December 21, 2018

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-5528-ANPRM, Medicare Program; International Pricing Index Model for Medicare Part B Drugs

Dear Administrator Verma:

The National Comprehensive Cancer Network® (NCCN®) is pleased to comment on the Centers for Medicare & Medicaid Services (CMS) Advance Notice of Proposed Rulemaking (ANPRM) to consider testing an international pricing model on Part B drugs and biologics through the Center for Medicare and Medicaid Innovation (CMMI) as they relate to NCCN’s mission of improving and facilitating, quality, effective, efficient, and accessible cancer care.

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 their derivatives help ensure access to appropriate care, clinical decision-making, and assessment of quality improvement initiatives.

Since 2008, CMS has recognized the NCCN Drugs & Biologics Compendium (NCCN Compendium®) as a mandated reference for establishment of coverage policy and coverage decisions regarding the use of drugs and biologics in cancer care and in 2016, NCCN was recognized by CMS as a qualified provider-led entity (PLE) for the Medicare Appropriate Use Criteria (AUC) Program. Through this qualification, CMS recognized NCCN as a group qualified to develop AUC and establish policy and decision-making for diagnostic imaging in patients with cancer. NCCN Imaging Appropriate Use Criteria (NCCN Imaging AUCTM) are available free of charge to registered users of NCCN.org and can be accessed at NCCN.org/ImagingAUC.

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, and NCCN Guidelines and Library of Compendia products are utilized by commercial payers that represent more than 85 percent of covered lives in the United States. NCCN works with HIT vendors through permissions and licensing arrangements to utilize the NCCN Guidelines
and the NCCN Compendium® when making decisions that impact patient access to appropriate therapy, including eviCore and CVS Health NovoLogix. NCCN recognizes that financial toxicity is an all too common barrier to patient access to high-quality cancer care and supports initiatives to reduce the financial burden on patients while also ensuring patient access to evidence-based cancer care. NCCN is grateful for the opportunity to provide comment on the IPI model and will focus our comments on IPI provisions that will have the most immediate impact on patient access to evidence-based, high-quality care.

**Lowering drug spend can be achieved by adherence to guidelines or pathways**

NCCN believes that the optimal way to lower total drug spending and reduce patient cost is through the adoption of policies that require participating physicians and vendors to adhere to professional society and recognized guidelines in treatment decisions. Specifically, we believe that the NCCN Guidelines are an excellent resource to reduce drug spending in Medicare Part B while also ensuring and maintaining quality of care.

The IPI model as currently proposed does not mention mandatory adherence to guidelines, or even the more strict use of mandatory pathways, but in both cases deference to specialty societies promotes physician participation and, in the case of oncology, aligns with the administration’s implementation of Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the Oncology Care Model (OCM). NCCN also recommends the inclusion of off-label use in the IPI model if supported by NCCN Compendium, as statute allows Medicare to cover the use of drugs and biologics for off-label, medically accepted indications of FDA-approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen – as determined by recognized compendia (1861(1)(2)(B))\(^1\). The NCCN Compendium is recognized by public and private insurers alike and has shown significant cost reductions when used for coverage and reimbursement decisions. In both cases, the CMS could easily implement such changes with a minimum of physician and provider burden. CMS could require a modifier to “attest” that guidelines or pathways were utilized when a physician or provider bills the local Medicare Administrative Contractor (MAC). Similarly, CMS could instruct its audit contractors (RAC, ZPIC, etc.) to randomly conduct chart reviews to ensure professional society guidelines were utilized to ensure standardization across the healthcare system and avoid placing the reporting burden on physicians and providers.

NCCN and its clinical partners have shown such adherence can lead to appreciable budget savings in both total and episodic costs of care. 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 significantly reduced total and episodic costs of care.\(^2\) In Florida, United Healthcare adopted a 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 to 1 percent. Additionally, when

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\(^{1}\) Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, 50 - Drugs and Biologicals

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.

This model implemented within the IPI model could both ensure access to evidence-based cancer care and significantly reduce overall and episodic drug spend. The same model has been expanded through the NCCN – eviCore partnership to several additional national and regional private payers. Both NCCN and eviCore support the notion that mandating such attestation in the Medicare fee for service and Advantage populations could lead to appreciably more savings than United Healthcare experienced its own commercial population. The model can be used in other medical specialties and eviCore and CVS Health NovoLogix are working in more than the oncology therapeutic area. We encourage CMS to consider this model for implementation, along with appropriate safeguards for patient access, within the IPI model.

**A more measured rollout could result in higher satisfaction**

CMS seeks comment on how to avoid unintended consequences on the interaction of the IPI model with other programs and services. While the ANPRM’s provision adopts the position that all providers have the resources to implement this model successfully; in fact, many providers are still adjusting to the reporting requirements under MACRA. According to Cardinal Health’s 2017 survey report, 2017 Oncology Insights: Views on Reimbursement, Access and Data from Specialty Physicians Nationwide, oncologists lacked confidence in their ability to execute MACRA requirements. Specifically, only 10 percent of surveyed oncologists believed their practice currently had the resources and staffing necessary to manage MACRA implementation. More concerning, 16 percent of surveyed oncologists reported consideration of mergers with larger entities to meet MACRA requirements and achieve financial success.3

Additionally, some providers are still adjusting to the requirements of OCM and are now experiencing significant savings for the Medicare program. These providers may not have the operational bandwidth to adjust utilization management strategy, drug distribution systems, storage facility management, and registration systems to succeed under this new model. Further, the IPI language seems to undermine providers that have put their time and resources into achieving savings for the Medicare program; not allowing for a carve out or waiver for those already planning to take risk under the current model. Finding accommodation for OCM participation as well as consideration for those practices that attest MACRA or other internal administrative issues make it difficult to participate at this time will protect the sustainability of CMS’ proposal by ensuring providers with capable administrative resources enter the IPI model and limiting exposure to practices susceptible to loss of financial viability due to administrative burden.

In 2016, CMS recognized NCCN as a qualified PLE for the new Medicare AUC Program for developing AUC and establishing policy and decision-making for diagnostic imaging in cancer

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patients. To be qualified by CMS, a PLE must adhere to the evidence-based processes described in 42 CFR 414.94(e)(1) when developing or modifying AUC. PLEs must apply to CMS to become qualified and the application must include a statement as to how the entity meets the definition of a PLE and document adherence to each of the qualification requirements. NCCN applauds CMS for helping to accelerate the PLE designation through a straightforward, transparent application process that allows physicians to minimize regulatory burden while elevating the practice of medicine through the use of rigorous peer-reviewed evidence. Under a construct similar to the PLE or the qualified Clinical Decision Support Mechanisms (CDSM) model, we feel that potential vendors under the IPI model should follow a similar transparent application process and qualification requirements in order to help streamline necessary clinical elements and help incorporate the most current clinical evidence beneficial to Medicare beneficiaries.

In the IPI ANPRM, CMS requests comment on the exclusion of certain types of physician practices and/or hospital outpatient departments (HOPDs) from the model as well as the inclusion or exclusion of PPS-exempt hospitals. PPS exempt cancer hospitals have long been recognized as unique for their sole mission to treat people with cancer and, as such, have been exempted from traditional reimbursement systems as outlined in statute. As such, we agree with the Alliance of Dedicated Cancer Centers’ comment that PPS-exempt cancer hospitals should also be exempted from the IPI model.

**Maintaining off-label use of anti-cancer medicines is critical**

CMS requests feedback on whether to determine inclusion of drugs based on FDA approved indications only or include off-label use if supported by clinical guidelines or compendia. Many cancer treatments are effective against cancer beyond the FDA-approved indications, including for less common tumors or clinical situations. To ensure patient safety and promote timely access to high-quality cancer care, the NCCN Compendium is recognized by CMS under the Medicare Benefit Policy Manual as a mandated reference for medically accepted unlabeled uses of FDA-approved drugs and biologics administered in an anticancer chemotherapy regimen. Off-label therapies play a significant role in oncology and the absence of a labelled indication does not indicate absence of evidence supporting an indication or lack of clinical benefit to patients. Additionally, the absence of a labelled indication is more likely with generics, which may also be the most cost-effective treatment. Given the important role off-label therapies play in cancer care delivery, we urge CMS to maintain patient access to off-label uses if supported by CMS-recognized compendium, such as the NCCN Compendium or specialty-society guidelines, such as the NCCN Guidelines.

Vendors should be required to ensure that all guideline recommended therapies, on- and off-label, are available within their product offerings. Given the significant access implications for patients with cancer, we request further clarity on the implications for reimbursement of off-label uses if CMS determines the inclusion of drugs based on FDA approved indications only (i.e., would off-label, medically accepted indications continue to be accessible to patients outside of the IPI at ASP+6%). Appropriate safeguards need to be in place to ensure patient access to medically-accepted indications in oncology, as defined in statute.
CMS Should Provide Clarity on Model Coordination to Protect Timeliness of Care and Access

NCCN requests further clarity on several process mechanisms to ensure IPI protects patient access to care and timely access to new and appropriate drugs and biologics. In particular, NCCN seeks clarity on how this model will take additional steps to ensure timely access to new drugs under the negotiation processes and targets. CMS aptly notes in the ANPRM that the previous iteration of CAP resulted in operational inefficiencies and delays in access to needed care and this was particularly impactful in oncology. It is unclear how the current model will implement safeguards to ensure patients are able to access appropriate drugs and biologics in a timely manner. It also remains unclear which parties will be held responsible if compromised drugs are delivered to providers and how drugs requiring further compounding will be handled. Lastly, NCCN seeks clarity on how this model will interface with large provider institutions with multiple sites. One provider may have some, but not all, sites included within the geographic testing regions for this model. How does CMS foresee this being implemented and has CMS considered how this might impact administrative burden?

NCCN appreciates the opportunity to respond to the Advanced Notice of Proposed Rulemaking on the CMMI International Pricing Index Model for Medicare Part B Drugs. 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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