

Robert W. Carlson, MD Chief Executive Officer carlson@nccn.org

March 3, 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: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192-P)

Dear Administrator Brooks-LaSure:

The National Comprehensive Cancer Network® (NCCN®) appreciates the opportunity to comment on the proposed 2023 Policy and Technical Changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit Programs as it relates to NCCN's mission of improving and facilitating, quality, effective, equitable, and accessible cancer care. In particular, NCCN will focus our comments on the provisions regarding network adequacy, language accessibility, and assessing social determinants of health for dually eligible beneficiaries.

NCCN Background

As an alliance of 31 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

NCCN Member Institutions

Abramson Cancer Center at the University of Pennsylvania

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 Davis Comprehensive Cancer Center

UC San Diego Moores Cancer Center

UCLA Jonsson Comprehensive 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

UT Southwestern Simmons Comprehensive Cancer Center

Vanderbilt-Ingram Cancer Center

Yale Cancer Center/Smilow Cancer Hospital

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 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.

Network Adequacy

Within the proposed rule, CMS outlines proposals intended to ensure network adequacy, a crucial component of accessible care. NCCN applauds CMS for taking steps to address this important issue. In particular, CMS proposes to require that rather than simply attesting to network adequacy, plan applicants must demonstrate they have a sufficient network of contracted providers to care for beneficiaries before CMS will approve an application for a new or expanded MA plan. NCCN agrees with CMS that requiring that plans demonstrate this prior to approval will protect beneficiaries and promote more accessible care. NCCN thanks CMS and supports this proposal.

NCCN would also like to draw to CMS' attention 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. 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.

¹ 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.

² 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/iamaon-col.2015.3151.

³ 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

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. 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.

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 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.

Multi-lingual Materials

CMS proposes to reinstate the requirement that MA plans include a multilanguage insert that would inform the reader, in the top fifteen languages used in the U.S., that interpreter services are available for free whenever a Medicare beneficiary is provided a CMS required material (ex: Evidence of Coverage, Annual Notice of Change, etc). 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.⁶ As such, NCCN applauds CMS for this proposal and supports reinstating this requirement.

⁴ 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-plannetworks-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/

⁵ 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.

⁶ The Commonwealth Fund. (2007). Language barriers to health access among Medicare beneficiaries. Retrieved on February 1, 2022 from

https://www.commonwealthfund.org/publications/journal-article/2007/feb/language-barriers-health-care-access-among-medicare

Assessing the Social Determinants of Health for Dually Eligible Beneficiaries

CMS proposes to require Special Needs Plans (SNPs) to include specific standardized questions on Social Determinants of Health (SDOH) including housing stability, transportation, and food security within their existing Health Risk Assessments (HRAs). CMS notes that SNPs are required to provide care coordination and that gathering this information within the HRA will help to inform care coordination activities and ultimately improve care outcomes.

Throughout 2020 and 2021, 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 (US) 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 recommendations within both the HERC and the policy framework outline the importance of addressing the SDOH. Further, the working group emphasized the importance of collecting data on SDOH to inform both systems and care planning and coordination. NCCN believes CMS' proposal aligns well with this recommendation and meets a critical system need.

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. NCCN agrees that querying patients on these issues is critical to the provision of quality ad accessible care and applauds CMS for this proposal.

Lowering Beneficiary Cost-sharing

CMS proposes a new policy requiring Part D plans to apply all price concessions they receive from network pharmacies to the point of sale, ensuring that the beneficiary shares in the savings. CMS proposes to achieve this by redefining the negotiated price as the baseline, or lowest possible, payment to a pharmacy. NCCN agrees with CMS that this policy would reduce beneficiary out-of-pocket (OOP) costs and improve pricing transparency. Addressing OOP costs is crucial to reducing barriers to cancer care, increasing treatment adherence, and improving care outcomes. As such, NCCN supports this proposal.

In sum, NCCN respectfully requests that CMS:

- Finalize the proposal that MA plans demonstrate network adequacy prior to plan approval or expansion.
- Add NCI designated cancer centers and tertiary/quaternary referral centers to the facility specialty list to ensure patients with cancer can access an appropriate level of care;
- Finalize the proposal to require multi-lingual inserts alerting MA beneficiaries to free interpretation services;
- Finalize the proposal to require SNPs to include questions on housing, transportation, and food security within the HRA.
- Finalize the proposal to redefine the negotiated price as the baseline payment to a pharmacy to reduce patient OOP costs.

NCCN appreciates the opportunity to comment on the proposed 2023 Policy and Technical Changes to the Medicare Advantage (MA) and Medicare Prescription Drug Benefit Programs. NCCN would be happy to serve as a resource and looks forward to working together to advance access to high quality, equitable, and accessible cancer care.

Sincerely,

Robert W. Carlson, MD Chief Executive Officer

assa

National Comprehensive Cancer Network

carlson@nccn.org 215.690.0300

Appendix A

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

Appendix B

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







d Cancer Society®
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: 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.