



National
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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-1656-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program

Dear Acting Administrator Slavitt:

National Comprehensive Cancer Network® (NCCN®) is pleased to comment on CMS proposals, in this Notice of Proposed Rulemaking (NPRM), 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.

Fred & Pamela Buffett
Cancer Center

Case Comprehensive Cancer
Center/University Hospitals
Seidman Cancer Center and
Cleveland Clinic Taussig
Cancer Institute

City of Hope Comprehensive
Cancer Center

Dana-Farber/Brigham and
Women's Cancer Center
Massachusetts General Hospital
Cancer Center

Duke Cancer Institute

Fox Chase Cancer Center

Huntsman Cancer Institute
at the University of Utah

Fred Hutchinson Cancer
Research Center/
Seattle Cancer Care Alliance

The Sidney Kimmel
Comprehensive Cancer
Center at Johns Hopkins

Robert H. Lurie Comprehensive
Cancer Center of Northwestern
University

Mayo Clinic Cancer Center

Memorial Sloan Kettering
Cancer Center

Moffitt Cancer Center

The Ohio State University
Comprehensive Cancer Center -
James Cancer Hospital and
Solove Research Institute

Roswell Park Cancer Institute

Siteman Cancer Center
at Barnes-Jewish Hospital
and Washington University
School of Medicine

St. Jude Children's
Research Hospital/
The University of Tennessee
Health Science Center

Stanford Cancer Institute

University of Alabama at
Birmingham Comprehensive
Cancer Center

UC San Diego
Moore's Cancer Center

UCSF Helen Diller Family
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University of Colorado
Cancer Center

University of Michigan
Comprehensive Cancer Center

The University of Texas
MD Anderson Cancer Center

University of Wisconsin
Carbone Cancer Center

Vanderbilt-Ingram
Cancer Center

Yale Cancer Center/
Smilow Cancer Hospital

Additionally, in July 2016, CMS recognized NCCN as a qualified provider-led entity (PLE) for the new Medicare Appropriate Use (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.

Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

Overall, NCCN supports Medicare transitional pass-through payments to ambulatory surgical centers (ASC) as a way of fostering patient access to medical devices, drugs and biologicals without increasing an ASC's costs or overall spending in the US health care system. CMS proposes, "beginning with pass-through drugs and biologicals newly approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs and biologicals to afford a pass-through period that is as close to a full 3 years as possible for all pass-through payment drugs" (81 FR 45657). **Since CMS currently makes these updates annually, NCCN believes this proposal, if finalized, would eliminate pass-through eligibility period variability by ensuring an even, consistent level of patient access to innovative drugs and biologicals. We believe it also ensures appropriate incentives for innovation.**

For instance, under the current process, a new drug or biological receiving pass-through status on January 1 would receive 3 years of pass-through status, whereas a new drug receiving pass-through status on July 1 would receive only 2 and ½ years of pass-through status. Under the proposal, the drug receiving pass-through status on July 1 would also receive a 3-year pass-through status.

For the same reasons discussed above, NCCN also supports CMS' proposal (81 FR 45653) for a quarterly, as opposed to annual, expiration of pass-through status for devices.

Proposed OPPS Payment to Certain Cancer Hospitals Described by Section 1886(d)(1)(B)(v) of the Act

For CY 2017, CMS proposes to continue its policy to provide additional payments to 11 specified cancer hospitals so that each cancer hospital's payment-to-cost ratio (PCR) is equal to the weighted average PCR for other Hospital Outpatient Prospective Payment System (OPPS) hospitals. **In an effort to ensure the 11 specified cancer hospitals are able to continue to deliver high quality care, NCCN supports CMS efforts to ensure that these hospitals' payments are not lower than it would have been under OPSS and other hospitals, simply based on the cost of care and severity of cases seen.**

Payment for Services Furnished in Off-Campus PBDs to Which Sections 1833(t)(1)(B)(v) and 1833(t)(21) of the Act Apply (Nonexcepted Off-Campus PBDs)

CMS notes that many off campus provider based departments (PBDs) were initially enrolled in Medicare as freestanding physician practices and subsequently acquired by hospitals (81 FR 45688). CMS further contends that because many of the services furnished in off-campus PBDs are identical to those furnished in freestanding physician practices, it is proposing to start paying for certain "nonexcepted items and services" under the Medicare Physician Fee Schedule (MPFS) instead of under the OPSS, as Section 1833(t)(21)(C) provides that payments for nonexcepted items and services be made under the applicable

payment system under Medicare Part B (other than under OPPOS). That said, it is worth also noting that many remotely located outpatient services of Dedicated Cancer Centers did not start out as freestanding physician practices, however these services, which are often far more complex than care provided in other types of physician office settings, would be negatively affected by the CMS proposal if finalized.

NCCN is concerned that this proposal, if finalized, would negatively impact patient care as it could inadvertently penalize providers for providing services that have historically been reimbursed at a higher rate under OPPOS than would be under MPFS. That is, a restriction to bill under only the MPFS would not only discourage providers from providing and billing additional services, such as chronic care management and care coordination, but would also be inconsistent with CMS' overarching goal of trying to achieve higher quality, value-based care.

Furthermore, this proposal includes drawing a distinction between the types of services that can be provided at an excepted hospital outpatient department, in which new "clinical families of services" (as defined by the proposed rule) would be reimbursed at the MPFS rate.

If finalized, this proposal could prevent expansions of the clinical families of services offered at an excepted facility from being reimbursed at the OPPOS rate, which in turn would affect PBD's abilities to offer and deliver the highest quality cancer care to patients. Cancer care, in particular, is a field marked by constant innovation; as technological and scientific advancements in care delivery occur, we urge CMS not to discourage providers' abilities to offer what may not only be innovative care but also the highest standards of care, due to reimbursement issues.

Proposed OPPOS Payment for Codes G0296 and G0297 for Low-dose CT Lung Cancer Screening Shared Decision Making Session and Low-dose CT Lung Cancer Screening

For CY 2017, CMS proposes to cut reimbursement for Codes G0296, low-dose CT lung cancer screening shared decision making session, and G0297 low-dose CT (LDCT) lung cancer screening by 64 and 44 percent, respectively, in comparison to 2016 payment rates. **NCCN is concerned that this proposal, if finalized, would adversely affect access to the shared decision making visit and corresponding LDCT scan. Lung cancer can often be successfully treated if diagnosed at an early stage, however the large majority of patients are diagnosed with later stage disease. Therefore, lung cancer deaths in the United States can be mitigated by the adoption of federal policies to promote widespread screening of at-risk populations using LDCTs. If the reimbursement rates are too low, hospital outpatient departments may eliminate existing LDCT lung cancer screening services that they deem cost prohibitive because they will not be able to afford to offer the services. Qualifying patients, especially underserved poor and minority patients who rely on the hospital outpatient departments for health care services, may be unable to receive annual screens due to steep cuts in reimbursement.**

Proposed New Hospital Outpatient Quality Reporting Program Quality Measures for the CY 2020 Payment Determinations and Subsequent Years

OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy Measure

CMS proposes to add this measures to the Hospital Outpatient Quality Reporting (OQR) Program based on cited evidence that "hospital admissions and ED visits among cancer patients receiving chemotherapy are often caused by predictable, and manageable, side effects from treatment" (81 FR 45711). **While NCCN agrees that avoiding complications and having necessary early interventions following chemotherapy in an effort to reduce unnecessary ED visits and hospitalizations is ideal, we**

believe the measure should adjust for those ED visits and hospitalizations which may be necessary, so as not to create patient safety issues (e.g. under-dosing chemotherapy to keep patients out of the hospital) and value issues (e.g. overdosing growth factors and anti-emetics to keep patients out of the hospital). Stated another way, the measure, as described in the NPRM, would measure the number of ED visits admissions but would not consider whether appropriate action was taken to prevent admissions or if the admission was appropriate and unavoidable. Therefore, we believe a measure looking at the medical history of admitted patients to see whether they had received appropriate prophylactic measures to prevent toxicity and to assess the appropriateness of hospitalization or ED visits would be more meaningful than a simple count of ED visits and hospitalizations.

There are inherent risks in chemotherapy as a treatment strategy. Very few medical areas have drugs approved in which there are significant numbers of fatalities attributed to the agent in clinical trials. Oncology is the exception because the risk benefit ratio favors use of these toxic therapies. When developing a cytotoxic agent one of the goals is to establish the therapeutic index, or dose at which optimal benefit is achieved with acceptable toxicity. Dose reduction can affect the efficacy of treatment so every attempt is made to maintain dose intensity and to support the patient through the toxicities. While appropriate measures can reduce the incidence and severity of these toxicities, they do not eliminate them. Our concern is that by using hospital and ED usage as a measure, it will encourage clinicians to either reduce doses to subtherapeutic ranges where resistant cancer clones will be established or discourage them from encouraging patients who need emergent care to go to the hospital to receive it.

OP-37a-e: Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey Measures

CMS proposes to adopt the OAS CAHPS survey measures into the OQR Program based on the belief that pain control is an appropriate part of routine patient care that hospitals should manage and is an important concern for patients, their families and their caregivers. CMS also points out that the survey questions focus on pain management communication and information provided as opposed to pain treatment received (81 FR 45718). **NCCN supports this proposal for the reasons CMS has stated and also believes in the importance of pain management communication that includes communication with patients about pain-related issues, setting expectations about pain, shared decision-making and proper prescription practices.**

Proposed Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs: Removal of the Clinical Decision Support (CDS) and Computerized Physician Order Entry (CPOE) Objectives and Measures for Eligible Hospitals and CAHs

CMS proposes to eliminate the CDS and CPOE objectives and measures for eligible hospitals and critical access hospitals (CAHs) attesting under the Medicare EHR Incentive Program and subsequent years. Because these measures have had high attestation rates, CMS believes that the measures are “topped out” with no further room for performance improvement. **NCCN respectfully disagrees with CMS’ proposal to remove the CDS and CPOE measures from the EHR Incentive Program for eligible hospitals and CAHs and requests that they remain in the program.**

Although these measures may have had historically high attestation, this does not mean they have had consistently high performance across all provider specialties within each eligible hospital or CAH. As discussed at the recent multi-stakeholder NCCN Policy Summit: Emerging Issues and Opportunities in Health Information Technology in Washington DC on June 27, 2016, CDS has made significant headway in

the primary care space but lags behind in specialty care and the technology vendor community must quickly catch up.

Illustrating this point, according to a CMS report of eligible professionals (EPs) participating in the Medicare EHR Incentive Program, only 2% of the Medicare EHR payments made between 2011-2013 were made to oncologists and hematologists.¹ Furthermore, according to the 2014 PQRS experience report, only 8% of oncologists, 2% of nuclear medicine physicians and radiation oncologists and 1% or less of interventional radiologists, radiologists and pathologists participated via EHR reporting.² These data show that there is room for increased EHR adoption in oncology care and opportunity for improved use of clinical decision support.

Aligned with the objective to enhance oncology clinical decision support, NCCN is currently digitizing its 62 guidelines, which include nearly 1,800 pages of decision support algorithm. NCCN has also been working with IT vendors to digitize chemotherapy order templates. Digitizing cancer care guidelines for CDS and chemotherapy order templates are extremely important efforts for empowering oncology care providers to make better and safer care decisions.

CMS also states that it proposes to remove the CDS measure and objectives in an effort to reduce provider reporting burden and that eligible hospitals and CAHs may continue to independently track activities to the CDS objective and measures for their own quality improvement goals or preferences. **However, NCCN believes that having robust CDS in oncology care (which does not yet exist today) should streamline the shared-decision making process, which aligns to CMS' National Quality Strategy goals, thereby reducing reporting burden. Furthermore, under CMS' proposal, removing the CDS objective and measures from the EHR Incentive Program may actually discourage eligible hospitals and CAHs to continually invest in technology that contains more robust CDS and order templates in the future.**

Proposed Changes to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs: Proposed Changes to the Objectives and Measures for Stage 3 (42 CFR 495.24) in 2017 and 2018

CMS has proposed to reduce the threshold for eligible hospitals and CAHs attesting to:

- the *Patient Access* measure, under the *Patient Electronic Access to Health Information* objective, from 80 to 50 percent, based on Health IT vendor development concerns.
- the *View, Download, and Transmit (VDT)* measure, under the *Coordination of Care through Patient Engagement* objective, from more than 5 percent to at least one patient, based on hospital concerns regarding implementing the objectives and measures requiring patient action, such as patients having limited proficiency with or lack of access to IT as well as patients declining access.
- The *Secure Messaging* measure, under the *Coordination of Care through Patient Engagement* objective, from more than 25 percent to more than 5 percent, based on feedback that patients in the hospital for an isolated incident may not have significant reason for a follow up for a secure message or patients may decline to access messages.
- The *Patient Care Record Exchange* measure, under the *Health Information Exchange (HIE)* objective, from more than 50 percent to more than 10 percent, based on widespread concerns of the lack of HIT interoperability.

¹ EHR Incentive Programs Data Brief. November 2013.

https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/DataBrief_November2013-.pdf Accessed August 27, 2016

² 2014 PQRS Experience Report, Including Trends (2011-2015). <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/pqrs/analysisandpayment.html>. Accessed June 20, 2016

- The *Request/Accept Patient Care Record* measure, under the *Health Information Exchange (HIE)* objective, from more than 40 percent to more than 10 percent, based on widespread concerns of the lack of HIT interoperability.
- The *Clinical Information Reconciliation* measure, under the *Health Information Exchange (HIE)* objective, from more than 80 percent to more than 50 percent, based on widespread concerns of the lack of HIT interoperability.
- The *Public Health and Clinical Data Registry Reporting* objective requirements to any combination of three measures out of the six measures available under Stage 2 requirements, based on the difficulty hospitals have in finding registries that allow for successful attestation.

NCCN can appreciate the challenges and concerns in HIT but is concerned that reducing the above measurement thresholds discourages health IT vendors from more quickly achieving the interoperability objectives necessary for delivering higher quality patient care and are also in direct conflict with the Office of the National Coordinator for Health Information Technology's stated interoperability goals. Furthermore, NCCN believes exclusions could be made to those measures in which patients decline access, have limited IT access, or for which a secure message communication is unnecessary. NCCN urges CMS to continue incentivizing HIT advancement and interoperability in the technology vendor community in such a way does not penalize hospitals and CAHs if EHR Incentive Program objectives and measures cannot be met under the HIT currently available today.

We again appreciate the opportunity to respond to CMS' proposals. If you have any questions, we would welcome the opportunity to discuss our comments further.

Sincerely,



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