September 24, 2018

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1693-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (CMS-1695-P)

Dear Administrator Verma,

On behalf of the National Policy Board and physicians of The US Oncology Network (The Network)[1], I thank you for the opportunity to comment on CMS-1695-P "Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model (CMS-1695-P)" (Proposed Rule), as published on July 31, 2018, in the Federal Register.

The Network is committed to working with the Centers for Medicare & Medicaid Services (CMS) to enhance the delivery of cancer care and protect patient access to high-quality care in the most efficient manner. Community-based oncology centers, like those in The US Oncology Network, are central to success in the battle against cancer. The Network unites physicians around a common vision of expanding patient access to the highest quality state-of-the-art care close to home, and at lower costs for patients and the health care system as a whole. Our mission is to help patients fight cancer, and win.

Unfortunately, access to community-based practices has declined over the past decade due in part to reimbursement policies and regulations that disadvantage independent physician practices in favor of large, complex healthcare systems. The Network applauds efforts by the Administration and CMS to curb consolidation in the healthcare

[1] The US Oncology Network is one of the nation's largest networks of community-based oncology physicians dedicated to advancing cancer care in America. Like-minded physicians are united through The Network around a common vision of expanding patient access to high-quality, integrated cancer care in communities throughout the nation. Leveraging healthcare information technology, shared best practices, refined evidence-based medicine guidelines, and quality measurements, physicians affiliated with The US Oncology Network are committed to advancing the quality, safety, and science of cancer care to improve patient outcomes. More information about The US Oncology Network can be found at www.usoncology.com.

marketplace, promote competition and improve the viability of private practicing physicians which will lead to lower healthcare costs and expand access to care.

The Network will focus our comments on four specific provisions included in this Proposed Rule:

1) Proposal and Comment Solicitation on Method to Control for Unnecessary Increases in the Volume of Outpatient Services;
2) Expansion of Services at Off-Campus Provider-Based Departments (PBDs) Paid Under OPPS (Section 603);
3) Proposal to Apply 340B Drug Payment Policy to Off-Campus Departments of a Hospital Paid Under the Medicare Physician Fee Schedule; and
4) Request for Information on Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Proposal and Comment Solicitation on Method to Control for Unnecessary Increases in the Volume of Outpatient Services

CMS proposes to institute the PFS-equivalent rate for clinic visit services performed at excepted off-campus provider based departments (PBD) to control unnecessary volume increases in the outpatient setting for these services. The Network strongly supports this proposal and encourages CMS to explore additional opportunities to expand site neutral payments for all clinically appropriate outpatient services.

For more than a decade, The Network has raised awareness of the negative consequences payment disparity across sites of service has on our nation's healthcare system. Reimbursement policies that pay hospital owned outpatient facilities higher rates for the exact same services provided in independent physician practices have increased costs to patients, insurers and taxpayers, as well as resulted in marketplace consolidation that limits patient choice by reducing access to care in the community-setting. Data shows that hospital acquisitions of private practices has skyrocketed in recent years - between 2012 and 2015, the number of physician practices employed by hospitals grew by 31,000 practices with 13,000 physician practices acquired from July 2014 to January 2015 alone[2]. Community oncology practices have been hit particularly hard by consolidation. A study in Health Affairs on hospital-physician consolidation found oncology had the highest rate of vertical integration at 54% in 2017[3], a substantial increase from an already concerning 20% in 2007.

When access to community-based care is impacted, patients and Medicare are on the hook for increased health care costs. Patient co-payments are approximately 10% higher in an off-campus PBD, equaling more than $650 in additional costs for each Medicare beneficiary fighting cancer per year. Additionally, the average out-of-pocket patient cost for commonly used cancer drugs is $134 more per dose if received in the outpatient hospital setting[4]. These costs add up. Data shows over a three-year period, Medicare beneficiaries paid $4.05 million more in out-of-pocket costs because of higher patient co-payments at off-campus PBDs than they would have for the exact same chemotherapy services if received at community cancer practices[5].

Congress recognized the negative impact payment differentials have on the healthcare system and passed the Bipartisan Budget Act of 2015, which included a site neutral payment provision for all newly acquired and newly built

[2] PAI: Physician Practice Acquisition Study: National and Regional Employment Changes; September 2016
[3] Health Affairs: Hospital-Physician Consolidation Accelerated in the Past Decade in Cardiology, Oncology; July 2018
[4] IMS Institute, "Innovation in Cancer Care and Implications for Health Systems: Global Oncology Trend Report," May 2014
[5] The Moran Company, "Results of Analyses for Chemotherapy Administration Utilization and Chemotherapy Drug Utilization, 2005-2011 for Medicare Fee-for-Service Beneficiaries," May 2013

off-campus PBDs. The Network commended CMS' implementation of Section 603 in the CY17 OPPS final rule and is very encouraged by CMS' proposal in the Proposed Rule to implement site neutral payments for outpatient clinic visits at all off-campus PBDs. The site neutral payment policy for Evaluation and Management (E&M) services in the Proposed Rule is a necessary step in the right direction and The Network urges the agency to examine other outpatient services for inclusion, such as the administration of chemotherapy, where volume has increased due to hospital ownership of physician practices. From 2011 to 2016, the volume of OPPS clinic visits increased by 43.8% and OPPS chemotherapy administration increased by 56.1%. Meanwhile, in freestanding physician offices, the volume of office visits grew by only 0.4%, and chemotherapy administration decreased by 13.4%[6].

The Network further encourages CMS to evaluate implementing payment rates in a budget neutral manner by setting payments for cancer drug administration and other cancer care services at a rate that falls between the current higher OPPS rate and the lower rate for physician offices. The new consistent rate shared across settings would support access to community cancer clinics, while removing the unfair payment advantage currently awarded to off-campus PBDs, all while maintaining budget neutrality. We have supported legislation that would equalize payment rates for cancer services during the past two Congresses, including *the Medicare Patient Access to Treatment Act of 2015*, which would have required changes to payment rates to be budget neutral. Lastly, when evaluating implementation of site neutral payments in a budget neutral manner, we strongly encourage CMS take into account patient out-of-pocket costs to ensure patients are not negatively impacted.

Expansion of Services at Off-Campus Provider-Based Departments (PBDs) Paid Under OPPS (Section 603)

The Proposed Rule includes a proposal to reimburse new clinical families of services at excepted off-campus PBDs at the PFS-equivalent rate. The Network supports this policy and urges CMS to finalize it for CY 2019.

In the CY2017 OPPS Proposed Rule, CMS solicited comments on proposals to limit clinical service line expansion or volume increases at excepted off-campus PBDs. In its comments, The Network offered support for a limitation on the scope of services excepted off-campus PBDs are able to furnish and bill at the higher OPPS rate and urged CMS to move forward with the policy. The Network appreciates CMS revisiting this proposal and including it in the CY19 Proposed Rule.

CMS correctly notes that the intent of Section 603 was to remove the payment inequity incentive for hospitals to purchase physician practices. Allowing excepted off-campus PBDs to furnish new types of services under OPPS would perpetuate acquisition of independent physicians as hospitals could fold those physicians into existing excepted off-campus PBDs and charge Medicare and patients higher rates. This could further result in an increased shift in the site of service from lower paid settings into the higher paid excepted off-campus PBD. CMS is right to be concerned with this trend as community cancer clinics have experienced a 30% shift in the site of service for chemotherapy administration from the physician-office setting to the more-costly hospital outpatient setting[7].

The Network disagrees with comments insinuating that site neutral payments for new clinical families of services would stifle innovative care delivery and use of new technologies. Rather, this proposal would simply eliminate a loophole for hospitals to gain higher reimbursement rates through consolidation. Excepted off-campus PBDs will be able to expand services, they will just be reimbursed at a more appropriate and equitable rate.

[6] http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf?sfvrsn=0

[7] Milliman Report, April 2016: Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014

Proposal to Apply 340B Drug Payment Policy to Off-Campus Departments of a Hospital Paid Under the Medicare Physician Fee Schedule

CMS is proposing to pay Average Sales Price (ASP) -22.5% for 340B acquired drugs furnished by non-excepted off-campus PBDs. The Network commends CMS for continuing to evaluate and address the growth of the 340B drug discount program in an effort to lower out-of-pocket costs for patients, stem consolidation and preserve patient access to community-based care.

The Network supports the underlying goal of the 340B drug discount program which is largely aimed at stretching scarce federal resources to benefit indigent patients in critical access areas. However, we believe the program's recent growth may be contributing to the consolidation of community oncology practices. Based on an internal study from the Community Oncology Alliance[8], it is estimated that roughly 658 community cancer practices have been acquired by or affiliated with hospitals since 2008, with a significant portion of those transactions believed to be leveraged with 340B benefits. This has resulted in a shift in the site of service for chemotherapy administration from the physician-office setting to other, more-costly outpatient settings.

In fact, 10 years ago over 80% of cancer care was delivered in the community-based setting – today that number is closer to 50%[9]. This trend not only creates patient access issues, but often results in higher healthcare and patient out-of-pocket costs. The Network is committed to ensuring all cancer patients receive high quality, clinically appropriate care. We firmly believe in the value of community-based providers, who are at the front line of care delivery, providing local solutions to meet the needs of their patients.

For policymakers and regulators to properly assess the scope and value of the 340B program, The Network supports increased transparency through public reporting on meaningful data that provides additional clarity on a covered entity's patient mix, savings associated with enrollment, revenue associated with 340B-eligible outpatient drugs/services and charity care or patient services underwritten by 340B proceeds. We also encourage consideration of separate detailed reporting of these transparency measures for off-campus outpatient facilities to ensure accurate savings and revenue data is understood for child sites that may have a different patient profile than that of the covered entity.

This data is an essential component for informed oversight and will provide an opportunity for eligible entities to demonstrate how they are using funds derived from the program to benefit patient care. To ensure overall program integrity, operability and proper analysis of the data submitted, the Health Resources and Services Administration (HRSA) needs the tools to sufficiently administer and refine the program.

Request for Information on Leveraging the Authority for the Competitive Acquisition Program (CAP) for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

CMS is requesting information on design considerations for developing a potential model that would test private market strategies and increase competition for Part B drugs and biologicals. The Network is opposed to the

[8] 2018 Community Oncology Alliance, Practice Impact Report. Full Report available at: https://www.communityoncology.org/downloads/pir/COA-Practice-Impact-Report-2018-FINAL.pdf

[9] Milliman Report, April 2016: Cost Drivers of Cancer Care: A Retrospective Analysis of Medicare and Commercially Insured Population Claim Data 2004-2014

<u>fundamental tenets of a Competitive Acquisition Program (CAP)-like model and urges CMS refrain from re-launching the CAP program, as such a model could have negative implications for patient access and provider prescribing flexibility.</u>

The Network believes that models developed under the Centers for Medicare and Medicaid Innovation (CMMI) should be voluntary, targeted, patient-centered, transparent and supported by data. Properly constructed alternative payment models have the potential to produce positive effects on patient care while generating savings for Medicare. We know this through our collaboration with CMS and CMMI on the development and implementation of the Oncology Care Model (OCM). Today, sixteen US Oncology Network practices, encompassing 900 physicians and 58,000 unique patients, are participating in the voluntary model aimed at improving coordination, appropriateness of treatment, and access to care for beneficiaries undergoing chemotherapy. This partnership has led to a robust line of communication between The Network and CMMI, both of which are invested in success of the OCM and committed to improving outcomes for chemotherapy patients while realizing savings for the Medicare program.

The Network is concerned that allowing vendors to employ formulary and utilization management (UM) techniques in a CAP-like model could place burdensome restrictions on oncology drugs. These restrictions would not only create access barriers for patients, but would also remove physician prescribing autonomy. Clinical judgment is crucial in making complex treatment decisions for cancer patients. In a recent Community Oncology Alliance (COA) survey of oncologists, hematologists, and rheumatologists, 61% of providers said they believe a CAP would diminish their prescribing autonomy and ability to tailor prescriptions to the patient. Additionally, 88% said they believe a CAP would take care decisions away from the best person in the best position to make that decision[10]. Limiting an oncologist's ability to provide current, cutting-edge treatments could result in inferior outcomes for Medicare beneficiaries with cancer.

The Network is particularly concerned that a CAP-like model in which a third-party vendor is responsible for elements of the drug supply chain could have significant implications for the storage and safe handling of hazardous drugs. Currently, highly-trained physicians, who have the proven expertise to do so, can safely stock, monitor and administer their patients' drugs. Transferring that power to an outside entity that is not specially trained in providing care for patients could create significant safety risks. This is especially true in cancer care, where complex and volatile drug regimens often require providers to make changes at the point of care, such as dosing adjustments, using their clinical judgment. These drugs are delivered in the physician office due to the specialized training needed to ensure the integrity of these critical medications including safe handling and temperature controlled storage. Practices in The Network also keep an adequate supply of cancer medication on hand to ensure they are able to treat urgent patient appointments.

The Network appreciates the importance of holding down drug costs in cancer care. Indeed, that has been our mission for quite some time. As a prelude to our participation in the OCM, physicians in The Network sought to strengthen relationships with patients and payers by selecting regimens that demonstrate value over volume and reduce non-evidence-based variability in treatment. As a result, we developed Level I Pathways nearly a decade ago, now known as Value Pathways powered by NCCN. Value Pathways are evidence-based guidelines that re-direct the wide range of oncology treatments into more precise, clinically proven treatment options. The Pathways are physician-driven and designed to reduce variability, hospitalizations, and excessive care at the end of the life. According to a study in the Journal of Oncology Practice on patients treated both with and without our Level I Pathways, adherence to pathways

[10] https://www.communityoncology.org/2018/05/16/may-16-coa-physician-survey-medicare-part-b-proposals-will-harm-patients-increase-costs-and-bureaucracy/

lowered overall costs of care with equal or better outcomes. The results included a 22% lower frequency of chemotherapy infusion visits, a 23% lower frequency of non-chemotherapy agents, and a 35% reduction in outpatient costs[11].

For these reasons, The Network urges CMS abstain from instituting a CAP- like program for Part B drugs. As CMS looks for ways to manage costs, The Network encourages the agency to build upon strategies already working to hold down drug costs in oncology care.

Conclusion

On behalf of the National Policy Board of The US Oncology Network and our more than 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, we thank you for the opportunity to provide our comments on Proposed Rule CMS-1693-P. We are grateful to be able to engage in substantive discussions and welcome practice site visits with CMS officials. If you have any questions regarding issues raised in this letter, please contact Ben Jones at Ben.Jones@usoncology.com.

Lucy Langer, MD
Chair, National Policy Board
The US Oncology Network

[11] https://www.ncbi.nlm.nih.gov/pubmed/20539725