January 22, 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-4180-P-Proposed Rule Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma:

The National Comprehensive Cancer Network® (NCCN®) is pleased to comment on the Centers for Medicare & Medicaid Services (CMS) Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses as it relates to NCCN’s mission of improving and facilitating, quality, effective, efficient, and accessible cancer care.

NCCN supports CMS’ efforts to address rising drug costs in the Medicare program and encourages the use of adherence to evidence-based guidelines to reduce drug spend while safeguarding clinically appropriate patient access to quality care. This strategy in part addresses significant concerns about several provisions of the proposed rule. In particular, NCCN is concerned that imposing utilization management tools within the protected classes of Medicare Part D without requiring adherence to evidence-based guidelines will have serious consequences for Medicare beneficiaries with cancer. Similarly, the utilization of step therapy for Part B oncologic drugs could limit the ability of providers to make appropriate treatment decisions and negatively impact care outcomes, especially in oncology. NCCN also thanks CMS for provisions relating to increasing patient and prescriber access to relevant health purchasing information and encourages CMS to ensure the information provided is both timely and clinically appropriate through the use of evidence-based guidelines.

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. 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 biologies in cancer care. Additional resources include the NCCN Chemotherapy Order Templates (NCCN Templates®) that outline chemotherapy, immunotherapy, supportive care agents, monitoring parameters, and safety instructions based directly on recommendations within the NCCN Guidelines. NCCN continues to expand its library of chemotherapy order templates, as well as collaborate with health information technology (HIT) vendors to incorporate the templates into Electronic Health Record (EHR) as standard cancer treatment protocols for use at point of care.

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 AUC™) 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 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 is grateful for the opportunity to provide comment on the proposed rule and will focus our comments on provisions that will have the most immediate impact on patient access to evidence-based, high-quality care.

Protected Classes

The proposed rule includes several proposals related to the six Protected Classes of Drugs in Medicare Part D, which include antineoplastics (drugs used to treat cancer). CMS proposes three exceptions to the protected class policy that would allow Part D plan sponsors to (1) Implement broader use of prior authorization and step therapy for protected class drugs including to determine for protected class indications; (2) exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing source drug or biological product, regardless of whether the older
formulation remains on the market; and (3) exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period. NCCN appreciates the opportunity to provide comment on how these provisions may impact patient access to evidence-based, high-quality cancer care.

Anticancer drugs have been included in the protected classes due to the highly individualized and complex nature of cancer care. In cancer, therapies have different indications, different mechanisms of action, and different side effects, depending on the person’s cancer diagnosis. Even for patients with the same cancer diagnosis, the same therapeutic treatment may be insufficient or not recommended based on the NCCN Guidelines. Additionally, the ability for the clinician and patient to identify the most effective drug is crucial to clinically appropriate and evidence-based cancer treatment. NCCN has serious concerns that a proposal to restrict access to drugs in the protected classes will impede patient access to life-saving anticancer drugs. Imposing utilization management tools without requiring adherence to evidence-based guidelines may have grave consequences for Medicare beneficiaries with cancer. Additionally, NCCN has concerns that the proposal to restrict drugs representing a new formulation of an existing drug, even if the older formulation is no longer on the market may create significant barriers to patient access to medically necessary drugs. By only including one example in the proposed rule, NCCN is particularly concerned that CMS did not include enough data or analysis on how this proposal may impact patient access. This proposal may be particularly detrimental in oncology. As such, NCCN urges the administration to reconsider this proposal.

CMS notes in the proposed rule that utilization management edits would be subject to CMS approval and CMS “would not approve onerous prior authorization criteria that are not clinically supported”. If this proposed rule is implemented for oncology treatments in the protected class, we urge CMS to require referencing of medical standards and evidence-based medicine using the NCCN Guidelines to ensure no Guideline concordant care is denied.

NCCN believes that the optimal way to lower total drug spending and reduce patient cost while safeguarding clinically appropriate patient access is through the adoption of policies that require adherence 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 Parts B and D while also ensuring and maintaining quality of care.

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. 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 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 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.

**Step Therapy in Medicare Advantage Part B**

In the proposed rule, CMS proposes requirements under which Medicare Advantage plans may implement step therapy as a utilization management tool for Part B drugs as was initially outlined in the August 2018 CMS Memo to Medicare Advantage organizations: “Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage.” As was noted in our September 2018 response to this memo, NCCN feels strongly that allowing Medicare Advantage plans to use step therapy for Part B Drugs, except as indicated within evidence-based clinical practice guidelines, could threaten the provider-patient relationship, as well as restrict optimal clinically appropriate cancer treatment and care for Medicare beneficiaries. The utilization of step therapy for Part B oncologic drugs could limit the ability of providers to make informed treatment decisions for the care of their patients, effectively taking clinical care decisions away from doctors and shared decision making from patients, thus negatively impacting the quality of care delivered. NCCN urges CMS to consider utilizing recognized guidelines and compendia, such as NCCN’s, as a safeguard to ensure that appropriate access to evidence-based cancer treatment is not compromised for patients with cancer.

CMS specifically seeks comment on whether to allow Medicare Advantage plans to require an enrollee to try and fail an off-label medically-accepted indication before

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providing access to a drug for an FDA-approved indication. CMS notes that using off-label drugs in step-therapy would only be allowable where the off-label indication is supported by widely-used treatment guidelines or clinical literature that CMS considers best practices. NCCN thanks CMS for recognizing the critical role that off-label therapies play, particularly in oncology, as well as the important role that clinical guideline organizations play in informing evidence-based care. However, NCCN has concerns that implementing fail first policies within oncology may have serious consequences for patients. Oncology is an increasingly individualized specialty in which a patient’s first line of treatment may play a role in which future therapies may be employed. As such, fail first policies are not clinically appropriate within oncology except as indicated by evidence-based clinical practice guidelines. NCCN recommends the adoption of policies that require adherence to professional society and recognized guidelines in treatment decisions, as outlined in further detail above. Implementing this model promises to significantly reduce overall and episodic drug spend without compromising patient access to evidence-based cancer care.

**Facilitating Patient Access to Meaningful Health Purchasing Information**

The proposed rule includes three provisions intended to increase patient access to health purchasing information. These provisions include: (1) incorporating new requirements under the “Know the Lowest Price Act of 2018” Part D regulation by adding a paragraph that specifies that a Part D sponsor may not prohibit a pharmacy from, nor penalize a pharmacy for, informing a Part D enrollee of the availability of a prescribed drug at a lower cash price than what they would be charged within their plan (2) proposing to require a real time benefit tool (RTBT) to serve as an adjunct to existing SCRIPT and Formulary and Benefits standards to make beneficiary-specific drug coverage and cost information visible to prescribers and (3) proposing to require Part D sponsors to include information about negotiated price changes and lower cost therapeutic alternatives in the Part D Explanation of Benefits (EOB).

**Prohibition of “Pharmacy Gag Clauses”:** NCCN supports greater access to health information so that patients are empowered to make the best treatment and health purchasing choices and appreciates CMS’ efforts in this area. In particular, NCCN applauds CMS’ proposal to incorporate into Part D regulation protections to ensure pharmacists are able to provide patients with all relevant purchasing information. Financial toxicity is a significant concern for a majority of patients with cancer and providing beneficiaries with relevant cost information is an important first step to combatting financial toxicity. We support this proposal and thank CMS.

**Part D Explanation of Benefits:** While NCCN supports greater patient access to health care information, providing information on “lower cost therapeutic alternatives” in the patient Explanation of Benefits means the information will reach patients after treatment choices have been made and may not reach patients until treatment is well
underway. Additionally, we are concerned about the potential for patient confusion as the proposed definition of a lower cost therapeutic alternative is quite broad and may result in patients receiving cost information on medications that are not clinically appropriate. We encourage CMS to put the appropriate safeguards in place to ensure “lower cost therapeutic alternatives” provided to the patient in the EOB and to the provider in the RTBT are based on evidence-based medicine, consistent with clinical practice guidelines, such as the NCCN Guidelines. The use of a RTBT may be a promising proposal to improve prescriber access to patient cost information, if the information provided is individualized, accurate, and informed by evidence-based guidelines. NCCN encourages CMS to pursue policies that will provide patients with meaningful, actionable information about their cost-sharing responsibility at the beginning of the treatment process. This information may be used as a starting point for shared decision-making considering the patient’s own value system.

NCCN recommends the use of the NCCN Guidelines® with NCCN Evidence Blocks™ for assistance in patient decision making. NCCN Guidelines® with NCCN Evidence Blocks™ are a visual representation of five key components of value that provide important information about specific recommendations contained within the NCCN Guidelines. These five components are: efficacy, safety, quality and quantity of evidence, consistency of evidence, and affordability. The NCCN Guidelines with NCCN Evidence Blocks™ can be used as early as in the physician’s office, when the decision-making process begins. Additionally, the NCCN Guidelines with NCCN Evidence Blocks™ are free of charge for non-commercial use and physicians and patients may access them free of charge online.

NCCN appreciates the opportunity to respond to the CMS Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. 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,

[Signature]

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