A Proposal for a Voluntary Medicare Demonstration to Support Higher Quality, More Affordable Cancer Care by Using Evidence-Based Clinical Pathways for Oncology

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OVERVIEW

There is a critical need to control the costs of cancer care in the United States, but this must be accomplished in a way that preserves and improves the ability of patients to obtain high-quality oncology services. A new cancer-focused Advanced APM is necessary to address shortcomings in both the traditional fee-for-service Medicare program and to continue building upon the first steps taken by the Oncology Care Model (OCM).

The American Society of Clinical Oncology (ASCO) developed this proposal to address unmet needs under Medicare by enabling all oncology practices to deliver higher quality care at lower cost. ASCO's proposal offers the opportunity for all oncology practices— independent, physician-owned, academic, urban, and rural – to participate in innovative approaches to cancer care delivery. ASCO's model enhances value, quality of care, and the patient experience by:

- Providing resources that better support the full range of services needed for care planning and management;
- Reducing unwarranted variation—and cost—by promoting evidence-based care; and
- Organizing reimbursement so that practices may deploy resources in a way that works for their individual setting.

Specifically, ASCO's proposal will:

**Use Evidence-Based Clinical Pathways for Oncology.** Evidence-based clinical pathways—when appropriately developed and maintained—provide an efficient, transparent, and nimble mechanism for safeguarding patients, reducing unwarranted variation in care, controlling resource use, and accommodating rapid changes in scientific discovery.

**Use Meaningful Performance Measures that Hold Practices Accountable for the Delivery of High-Value, High Quality Cancer Care.** Under this proposal, oncology practices are accountable for providing high-quality, evidence-based, and value-based care in well-defined ways:
• Avoiding unnecessary emergency department visits and hospital admissions for complications of cancer treatment;

• Following evidence-based clinical oncology pathways for the appropriate use of drugs, laboratory testing, and imaging studies (for example, using lower-cost drugs, tests, and imaging where evidence shows equivalency with higher-cost treatments and tests);

• Following evidence-based guidelines for high quality care near the end of a patient’s life; and

• Providing care consistent with the standards of quality defined by ASCO and the broader oncology community.

**Provide Fair and Flexible Payment to Support the Full Scope of Services Needed for High-Quality Patient Care.** Oncology practices would receive additional payments to support initial patient evaluation and the development of treatment plans, enhance care coordination, better support symptom management throughout the course of treatment, and deliver post treatment/survivorship services. Episode based payments would remove existing links between face-to-face physician visits and reimbursement. Instead, practices will be free to deploy resources and staff in a way that matches their practice style and setting. Services such as extended office hours, 24/7 access to practice providers, financial counseling, and psychosocial support are needed to enhance the patient experience, to prevent avoidable emergency department visits and hospitalizations, improve quality, and reduce cost of care.

**Achieve Significant Cost Savings.** This proposed demonstration project will achieve significant cost savings for the Medicare program in direct health care costs ranging between 5 to 30 percent per patient. Taking full advantage of clinical pathways for both treatment (Treatment Pathways) and the avoidance and management of complications (Triage Pathways) is labor-intensive and requires investment. However, the returns are significant, reducing health care costs for health insurers, employers, and patients.

**Promote Timely Access and Safe Administration of Oral Cancer Drugs and Protect Against Counterproductive Policies Imposed by Pharmacy Benefit Managers.** Oral anti-cancer drugs have side effects and toxicities that require the same careful monitoring and management necessary when administering traditional chemotherapy. Further, the need for timely access to treatment is no different for oral versus infused therapies. Under this demonstration project, oncology practices would receive fair and adequate financial support to manage safe delivery of oral medications. To ensure timely access to the full scope of drugs used in anticancer regimens, physician practices adhering to the requirements of this proposed demonstration would be recognized as in-network pharmacies by Medicare Part D plans and Medicare Advantage plans without administrative burdens or excessive fees from
pharmacy benefit managers or otherwise (including direct and indirect remuneration (DIR) fees).

**Permit Voluntary Participation by Oncology Providers and Medicare Beneficiaries.** Participation in this demonstration by oncology professionals should be voluntary, and Medicare beneficiaries should always have assurances that practices will identify, discuss, and honor their wishes regarding cancer care to the fullest extent possible. Nonetheless, as the largest professional society representing medical oncologists throughout the United States, we are confident that the oncology community will embrace this proposal and that the vast majority of oncology patients will be appreciative of the patient-centric approach to care, as well as the important roles that clinical pathway safeguards and quality measures play in this proposal.

**Adopt Shared Savings with Options for Two-Sided Risk.** This proposal provides a mechanism to share savings with providers, adopts two-sided risk in ways that account for the individual complexity of each patient, and relies on adherence to clinical oncology pathways that are both evidence-based and value-based. This proposal will include an innovative approach to accommodate cost outliers using private sector reinsurance to limit the risk within reasonable boundaries for individual patients or cohorts of patients with excessive costs. In this way, participating physicians will be subject to meaningful risk, but they will also be protected from unsustainable losses due to outliers that cannot be absorbed within the relatively modest size of most oncology practices.

**Increased Emphasis and Flexibility on Measures of Quality of Care.** Adherence to clinical pathways will be a key metric for quality under this proposed demonstration. Full participation in shared savings will require concordance with clinical pathways in excess of a specified percentage of qualifying patients. Participation in shared savings will also depend on costs incurred and performance on quality measures. This proposal includes the opportunity to deploy and collect data from significant numbers of sophisticated, cutting-edge quality measures developed for oncology by ASCO. ASCO maintains and continuously updates over 180 measures designed for use in medical oncology through ASCO’s Quality Oncology Practice Initiative (QOPI), QOPI Reporting Registry (QCDR), and ASCO’s QOPI Certification Program.

**Provide Data Collection Relief to Practices and Clinicians.** Reporting of pathway utilization provides patient clinical data about the individual patient (such as stage, genomic markers, line of therapy, therapy intent) without additional data submission and practice resource utilization—reducing the documentation burden of the clinician and practice.

**Address Inadequacies in the Oncology Care Model.** This demonstration design addresses limitations of the existing Oncology Care Model (OCM). In contrast to the OCM (and consequently, in contrast to traditional fee-for-service Medicare), this proposed demonstration provides:
• An opportunity to position clinical pathways for oncology in a central role to achieve higher quality and greater savings, which recognizes and integrates the care provided under this demonstration with the growing efforts of private health insurers to use clinical oncology pathways in their day-to-day operations;

• Greater accountability for providers to prevent avoidable complications and costs and to use lower-cost drugs, tests, and imaging options when supported by scientific evidence;

• A more reasonable environment to encourage providers to accept complex, challenging cases without exacerbating perverse incentives to avoid the most vulnerable and costly patients—clinical oncology pathways provide a more targeted and more fair instrument to account for drug costs rather than simplistic approaches that penalize physicians who are willing to treat patients with complicated forms of cancer that inherently have expensive treatments;

• Sufficient financial resources to provide the labor-intensive resources necessary to protect the greatest number of patients from avoidable complications that undermine quality of life and contribute significantly to the overall cost of care; and

• Options to include substantially more quality measures that can evolve on a timely basis, drawing from the cutting-edge group of over 180 measures that ASCO maintains and continuously updates as well as new measure development for oncology care.

A more detailed discussion of these elements follows below.

DISCUSSION

I. Use of Evidence-Based Clinical Pathways for Oncology.

Clinical pathways for oncology play a central role in this proposed demonstration. This reflects the growing trend among private insurers to use clinical oncology pathways as an essential tool for promoting quality, reducing undesirable variability, and ensuring the most appropriate use of financial resources in cancer care.

• In many regions of the country, the majority of cancer patients with private insurance now receive oncology care under clinical pathways.

• The use of clinical pathways often results in substantial reductions in overall costs of oncology care, including reductions of approximately one-third of costs in common types of cancer.¹

Evidence-based clinical pathways—when appropriately developed and maintained—provide an efficient, transparent, and nimble mechanism for safeguarding patients, controlling resource use, and accommodating rapid changes in scientific discovery.

The growing prevalence of clinical pathways for oncology in the private sector highlights the need for CMS to implement a demonstration in which pathways play a central role in promoting quality and controlling costs. The medical literature defines specific characteristics that should be considered under this demonstration for best practices in the design, modification, and use of clinical pathways for oncology.²

Well-designed clinical pathways provide a straightforward way to assess and reward cost-efficiency in care, and also take into account important clinical nuances among patients. There is great variability in the resources necessary to treat different forms and stages of cancer; merely comparing aggregate costs among oncology providers is a blunt instrument that creates perverse incentives to avoid patients with complex clinical cases that are expensive to treat properly.

However, properly developed clinical pathways provide a mechanism for promoting and measuring adherence to value-based guidelines, including the appropriate use of oncology drugs. Oncology pathways balance the considerations of clinical efficacy, safety, toxicities, cost, and scientific advances, including the growing customization of therapy based on molecular diagnosis.

II. **Use Meaningful Performance Measures that Hold Practices Accountable for the Delivery of High-Quality, High-Value Cancer Care.**

This demonstration requires oncology practices to provide oncology care using strategies that result in high-quality, evidence-based, and value-based care. Oncology practices would be required to meet certain performance levels in each of these areas. If they fail to meet these performance levels, the Agency could reduce supplemental payments or modify the ability of a practice to participate in shared savings.

*Avoiding emergency department visits and hospital admissions for complications of cancer treatment.* Supplemental payments available under this demonstration project will allow practices to more efficiently and effectively manage care and provide services designed to help their patients avoid complications of treatment such as nausea, dehydration, and infections rather than visiting the emergency department or being admitted to the hospital. The Medicare program would work with oncology

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practices to provide timely access to information about the emergency department and hospitalization rates for their patients.

Following evidence-based clinical oncology pathways for the appropriate use of drugs, laboratory testing, and imaging studies (using lower-cost drugs, tests, and imaging where evidence shows equivalency with higher-cost treatments and tests). As described in Section I of this document, clinical pathways are an essential tool for promoting quality, reducing undesirable variability, and ensuring the most appropriate use of financial resources for cancer care. Pathways permit sufficient flexibility to preserve decision making autonomy for oncologists and are nimble enough to evolve as new clinical evidence is developed.

Following evidence-based guidelines for high quality care near the end of a patient’s life. An initial set of guidelines draw on existing measures from ASCO’s Choosing Wisely guidelines and ASCO’s Quality Oncology Practice Initiative (QOPI). These guidelines include protections against unnecessary chemotherapy at the end of life, ensuring hospice enrollment, and effective management of pain and other symptoms. These guidelines will be updated as new evidence emerges.

Providing care consistent with the standards of quality defined by ASCO and widely-recognized by the oncology community. Participating oncology practices would agree to provide cancer care consistent with accepted standards of quality as defined by ASCO and the oncology community. Practices would be required to report on a subset of QOPI quality measures in a way that would not impose undue administrative or regulatory burden.

III. Provide Fair and Flexible Payment to Support the Full Scope of Services Needed to Provide High-Quality Patient Care.

Oncology practices would receive additional payments designed to support delivery of the full scope of high-quality services that cancer patients need. Payment would provide the resources and flexibility for practices to tailor services to the unique needs of individual patients—and to deploy staff and resources in a way that best suits their individual practice environment. Supportive services necessary to prevent avoidable emergency department visits and hospitalizations can improve quality of care and significantly reduce cost to the Medicare program.

The current payment system for oncology relies too heavily on reimbursement for a small set of in-person services. There is substantial evidence showing that providing adequate resources to an oncology care team improves the quality and value of care. As described in Section IV, savings achieved under this proposal will far exceed the investment of providing additional payments proposed in this demonstration.

There are barriers to improving beneficiary care and reducing avoidable costs in the current fee-for-service payment system, including inadequate payments for several types of services. Notably, current fee-for-service payments are insufficient for
diagnosis and treatment planning services, care management, and management of patients on clinical trials. With the rapid expansion of advanced diagnostic testing, the constant innovation in treatment options, and the growing importance of clinical trials in modern cancer care, these supplemental payments will fill longstanding and growing inadequacies in oncology reimbursement.

Under the proposed demonstration, the Medicare program would provide oncology practices with supplemental, non-visit-based payments. These payments will provide the necessary funds for care management activities that are not directly supported under the existing fee-for-service payment system. These four payment types are for new patient treatment planning, care management for treatment, active monitoring of care management, and participation in clinical trials.

For every new patient, an oncology practice would receive supplemental payments from diagnosis through six months after treatment. In addition to receiving the funds detailed above, providers are reimbursed under this proposal as they are today for services currently billable under the Medicare Physician Fee Schedule, including evaluation & management services, infusions of chemotherapy, and drugs administered or provided to patients in the practice. The new payments would represent less than a 5 percent increase in Medicare’s total spending during the period in which the patient is receiving treatment. Medicare beneficiaries would not pay cost sharing on these supplemental payments.

To develop these payment amounts, we can work with data from the National Practice Benchmark for Oncology and interviews with a sample of oncology practices to estimate the amount of time and money needed to provide the full scope of medically necessary services.

IV. **Achieve Significant Cost Savings.**

This proposed demonstration will achieve significant cost savings for the Medicare program. As described earlier in this document, this model requires the use clinical pathways and adherence to established guidelines on the appropriate use of drugs, laboratory testing, imaging studies. This model also provides payments to fund improved care management. Together, these requirements and payments will result in a net reduction of Medicare spending for cancer patients.

Even though oncology practices will receive supplemental payments, the Medicare program will achieve a net cost savings through reduced chemotherapy and drug expenditures, reduced drug test and imaging expenditures, and reduced emergency department and hospitalization expenditures. Because of lower spending per patient, Medicare beneficiaries will see reductions in out-of-pocket costs during treatment.

V. **Promote Timely Access and Safe Administration of Oral Cancer Drugs and Protect Against Counterproductive Policies Imposed by Pharmacy Benefit Managers.**
Individuals with cancer require access to oncology practices that can dispense and manage the use of oral cancer drugs in a timely and efficient manner. In many instances, the anticancer drug regimen required by each patient includes a combination of three to five different prescription drugs, including a combination of intravenous, injectable, and oral medications.

One of the keys to successful and cost-effective cancer care is to ensure that the right patient receives the right therapy at the right time. To this end, many independent oncology practices invest the resources and effort necessary to dispense oral cancer medications, providing their patients with timely access to all of the drugs therapies prescribed to treat their cancer.

This proposed demonstration includes safeguards to protect on-site dispensing of oral cancer drugs and ensure patient access to these services. The use of clinical pathways for oncology helps ensure appropriate care. In fact, private insurers typically reduce administrative burdens such as prior authorizations when oncology practices adopt clinical pathways for oncology.

To protect the interests of patients and avoid counterproductive administrative burdens, this proposal ensures that physician practices adhering to the requirements of this proposed demonstration are recognized as in-network pharmacies by Medicare Part D plans and Medicare Advantage plans without administrative burdens or excessive fees from pharmacy benefit managers or otherwise (including direct and indirect remuneration (DIR) fees).

In addition, this proposal ensures that oncology practices receive fair and adequate financial support to manage the potential side effects and oversight of anticancer regimens that include oral prescription drugs. As discussed in Sections II and III above, this proposed demonstration will ensure that providers receive the full scope of resources necessary to manage oncology care and avoid preventable complications, emergency department visits, and hospitalizations.

VI. Permit Voluntary Participation by Oncology Providers and Medicare Beneficiaries.

Participation in this demonstration by oncology professionals should be voluntary, and Medicare beneficiaries should always have assurances that their wishes regarding cancer care will be identified, discussed, and honored to the fullest extent possible.

This demonstration embraces the private sector trend to use clinical pathways for promoting high-value oncology care. When properly used, clinical pathways protect physician and patient choice by allowing variations from pathway recommendations when medically appropriate. Physician and patient choice are important considerations under this proposed demonstration. The optimal use of clinical pathways in oncology allows for treatment of some patients “off-pathway” based on the details of individual situations and preferences. Inherent in the use of pathways is the understanding that
some acceptable percentage of deviation from pathway recommendations is both allowed and expected. In fact, as described in the medical literature, 100 percent concordance with pathway recommendations is often a red flag for low quality of care.⁴

As the largest professional society representing medical oncologists throughout the United States, we anticipate that the oncology community will embrace this proposal and that the vast majority of oncology patients will be appreciative of the patient-centric approach to care, as well as the important roles that clinical pathway safeguards and quality measures play in this proposal.

VII. **Adopt Shared Savings with Options for Two-Sided Risk.**

This proposal provides a mechanism to share savings with providers and adopt two-sided risk in ways that account for the individual complexity of each patient, taking into consideration adherence to clinical oncology pathways that are both evidence-based and value-based.

This proposed demonstration will allow providers to share in two-sided risk and provide a financial incentive to enhance the management of care for cancer patients. The risk sharing is based on setting episodic budgets based on the phase of treatment while taking into account individual characteristics that have direct impacts on the labor-intensity and cost of providing high-quality, high-value care for each patient—including characteristics such as type, stage, and genetic mutation associated with each patient’s disease.

These risk adjustment data are essential to develop treatment episodes that are fair to providers and that set appropriate financial incentives for providers to accept and treat patients with particularly challenging types and stages of cancer.

Budgets that are adaptable to each phase of treatment ensure fair and accurate measurement of the cost of providing cancer treatments and minimizing avoidable complications. This proposal includes three phase-based and risk adjusted budgets: (1) new patient phase; (2) treatment phase; and (3) active monitoring phase. The New Patient budget is based on the costs of practice services and testing that the practice orders for a new patient before treatment begins. The Treatment Budget would include the costs of practice services and the expected costs of drugs, hospital emergency department visits, hospital admissions, and laboratory and other testing while cancer treatment is underway. The Active Monitoring Budget is based on practices services and testing that is ordered for the patient after treatment concludes.

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We anticipate that the initial year of this demonstration project will focus on data collection for establishing benchmarks, and as a result, shared savings and risk will be deferred to the second year of the demonstration. Once clinically appropriate budgets reflecting the phase of care are established, CMS and private payers would assess whether an oncologist effectively managed care by determining if the costs of care exceed, match or are less than the budgeted amount. Oncologists would be eligible to share in any savings that fall below the budget while they would be required to share in losses that result from exceeding the budgeted amount.

Certain safeguards are required to encourage the treatment of complex patients and to protect oncologists from unfair and counterproductive financial penalties when treating high-risk, costly, or especially complex patient populations. This proposal will include an innovative approach to account for cost outliers using private sector reinsurance to limit the risk within reasonable boundaries for individual patients or cohorts of patients with excessive costs. In this way, participating physicians will be subject to meaningful risk, always maintaining significant “skin in the game.” However, they will also be protected from unsustainable losses due to outliers that cannot be reasonably absorbed within the relatively modest size of most oncology practices. Physician practices that demonstrate ongoing patterns of cost outliers are likely to incur increased fees for reinsurance.

VIII. Increased Emphasis and Flexibility on Measures of Quality of Care.

Adherence to clinical pathways will be a key metric for quality under this proposed demonstration. Full participation in shared savings will require concordance with clinical pathways in excess of a specified percentage of qualifying patients. Participation in shared savings will also depend on costs incurred and performance on quality measures.

This proposal recognizes the need for ensuring the use of measures that are meaningful for oncology care while ensuring that the resources and effort invested in measure reporting is worthwhile and valuable to improve patient care. The proposed demonstration will facilitate improvements in the quality of care by requiring participants to report data on a robust set of cancer specific quality measures that are based on ASCO’s Quality Oncology Practice Initiative (QOPI). There are longstanding and well known gaps in CMS quality reporting for specialty areas of medicine, and this is especially problematic in oncology. The current quality measure sets used in MIPS fall short of the clinical specificity needed to promote improvements in cancer care.

In stark contrast to the MIPS measures for oncology, QOPI consists of over 180 cancer specific measures that have gained widespread acceptance in the oncology community. The proposed demonstration would require providers to meet or exceed the QOPI performance benchmarks and focus on high-priority QOPI measures including those related to end of life care. A practice that receives QOPI Certification would be deemed to have met the model’s quality standards.
In addition, this demonstration would create safeguards to protect and reward physician practices that opt to report on measures that are challenging or difficult. In this way, the proposal would eliminate the counterproductive incentives that exist under MIPS to identify measures that give the greatest chance of avoiding a penalty. As implementation progresses, the demonstration will provide flexibility to adopt new oncology-specific measures that reflect cutting-edge trends in oncology care.

Robust quality measures and appropriate use guidelines are necessary to protect patients from underutilization. This demonstration embraces the use of clinical pathways to reduce undesired variations in drug utilization and ensure that oncology professionals select the right drug, for the right patient, at the right time.

IX. **Provide Data Collection Relief to the Practice and Clinician.**

Reporting of pathway utilization provides patient clinical data about the individual patient (such as stage, genomic markers, line of therapy, therapy intent) without additional data submission and practice resource utilization—reducing the documentation burden of the clinician and practice.

X. **Address Inadequacies in the Oncology Care Model.**

This proposed demonstration addresses limitations in the existing OCM. In contrast to OCM (and consequently, in contrast to traditional fee-for-service Medicare), this proposed demonstration provides:

- An opportunity to position clinical pathways for oncology in a central role to achieve higher quality and greater savings, which recognizes and integrates the care provided under this demonstration with the growing efforts of private health insurers to use clinical oncology pathways in their day-to-day operations;

- Reporting of pathway utilization provides patient clinical data about the individual patient (including stage, genomic markers, line of therapy, therapy intent) without additional data submission and practice resource utilization—reducing the documentation burden of the clinician and practice

- Greater accountability for providers to prevent avoidable complications and costs and to use lower-cost drugs, tests, and imaging options when supported by scientific evidence;

- A more reasonable environment to encourage providers to accept complex, challenging cases without exacerbating perverse incentives to avoid the most vulnerable and costly patients—clinical oncology pathways provide a more targeted and more fair instrument to account for drug costs rather than simplistic approaches that penalize physicians who are willing to treat patients with complicated forms of cancer that inherently have expensive treatments;
• Sufficient financial resources to provide the labor-intensive resources necessary to protect the greatest number of patients from avoidable complications that undermine quality of life and contribute significantly to the overall cost of care; and

• Options to include substantially more quality measures that can evolve on a timely basis, drawing from the cutting-edge group of over 100 measures that ASCO maintains and continuously updates for oncology care.

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We look forward to discussing this proposed demonstration. Please contact Sybil Green at (571) 483-1620 with any questions or follow up.