September 6, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-1654-P, Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model

Dear Acting Administrator Slavitt:

The National Comprehensive Cancer Network® (NCCN®) is pleased to comment on the CMS proposal for revisions to payment policies under the calendar year 2017 Physician Fee Schedule as they relate to NCCN’s mission of improving the quality, effectiveness, and efficiency of cancer care so that patients can live better lives.

As an alliance of 27 leading academic cancer centers in the United States that treat hundreds of thousands of cancer patients annually, NCCN is a developer of authoritative information regarding cancer prevention, screening, diagnosis, treatment, and supportive care that is widely used by clinical professionals. NCCN Clinical Practice Guidelines in Oncology® (NCCN Guidelines®) represent the standard of care for clinicians and policy makers. The NCCN Guidelines® and their derivatives help ensure access to appropriate care, clinical decision making and assessment of quality improvement initiatives. NCCN Guidelines are the recognized standard for clinical policy in cancer care and are the most thorough and frequently updated clinical practice guidelines available in any area of medicine.

Since June 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.
Additionally, in June 2016, CMS recognized NCCN as a qualified provider-led entity (PLE) for the new Medicare Appropriate Use Criteria (AUC) Program for developing AUC and establishing policy and decision-making for diagnostic imaging in cancer patients. NCCN Imaging AUC™ support clinical decision-making around the use of imaging in patients with cancer by outlining all imaging procedures recommended in the NCCN Guidelines®, including radiographs, computed tomography (CT) scans, magnetic resonance imaging (MRI), functional nuclear medicine imaging (PET, SPECT), and ultrasound. NCCN is committed to assuring that the most up-to-date recommendations are available and reviews and updates the NCCN Imaging AUC™ on a continual basis to ensure that the recommendations take into account the most current evidence.

**Appropriate Use Criteria for Advanced Diagnostic Imaging Services**

In this Notice of Proposed Rulemaking (NPRM), CMS proposes requirements and processes for specification of qualified clinical decision support mechanisms (CDSMs) under the Medicare AUC program; the initial list of priority clinical areas and exceptions to the requirement that ordering professionals consult specified applicable AUC when ordering applicable imaging services.

NCCN supports CMS' proposal to define CDSM under §414.94(b) as an interactive, electronic tool for use by clinicians that communicates AUC information to the user and assists them in making the most appropriate treatment decision for a patient's specific clinical condition.

CMS requests comment on communicating appropriateness ratings to ordering practitioners, such as numeric ratings, a dichotomous yes/no or a red, yellow or green light. Individual patient factors and preferences strongly influence decision-making in cancer care; therefore, NCCN does not believe a binary yes/no rating system to be appropriate. Rather, we encourage the use of a rating system that incorporates both the level of evidence and expert consensus and conveys a range of ratings resulting from these metrics. Additionally, overarching language such as 'appropriate', 'may be appropriate', or 'not appropriate', as well as color indicators, may be helpful for display purposes to quickly indicate appropriate imaging to the ordering physician. The use of a binary yes/no rating is not preferred as it obscures information related to the level of evidence and consensus and may cause confusion when choosing between multiple 'appropriate' imaging tests.

In the CY 2016 PFS final rule with comment period, CMS established that it would identify priority clinical areas through rulemaking, and that these may be used in the determination of outlier ordering professionals in a future phase of the Medicare AUC program. As a result, CMS solicits comment in this CY 2017 NPRM on a proposed initial set of 8 priority clinical areas and recommendations for other clinical areas that should be included. Of the 8 priority clinical areas proposed, one is specific to cancer: “Cancer of the lung (primary or metastatic, suspected or diagnosed),” and NCCN supports inclusion of this clinical area.

Based on the claims analysis methodology of assessing percentage of total services and payments that CMS used for selecting the 8 priority clinical areas, entitled '2014 Medicare Claims Data for Selected Advanced Imaging Services,' NCCN also suggests the inclusion of Prostate Cancer (Malignant neoplasm of the prostate) as an additional priority clinical area (Total Services: 838,764; Total payments: $75,965,274).

CMS also proposes to add §414.94(g)(1) to establish qualifications and requirements for qualified CDSMs. NCCN fully supports the proposed requirement to identify the appropriate use criteria consulted if the CDSM makes available more than one criterion relevant to a consultation for a patient's specific clinical scenario. As the CDSMs, under the proposal, would be able to incorporate specified applicable AUC from more than one qualified PLE (§414.94(g)(1)(iv)), it will be critically important that
the PLEs and their corresponding AUC are clearly identified at the point of order and that subsequent reporting and data analysis easily differentiate between the AUC source used.

NCCN also supports the proposed requirement (§414.94(g)(1)(vii)) that CDSMs update AUC content at least every 12 months to reflect revisions or updates made by qualified PLEs to their AUC sets or an individual appropriate use criterion, with the exception that AUC be removed more expeditiously in the event a qualified PLE determines an existing AUC to be potentially dangerous to patients and/or harmful if followed. As with the requirements set forth for a qualified PLE, NCCN believes that the timely and continual update of the AUC within the CDSM is critically important for ensuring that the highest standards of quality of care are current and available for clinical consideration at the point of care.

**Medicare Shared Savings Program**

As part of NCCN’s mission of improving the quality, effectiveness, and efficiency of cancer care so that patients can live better lives, we believe beneficiary choices of providers and treatment are essential. For this reason, NCCN supports CMS’ proposal to supplement the current Medicare Shared Savings Program (MSSP) beneficiary assignment process with a voluntary beneficiary alignment process that incorporates beneficiary attestation about their “main doctor,’ as doing so could help patients engage better with the provider they consider responsible for coordinating their overall care and improve care management from the accountable care organization (ACO) side.

Consistent with comments NCCN recently submitted regarding the Merit-Based Incentive Payment System (MIPS) (CMS-5517-P) NPRM, we support the MSSP’s efforts to continue to align quality measures across quality and value-based purchasing programs so that comparisons of patient outcomes can be made across various care models and a consistent standard of care can be delivered. Specifically, we support steps taken to ensure alignment of the MSSP ACOs, the Physician Quality Payment Program and the recommendations from the Core Quality Measures Collaborative, as such synergies should hopefully result in improved, streamlined quality measurement of patient care.

We again appreciate the opportunity to respond to the CY 2017 Physician Fee Schedule NPRM. If you have any questions, we would welcome the opportunity to discuss our comments further.

Sincerely,

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