018291

      Subtopic(s): Issues in care delivery
      Type of Source: Perspective article
      Objective: Article discusses health care waste, efforts to reduce it, and future challenges.
      Main Findings: N/A
      Strengths/Limitations: N/A
      Generalizability to Medicare Population: N/A
      Methods: N/A

Quality Payment Program, U.S. Department of Health & Human Services. CMS Quality Payment Program MIPS Overview. https://qpp.cms.gov/mips/overview. Accessed July 16, 2019.

      Subtopic(s): Issues in care delivery
      Type of Source: Website
      Objective: Introduction and overview of the Merit-based Incentive Payment Systems (MIPS) and Advanced Alternative Payment Models (APMs).
      Main Findings: N/A
      Strengths/Limitations: N/A
      Generalizability to Medicare Population: N/A
      Methods: N/A

III.   Research Questions, Data Sources, Key Words, Search Term Table, and Methods

The environmental scan includes a review of information from existing peer-reviewed and non-peer-reviewed publications. We conducted a formal search of major medical, health services research, and general academic databases. We also conducted targeted searches of content available in the grey literature. We reviewed the websites of professional associations/societies and CMS for relevant evaluation reports and program documentation. Exhibit 2 below lists the full list of research questions motivating this environmental scan, search terms, and sources used.

Exhibit 2: Search Strategy

Research Questions	Preliminary Search Terms	Sources
Epidemiology of Cancer		
Clearly define the issue / population by addressing the following: 1. What is the prevalence of types of cancer covered by OCM among Medicare beneficiaries? What is the prevalence of the most common types of cancer (using top 20) not covered by OCM? What are the characteristics (socio-demographic [including geography, e.g., area deprivation index], dual eligibility, comorbidity) of Medicare beneficiaries with these conditions? 2. What outcomes are associated with cancer diagnoses (e.g. hospitalizations, ED visits, Medicare spending)?	Cancer, prevalence, Medicare Cancer, outcomes, Medicare Emergency room/department (ER/ED) visit, hospitalization, admission, acute care utilization	PubMed Google Scholar American Community Survey (ACS) National Health Interview Survey (NHIS) Sources cited in proposal
Issues in Payment Policy		
3. What are Medicare payment rules on oncology services and medications, particularly as handled in Part B versus Part D? What types of supports are covered? 4. What is the context and impact of the seven regulations noted in the proposal as potential targets for waivers? 5. What, if any, other payment models (e.g. CMMI's OCM, Anthem's Cancer Care Quality Program, BCBSNC's Medical Oncology Program, MD Anderson) or proposed payment models (e.g. IOBS's Making Accountable Sustainable Oncology Networks or HMH-Cota's Oncology Bundled Payment Program) exist to address value-based payment in oncology care? How are providers paid in these models? What are the risk-sharing arrangements? 6. In episode-based payment models for oncology care, what is the triggering event? What is the length of episode? Are any services excluded from the episode? 7. To what extent is Total Cost of Care used in oncology payment models? Are there limitations to doing so?	Oncology medication, drugs & pharmaceuticals Oncology episode-based payment Episode trigger Episode length Cancer patient categorization pricing Criminal penalties for acts involving Federal health care programs Program Integrity – Medicare and State Health Care Programs. Subpart C. Permissive Exclusions– Exceptions OIG Compliance Program Guidance to Pharmaceutical Manufacturers Payment for covered outpatient drugs Code of Federal Regulations. Determination of best price. Use of average sales price payment methodology Basis of Payment	MedPAC MACPAC Medicare coverage database PubMed Google Scholar CMMI Medicaid.gov Medicare Claims Processing Manual CFR Federal register

Research Questions	Preliminary Search Terms	Sources
Problems in Care Delivery		
8. What clinical delivery standards comprise the Oncology Medical Home model? Has the model been evaluated? What are the results? 9. What cancer care services are considered high value? What cancer care services are considered low value? 10. What is the standard of care related to cancer drug treatment? 11. Are there different issues in care delivery and payment for community-based vs. hospital-based oncologists?	Oncology Medical Home Choosing Wisely Value-Based Insurance Design Oral cancer care therapies Supportive cancer care therapies In-office dispensing Community-based oncologist Hospital-based oncologist Patient experience Patient-reported quality of life Cancer guidelines Clinical decision supports + cancer care + oncology care	Cochrane NCQA CMS Measures Inventory Tool PubMed Google Scholar CMMI Sources cited in proposal and appendices American Society of Clinical Oncology
Results of Proposed or Similar Models		
12. What are the results of evaluations of OCM and similar interventions (e.g., commercial)? Do any of these evaluations assess payment for the model (vs. evidence of effectiveness and costs)? 13. Have the new components of OCM 2.0 been implemented and studied in the past? What are the results of the payment and care delivery features proposed? 14. What other demonstrations, waivers, etc. have included an oncology component (e.g., radiation oncology alternative payment model (RO-APM), commercial programs)? Are there published evaluations of these models? 15. What areas for improvement have been identified for the OCM model in evaluations and the literature? Does OCM 2.0 address those concerns?	OCM, Oncology Care Model Radiation Oncology Alternative Payment Model	Google Scholar PubMed CMMI Sources cited in proposal Medicaid.gov PTAC transcripts for other oncology care models (especially MASON, HMH-Cota)

Three NORC staff members between July 9, 2019, and July 18, 2019, conducted more than 75 searches of major medical and academic databases, including PubMed and the University of Chicago Library; government websites including MedPAC, CMS, and CMMI; and Google Scholar. Searches were generally restricted to the past five years, except when conducting searches on programs that predate this time period (e.g., landmark oncology care programs or OCM 2.0 precursor programs). Human filtering was conducted on search results based on whether the title and abstract of the materials found matched inclusion criteria.

IV. Appendices

Appendix A. Other Current and/or Pending Payment Models that Address Value-Based Payment in Oncology Care

Organization and model description	Provider payment	Episode triggering event	Items and services covered by the model	Patient engagement approach	Risk-sharing	Shared savings calculation	How are savings generated?
Bundled Payment							
CMMI's OCM[1] was developed for all cancer types. The aim is to better align financial incentives, to enable a more coordinated oncology care at lower cost.	$160 per-beneficiary, Monthly Enhanced Oncology Services (MEOS) payment. Performance-based payments if the episode expenditures reduced compared to benchmark.	After an enrollee receives a qualifying chemotherapy drug, OCM targets chemotherapy and corresponding care for the following six months.	Patient navigation, IoM care plan, 24/7 patient access, treatment compliance with nationally recognized clinical guidelines.	1) Treatment plan conversation and shared decision-making; 2) education, coaching and self-management; 3) modes for tracking experiences; 4) open care plans; 5) partnering to guide practice improvement[8]	One-sided: - Medicare discount: 4%, to be applied to the benchmark to calculate the final target price. - Must qualify for performance-based payment by mid 2019 to remain in one-sided risk Two-sided (since 2017) : - Either 20% of benchmark for stop-gain/stop-loss and 2.75% Medicare discount or 16%/8% of practice revenue including additional chemo (if applicable), minimum threshold for recoupment of 2.5%, and 2.5% Medicare discount	Shared savings are based on meeting quality measures and reducing total cost of care.[9]	Lower spending through improved care coordination and access to care.

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[8] Booz Allen Hamilton. Key drivers and change package. 2018:82. https://innovation.cms.gov/Files/x/ocm-keydrivers-changepkg.pdf. Accessed August 5, 2019.
[9] The Oncology Care Model (OCM). McKesson. https://www.mckesson.com/specialty/oncology-care-model. Accessed July 26, 2019.

Organization and model description	Provider payment	Episode triggering event	Items and services covered by the model	Patient engagement approach	Risk-sharing	Shared savings calculation	How are savings generated?
MD Anderson and UnitedHealthcare[4] retroactively targets head and neck cancers that were not concurrent, recurrent, or metastatic.	There are eight payment bundles developed for the program, all around evidence-based protocols. Additional provider payment details are unavailable.	New diagnosis of lip or oral cavity, laryngeal, oropharyngeal and salivary gland tumors, with exclusions.	Primary cancer treatment (i.e., surgery, radiation therapy, chemotherapy) and one year of care, including inpatient care, surgical reconstruction, emergency visits, diagnostic imaging, internal medicine, and preventive care.	Model lists patient experience as a priority of design.	There is a stop-loss provision for the relatively few patients (estimated 1%) with higher-than-normal cancer costs.	Actual cost versus predicted costs	Based on a number of quality measures, although a detailed rationale to the approach was not available.
21st Century Oncology and Humana[10] introduced case rate payments at one multi-site radiation oncology provider to compare to other fee-for-service sites.	Retrospective case rate payment	Patients treated with 2- dimensional 3- dimensional (2D3D) or intensity-modulated radiation therapy (IMRT) for specific cancers.	All services under guideline-based care based on the National Comprehensive Cancer Network, American Society for Radiation Oncology guidelines, and radiation oncology literature.	None outlined.	Not outlined.	Not outlined.	Not outlined.

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[10] Falit BP, Chernew ME., Mantz, CA. (2014). Design and implementation of bundled payment systems for cancer care and radiation therapy. *Int J Radiat Oncol Biol Phys*. 2014;89(5):950-953. https://doi.org/10.1016/j.ijrobp.2014.04.023

Organization and model description	Provider payment	Episode triggering event	Items and services covered by the model	Patient engagement approach	Risk-sharing	Shared savings calculation	How are savings generated?
RCCA and Horizon BCBS collaborated to implement a three-year nurse navigation pilot program using COTA software.	Monthly medical management fee for nurse navigators to manage patients	Not outlined.	No specificities outlined.	Nurse navigators to reach out to patients between appointments.	Not outlined.	Not outlined.	Reducing emergency room visits and hospital admissions.
BCBSCA and Valley Radiotherapy Associates implemented a single episode of care model for patients with breast cancer requiring radiation therapy.[11]	Case rate of all services provided for treatment.	Not outlined.	All radiation therapy services provided to treat breast cancer.	None outlined.	Not outlined.	Not outlined.	Not outlined.
UnitedHealth-care conducted a pilot (2009–2012) to treat patients with breast, colon, and lung cancer.	Episodic payment based on cancer type and fee for service.	Initial visit to the oncologist	Physician office visit, chemotherapy administration, chemotherapy medications, diagnostic radiology, laboratory, physician hospital care, hospice management, case management	None outlined.	Not outlined.	The study used actual total medical cost of care.	The study did not determine which expenses drove the differences in total medical cost, but a subset analysis found statistically valid decreases in hospitalization and therapeutic radiology usage.

[11] Anthem Blue Cross of California and Valley Radiotherapy Associates Developed New Agreement. McKesson. https://www.mckesson.com/about-mckesson/newsroom/press-releases/2016/anthem-blue-cross-of-california-and-valley-radiotherapy-associates-implement-new-rates-for-patients/. Published July 5, 2016. Accessed July 26, 2019.

Organization and model description	Provider payment	Episode triggering event	Items and services covered by the model	Patient engagement approach	Risk-sharing	Shared savings calculation	How are savings generated?
Shared Savings							
Advanced Medical Specialties established an oncology-specific Accountable Care Organization enrolling patients with the most common cancers (breast, digestive system, leukemia and lymphoma, female reproductive, male reproductive, and respiratory).	Fee for service payment with shared savings based on Quality Oncology Practice Initiative metrics	Not outlined.	All cancer costs	Patient education	Not outlined.	Savings of 2% or more are shared between the partners as long as quality metrics are met	Achieving adherence to pathways for chemotherapy and supportive care drugs, decreasing emergency department visits, and improving end-of-life planning
Moffitt Cancer Center and Florida Blue created an accountable care program in 2012 with 330 oncology providers.	Not outlined.	Not outlined.	All cancer treatment	Not outlined.	Not outlined.	Not outlined.	Decrease medical costs through value-based compensation.

Organization and model description	Provider payment	Episode triggering event	Items and services covered by the model	Patient engagement approach	Risk-sharing	Shared savings calculation	How are savings generated?
ASCO Patient-Centered Oncology Payment focuses on higher, more flexible payments to support patient care and accountability for oncology practices to provide high-quality care.	Four payments: $750 per month per patient for patient treatment planning, $200 per month per patient for care management during treatment, $50 per month per patient during treatment holidays and for up to six months after treatment for care management during active monitoring, and $100 per month per patient for participation in clinical trials while treatment is underway and for six months afterward for trials in which practice support is not available, as well as normal payments for E&M, chemotherapy infusions, advanced care planning, testing, imaging, and other cancer related services. There are two alternatives, consolidated payments for new patient, treatment months, and active monitoring, and a bundled payment.[12]	Patient is seen by an oncologist that is in the ASCO	All cancer costs	Patient and caregiver education and support services	No risk, payments are given per month per patient	There are no shared savings, spending reductions would arise from decreased use of ED visits, hospitalizations, and appropriate use criteria	Decrease avoidable ED visits and hospitalizations, ensure appropriate use of expensive drugs, laboratory tests and imaging services.

Organization and model description	Provider payment	Episode triggering event	Items and services covered by the model	Patient engagement approach	Risk-sharing	Shared savings calculation	How are savings generated?
Oncology Medical Homes							
Consultants in Medical Oncology and Hematology (CMOH) is an oncology patient centered medical home that specializes in diagnosis and management of cancers and blood diseases.	Not outlined.	Seen by an oncologist at the CMOH	All cancer costs, provided in the same location	Patient navigators and support staff for education and engagement	Not outlined.	Not outlined.	Minimizing unnecessary resource use (ED, admissions, outpatient visits)
Priority Health's Michigan OMH Demonstration Project	Modified provider payments: the average sales price payment methodology plus a care management fee calculated to increase total drug reimbursement, also reimburses for chemotherapy and treatment planning, and advanced care planning consultation	Priority Health patients receiving chemotherapy for a cancer diagnosis	All cancer costs	In year two, they will implement survivorship programs, patient distress screenings, and standardized patient satisfaction surveys	Not outlined.	There are shared savings, but the calculation was not published.	Adherence to practice-selected guidelines, institution of advanced care planning, and effective and standardized symptom management

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[12] ASCO. ASCO Releases Payment Reform Proposal to Support Higher Quality, More Affordable Cancer Care. https://www.asco.org/advocacy-policy/asco-in-action/asco-releases-payment-reform-proposal-support-higher-quality-more. Published January 27, 2016. Accessed July 29, 2019.

Organization and model description	Provider payment	Episode triggering event	Items and services covered by the model	Patient engagement approach	Risk-sharing	Shared savings calculation	How are savings generated?
Moffit Cancer Center and Aetna OMH is a whole-person and evidence-based approach to coordinated care with focus on quality, safety and enhanced access to care.	Not outlined.	Seen by an oncologist at Moffit Cancer Center	All cancer costs	Shared-decision making through clinical pathways, expanded hours, open scheduling, and new communication methods between patients and the hospital staff and physicians	Not outlined.	Not outlined.	Coordinated and integrated care for Aetna members
Aetna and RCCA is a whole-person and evidence-based approach to coordinated care with focus on quality, safety and enhanced access to care.	Not outlined.	Seen by an oncologist at RCCA	All cancer care	Evidence based personalized care	Not outlined.	Not outlined.	Coordinated and integrated care for Aetna members
Cigna Collaborative Care for Oncology is a pilot at independent oncology practices, including Virginia Cancer Institute, RCCA, and Florida Cancer Specialists	Patient management fee	Seen by an oncologist at a participating site	All cancer care	Not outlined.	Not outlined.	Shared savings are based on national spending benchmarks	Reducing outpatient costs, ED visits, and hospital admissions

Organization and model description	Provider payment	Episode triggering event	Items and services covered by the model	Patient engagement approach	Risk-sharing	Shared savings calculation	How are savings generated?
Payer Pathway Programs							
Anthem Cancer Care Quality Program[13] is evidence-based cancer treatment pathways, allowing participants to compare the planned treatment regimens against evidence-based clinical criteria.	Enhanced reimbursement of $350 per month[14] if providers register patients on the Anthem oncology website, input data, and adhere to pathways, enhanced payment for some generic chemotherapies	S-code of S0353 (initial patient) or S0354 (established patient) for treatment planning and care coordination for cancer, monthly fee begins with chemotherapy	All cancer care under the cancer treatment pathways	None outlined	One-sided: - Conditional on fulfilling the program requirements - No obligation if actual exceeds expected expenditures Two-sided: - Greater savings but must return a portion of any losses	Not outlined.	Reduce spending on drugs, ED, and hospital use
BCBSNC Medical Oncology Program uses the AIM Cancer Treatment Pathways and includes patient support tools.	Enhanced reimbursement. Pay for performance using s-codes for initial treatment (S (0353)) and established patient (S (0354)).	S-code of S0353 (initial patient) or S0354 (established patient) for treatment planning and care coordination for cancer	All cancer care under the cancer treatment pathways	None outlined	One-sided: - Conditional on fulfilling the program requirements Two-sided: - Greater savings but must return a portion of any losses	Not outlined.	Reduce spending on drugs, ED, and hospital use

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[13] Robinson JC. Value-Based Physician Payment in Oncology: Public and Private Insurer Initiatives. Milbank Q. 2017; 95(1):184-203. doi:10.1111/1468-0009.12249

[14] AIM Specialty Health. Enhanced Reimbursement FAQ. Cancer Care Quality Program. https://cancercarequalityprogram.com/pdf/EnhancedReimbursementFAQ.pdf

Organization and model description	Provider payment	Episode triggering event	Items and services covered by the model	Patient engagement approach	Risk-sharing	Shared savings calculation	How are savings generated?
			Models Proposed to PTAC[15]				
IOBS Making Accountable Sustainable Oncology Networks[5] (MASON) combines principles of OMH, fee for service, ambulatory payment classifications and diagnosis-related groups to create an Oncology Payment Category.	- Facility fee covers infusion overhead costs - All cancer care expenses at FFS rates - Drug charges submitted and paid at +2% for variability	Treatment of a Medicare patient at a MASON-affiliated practice	Expected fee for service payments for physician visits, imaging, lab, radiation therapy, surgery, infusion with a facility fee for infusion overhead, APCs for hospital outpatient care, DRGs for inpatient care, and PCOP payments for COME HOME medical infrastructure	Mobile patient engagement application to integrate pathways, monitor and collect feedback from patients on treatment compliance, toxicities, and experiences; shared decision making in pathways	Practices are at risk for only factors that they can control.	2% of the OPC reserved for quality pool and all quality measures are met, actual costs compared with OPC	Decreased use of ED and hospitalization, improved access to care and ancillary services
Hackensack Meridian Health (HMH)-Cota Oncology Bundled Payment Program[6] was developed to improve total cost of care with common cancers (breast, colon, rectal and lung).	The bundle price is on a prospective basis for a 12-month treatment episode. There is additional pay for performance metrics.	Treatment of a Medicare patient at HMH	All cancer costs	Not outlined	HMH will be at risk for the costs of delivering care if their costs exceed what they are paid.	Predicted versus actual expenses	Reducing variance in care

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[15] In addition to the two models listed below, the LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer model was also proposed to PTAC by the Large Urology Group Practice Association (LUGPA). The LUGPA model was specific to prostate cancer and focused on increasing use of active surveillance (and therefore decreasing use of medical/surgical interventions), rather than paying for cancer treatment.

V. Appendix B. List of Statutes and Regulations That Were Referenced in the COA Proposal

Statute/ Regulation	Location
42 USC § 1320a-7b. Criminal penalties for acts involving Federal health care programs	U.S. Code
42 CFR § 1001.952. Program Integrity—Medicare and State Health Care Programs. Subpart C—Permissive Exclusions. Exceptions	Code of Federal Regulations
68 FR 23731. OIG Compliance Program Guidance to Pharmaceutical Manufacturers	Federal Register
42 USC § 1396r–8. Payment for covered outpatient drugs	U.S. Code
42 CFR § 447.505. Payments for Services. Subpart 1—Payment for Drugs. Determination of best price	Code of Federal Regulations
42 USC § 1395w–3a. Use of average sales price payment methodology	U.S. Code
42 CFR § 414.804. Payment for Part B Medical and Other Health Services. Subpart J—Submission of Manufacturer's Average Sales Price Data. Basis of payment	Code of Federal Regulations