



National Comprehensive
Cancer Network®

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NCCN Member Institutions

Abramson Cancer Center
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Fred & Pamela Buffett
Cancer Center

Case Comprehensive Cancer
Center/University Hospitals
Seidman Cancer Center and
Cleveland Clinic Taussig
Cancer Institute

City of Hope National Medical Center

Dana-Farber/Brigham and
Women's Cancer Center
Massachusetts General Hospital
Cancer Center

Duke Cancer Institute

Fox Chase Cancer Center

Huntsman Cancer Institute
at the University of Utah

Fred Hutchinson Cancer
Research Center/
Seattle Cancer Care Alliance

The Sidney Kimmel
Comprehensive Cancer
Center at Johns Hopkins

Robert H. Lurie Comprehensive
Cancer Center of Northwestern
University

Mayo Clinic Cancer Center

Memorial Sloan Kettering
Cancer Center

Moffitt Cancer Center

The Ohio State University
Comprehensive Cancer Center -
James Cancer Hospital and
Solove Research Institute

O'Neal Comprehensive
Cancer Center at UAB

Roswell Park Comprehensive
Cancer Center

Siteman Cancer Center
at Barnes-Jewish Hospital
and Washington University
School of Medicine

St. Jude Children's
Research Hospital/
The University of Tennessee
Health Science Center

Stanford Cancer Institute

UC San Diego
Moore's Cancer Center

UCSF Helen Diller Family
Comprehensive Cancer Center

University of Colorado
Cancer Center

University of Michigan
Rogel Cancer Center

The University of Texas
MD Anderson Cancer Center

University of Wisconsin
Carbone Cancer Center

Vanderbilt-Ingram
Cancer Center

Yale Cancer Center/
Smilow Cancer Hospital

December 13, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Oncology Care First Model: Informal Request for Information

Dear Administrator Verma:

The National Comprehensive Cancer Network® (NCCN®) is pleased to comment on the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (Innovation Center) Oncology Care First Model: Informal Request for Information (RFI) as it relates to NCCN's mission of improving and facilitating, quality, effective, efficient, and accessible cancer care. NCCN appreciates CMS's continued efforts to move toward value based care in oncology. NCCN applauds CMS and the Innovation Center for investing in the development of the Oncology Care Model (OCM) and building on lessons learned from OCM with the proposal of the Oncology Care First Model. NCCN appreciates the opportunity to provide feedback on the proposed model and will focus our remarks on the Participant Redesign and Payment Methodology sections of the Request for Information.

NCCN Background

As an alliance of 28 leading academic cancer centers in the United States that treat hundreds of thousands of patients with cancer annually, NCCN is a developer of authoritative information regarding cancer prevention, screening, diagnosis, treatment, and supportive care that is widely used by clinical professionals and payers alike. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States.

NCCN Guidelines® and Library of Compendia products help ensure access to appropriate care, clinical decision-making, and assessment of quality improvement initiatives. The NCCN Drugs & Biologics Compendium (NCCN Compendium®) has been recognized by CMS and clinical professionals in the commercial payer setting

since 2008 as an evidence-based reference for establishment of coverage policy and coverage decisions regarding off-label use of anticancer and cancer-related medications. NCCN was recognized by CMS in 2016 as a qualified Provider Led Entity (PLE) for the Medicare Appropriate Use Criteria (AUC) Program for the development of AUC and the establishment of policy and decision-making for diagnostic imaging in patients with cancer.

NCCN imposes strict policies to shield the guidelines development processes from inappropriate external influences. The “firewall” surrounding the NCCN Guidelines processes includes: financial support policies; panel participation and communication policies; guidelines disclosure policies; and policies regarding relationships to NCCN’s other business development activities. The guidelines development is supported exclusively by the Member Institutions’ dues and does not accept any form of industry or other external financial support for the guidelines development program. The NCCN Guidelines are updated at least annually in an evidence-based process integrated with the expert judgment of multidisciplinary panels of expert physicians from NCCN Member Institutions. The NCCN Guidelines are transparent, continuously updated, available free of charge online for non-commercial use and through a multitude of HIT vendors.

Model Timing

NCCN agrees with the Innovation Center that the implementation of OCF should be timed in such a way that it does not disrupt care for current OCM participants. The Innovation Center notes that OCM is scheduled to end in mid-2021 with six-month episodes initiating no later than December 31, 2020, and proposes that the OCF Model start in January 2021. NCCN agrees with this timeline but urges CMS to publish a proposed model with adequate detail in an expedient manner allowing ample time for stakeholder evaluation and feedback.

Participant Redesign Activities

The proposed OCF Model retains the six participant redesign activities included within OCM and adds an additional activity “gradually implement electronic patient-reported outcomes (ePROs)”. NCCN applauds these proposals as initiatives that have helped to move the field of oncology toward high-quality, patient-centered cancer care. NCCN particularly applauds the incorporation of guideline adherent care, patient navigation, care coordination, and patient reported outcomes.

Guideline Adherence

NCCN would like to thank the Innovation Center for proposing the continued requirement of adherence to nationally recognized guidelines as a method to ensure quality of care. As previously mentioned, the NCCN Guidelines are transparent and continuously updated, ensuring Guidelines are reflective of the most current and comprehensive body of clinical evidence available. Numerous independent studies have proven that adherence to NCCN Guideline concordant care changes care delivery and improves outcomes for patients. Impacts proven through concordance with our Guidelines include: improved rates of survival for colon cancer, ovarian cancer, gastric cancer, nasopharyngeal cancer, and pancreatic cancer; decreased locoregional recurrence of melanoma; and improved pain control.^{1,2,3,4,5,6} These studies underscore the importance of guideline adherence as a baseline to ensure patient access to appropriate clinical care.

Adherence to Guidelines also reduces health care costs. A peer-reviewed, published study by UnitedHealthcare, eviCore and NCCN entitled “Transforming Prior Authorization to Decision Support” demonstrated mandatory adherence to NCCN Guidelines and NCCN Compendium significantly reduced total and episodic costs of care. In Florida, UnitedHealthcare adopted an integrated prior authorization tool using NCCN real-time decision support over a one-year period and explored 4,272 eligible cases; only 42 denials occurred. Specifically, the study found that adding decision support to prior authorization reduced denials from 4 to 1 percent. When compared to UnitedHealthcare’s cancer drug costs nationwide, the study found that mere adherence to NCCN Guidelines and Compendium reduced chemotherapy drug cost trends by 20 percent; a savings of \$5.3 million for the State of Florida. Administrative burden was also reduced through the integration of the decision-making tool as the majority of prior authorization requests were approved immediately; the remaining requests were approved within 24 hours.⁷

Additionally, a recently published study "Guideline Discordance and Patient Cost Responsibility in Medicare Beneficiaries With Metastatic Breast Cancer" by Williams, et.al found median cost for metastatic breast cancer patients receiving guideline-

1 Foster, et al., *Annals of Surgical Oncology* 2008 15:2395-2402; doi: 10.1245/s10434-008-0021-0
<https://www.ncbi.nlm.nih.gov/pubmed/18600380>

2 Visser, et al., *Journal of International Hepato-Pancreato-Biliary Association* 2012 14(8): 539-547; doi: 10.1111/j.1477-2574.2012.00496.x <https://www.ncbi.nlm.nih.gov/pubmed/22762402>

3 Bristow, et al., *Journal of the National Cancer Institute* 2013 105(11):823-832; doi: 10.1093/jnci/djt065
<https://www.ncbi.nlm.nih.gov/pubmed/23539755>

4 Bristow, et al., *Gynecologic Oncology* 2014 132(2):403-410; doi: 10.1016/j.ygyno.2013.12.017
<https://www.ncbi.nlm.nih.gov/pubmed/24361578>

5 Mearis, M, Shega, JW, and Knoebel, RW *Journal of Pain and Symptom Management* 2013 48(3) 451-458; doi: 10.1016/j.jpainsymman.2013.09.016 <https://www.ncbi.nlm.nih.gov/pubmed/24439844>

6 Schwam et al., *Clinical Oncology* 2016 28(6):402-409; doi: 10.1016/j.jpainsymman
<https://www.ncbi.nlm.nih.gov/pubmed/26868285>

⁷ Lee N. Newcomer, Richard Weininger, and Robert W. Carlson, *Journal of Oncology Practice* 2017 13:1, e57-e61,
<http://ascopubs.org/doi/full/10.1200/JOP.2016.015198>

discordant treatment was \$7,421 versus \$5,171 for those receiving guideline-concordant care⁸. In adjusted models, guideline-discordant treatment was significantly associated with \$1,841 higher patient out-of-pocket costs. Guideline adherence within value-based models like OCM and now OCF show potential to improve quality of care, efficiency of care and affordability of care.

Care Coordination and Patient Navigation Services

The OCF model proposes to continue the requirement that participating Physician Group Practices “provide the core functions of patient navigation” and “document a care plan for beneficiaries that contains the 13 components of the Institute of Medicine’s (IOM) Care Management Plan”. NCCN agrees that these services are integral to moving oncology toward patient-centered care and applauds the Innovation Center for building on the success of these activities within OCM.

Electronic Patient Reported Outcomes (ePROs)

NCCN agrees with CMS that Patient Reported Outcomes are a valuable tool and should be collected. A recent survey on utilization of PROs at NCCN Member Institutions found that the overwhelming majority of sites collected the Patient Health Questionnaire (PHQ), in either PHQ-2 or PHQ-9 format. Additionally, many providers use validated instruments like the PROMIS tool. NCCN appreciates that CMS notes the timeline for implementation should be gradual given current Health Information Technology (HIT) PRO products are not widely available. NCCN has heard from members that most validated PRO tools do not currently have the capability to integrate into Electronic Health Records. As such, NCCN supports the inclusion of ePROs within the model but encourages CMS to implement a timeline that allows technology to catch up to practice.

Access to Meaningful Data to Improve Care Delivery

NCCN supports the continued inclusion of the participant redesign activity “utilize data for continuous quality improvement”. NCCN has heard from numerous OCM participants that having access to their data has been transformative to their ability to improve care. However, NCCN has also heard feedback that it would be helpful to receive the data in a more timely manner. As such, NCCN encourages CMS to consider mechanisms that may expedite participants’ receipt of data.

Quality Measurement

NCCN believes the optimal way to ensure quality care while improving value, and reducing clinical burden is through evidence-based care. In 2016 NCCN established an advisory committee, the NCCN Quality and Outcomes Committee, comprised of experts from NCCN Member Institutions and other stakeholders, including payers,

⁸ Williams et al., Journal of the National Comprehensive Cancer Network 2019 17(10) doi: <https://doi.org/10.6004/jnccn.2019.7316>

patient advocacy, community oncology, and health information technology representatives. The Committee was charged to review the existing quality landscape, and identify contemporary, relevant cancer quality and outcomes measures by both evaluating current validated measures and proposing new measure concepts to fill crucial gaps. The Committee's first manuscript outlining the review process is expected to be published in early 2020 and contains an endorsement of high-impact oncology measures. Endorsed measures include cross-disease and disease-specific measures. NCCN encourages the Innovation Center to consider these measures for inclusion within the model. NCCN would be happy to discuss these high impact measures and their applicability within the OCF in additional detail following publication.

Payment Methodology

NCCN appreciates that the RFI as written is intended to be an initial framework of the model. However, without additional detail on the formulas the Innovation Center intends to use for the Monthly Population Payment (MPP), Performance Based Payment (PBP), and risk stratification it is not possible to provide comment on the impact these mechanisms are likely to have.

The Informal RFI as written contains a number of areas requiring further clarification. The MPP will include a management component and an administration component but it is unclear how variance in therapy delivery methods (e.g. oral vs infused chemotherapies) will be accounted for. Additionally, if a new therapy is introduced to the market requiring multiple visits, how will this cost be accounted for? It is also unclear whether the benchmarking will be based on OCM practices or national benchmarks. Additionally, the Innovation Center states that for the PBP, the benchmark will be *"based on a combination of PGP participant-specific, regional, and national historical Medicare payments during episodes from the baseline period."* While it is challenging to assess the exact impact of this proposal without further detail, NCCN has concern that the proposed benchmark may unintentionally punish historically efficient practices and practices currently participating in OCM that are likely to have already maximized cost savings. NCCN encourages CMS to consider ways to reward rather than punish historically efficient practices.

NCCN also has concern about the proposal to require current OCM practices to assume 2-sided risk immediately. The Innovation Center states that *"The potential OCF Model would require all PGP participants that participated in OCM to be in two-sided risk for the full duration of their participation in the OCF Model."* Early adopters of value based delivery and payment models should be rewarded for their willingness to innovate. Holding current OCM practices to a higher standard may unintentionally

send a poor message and act as a disincentive to providers considering early adoption of future value-based models.

Value-based models may unintentionally incentivize under-utilization of services, particularly for higher-cost innovative therapies. The RFI notes the Innovation Center is considering “*making the novel therapies adjustment at the cancer type level rather than the participant level as is done in OCM.*” NCCN believes that the proposal to make the adjustment at the cancer type level is a positive step toward reducing the disincentive to provide novel therapies when clinically appropriate.

NCCN appreciates the opportunity to respond to the CMS and Innovation Center Oncology Care First Model: Informal RFI. We welcome the opportunity to discuss our comments further and look forward to working together to ensure Medicare beneficiary timely access to high-quality cancer care.

Sincerely,

A handwritten signature in black ink, appearing to read 'Robert W. Carlson', with a stylized flourish at the end.

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