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Via Electronic Submission

December 10, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Oncology Care First Model: Informal Request for Information

Dear Administrator Verma:

The American Society of Clinical Oncology (ASCO) appreciates your Request for Information (RFI) on the conceptualized Oncology Care First (OCF) payment model. We recognize recent efforts by the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) to engage the medical community in the development and improvement of its payment models.

ASCO is the national organization representing over 45,000 physicians and other health care professionals specializing in cancer prevention, diagnosis, and treatment. ASCO members are dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidenced- based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans, including Medicare beneficiaries and Medicaid enrollees.

ASCO has long been a proponent of evolving the current Medicare payment model to better enable advancement of high-quality, well-coordinated cancer care. In 2014, we released our first major work product of such efforts, entitled Consolidated Payments for Oncology Care (CPOC), followed the next year by the Patient-Centered Oncology Payment Model (PCOP). Since that time, we have strived to be a resource for CMS and the Innovation Center, sharing additional ideas for improving cancer care, including our work on Clinical Treatment Pathways.¹

¹ In 2016, ASCO published a Policy Statement on Clinical Pathways in Oncology, followed by Criteria for High-Quality Clinical Pathways in Oncology, and an assessment of four prominent pathways organizations. See <https://www.asco.org/practice-guidelines/cancer-care-initiatives/clinical-pathway>.

Making a world of difference in cancer care

In the RFI, the Innovation Center asks precise questions about ways to improve and evolve the current Oncology Care Model. Our comments below are based on ASCO's own research into alternative payment strategies and we offer them in response. We have also attached a copy of our recently updated PCOP model for consideration as you move forward.

The potential OCF Model would seek to improve health outcomes and quality of care for Medicare beneficiaries with cancer. How could the potential model support participants' care transformation through practice redesign activities? Specifically, how could the potential model build on lessons learned from the implementation of the practice redesign activities included in the Oncology Care Model (OCM)? What revisions or additions should be made to the OCM practice redesign activities in the potential model?

ASCO encourages the inclusion of Clinical Pathways in OCF.

ASCO recommends that clinical pathways be included in OCF as a care redesign activity, along with pathway adherence as both a quality and a cost measure. Pathway adherence would be used in lieu of including oncolytic drugs in the cost-of-care measurement.

High-quality oncology clinical pathways are detailed, evidence-based treatment protocols that guide care for patients with specific types and stages of cancer. When properly designed and implemented, oncology pathways can serve as an important tool in improving care quality and reducing costs. Often imbedded within real-time, online decision-support tools, clinical pathways have demonstrated decreased hospitalizations and drug costs.^{2,3,4}

Based on growing evidence that demonstrates the impact of pathways in achieving consistent delivery of evidence-based, high value care, ASCO has embedded use of pathways as a core element of the updated PCOP model and adherence to pathways as a key care redesign activity and quality metric. Because cost is factored into pathway recommendations for therapeutically similar or equivalent treatments, pathways adherence may be used as a meaningful surrogate for drug costs. This holds providers accountable for appropriate utilization, not the list price of drugs, which is not in their control.

Clinical pathways are appropriately integrated into any value-based model and ASCO is eager to work with the Agency to explore ways in which pathways can further its goal of delivering high-quality, value-based cancer care.

² See Hoverman JR, Cartwright TH, Patt DA, et al: Pathways, outcomes, and costs in colon cancer: retrospective evaluations in two distinct databases. *J Oncol Pract* 7, 52s-59s, 2011

³ Neubauer MA, Hoverman JR, Kolodziej M, et al: Cost effectiveness of evidence-based treatment guidelines for the treatment of non-small-cell lung cancer in the community setting. *J Oncol Pract* 6(1), 12-18, 2010

⁴ Gautam S, Sylwestrzak G, Barron J, et al: Results from a health insurer's clinical pathway program in breast cancer. *J Oncol Pract*, e711-e721, 2018

CMS should allow for flexibility in the use of patient reported outcomes (PROs).

ASCO has supported the development of methods and evidence for use of patient-reported outcomes (PROs) in clinical oncology care. ASCO has had an active PRO Task Force since 2012 and has partnered in two ongoing national trials evaluating PROs in routine care settings for improving outcomes and assessing quality of care. Scientific evidence supports the value of PROs in symptom monitoring as a mechanism for improving the patient experience, communication, symptom control, quality of life, reducing emergency room visits, increasing tolerability of cancer treatment, and, in two randomized controlled trials, improving overall survival.^{5,6} Despite this evidence, implementation of PROs in routine cancer care has been limited, in part because of reimbursement issues. Inclusion of PROs as a requirement of OCF may provide the necessary incentive and support for practices to implement and sustain this practice enhancement.

Although use of PROs has shown benefit, there are unique challenges associated with their implementation. These include additional time for information collection and direct interaction with patients, modification of workflow, potential requirements for new technology, and even alterations in practice culture. Adjustments must be made address unique regional, cultural, economic, and language challenges facing each practice's patient population. There is a risk of low uptake by patients if implementation is not adequately supported by staff, workflow changes, and training.

For these reasons, we support gradual uptake of PROs. An appropriate approach could include a suggested timeline, for example: identification of a PRO data collection strategy and workflow modification plan in year 1; pilot PRO implementation in selected clinics in year 2; broader rollout in year 3; performance evaluation in year 4 (including reporting of compliance rates and provider clinical management responses to PRO reports); and accountability/performance measures in year 5.

PRO measures should be valid, reliable, and sensitive, as well as publicly available. The National Institutes of Health (NIH) have developed tools that meet these criteria: the PRO-CTCAE and PROMIS. A workgroup and document with suggested procedures would be helpful to provide recommended standards and standardization for technology, workflow, and PRO approach, such as specific symptoms to consider collecting; other domains such as physical function or financial toxicity to consider; timing and frequency of PRO collection; ideal software attributes and functionality; alert algorithms; approaches to training staff (particularly navigators) and patients; potential staff standard procedures for addressing PRO alerts and reports; and assessment metrics.

Practice transformation is difficult, and PRO implementation may not be immediately successful, requiring successive iterations and co-learning between practices to refine the approach. ASCO supports, as suggested by speakers at the open session, dedicated funds to support practice adoption of

⁵ Basch E, Deal AM, Dueck AC, et al. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment. *JAMA*. 2017;318(2):197–198. doi:<https://doi.org/10.1001/jama.2017.7156>

⁶ Basch E, Barbera L, Kerrigan CL, and Velikova G: Implementation of Patient-Reported Outcomes in Routine Medical Care. *American Society of Clinical Oncology Educational Book 2018*:38, 122-134

PROs. PROs are key for understanding the patient experience and engaging patients in care. Therefore, despite the inevitable initial challenges and setbacks, with adequate resources and foresight, evidence suggests that they will result in high rates of patient compliance and clinical benefits.

Care redesign activities should mirror the principles of the oncology medical home delivery model and provide a multi-tiered path to adoption.

ASCO and the Community Oncology Alliance have conducted significant work in improving the delivery of cancer care through development of a comprehensive oncology medical home model. In doing so, we recognize the considerable investment being made by practices to transform their care teams. We believe that, rather than requiring practices to comply with all care design activities within six months, OCF should consider differences in care delivery and practice readiness among new practices, i.e. those who have not participated in OCM the past five years, as compared to current OCM practices who have already worked through significant practice transformation.

ASCO's PCOP does this by offering two tracks to allow practices at varying stages of transformation to engage at a level that allows for successful participation. In Track 1, practices must deliver certain entry level care transformations and in Track 2, practices that have already begun to adopt oncology medical home standards must demonstrate performance on a more complete set of requirements.

PCOP includes care delivery requirements in the following categories:

- Patient Engagement
- Availability and Access to Care
- Comprehensive Team-Based Care
- Quality Improvement
- Safety
- Evidence-Based Medicine
- Technology

Offering a way for broad participation by diverse practices will speed the practice transformation that is critical to achieving the Administration's—and the broader community's—goal for transition to a value based payment system.

We welcome feedback on the potential payment methodology, including the structure and design of the monthly population payment and the performance-based payment. We are considering the inclusion of additional services in the monthly population payment, such as imaging or lab services, and seek feedback on adding these or other services to the monthly population payment.

CMS should not include imaging or lab services in the monthly population payment at this time.

ASCO previously analyzed potential impact of including imaging and laboratory services in our alternative payment models. We found significant variation in the timing and delivery of such services, indicating that they are too unstable for inclusion in a standardized model design at this time. For

example, next generation sequencing in lung cancer may be performed prior to the initiation of a first-line therapy, in which case it would not be captured in an OCF episode. It could also be performed after initial treatment failure. Depending on timing, this could be captured in the OCF episode. Also, sequencing may be performed in-house through use of a commercially available NGS platform—or it might be referred to another clinical genomic laboratory. There are many other questions, including whether providers would be responsible for services outside of the participating physician group practice (PGP) and hospital outpatient department (HOPD), how the timing of certain diagnostic tests would affect cost performance (e.g., do some episodes show tests predating the trigger event, how would OCF account for such variation, how would OCF adjust payments for developments/coverage of new diagnostic tools, etc.⁷). There are many uncertainties that must be addressed before moving forward with this proposal.

As an alternative to including imaging or lab services in the monthly population payment, we recommend that CMMI study how comprehensive clinical pathways may be used not only to address drug costs, but also appropriate use of diagnostic services, as an alternative to prior authorization or fragmented decision-support tools.

CMS should reconsider recoupment of the monthly population payment (MPP).

For an innovative payment model to work, it must provide some degree of stability in expected payments to a practice. In the OCF, CMS is proposing to continue performance-based payments (PBPs) that are linked, at least in part, to quality measures as well as target benchmarks. This methodology is not unlike the current OCM and is familiar to current and potential participants. However, CMS also is proposing potential recoupment of a portion of the MPP if subsequent reconciliation reveals an “overpayment” based on retrospective analysis of case mix. This would put practices at risk for a “claw back” of payment that has already been made and applied toward enhancing patient services in the practice. Further, such recoupment is not based on performance, and is based on conditions beyond the control of the practice. If a practice is essentially asked to guess how much of their MPP they may have to return to CMS, it will be difficult for the practice to commit to using this resource for practice redesign and to enhance patient services, which would seem to negate the point of the MPP.

We encourage feedback on the conceptualized risk arrangements, in particular, how a downside risk arrangement might be best constructed in terms of the level of risk.

CMS should consider an alternative to the total cost-of-care methodology.

ASCO has previously shared its concern with current risk arrangements included in OCM. Specifically, ASCO does not support holding physicians responsible for the list price of drugs. Instead, physicians should be held accountable for utilization of services, including drugs. Feedback from OCM participants

⁷ On October 29, 2019, CMS released a proposed decision memo for next generation sequencing in some advanced cancers. <https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=296>

has revealed that the OCM prediction model fails to account for the appropriate utilization for high-priced drugs, disadvantaging providers who specialize in certain cancers.^{8,9}

With PCOP, ASCO has shown that there is an alternative methodology that CMS can successfully adopt for its payment methodology. In summary, PCOP makes variable a portion of its monthly care management and consolidated payments, with payments adjusted based on performance against quality, cost, and pathway adherence measures. Rather than requiring practices to develop in-house expertise in actuarial science or direct a portion of payments to reinsurance premiums, this methodology provides for prospective adjustments to revenue based on past performance.

Alternatively, CMS should extend the one-sided risk track

CMS has proposed that practices currently in the OCM that move to the OCF would automatically participate in two-sided risk (financial upside and downside), while practices coming into the OCF without OCM experience may be allowed the option of a one-sided risk track (financial upside only) for a limited time (e.g., the first year). CMS also proposes multiple two-sided risk tracks: moderate risk on Track A and a more aggressive Track B, where risk would be defined as a percent of the PGP participant's episode benchmark amount.

We are concerned that limiting new practices' participation in the one-sided risk track to only one year provides insufficient time to tackle the challenges associated with practice transformation and patient access to primary care and other ambulatory services. The lack of an adequate transition period for new practices, plus a requirement for immediate assumption of two-sided risk for current OCM practices, may discourage otherwise-qualified practices from participating in the OCF. In the OCM as currently structured, a small percentage of practices opted for two-sided risk, and it is not clear that a restructured OCF would remove enough of the barriers to assumption of two-sided risk that it would be feasible for any but the largest practices.

We encourage CMS to fully leverage the one-sided track as an on-ramp for new practices to an advanced oncology APM with two-sided risk. This would allow both for initial participation by a greater mix of practices, and move more practices toward two-sided risk on a schedule that gives them time to invest in and become confident with practice redesign prior to taking on financial risk that could prove devastating if managed incorrectly.

⁸ Lyss AJ, Supalla SN, Schleicher SM. The Oncology Care Model—Why It Works and Why It Could Work Better: Accounting for Novel Therapies in Value-Based Payment. *JAMA Oncol*. Published online October 31, 2019. doi:<https://doi.org/10.1001/jamaoncol.2019.4385>

⁹ Theroux HH, Isola LM, Liu M, Williams A. Influence of pomalidomide and lenalidomide on total cost of care for Medicare beneficiaries with multiple myeloma under the oncology care model (OCM). *Blood*. 2018;132(suppl 1):2252. doi:10.1182/blood-2018-99-116657

We invite feedback on the interest of physician group practices (PGPs) and hospital outpatient departments (HOPDs) in participating in a potential OCF Model. We are particularly interested in hearing from PGPs and HOPDs about the conceptualized participation eligibility parameters (e.g., the grouping concept), and whether they think that meeting those parameters would be feasible. We also invite feedback from potential payer partners, including commercial payers and state Medicaid agencies. We welcome suggestions about the model concept that would better incentivize participation in the potential model.

CMS should solicit further input from the payer community as to the barriers for true multi-payer participation.

The Innovation Center has previously reported that 10 payers are currently participating in OCM, with 56 practices participating with one or more payer. We encourage CMS to explore why there is a lack of uptake from the payer community and how to solve for this in the OCF model. It should be noted that CMS has been successful developing multi-payer models, such as Comprehensive Primary Care Plus. In updating the PCOP model, ASCO included representatives from the payer community, which led to the creation of “PCOP Communities,” consisting of providers, payers, employers, and others to implement a multi-stakeholder model.

ASCO recommends that CMS adopt the Patient-Centered Oncology Payment model.

We recently released a major update to our Patient-Centered Oncology Payment (PCOP) model, an alternative payment model designed to support transformation in cancer care delivery and reimbursement while ensuring that patients with cancer have access to high-quality, high-value care. The updated model reflects lessons learned from previous demonstration programs, including a PCOP pilot in New Mexico.

PCOP transforms cancer care using three major approaches: improved care delivery and coordination through an oncology medical home framework, which has shown improved outcomes and reduced costs; a performance based reimbursement system that relies on patient-centered standards and transitions to bundled payments; and consistent delivery of high quality care using clinical pathways that adhere to ASCO criteria.

Modeling all-payer data from the Maine Health Data Organization, ASCO has projected significant potential for PCOP to yield cost savings—up to 8% across the healthcare system. The model accommodates diverse practices and care settings and is designed to guide participants through the implementation process.

Through the framework laid out in the PCOP model, we believe CMS can achieve its goal of a truly multi-payer model that improves care delivery and reduces costs. Paired with initiatives such as the Comprehensive Primary Care Plus model, PCOP offers communities the tools and flexibility to address their pressing local health needs. We encourage CMS to adopt this model also, either under CMMI or through waiver authority to local contractors.

We appreciate the opportunity to provide feedback on this new concept and look forward to working with you as you move forward. We are happy to answer any questions you might have about our comments or ASCO's PCOP model. Please don't hesitate to contact Brian Bourbeau at brian.bourbeau@asco.org with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Howard A. Burriss III". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Howard A. "Skip" Burriss III, MD, FACP, FASCO
President, American Society of Clinical Oncology

enclosure