

December 31, 2018

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Seema Verma
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM)

Dear Administrator Verma,

On behalf of The US Oncology Network, which represents over 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to provide feedback on the advance notice of proposed rulemaking (ANPRM) regarding a potential International Pricing Index (IPI) Model for Part B drugs.

The US Oncology Network (“The Network”) is one of the nation’s largest and most innovative networks of community-based oncology physicians, treating more than 995,000 cancer patients annually in more than 450 locations across 25 states. The Network unites over 1,400 like-minded physicians around a common vision of expanding patient access to the highest quality, most cost-effective integrated cancer care to help patients fight cancer, and win. We are committed to value-based care models that lead to improved patient care, better quality and cost savings.

As community-based providers of complex cancer care, we appreciate the administration’s efforts to improve the affordability of drugs. However, we have strong concerns regarding the IPI Model under consideration, which would fundamentally disrupt patient access to timely, personalized cancer treatment options close to home. The proposed model could further escalate consolidation in oncology care and impede ongoing investments and efforts to transition toward value-based care delivery.

Given these concerns and the specific issues outlined below, The US Oncology Network urges CMS to not move forward with the IPI model. We encourage CMS to develop and test value-based care initiatives in collaboration with physicians, patients and other stakeholders that will not result in significant and irreversible disruption to the entire care delivery system. The Network stands ready to work with the administration and Congress to consider voluntary, patient-centered and evidence-based models aimed at reducing costs while protecting access to safe and timely care.

To facilitate review, our comments will focus on the following elements of the IPI Model that are of the most concern:

- The IPI’s mandatory participation will jeopardize the success and savings achieved from voluntary value-based payment models, like the OCM, and make it unrealistic for CMS to extract usable data.
- Inserting a third-party vendor in the procurement and distribution of Medicare Part B drugs will disrupt Medicare patients’ access to personalized cancer treatment and introduce an unparalleled level of complexity and administrative burden for community-based providers.
- The IPI model flat-fee does not adequately account for provider risk and operational challenges, nor does it fully account for the inherent system costs that would remain.
- The IPI model could limit patient access to novel, innovative therapies not available in other countries.

- The disruptive elements of the IPI model pose excessive risk and unpredictability to community-based practices and could result in providers closing their doors, further pushing patients out of the community-setting and into less convenient, more costly settings of care.
- We believe the answer lies in proven strategies such as the development of voluntary, targeted, collaborative payment models such as the OCM and use of evidence-based treatment guidelines such as Value Pathways.

Model Design and Scope

The Network is opposed to the mandatory nature of the proposed demonstration, particularly given the proven success of properly constructed, voluntary alternative payment models that have experienced sizeable patient and provider enrollment. The Network is proud to support more than 900 physicians participating in one such model, the Oncology Care Model (OCM). The OCM is an episode-based payment model demonstrating a successful transition from fee-for-service to value-based payment. The Network's 15 participating practices have voluntarily accepted the challenge of managing all aspects of a cancer patient's care for a 6-month episodic period (including the overall cost of drugs) and are starting to see meaningful results.

In the first 24 months of the OCM, Network providers enrolled more than 65,000 unique patients, which is a testament to the cooperative approach CMMI took in developing and implementing the voluntary model, including addressing many stakeholder questions and concerns throughout the process. Due to the practice transformation focus and investments made by The Network's OCM practices, patient care has been enhanced. For example, Medicare patients in the OCM receive comprehensive care management plans, exposure to navigators and social workers, advanced care planning, survivorship advice, estimated total out-of-pocket costs and formalized team care. In the most recent OCM performance period results for The Network, these reforms and investments have reduced hospital admissions and expensive emergency room visits. Moreover, our practices alone have realized more than \$20 million in savings for Medicare through participation in the OCM while being able to appropriately manage all aspects of the care delivery, including drug inventory.

The cornerstone of The Network's success in the OCM is a shared commitment and adherence to oncology evidence-based Value Pathways. For over a decade, physicians and clinicians in The Network have developed treatment guidelines designed to reduce variability, hospitalizations and excessive care at the end of life. Value Pathways are continually evaluated as new FDA-approved cancer treatments come to market and existing treatments receive new indications. The physician-led review focuses primarily on the efficacy and toxicity of treatments and how each option will impact patient outcomes. In instances where evidence shows equivalent efficacy and toxicity, treatment cost is the determining factor as to whether or not a treatment option is incorporated into a pathway. Adherence to pathways has been proven to lower the overall cost of care with equal or better outcomes.¹ In 2013, The Network joined forces with the National Comprehensive Cancer Network[®] (NCCN) to form Value Pathways Powered by NCCN™. The NCCN guidelines serve as a foundation and validation for our clinical content and The Network adds cost comparisons to arrive at a succinct list of value-based, cost effective treatment choices.

The Network is deeply concerned that the IPI model puts the measurable progress made from the OCM at risk. CMS specifically notes the IPI model would overlap with the OCM and other value-based payment programs, jeopardizing the viability of voluntary models with proven results for patients and the Medicare program. Practices have made significant financial and administrative investments in additional staffing, technology, enhanced operational workflow

¹ Neubauer MA, Hoverman JR, Kolodziej M, et al. (2010) Cost effectiveness of evidence-based treatment guidelines for the treatment of non-small-cell lung cancer in the community setting. J Oncol Pract 6:12–18. <http://m.jop.ascopubs.org/content/6/1/12.abstract>

and triage services to successfully participate in the OCM. The administrative burdens and costs associated with the IPI model would destabilize most community practices and be unsustainable for those already invested in the transition from fee-for-service to value-based care.

As demonstrated above, The Network supports The Innovation Center's Triple Aim to achieve better health outcomes, higher quality care and lower Medicare costs. However, we believe the IPI model runs counter to this mission and exceeds CMS' statutory authority. The IPI model would force an unproven, untested hypothesis on half of Medicare beneficiaries that could have very serious consequences for patient access, patient outcomes and overall costs. The IPI model lacks a patient-centered focus and could result in disparate care for beneficiaries being treated in geographic areas subject to the model. Unlike the OCM's patient notification and opt-out requirement, the IPI model would be forced on cancer patients with no notice or explanation of the extensive change to their care delivery. Further, a recent study concluded the vast majority of Medicare beneficiaries will not benefit from lower out-of-pocket costs from the IPI model.² **The Network strongly believes CMMI should pilot new, patient-centered care delivery models in a limited and targeted segment with voluntary participation to prevent overlap with current APMs that have shown measurable success.**

Another troubling aspect of the expansive nature inherent in the IPI model is the lack of a control group which will likely make it unrealistic for CMS to extract usable data from the model outcomes. Regardless of mandatory geographic randomization for certain providers, CMS is essentially proposing to impact ***all*** providers administering Part B drugs as the price of IPI-acquired treatments will be included in the nationwide Average Sales Price (ASP) resulting in drastic changes in reimbursement for virtually every Part B provider in the country. A recent Avalere analysis estimates a -7 percent impact for oncology drug reimbursement, a severe cut that many community providers will not be able to absorb.³ This will have a devastating and compounding impact on community-based cancer clinics who have experienced repeated reductions in reimbursement over the last decade. The result of this proposal is very likely a furthering of consolidation in the oncology space, decreasing access to community-based care and increasing healthcare costs as patients are forced into more expensive care settings.

Model Vendors

The Network opposes inserting a third-party vendor in the procurement and distribution of Medicare Part B drugs due to the negative implications for patient access to timely care and provider autonomy. The IPI model will significantly impact community-based cancer clinics' ability to maintain sufficient inventory, treat emergent patients and make dosing adjustments at the point of care. The Network warns that the IPI may create challenges for community oncology practices to offer personalized cancer treatment to Medicare patients and would introduce an unparalleled level of complexity and administrative burden.

Cancer therapies consist of complex and volatile drug regimens that are dynamic and frequently adjusted at the point of care based on a patient's ever-changing circumstance (disease progression, weight variation, drug sensitivity, etc.). Currently, highly-trained physicians, who have the proven expertise to do so, can safely stock, monitor and administer their patients' drugs allowing for closely supervised dose adjustments, drug substitutions and drug additions that are often made to optimally manage toxicity.

² Avalere: International Price Index Model's Impact on Patients and Providers: <https://avalere.com/insights/international-price-index-models-impact-on-patients-and-providers>

³ Avalere: International Price Index Model's Impact on Patients and Providers: <https://avalere.com/insights/international-price-index-models-impact-on-patients-and-providers>

Transferring this responsibility to an outside entity that is not a part of the patient's care team or specially trained in providing care for patients introduces new risks and system costs, jeopardizing patient safety and creating barriers to timely treatment. Model participants would need to manage separate drug distribution channels and inventories, and multiple billing capabilities and EHR platforms. Drugs would also need to be ordered prior to patient appointments limiting the ability for oncologists to make day-of dosing adjustments for IPI cancer patients, potentially delaying care and causing unnecessary drug waste. Additionally, optimal care regimens often span across Medicare Part B & D programs making separate inventories and coordinated access extremely complex under an IPI model.

The Network remains very concerned with the potential use of utilization management (UM) techniques by third-party vendors that could impede access to cancer treatments by limiting the full breadth of available therapies. We currently see the consequences of third-party vendors in the Part D program denying treatments prescribed based on a physicians' assessment of clinical need due to arbitrary prior authorization, step therapy requirements or formulary restrictions that only serve to benefit the vendors themselves, typically Pharmaceutical Benefit Managers (PBMs). The Network believes that providers are better suited to direct treatment to less expensive medications without compromising clinical efficacy. CMS should embrace proven methods, such as evidence-based pathways programs, to drive value-based treatment choices.

Flat-Fee Payment Alternative for Providers

CMS' premise for the flat-fee provider payment included in the IPI model is based on a flawed assumption that providers' prescribing decisions are influenced by a potential incentive to use higher priced drugs rather than the clinical considerations that truly influence a provider's choice in prescribing therapeutic alternatives, especially as it relates to cancer. There is no evidence to support CMS' claim that the current system incentivizes physicians to prescribe higher cost drugs. Conversely, a study conducted by UnitedHealthcare designed to eliminate any "incentive" in community oncology practices proved the exact opposite to the CMS assumption. According to the study, "eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy." The spending on drugs in this study increased by 179 percent.⁴ The Network strongly believes that the premise for this flat-fee payment is based on a flawed assumption that has never been proven to be true and could result in increased drug utilization. **Alternatively, we urge CMS to build upon payment reforms that are bending the cost curve through comprehensive approaches to patient care rather than models focused on a singular component such as drug costs.**

The IPI model also runs counter to CMS' goal of reducing provider burden and the financial risk associated with Part B drugs. As structured, participants in the IPI model will bear significant risk as they will be required to separately maintain a costly IPI-specific inventory and distribution management system, pay for a newly created vendor (and/or distribution) fee and collect patient co-insurance for beneficiary out-of-pocket costs associated with the drug. The risk associated with the collection of patient co-insurance is substantial alone as approximately 16 percent of current patients undergoing treatment at Network practices do not have supplemental coverage. In the IPI, the provider will not own the drug, but will be responsible for significant new costs and remain bound to collect co-insurance which entails significant financial risk and drains practice time and resources that could be better spent on patient care.

Similarly, the IPI model flat-fee does not fully account for the inherent system costs that would remain. Over the next 12 months, oncology practices will likely be required to comply with U.S. Pharmacopeia Chapters 797 or 800 regulations for sterile preparation for pharmaceutical compounding and handling of hazardous drugs. The overhead

⁴ Journal of Oncology Practice: Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model. Available at: <http://jop.ascopubs.org/content/10/5/322.full>

costs to maintain a compliant facility are significant including ongoing professional education, environmental monitoring, storage and testing of finished products, and typically require substantial redesign and expansion of physical space dedicated to state-of-the-art drug preparation. It will be important to understand the cost burden on modest sized community practices if a large portion of the drug inventory management is transferred to a third-party vendor. The Network is concerned that CMS' failure to recognize escalating practice costs associated with operating and maintaining sterile preparation and disposal facilities could jeopardize patient safety.

When accounting for the complexities, provider risk and newly created costs, the IPI model threatens practice viability. **The Network is deeply concerned the proposed changes to the add-on payment methodology in conjunction with other disruptive elements of the IPI model pose excessive risk and unpredictability to community-based practices and could result in providers closing their doors, further pushing patients out of the community-setting and into less convenient, more costly settings of care.**

Reference-Based Pricing

The Network is concerned the IPI model could limit patient access to novel, innovative therapies not available in other countries. The current, market-driven system in the United States has enabled patients to access a variety of innovative, life-saving cancer treatments. Out of 74 cancer drugs launched between 2011 and 2018, 95 percent are available in the United States, but only 74 percent are available in the United Kingdom, 49 percent in Japan, and 8 percent in Greece.⁵ This has coincided with a mortality rate for cancers that is lower in the U.S. than in other comparable countries.⁶ Again, we have serious concerns that the IPI model will result in decreased access to care for Medicare beneficiaries with cancer.

Solutions

These factors lead to a disproportionate and disruptive impact to complex specialties like oncology. The Network appreciates that opportunities exist within cancer care to demonstrate value, improve quality, strengthen patient outcomes, and hold down costs. We believe the answer lies in proven strategies such as the development of voluntary, targeted, collaborative payment models such as the OCM and use of evidence-based treatment guidelines such as Value Pathways.

On behalf of The US Oncology Network, thank you for the opportunity to provide our comments on the International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM). We welcome the opportunity to discuss the issues outlined above with you and your staff. Should you have any questions, please contact Ben Jones, Vice President of Government Relations and Public Policy, at Ben.Jones@usoncoloy.com.



Michael Seiden, MD, PhD
President
The US Oncology Network



Marcus Neubauer, MD
Chief Medical Officer
The US Oncology Network

⁵ <https://www.wsi.com/articles/why-are-drugs-cheaper-in-europe-1540760855>

⁶ <https://www.healthsystemtracker.org/chart-collection/mortality-rates-u-s-compare-countries/#item-compared-similar-countries-u-s-relatively-low-mortality-rate-cancers>