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September 02, 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 and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1770-P)

Dear Administrator Brooks-LaSure:

The National Comprehensive Cancer Network® (NCCN®) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services (CMS) Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1770-P) as it relates to NCCN's mission of improving and facilitating, quality, effective, equitable, and accessible cancer care. NCCN will focus our comments on the provisions regarding colorectal cancer screening, equity adjustment and measures, and the newly introduced oncology specific MIPS Value Pathway.

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.

Colorectal Cancer Screening Provisions

CMS proposes an expansion of coverage for colorectal screening. Specifically, CMS proposes to modify existing payment limitations to expand coverage of colorectal cancer screening to individuals age 45 and above and also proposes to cover follow-up colonoscopy following a positive stool-based screening without additional cost-sharing. NCCN agrees with and supports these proposals. As CMS notes within the rule, the USPSTF recently updated their recommendations to align with these proposed coverage changes. The NCCN Guidelines for Colorectal Cancer Screening® also recommend colorectal cancer screening at age 45 and above for average risk individuals. Additionally, a follow up colonoscopy should be recommended following a positive stool-based screening according to the NCCN Guidelines for Colorectal Cancer Screening®. Accordingly, NCCN supports CMS in making this appropriate and critical coverage change to ensure appropriate patient access to recommended cancer screening and prevention services.

Health Equity Adjustments and Measures

Within the proposed Physician Fee Schedule rule, CMS notes that "in recent years growth in the number of beneficiaries assigned to ACOs has plateaued; higher spending populations are increasingly underrepresented" by ACO's in the Shared Savings Program and that data shows Black/African American, Hispanic/Latinx, Asian/Pacific Islander, and American Indian/Alaska Native beneficiaries are less likely to be assigned to a Shared Savings Program ACO than Non-Hispanic White beneficiaries. To address this, CMS proposes to "implement a health equity adjustment to an ACO's quality performance score to recognize high quality performance by ACO's with high underserved populations". NCCN agrees that providers who are excelling at providing high quality services to underserved populations should be recognized and rewarded. NCCN thanks and applauds CMS for this proposal that aligns with CMS' greater efforts to advance more equitable systems of care. NCCN notes that this is one important step but that broader systems frameworks to advance equitable care practices across all providers, regardless of whether they

serve a large or small percentage of underserved beneficiaries, is needed. NCCN outlines one strategy to incentivize and advance more equitable care practices below.

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 CMS across attempts to better measure and advance equitable care delivery and can be a useful tool for ACO's seeking to improve their practice. Additionally, the HERC can serve as an important transparency tool for patients.

CMS also seeks comment on the potential future inclusion of two new structural measures in the APM Performance Pathway (APP) measure set: Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health. NCCN notes that the Elevating Cancer Equity Working Group, endorsed a need for better collection of social determinants of health data at the point of care. As such, NCCN applauds and supports CMS' consideration of inclusion of these new structural measures.

MIPS Value Pathways

NCCN acknowledges the efforts by CMS to move away from siloed reporting of measures and activities toward focused sets of measures and activities that are more meaningful to a clinician's specialty. NCCN appreciates the opportunity to provide comment on the proposed Advancing Cancer Care MIPS Value Pathway (MVP). 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, 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 resulting publication contained an endorsement of 15 high-impact measures in oncology, including five end of life measures.\(^1\) As such, NCCN applauds CMS for the inclusion of two end of life measures in the proposed quality measure set.

Additionally, NCCN wishes to applaud CMS on the inclusion of pain management measures in the Advancing Cancer Care MVP. Pain is one of the most common symptoms associated with cancer and cancer treatment, and as such NCCN has published the NCCN Clinical Practice Guidelines in Oncology Adult Cancer Pain.² This continuously updated guideline provides evidence-based information regarding appropriate cancer pain screening, management, and care plans, and may serve as a resource for Advancing Cancer Care participants.

NCCN appreciates CMS's focus on appropriate biomarker testing through inclusion of breast, colorectal, and lung measures (Appropriate Treatment for Patients with Stage I (TIc) – III HER2 Positive Breast Cancer, RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy, and Mutation testing for lung cancer completed prior to start of targeted therapy). NCCN understands the limitations of measurement, particularly within the biomarker space, however would like to highlight the importance of biomarker testing for non-small cell lung cancer prior to the start of any systemic therapy. NCCN recommends that CMS encourage the expansion of this measure to encompass all patients treated for stage IV lung cancer, regardless of planned therapy type, and in the interim to issue appropriate evidence-based guidance to practices. NCCN shares a commitment to evidence-based treatment decisions, and as such offers the NCCN Biomarkers Compendium as a resource. The NCCN Biomarkers Compendium is updated in conjunction with the NCCN Guidelines on a continual basis, and contains relevant information designed to support decision-making around the use of biomarker testing in patients with cancer.

Finally, NCCN would like to call attention to the final two QCDR measures listed in the Advancing Cancer Care MVP. The descriptive text following PIMSH2 and PIMSH8 appears to be reversed. NCCN offers the following suggestion for this section:

¹ D'Amico, Thomas A., et al. "Quality measurement in cancer care: a review and endorsement of high-impact measures and concepts." Journal of the National Comprehensive Cancer Network 18.3 (2020): 250-259.

² National Comprehensive Cancer Network. (2022). Adult Cancer Pain (version 2.2022). Retrieved from https://www.nccn.org/professionals/physician_gls/pdf/pain.pdf

- PIMSH2: Oncology: Utilization of GCSF in Metastatic Colorectal Cancer: This QCDR measure assesses the use of GCSFs in accordance with current guidelines.
- PIMSH8: Oncology: Mutation testing for lung cancer completed prior to start of targeted therapy: This QCDR measure assesses clinical practice guideline compliance regarding implementation of mutations testing to optimize diagnosis and disease management.

NCCN appreciates the opportunity to comment on the CMS Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1770-P). 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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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.