September 25, 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: CMS-1715-P Medicare Program: Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2020

Dear Administrator Verma:

The National Comprehensive Cancer Network® (NCCN®) is pleased to comment on the Centers for Medicare & Medicaid Services (CMS) Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B Proposed Rule (CMS-1715-P) as it relates to NCCN’s mission of improving and facilitating, quality, effective, efficient, and accessible cancer care. NCCN appreciates the opportunity to comment and will focus our remarks on the proposed modifications to the Evaluation and Management (E/M) Visits, Open Payment Systems, and MIPS Value Pathways.

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 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 health information technology (HIT) vendors.

**Evaluation and Management (E/M) Visits**

In the CY 2019 Physician Fee Schedule proposed rule, CMS proposed extensive changes to the evaluation and management visit system including a proposal to move to a blended payment rate for evaluation and management visits Levels 2-5 for new and established patients. During the CY 2019 public comment period, NCCN commented in opposition to this proposal. NCCN noted with concern that the proposal would have detrimental consequences for patients with cancer who are most often seen at visit levels 4 or 5 which are paid at higher rates. Delivery of cancer care is complex and virtually all patients require a level 4 or 5 visit in order to provide an optimal cancer diagnosis and evidence-based cancer treatment.

NCCN conducted a survey of member institutions to query the percentage of evaluation and management physician visits occurring at levels 1-5 at academic cancer centers across specialties for calendar year 2017. NCCN’s survey, with 11 member institutions responding, found that for the academic cancer centers responding, evaluation and management visits classified as level 4 comprise 27% of new patients and 42% of established patients and visits classified as level 5 comprise 49% of new patients and 30% of established patients. The overall impact for these centers was projected to be a 22% reduction in revenue for new patient visits and a 16% reduction in revenue for established patient visits. As such, NCCN concluded that shifting to a blended payment rate will penalize oncology and other specialties treating the sickest and most clinically complex patients.

In the final CY 2019 Physician Fee Schedule, CMS finalized the assignment of a single payment rate for levels 2 through 4 office/outpatient E/M visits beginning in CY 2021. Following the publication of this final rule, CMS continued to evaluate public feedback. During the same time period, the AMA/CPT convened the Joint AMA CPT Workgroup on E/M to develop an alternative solution to the new E/M structure and coding mechanisms. In the proposed CY 2020 Physician Fee Schedule, CMS proposes to adopt the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA/CPT. For levels 2 through 5 office outpatient E/M visits, the code level reported
would be decided based on either the level of medical decision-making (MDM) or the total
time personally spent by the reporting practitioner on the day of the visit including face-to-
face and non-face-to-face time.

NCCN applauds CMS for this proposal and encourages CMS to finalize the policy as
proposed. NCCN notes that this proposal addresses administrative burden and also
appropriately funds complex care and ensures access for Medicare beneficiaries with
cancer.

**Open Payments System**

In the CY 2020 Proposed Physician Fee Schedule, CMS proposes to add physician
assistants, nurse practitioners, clinical nurse specialists, certified registered nurse
anesthetists, and certified nurse midwives to the list of care providers for whom
manufacturers must submit Open Payment data beginning in CY 2022. In addition, CMS
proposes to require reporting on three new categories of payments or transfers of value:
debt forgiveness, long-term medical supply or device loan, and acquisitions. NCCN agrees
with CMS that transparency and rigorous conflict of interest policies are critical to ensuring
appropriate care. As such, NCCN thanks CMS for considering adjustments to the Open
Payment System.

In a recent article in *Cancer* entitled Real Transparency in Medicine: Time to Act, Dr.
Robert Carlson, CEO of NCCN and Dr. Clifford Hudis, CEO of the American Society of
Clinical Oncology (ASCO), highlight gaps inherent within the medical field's fragmented
systems for reporting conflicts of interest.¹ Specifically, the authors note that the Open
Payments system requires content only from companies with products covered by federal
programs in the United States and misses numerous potential conflicts of interest including
equity holdings and patents for premarket products as well as spousal/domestic
partner/dependent employment or holdings. Additionally, annual analyses conducted
internally at NCCN have found Open Payment system data to be inaccurate or misleading
approximately 50% of the time when reported payments appear to exceed NCCN
thresholds. Additionally, the article reports that both NCCN and ASCO frequently find
discordance between the conflicts of interest reported to their respective organizations and
those reported to Open Payments.

The authors of the article note that the frequency of discordance among conflict of interest
disclosures is often due to differences in terminology and definitions, inconsistency in
reporting requirements, and delays in Open Payments reporting. Proposed solutions
include standardized definitions of terminology and standardized reporting requirements
including indirect payments, relationships with pre-commercial companies, and family
member relationships. Additionally, the creation of one source of universal disclosure
would streamline and simplify reporting and the development of a real-time notification
system for sunshine reporting would prevent disconnects and time-lags in reporting.

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10.1002/emo.32407
NCCN recognizes that CMS may not have the authority to implement all of these proposed solutions but encourages CMS to consider areas where it may be able to facilitate steps toward realizing these goals. A medical system with truly transparent and universal reporting of conflicts of interest will serve the interests not only of patients, but also of payers, clinicians, and the health system as a whole. NCCN thanks CMS for examining areas of potential improvement within the Open Payments system and encourages CMS to consider the additional gaps and potential solutions outlined above.

**MIPS Value Pathways Request for Information**

NCCN acknowledges the efforts by CMS to implement quality measurement programs that are meaningful to patient care, and appreciates the opportunity to provide comment on the proposed MIPS Value Pathways (MVP) program. As mentioned in the MVP Request for Information, broad changes to the MIPS program may significantly impact practices and providers, therefore NCCN thanks CMS for seeking public input on the development and application of this new program.

NCCN believes the optimal way to ensure quality care while improving value, and reducing clinical burden is through evidence-based 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. 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. These studies underscore the importance of improving dissemination of the Guidelines and their implementation and uptake in practice.

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

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4 Bristow, et al., Journal of the National Cancer Institute 2013 105(1):823-832; doi: 10.1093/jnci/djt065


7 Schum et al., Clinical Oncology 2016 28(6):402-409; doi: 10.1016/j.jpainsymman
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.\(^8\)

Due to the demonstrated value of the Guidelines and utilization across stakeholders, CMS should consider requiring measures included in oncology-specific MVPs to adhere to NCCN or other evidence-based, up-to-date clinical practice guidelines. In addition to offering uniformity across cancer MVPs, this would also offer an evergreen removal factor as evidence changes and standards are updated.

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 Committee’s first manuscript outlining the review process is expected to be published later this year and contains an endorsement of high-impact oncology measures. Endorsed measures include cross-disease and disease-specific measures. Disease-specific measures can be considered as candidates for inclusion on individual MVPs. Cross-disease measures, such as end of life measures, are appropriate for all cancer types and should be considered for inclusion in all oncology MVPs.

Additionally, empowering both clinicians and patients to easily access NCCN content through a digital platform that is interoperable is critical to the advancement of high-quality, evidence-based cancer care. NCCN is enabling its content, including Guidelines and derivative products, to permit integration into all types of technology for use by all stakeholders. More specifically, NCCN collaborates with HIT vendors to integrate the NCCN Guidelines and compendia products allowing for access to evidence-based recommendations through Electronic Health Records (EHR) systems and chemotherapy treatment management modules. The integration of NCCN products into HIT helps to standardize cancer treatment protocols for use at point of care across all EHR technology in the patient care continuum. Such integration of NCCN Guidelines into Electronic Health Records offers the opportunity for oncology practices to demonstrate ongoing interoperability.

Finally, NCCN appreciates the opportunity to comment on the inclusion of Patient Reported Outcomes (PROs) in MVPs. 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. In alignment with CMS’s effort to reduce reporting burden, NCCN feels it would be appropriate to employ these tools for inclusion of PROs in MVPs.

NCCN appreciates the opportunity to respond to the Proposed Revisions to Payment Policies under the Medicare Physician Fee Schedule, Quality Payment Program and Other Revisions to Part B for CY 2020. NCCN thanks CMS for proposals to adopt the AMA/CPT Evaluation and Management guidance framework. We encourage CMS to consider changes to the Open Payments system as outlined in the Cancer article Real Transparency in Medicine: Time to Act. Lastly, NCCN encourages CMS to consider high-quality evidence-based guidelines as a resource when developing the MIPS Value Pathways. 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,

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