The US Oncology Network

April 6, 2020

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-4190-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4190-P)

Dear Administrator Verma:

On behalf of the physicians of The US Oncology Network (The Network), thank you for the opportunity to comment on the "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly" Proposed Rule, as published on February 18, 2020, 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. We are one of the nation's largest and most innovative network 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 on their cancer journey.

As community-based providers of complex cancer care, we appreciate CMS' commitment to strengthening Medicare Part C (Medicare Advantage) and Part D programs through improved access to quality, affordable care and increased transparency for patients and providers. The Network will focus our comments on three specific provisions included in the Proposed Rule:

1. Permitting a Second, "Preferred," Specialty Tier in Part D;
2. Beneficiary Real Time Benefit Tool (RTBT); and
3. Establishing Pharmacy Performance Measure Reporting Requirements.

<u>Permitting a Second, "Preferred," Specialty Tier in Part D</u>
CMS proposes allowing Part D plans to establish a second, preferred specialty tier with lower cost sharing than the current specialty tier. Under this proposal, plans would be able to place any product that exceeds the specialty tier cost threshold—which CMS proposes to increase from $670 in 2020 to $780 in 2021

through changes in the threshold methodology—on either the preferred or non-preferred specialty tier. Drugs eligible for placement on either specialty tier would have to meet certain cost thresholds. **The Network urges caution in advancing policies that could undermine clinical decision making by physicians on behalf of their cancer patients. We encourage CMS to not finalize this proposal to allow Part D plans to implement a second "preferred" specialty tier, which would strengthen perverse plan incentives in an already complex class of therapeutics and could negatively impact patient access to needed therapy.**

While the purpose of this proposal is to increase plan design flexibility, increase competition among specialty drugs with therapeutic alternatives, and steer utilization toward lower cost alternatives, it is an unproven system that could put cancer patients at risk. We fear this proposal would allow economic relationships established between pharmacy benefit managers (PBMs) and drug manufacturers to exert an outsized role in treatment planning, especially given that therapeutic alternatives do not exist for many cancer treatments. As CMS noted in the Proposed Rule, "…currently available tier model structures already allow Part D sponsors to negotiate rebates and distinguish their preferred high-cost Part D drugs by placing them on the preferred brand tier as opposed to the specialty tier…" Considering plan sponsors already have incentives to negotiate rebates and steer patients to preferred therapies, this proposal only complicates care delivery and distorts price transparency. Further, CMS specifically noted that it "remains concerned about whether this proposal will actually achieve the potential benefits to the Part D program and Part D enrollees asserted by stakeholders in support of two specialty tiers." The Network shares this concern. **Currently, CMS only allows for one specialty tier to protect patient access to this important class of drugs—the potential formulation of a second specialty tier would erode that structure completely.**

Similarly, drug formulary changes like what CMS is proposing often precipitates non-medical switching, whereby a treatment is changed to an alternative therapy for non-clinical reasons. Research indicates there is a cost associated with the non-medical switching of prescription drugs. Such changes can negatively impact patient outcomes, drug adherence, and utilization of healthcare services, which may actually increase net costs to the healthcare system due to higher administrative costs, treatment failure, and increased adverse events.[1] One of the most concerning drivers of non-medical switching is plan sponsors' increasing reliance on utilization management (UM) tools. UM tools interfere with the doctor-patient relationship by allowing a third-party to deny treatment that has been prescribed based on a physician's assessment of clinical need. For example, if plans are allowed to implement a preferred specialty tier, more patients may be subject to prior authorization (PA) requirements, whereby their health plan must approve a treatment before it can be administered or be required to first step through and fail less-effective therapies before receiving the most treatment option. These UM techniques, along with other drivers of non-medical switching, can have severe health consequences for cancer patients with complex, personalized care plans.

The Network believes that providers are best suited to direct treatment to less expensive medications without compromising clinical efficacy. For over a decade, our physicians and clinicians have developed evidence-based treatment pathways designed to reduce variability, hospitalizations and excessive care at the end of life. Value Pathways are continually evaluated as new FDA-approved cancer therapies come to market and existing therapies receive new indications. The physician-led review process focuses primarily on the clinical efficacy and toxicity of available treatment options as well as 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 clinical pathway.

[1] https://www.ncbi.nlm.nih.gov/pubmed/31081414

Related, The Network is concerned that for biosimilars and their reference products, a preferred specialty tier that would allow for differential placement of biosimilar and biologic products on separate specialty tiers could fuel stigma around biosimilars not being viewed as the same as their reference products. Community oncology providers and members of their multidisciplinary teams view biological reference products and their biosimilar equivalents through a similar efficacy lens and should be treated the same for tiering and formulary inclusion purposes. The Network also believes that a second, preferred high-cost specialty tier could substitute a prescriber's clinical judgement based solely upon cost. **Rather than allowing a patient's drug formulary to drive treatment decisions, CMS should embrace proven methods, such as evidence-based pathway programs, to drive value-based treatment choices.**

Beneficiary Real Time Benefit Tool (RTBT)

The Network commends CMS' proposal to require RTBTs to be made available to beneficiaries for access to formulary and benefit design information, including potential lower-cost drug alternatives. The Network is supportive of expanded access to RTBTs for beneficiaries as follow-up to the 2019 "Modernizing Part D and Medicare Advantage to Lower Prices and Reduce OOP Expenses" Final Rule[2] that will implement RTBTs for prescribers beginning in 2021. Complementary prescriber and beneficiary RTBTs will further promote personalized medicine, ensuring patients and their doctors have access to accurate, timely, patient-specific, real-time plan information. This information will facilitate greater patient engagement in care decisions, including an increased sensitivity to the cost of available treatment options, and may improve treatment adherence. While our physicians, nurses, social workers and other clinical staff work tirelessly to help cancer patients navigate treatment, additional tools like the prescriber and patient RTBTs will enhance the care we are able to provide.

One feature of the proposed beneficiary RTBT that is especially important is information on clinically appropriate formulary alternatives, including utilization management (UM) requirements. UM tools like prior authorization and step therapy often delay or deny time-sensitive care for patients. While The Network has expressed significant concern regarding the growing use of UM techniques, integrating these requirements in the prescriber and patient RTBTs will help our practices get the appropriate treatment to patients sooner. Incorporating these requirements in the beneficiary RTBT will also serve to further educate patients of the potential harm caused by these UM practices.

Establishing Pharmacy Performance Measure Reporting Requirements

The Network applauds CMS' proposal to require disclosure of pharmacy performance measures in Part D sponsors' network pharmacy agreements and CMS' subsequent publication of these measures to increase public transparency. Currently, applicable pharmacy performance measures vary widely with little transparency around financial rewards or penalties incurred by pharmacies after the point-of-sale. The Network agrees with CMS regarding the importance of uniform, standardized pharmacy measures. Should CMS decide to establish a standard set of performance metrics, The Network believes the set of standardized measures should pertain to the type of pharmacy, drug dispensed, and disease managed. Standardized performance measures would not only establish fair, transparent metrics across pharmacies, they would also avoid inherent conflicts of interest between pharmacy benefit managers (PBMs) that also own retail and/or specialty pharmacies competing for the same business.

[2] https://s3.amazonaws.com/public-inspection.federalregister.gov/2019-10521.pdf

In the oncology care space, many community-based cancer clinics have established medically integrated pharmacies so patients can access their oral chemotherapy prescriptions or other medications at the point-of-care. The Network is particularly concerned that retroactive pharmacy price concessions based on opaque pharmacy performance measures that vary across PBMs act as a disincentive to practices operating medically integrated pharmacies. Transparency of pharmacy performance measures will shed light on increasing pharmacy price concessions and facilitate the development of appropriate metrics across all pharmacy types.

CMS proposed collecting data elements to better understand how performance measures are applied by pharmacy type. The Network agrees with the data elements CMS identified and believes that the collection of retrospective information on success/failure thresholds and average scores or other statistics by pharmacy type and for each measure is essential. Currently, financial penalties are often based on targets beyond practices' control, such as CMS star ratings and/or quality measures directed toward primary care rather than specialty medications. For example, many of today's pharmacy performance measures focus on adherence and patient outcomes related to chronic conditions like diabetes, hypertension, and high cholesterol. While these are important measures, they do not integrate or appropriate measures specific to a patient's disease state, like cancer. If medically integrated specialty pharmacies are going to be evaluated on adherence and patient outcomes, those measures should be tailored to the pharmacy's specialty.

The Network appreciates CMS' recognition of the work of the Pharmacy Quality Alliance (PQA), which has been working to standardize quality measures used to assess pharmacy performance. While metrics for specialty pharmacies are on PQA's list of development priorities, it would be helpful for CMS to encourage the timely development of stakeholder consensus on these important measures. In the interim, **The Network supports the disclosure and publication of pharmacy performance measures in Part D sponsors' network pharmacy agreements as outlined in the Proposed Rule and supports a standardized and transparent set of metrics so long as they are directly relevant for the type of pharmacy being evaluated.**

Conclusion

On behalf of The US Oncology Network and our more than 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to provide our comments on Proposed Rule CMS-4190-P. We welcome the opportunity to discuss the issues outlines above and other critical issues impacting community cancer care 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@usoncology.com.

Sincerely,

Ben Jones
Vice President, Government Relations and Public Policy
The US Oncology Network