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August 31, 2022

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

RE: Request for Information on Medicare (CMS-4203-NC)

Dear Administrator Brooks-LaSure:

The National Comprehensive Cancer Network[®] (NCCN[®]) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services (CMS) Request for Information on Medicare (CMS-4203-NC) as it relates to NCCN's mission of improving and facilitating, quality, effective, equitable, and accessible cancer care. NCCN thanks CMS for releasing this important RFI with the goal of advancing equitable, high quality, and whole-person care that is affordable and sustainable for all Medicare beneficiaries. NCCN is pleased to provide information and resources to assist in this effort. NCCN's comments will focus on the role of clinical practice guidelines in reducing health inequities, opportunities to reduce disparities in access to guideline adherent care, opportunities to measure and incentivize equitable practice among Medicare Advantage provider networks including the Health Equity Report Card, steps Medicare Advantage plans can take to address Social Determinants of Health (SDOH), and the importance of network adequacy.

NCCN Background

As an alliance of 32 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 and renewed in 2021 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 is an alliance of leading cancer centers dedicated to improving and facilitating quality, effective, equitable, and accessible cancer care so all patients can live better lives.

NCCN imposes strict policies to shield the guidelines development processes from 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 are available through a multitude of health information technology (HIT) vendors.

Guideline Adherence as a Tool for Equity

Within the RFI, CMS requests information on steps that should be taken to ensure Medicare beneficiaries can access optimal care as well as examples of innovations to advance equitable care access. NCCN encourages CMS to work with Medicare Advantage plans to ensure greater beneficiary access to guideline adherent care which offers an important tool for equitable care. CMS may consider working with MA plans to leverage Clinical Decision Support Mechanisms (CDSM) to reduce prior authorization burden and unnecessary delays in care while also improving patient access to the highest quality of care.

Numerous independent studies have found adherence to NCCN Guidelines improves care delivery and outcomes for patients with cancer. Improved health outcomes proven through concordance with NCCN 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}. Medicare as well as many payers currently use NCCN Guidelines for coverage determinations. Non-adherence to guidelines has also been identified as a key contributor to inequities in care outcomes across race and ethnicity with some studies finding these disparities greatly

¹ Erickson Foster J, Velasco JM, Hieken TJ. Adverse outcomes associated with noncompliance with melanoma treatment guidelines. Annals of Surgical Oncology. 2008;15(9):2395-2402. doi:10.1245/s10434-008-0021-0

² Visser BC, Ma Y, Zak Y, Poultsides GA, Norton JA, Rhoads KF. Failure to comply with NCCN guidelines for the management of pancreatic cancer compromises outcomes. HPB. 2012;14(8):539-547. doi:10.1111/j.1477-2574.2012.00496.x

³ Bristow RE, Powell MA, Al-Hammadi N, et al. Disparities in ovarian cancer care quality and survival according to race and socioeconomic status. JNCI Journal of the National Cancer Institute. 2013;105(11):823-832. doi:10.1093/jnci/djt065

⁴ Bristow RE, Chang J, Ziogas A, Randall LM, Anton-Culver H. High-volume ovarian cancer care: Survival impact and disparities in access for advanced-stage disease. Gynecologic Oncology. 2014;132(2):403-410. doi:10.1016/j.ygyno.2013.12.017

⁵ Mearis M, Shega JW, Knoebel RW. Does adherence to National Comprehensive Cancer Network guidelines improve pain-related outcomes? An Evaluation of Inpatient Cancer Pain Management at an Academic Medical Center. Journal of Pain and Symptom Management. 2014;48(3):451-458. doi:10.1016/j.jpainsymman.2013.09.016

⁶ Schwam ZG, Sosa JA, Roman S, Judson BL. Receipt of care discordant with practice guidelines is associated with compromised overall survival in nasopharyngeal carcinoma. Clinical oncology (Royal College of Radiologists (Great Britain)). https://www.ncbi.nlm.nih.gov/pubmed/26868285. Published June 2016.

reduced or eliminated when guideline adherent care is received.^{7,8} As such, guideline adherence is a key tool to combat inequities in care outcomes across race and ethnicity.

Guideline adherent care has also been shown to decrease costs. A peer-reviewed, published study by United, eviCore, and NCCN entitled "Transforming Prior Authorization to Decision Support" demonstrated mandatory adherence to NCCN Guidelines and NCCN Compendium[®] using a real-time Clinical Decision Support Mechanism significantly reduced total and episodic costs of care while also reducing denials and increasing access to guideline-concordant care. In Florida, United Healthcare adopted a prior authorization tool using NCCN real-time decision support over one year and explored 4,274 eligible cases. At the conclusion of the study, United Healthcare found that adding decision support to prior authorization reduced denials to 1 percent. Additionally, despite reducing denials, when compared to United Healthcare's cancer drug cost trends nationwide, the study found that mere adherence to NCCN Guidelines and Compendium within the pilot reduced chemotherapy drug costs trends by 20 percent; a savings of more than \$5.3 million in the state of Florida. Administrative burden was also reduced through the integration of the decision-making tool as oncologists obtained immediate approvals online for 58 percent of cases without further interaction with the health plan required. Approval was granted for 95 percent of the remaining cases requiring further interaction in less than 24 hours.⁹ Additionally, NCCN Guidelines have been shown to lower healthcare costs caused by overutilization and inappropriate use of services and therapeutics. 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-discordant treatment was \$7,421 versus \$5,171 for those receiving guideline-concordant care. This study found an additional \$1,841 in out-of-pocket costs for patients receiving guideline dis-concordant care versus patients who received guidelines-concordant care.

NCCN member institutions frequently report significant administrative burden associated with prior authorization for Medicare beneficiaries in Medicare Advantage plans compared with traditional Medicare. NCCN members report that these onerous policies frequently lead to inappropriate delays in care. These reports are further affirmed in the 2022 HHS OIG Report on prior authorization in Medicare Advantage that concluded ""among the prior authorization requests that MAOs denied, 13 percent met Medicare coverage rules—in other words, these services likely would have been approved for these beneficiaries under original Medicare.".¹⁰ NCCN believes that greater use of simple guideline adherence through CDSMs can lead to improved cancer care outcomes, reduced costs to Medicare Advantage

⁷ Fang P, He W, Gomez D, Hoffman KE, Smith BD, Giordano SH, Jagsi R, Smith GL. Racial disparities in guideline-concordant cancer care and mortality in the United States. Adv Radiat Oncol. 2018 May 4;3(3):221-229. doi: 10.1016/j.adro.2018.04.013. PMID: 30202793; PMCID: PMC6128037.

⁸ Blom EF, Ten Haaf K, Arenberg DA, de Koning HJ. Disparities in Receiving Guideline-Concordant Treatment for Lung Cancer in the United States. Ann Am Thorac Soc. 2020 Feb;17(2):186-194. doi: 10.1513/AnnalsATS.201901-094OC. PMID: 31672025; PMCID: PMC6993802.

⁹. Newcomer LN, Weininger R, Carlson RW. Transforming prior authorization to decision support. Journal of Oncology Practice. 2017;13(1). doi:10.1200/jop.2016.015198

¹⁰ HHS Office of the Inspector General. Some Medicare Advantage Organization denials of prior authorization requests raise concerns about beneficiary access to medically necessary care. April 2022. Retrieved August 19, 2022 from <u>https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf</u>

plans and individual patients, reduced administrative burden, improved timeliness of care, and reduced disparities in care.

Innovations to Advance Health Equity

In 2020, NCCN, the National Minority Quality Forum (NMQF), and the American Cancer Society Cancer Action Network (ACS CAN) launched the Elevating Cancer Equity (ECE) initiative. The ECE initiative sought to better understand patient experiences of racial disparities in access to guideline adherent cancer care in the United States through surveys of patients, caregivers, and oncologists, and then to address these disparities through a framework of actionable policy and practice change recommendations developed by a working group of national experts. The ECE Working Group (ECEWG), comprised of 17 national experts on racial disparities in cancer care including patients, caregivers, physicians, researchers, and industry, arose from the initiative (see Appendix A for full membership list). Convened in January 2021, the ECEWG developed two products: 1.) the Health Equity Report Card (HERC) as a means to put forth both best practice recommendations and ensure appropriate and necessary accountability for health systems and 2.) a Policy Framework to advance more equitable systems of care (see Appendix B for the HERC and Policy Framework).

The Health Equity Report Card was developed by the ECEWG to advance more equitable practices arising from emerging and evidence-based methods to address inequities in care. The HERC includes 17 performance measures and equity practices across 4 domains: Community Engagement, Accessibility of Care and Social Determinants of Health, Addressing Bias in Care Delivery, and Quality and Comprehensiveness of Care. Providers receive a "grade" for each domain. NCCN is currently piloting the HERC in five academic cancer centers with plans to launch a pilot in community settings in 2023. Although the HERC was developed with cancer care in mind, the recommendations largely apply across disease states. NCCN believes that models like the HERC can be used by Medicare Advantage plans as a tool to recognize and incentivize more equitable care practices among their provider networks. Additionally, the HERC can serve as an important transparency tool for patients.

Social Determinants of Health

Within the RFI, CMS queries stakeholders on ways MA plans can address SDOH. Within the 2023 Medicare Advantage rule, CMS includes a requirement that Special Needs Plans (SNPs) include specific standardized questions on Social Determinants of Health (SDOH) including housing stability, transportation, and food security within their existing Health Risk Assessments (HRAs). NCCN thanks CMS for taking this important step and encourages CMS to also consider how supplemental benefit design can be further used to support innovative uses of health dollars that address SDOH. Additionally, the ECEWG referenced above stressed the importance of collecting data on SDOH to inform both systems and care planning and coordination. NCCN believes Medicare Advantage plans can play a key role in collecting SDOH data and using it to inform supplemental benefit design.

NCCN would also like to note NCCN's Distress Thermometer and Problem List as a resource in assessing risk and social determinants of health. The NCCN Distress Thermometer and Problem List is

a well-known screening tool among oncology providers. The Distress Thermometer measures distress on a 0 to 10 scale and the Problem List includes five areas of life: practical, family, emotional, spiritual/religious, and physical problems. Within the Problem List, patients are queried about Housing, Transportation, and Food Security among other variables. CMMI's Enhancing Oncology Model recently referenced the Distress Thermometer and Problem List as a tool for providers to address health related social needs and NCCN believes it can also be of use to Medicare Advantage plans seeking to better assess and understand beneficiary needs.

Network Adequacy in Medicare Advantage

Within the proposed rule, CMS requests information on how to improve network adequacy within Medicare Advantage plans. NCCN thanks CMS for drawing attention to this important issue and would like to draw CMS' attention to a critical gap in network adequacy for MA beneficiaries with cancer. NCI-designated centers offer specialized services often unavailable elsewhere, including interdisciplinary team-based care, the latest therapies and advancements in cancer treatment, cutting-edge technology, and greater access to clinical trials. Multiple studies have found that treatment at NCI-designated and academic cancer centers is tied to higher overall survival.^{11,12,13} Barriers to accessing care at these sites is particularly problematic for patients with rare, complex, or advanced cancers who would most benefit from comprehensive and multidisciplinary treatment.

A 2016 Kaiser Family Foundation (KFF) analysis found that one in five MA plans have no Academic Medical Center in-network and, among plans in an area with an NCI-designated cancer center, more than two in five did not include the cancer center in their network.¹⁴ KFF has also found wide variability in the share of oncologists included across MA plans. Additional analyses have found that oncologists associated with NCI-designated cancer centers are more likely to be excluded from narrow-network plans than oncologists not associated with an NCI-designated cancer center.¹⁵

NCCN supports network adequacy standards that allow health insurance companies to negotiate appropriate rates with all high quality, high value providers, including academic cancer centers, which frequently see higher severity cases and offer best in class and innovative therapies as well as access to clinical trials. However, NCCN recognizes that not all patients will be able to access an NCI-designated center due to location or other barriers and that other academic medical centers or tertiary referral

¹¹ Wolfson JA, Sun CL, Wyatt LP, Hurria A, Bhatia S. Impact of care at comprehensive cancer centers on outcome: results from a population based study. *Cancer*. 2015;121(21):3885-3893. doi:10.1002/cncr.29576.

¹² Pfister DG, Rubin DM, Elkin EB, et al. Risk adjusting survival outcomes in hospitals that treat patients with cancer without information on cancer stage. *JAMA Oncol.* 2015;1(9):1303-1310. doi:10.1001/jamaon- col.2015.3151.

¹³ Shulman, LN, Palis, BE, et al. Survival as a quality metric of cancer care: Use of the National Cancer Data Base to assess hospital performance. *Journal of Oncology Practice* 2018 14:1, e59-e72

¹⁴ KFF. (June, 2016). A study of Medicare Advantage plan networks in 20 counties finds that plans include about half of all hospitals in their area. Retrieved February 1, 2022 from https://www.kff.org/medicare/press-release/a-study-of-medicare-advantage-plan-networks-in-20-counties-finds-that-plans-include-about-half-of-all-hospitals-in-their-area-20-percent-of-plans-do-not-have-an-academic-medical-center-in-netwo/

¹⁵ Yasaitis L, Bekelman JE, Polsky D. Relation between narrow networks and providers of cancer care. *J Clin Oncol*. 2017;35(27):3131-3135. doi: 10.1200/JCO.2017.73.2040.

centers for comprehensive cancer care also play a key role in cancer care access. As such, NCCN urges CMS to include an additional facility criterion requiring each MA plan to offer at least one local NCI-designated cancer center or, in the absence of an NCI-designated cancer center, a tertiary or quaternary referral center for patients with rare or advanced cancers. NCCN recognizes that defining this type of provider may present challenges and encourages CMS to work with the provider and payer community to develop a standardized definition.

Addressing Language Barriers

Roughly 8% of Medicare beneficiaries have Limited English Proficiency (LEP). Studies have indicated that Medicare beneficiaries who have LEP are less likely to have access to a consistent source of care and less likely to receive important preventive care, including cancer screening tests.¹⁶ As such, NCCN recognizes that supporting linguistically appropriate care is a crucial component of high-quality health care. The Elevating Cancer Equity Working Group also recognized this when including in the HERC the recommendation that marketing and educational materials should be both culturally and linguistically representative of the community served. NCCN believes this recommendation should also apply to marketing and educational materials disseminated by Medicare Advantage plans. NCCN thanks CMS for taking a first step toward this within the 2023 Medicare Advantage rule wherein it reinstates the requirement that MA plans include a multi-lingual insert notifying beneficiaries of interpreter services. NCCN encourages CMS to work with MA plans, providers, patient advocacy groups, and beneficiaries to understand areas for further improvement in multi-lingual and culturally reflective educational and marketing materials.

NCCN appreciates the opportunity to comment on the CMS Request for Information on Medicare (CMS-4203-NC). NCCN is happy to serve as a resource and looks forward to working together to advance Medicare beneficiary access to equitable, high-quality cancer care.

Sincerely,

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¹⁶ The Commonwealth Fund. (2007). Language barriers to health access among Medicare beneficiaries. Retrieved on February 1, 2022 from <u>https://www.commonwealthfund.org/publications/journal-article/2007/feb/language-barriers-health-care-access-among-medicare</u>

Elevating Cancer Equity Working Group Members

- Chair: Shonta Chambers, MSW, Patient Advocate Foundation
- Chair: Robert Winn, MD, VCU Massey Cancer Center
- Zeke Aguilera, ACT Lead, ACS CAN
- Nadine Barrett, PhD, Duke University School of Medicine
- Linda Burhansstipanov, DrPH, MSPH, Native American Cancer Research Corporation
- Christina Chapman, MD, MS, Michigan Medicine
- Moon Chen, MPH, PhD, UC Davis Health
- Thomas Farrington, Prostate Health Education Network
- Carmen Guerra, MD, MSCE, Penn Abramson Cancer Center
- Chanita Hughes-Halbert, PhD, Medical University of South Carolina
- Marjorie Kagawa Singer, PhD, UCLA Fielding School of Public Health
- Mel Mann, MBA M.Ed, Patient Advocate
- Regina Martinez, Volunteer, ACS CAN
- Kris Rhodes, MPH(Anishinaabe), Retired Founding CEO, American Indian Cancer Foundation
- Brian Rivers, PhD, MPH Cancer Health Equity Institute, Morehouse School of Medicine
- Gerren Wilson, PharmD, Genentech
- Karen Winkfield, MD, PhD, Meharry-Vanderbilt Alliance

Elevating Cancer Equity: Recommendations to Reduce Racial Disparities in Access to Guideline Adherent Cancer Care





National Comprehensive Cancer Network[®]



Institutional and Practice Equity Report Card
Community Engagement
Incorporates meaningful community involvement in practice leadership through a community/patient advisory committee or designated board position that is reflective of:
 the community the health care systems serves or that is reflective of the community where the healthcare system resides or is reflective of the demographics identified through the community needs assessment.
Marketing and educational materials use messaging that is linguistically and culturally appropriate for the community served.
Contracts with or has formal and equitable partnership with community providers, community-based organizations, and/or faith-based organizations (when mutually appropriate and not harmful) for community engagement and/or patient navigation.
Demonstrates the results of the community health needs assessments are used as a tool for program development through documented action plan tied to results.
Accessibility of Care and Social Determinants of Health
Facilitates access to government, commercial, or community-based non-emergency transportation services or financial support for public transportation where available.
Collects Social Determinants of Health data at intake and throughout the continuum of care. Population-level data collected (z-codes) helps to guide patient care and population-level health management as documented through the medical record or meeting notes.
Offers flexible hours for screening and treatment appointments.
Offers culturally and linguistically representative patient navigators or community health workers through internal hiring or contracting with community-based organizations.
Establish a process to navigate patients with identified social needs to local and or national resources.
Training is provided to staff on barriers to clinical trial participation and there are targeted efforts to reduce barriers to clinical trial participation through connection to appropriate services.
Addressing Bias in Care Delivery
Diversity, inclusion, and equity is embedded into the practice, institution, or health system policies (Examples:

Diversity, inclusion, and equity is embedded into the practice, institution, or health system policies (Examples: recruitment, hiring, and promotion policies, resource allocation standards).

Adopts measures related to the recruitment, retention, and promotion of minority researchers and practitioners.

Implements Health Information Technology or other workflow processes to identify critical moments in shared decision making and care planning when disparate care can occur.

Incorporates disparities and equity framework into quality improvement activities.

Provides and requires annual implicit bias training for all employees.

Quality and Comprehensiveness of Care	
When appropriate, patients are offered or referred to appropriate preventive and supportive care services (e.g. smoking cessation and weight management programs, reducing exposure to environmental hazards).	
Clinical trial options are discussed with all patients as documented through medical records.	
Offers culturally and linguistically representative patient navigators or community health workers through internal hiring or contracting with community-based organizations.	

Elevating Cancer Equity Working Group Policy Change Recommendations

Congressional Recommendations

Clinical Trial Diversity: Congress should pass legislation requiring the FDA to consider clinical trial diversity as an element of the drug approval process in a way that is proportionate to the intended patient population.

Supporting Cancer Prevention: Congress should allocate funds for public awareness campaigns of lifestyle factors impacting cancer risk that are linguistically and culturally reflective.

Supporting Cancer Prevention: Congress should pass legislation allocating funds for public education on the importance of the Human Papillomavirus(HPV) vaccine.

Supporting Access to Screening: Congress should allocate additional funding for CDC screening programs including the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) and the Colorectal Cancer Control Program (CCCP). Congress should also allocate funds for screening that prioritizes cancers where disparities are particularly prevalent.

Supporting Access to Screening: Congress should allocate funds to be granted to community-based organizations to connect people with screening, early detection and treatment support. Congress should restore funds for the National Comprehensive Cancer Control Program.

Supporting a Diverse Healthcare Workforce: Congress should allocate funds to Historically Black Colleges and Universities (HBCUs), tribal colleges, and other minority serving institutions (MSIs) because they excel at care, practice, education, and community engagement.

Supporting Patient Navigation: Congress should pass legislation ensuring reimbursement of patient navigators and community health workers in Medicare/Medicaid/Private Insurance markets.

Social Determinants of Health: Congress should allocate funds for the reconnect loan and grant program and eliminate the household threshold requirement. Access to basic infrastructure like electricity has a critical impact on health.

CMS and Commercial Payer Recommendations

Ensuring Equitable Access to Genetic Testing and Cancer Risk Reduction: All payers should cover appropriate genetic counseling and testing for individuals at high risk of cancer as well as related risk reduction services.

Addressing Clinical Trial Participation Barriers: CMS should ensure Medicare, Medicaid, CHIP, and exchange plans offer coverage of the costs of clinical trial participation including parking, transportation, and lodging.

Patient Navigation: CMMI and commercial payers should include reimbursement for patient navigators, community health workers, care coordination, and connection to social support services in alternative payment models.

Federal Agency Recommendations

Data Collection: The Office of Management and Budget should revise their regulations dictating the collection and reporting of federal data on race and ethnicity. Data should be disaggregated from existing methods that fail to recognize the heterogeneity of African Americans, Pacific Islanders, Asians, Hispanics, American Indians and Alaska Natives.

Research: The Department of Health and Human Services should prioritize funds and resources for interdisciplinary research in SDOH and health disparities research. HHS should require health care systems to partner with community-based organizations to conduct research.

Cancer Prevention: The CDC should make the HPV vaccine an opt-out instead of an opt-in vaccine.

Patient Navigation: Create a Department of Labor code for Patient Navigators

State and Local Policymaker Recommendations

Medicaid Expansion: State governors and legislatures should expand their state Medicaid programs to increase access to screening, early detection and care.