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-1717-P Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems

Dear Administrator Verma:

The National Comprehensive Cancer Network® (NCCN®) is pleased to comment on the Centers for Medicare & Medicaid Services (CMS) Contract Year (CY) 2020 Proposed Hospital Outpatient Prospective Payment System Rule (CMS–1717–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 Laboratory Date of Service (DOS) policy and the site neutrality provisions within the proposed rule.

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 inappropriate 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 HIT vendors.

Clinical Laboratory Fee Schedule: Date of Service Provisions

In the CY 2018 OPPS/ASC final rule, CMS finalized an exception to the DOS policy for the hospital outpatient setting. This exception allowed the DOS for molecular pathology tests and certain ADLTs that are excluded from the OPPS packaging policy to be the date the test was performed rather than the date of specimen collection when certain conditions are met. Conditions for exception include if it was medically appropriate to collect the sample during the outpatient encounter and if the results of the test do not guide treatment provided during the hospital outpatient encounter. The intention of this policy was to address an unintended consequence of the original “14 day rule” which was a financial incentive for laboratories to perform testing on day 15, or after, following discharge in order to bill Medicare separately. The previous policy was creating unnecessary delays in patient access to appropriate testing.

During the public comment period following CMS’ CY 2018 OPPS/ASC proposed rule, NCCN commented in support of the proposed revisions to the laboratory DOS policy and 14 day rule. Specifically, NCCN stated that “In many cases, the complexities of these billing rules can lead to delays in the ordering of precision medicine tests, which can result in follow-on delays in test results and the initiation of treatment plans. This paradigm continues to negatively impact patients’ access to care and, in some cases, efficacy of treatment plans. As such, NCCN applauds CMS for revisiting its DOS policy and urges the agency to finalize its proposed modifications. More specifically, NCCN supports the creation of a new exception to the DOS policy for both molecular pathology tests and Advanced Diagnostic Laboratory Tests (ADLTs). Applying this policy to both molecular pathology tests and ADLTs will facilitate improved patient access to care by encouraging appropriate and timely
testing and treatment decisions so that patients and their providers can make the most informed treatment decisions."

In the CY 2020 Hospital Outpatient Prospective Payment System proposed rule, CMS solicits feedback on potential revisions to the laboratory DOS policy and 14 day rule. CMS notes that stakeholders have reported administrative difficulties implementing the exception including difficulty developing the systems changes necessary to provide the performing laboratory with the patient’s hospital outpatient status, beneficiary demographic information, and insurance information. To address these concerns, CMS proposes several potential solutions including changing the test results requirement.

According to the OPPS proposed rule, CMS believes that test results performed on a specimen collected during one hospital outpatient encounter are intended to guide treatment during a future hospital outpatient encounter and as a result should be considered a hospital service, billed by the hospital not the molecular or ADLT laboratory. CMS believes that a test’s relationship to a hospital outpatient encounter depends on several clinical issues that the ordering physician is most familiar with. CMS is considering a revision to the DOS exemption to specify that the ordering physician would determine whether the results of the ADLT or molecular pathology test are intended to guide treatment provided during a hospital outpatient encounter, if the other four requirements under are met.

NCCN has several concerns with the revisions as proposed. First, none of the proposed approaches address the historic patient access issues and delayed testing resulting from the 14 day rule. Additionally, requiring the ordering physician to determine whether a molecular pathology test does or does not guide treatment during the current or a future hospital outpatient encounter places an additional administrative burden on the physician. A physician may also be unable to predict whether test results will be used as part of a future hospital outpatient encounter. For example, if the test results are intended to guide decision-making on use of chemotherapeutics, drug infusions can occur in the physician office or the hospital outpatient department.

NCCN appreciates CMS’ attempt to address administrative burden but has significant concern that none of the approaches outlined within the proposed rule address the historic patient access issues that initially prompted the adjustments to the laboratory DOS and 14 day rule. NCCN supports maintaining the 2018 exemption as is in order to maintain patient access to timely and clinically appropriate biomarker testing.

**Site Neutrality Provisions**

CMS notes that in CY 2019 CMS began the phase in of payment at the Physician Fee Schedule (PFS) rate for clinic visits provided at an Exempted Off-campus Provider
Based Departments (PBD). The PFS-equivalent rate was 60 percent less than the OPPS rate. The finalized 60 percent payment reduction was phased in by applying half of the total 60 percent reduction in payment for a 30 percent reduction in payment in CY 2019. For CY 2020, CMS proposes to complete the phase in of the reduction and pay 60 percent less than the proposed OPPS rate. As noted in NCCN’s comment letters regarding the CY 2017, CY 2018, and CY 2019 OPPS Proposed Rules, that contained provisions to significantly cut OPPS rates, NCCN is concerned that this payment rate reduction may have potential negative consequences for patient access to comprehensive high-quality cancer care.

Specifically, NCCN is concerned that the reductions in payment will negatively impact patient care as it inadvertently penalizes providers for providing high-quality, comprehensive services that are typically available and provided at hospital-based facilities that are associated with higher investment and maintenance costs and that were historically reimbursed at a higher rate under OPPS. The services provided at these sites are often significantly more complex and comprehensive than care provided in other types of physician office settings. Cancer care, in particular, is a field marked by multidisciplinary care and constant innovation; as technological and scientific advancements in care delivery occur. NCCN urges CMS not to discourage providers’ abilities to offer what may not only be innovative care but also the highest standards of care.

NCCN appreciates the opportunity to respond to the Hospital Outpatient Prospective Payment System proposed rule. NCCN encourages CMS to maintain previous revisions to the laboratory DOS policy and 14 day rule to protect timely patient access to clinically appropriate care. Additionally, NCCN encourages CMS to reconsider payment reductions within the OPPS system for off-campus provider based departments. 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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