The US Oncology Network

January 25, 2019

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-4180-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P)

Dear Administrator Verma:

On behalf of The US Oncology Network (The Network)[1], which represents over 10,000 oncology physicians, nurses, clinicians, and cancer specialists nationwide, thank you for the opportunity to comment on CMS-4180-P "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P)" (Proposed Rule), as published on November 30, 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. We are 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.

As community-based providers of complex cancer care, we appreciate the administration's commitment to lower drug costs and reduce out-of-pocket costs for Medicare beneficiaries. We applaud the proposal to address the abuse of retroactive pharmacy price concessions, as well as implementation of the "Know the Lowest Price Act of 2018" to prohibit pharmacy gag clauses. However, we have concerns some of the proposals in the rule could limit patient access to cancer treatments and impede providers' ability to deliver patient-centered, appropriate care.

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

1) Flexibility to Manage Protected Classes;

[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.

2) Medicare Advantage and Step Therapy for Part B Drugs;
3) Prohibition Against Gag Clauses in Pharmacy Contracts; and
4) Pharmacy Price Concessions to Drug Prices at the Point of Sale.

Flexibility to Manage Protected Classes

The proposed rule would allow Part D plan sponsors to use prior authorization and step therapy for protected class drugs or exclude a protected class drug from a formulary if the drug is used for non-protected indications, is only a new formulation of an existing drug, or if the wholesale acquisition (WAC) price of a drug increased beyond the increase in the Consumer Price Index for all Urban Consumers (CPI-U) over a specific look-back period. **The Network is concerned the administration's proposal to allow Part D plans to delay or deny patient access to critical therapies could result in diminished outcomes for cancer patients.** Protected classes exist for a reason: because cancer patients need access to the full range of life-saving therapies that their physicians may prescribe.

For cancer patients, access to timely and individualized care is a necessity. Oncologists work closely with their patients to develop a personalized treatment plan by evaluating each patient's medical history, the presence of comorbidities, potential drug interactions, type and stage of cancer, specific mutations present, and intent of therapy, in addition to other patient and/or disease-specific factors. These factors are hard to capture with utilization management (UM) tools, such as prior authorization and step therapy. UM tools interfere with the doctor-patient relationship by allowing a third-party to deny a treatment that has been prescribed based on a physician's assessment of clinical need. UM tools may also result in care delays that are particularly detrimental to cancer patients. A patient may experience irreversible disease progression as they wait to receive the intended drug initially prescribed by his/her oncologist. For example, one study found that breast cancer patients who experienced a three month or more delay in treatment had a 12% lower 5-year survival rate compared with breast cancer patients with only a 0 to 3-month delay. [2]

Similarly, excluding protected class drugs from formularies if the drug is used for non-protected indications, is a formulation of an existing single-source or biological product, or if the price of the drug increased beyond the increase in the CPI-U may only serve to deny cancer patients access to necessary treatment. Advancements in cancer treatments have led to improved, more personalized, targeted treatment regimens and only the patient's trained cancer care team can best determine which therapies are most clinically appropriate for each patient's needs.

The rising use of UM tools in the commercial sector continues to burden physicians and staff, increase practice operating costs, and delay time-sensitive care for patients. Practices often employ one or more full-time employees devoted to navigating utilization management protocols across multiple payors, requiring significant investment in both human capital and infrastructure. In oncology, the past few decades have seen considerable advances in treatment, resulting in improvements in survival and patients' quality of life. Insurance companies evaluating prior authorization requests may not be up to date on current standards of care, and prior authorization requests may not even be conducted by a physician with the same specialty as the prescribing physician. A 2017 survey by the American Medical Association found that more than 90 percent of surveyed physicians reported care delays as a result of prior authorization, and 84 percent reported that the burden associated with prior authorizations for physicians and staff within their practice was high or extremely high[3].

[2] "Does A 'One-Size-Fits-All' Formulary Policy Make Sense?, Health Affairs Blog, June 2, 2016.
[3] https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/arc/prior-auth-2017.pdf

The Network warns that expanding the use of UM tools in Medicare will increase administrative burdens on community practices, increase overhead costs and ultimately deny patient access to needed physician-prescribed treatments.

Medicare Advantage (MA) and Step Therapy for Part B Drugs

CMS proposes to codify the policy announced in August of 2018 and implemented in January 2019 that would allow MA plans to apply step therapy requirements to Part B drugs. While The Network appreciates the standardization of implementation requirements across participating plans, including the requirement for the plan's pharmacy and therapeutics committee to review and approve step therapy programs as well as the expedited adjudication timeframe, **overall, we remain very concerned that the use of UM techniques could impede access to life saving treatments.**

The Network believes that providers are best suited to direct treatment to less expensive medications without compromising clinical efficacy. For over a decade, physicians and clinicians in The Network have developed 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 treatments come to market and existing treatments 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 pathway. Adherence to pathways has been proven to lower the overall cost of care with equal or better outcomes[4]. **Rather than force patients into a one-size-fits-all approach, CMS should embrace proven methods, such as evidence-based pathways programs, to drive value-based treatment choices and rely on providers for clinically appropriate utilization management.**

Further, the Department of Health and Human Services Office of the Inspector General recently studied the MA appeals process and found that Medicare Advantage Organizations overturned 75 percent of their own denials between 2014 and 2016[5], raising concerns that MA beneficiaries and providers were regularly denied appropriate services and payments. The Network strongly encourages the administration to ensure that this effort to manage drug costs does not prevent vulnerable cancer patients from accessing the clinically appropriate drugs they need.

The proposed rule would also allow MA plans that offer prescription drug coverage to require a Part D drug therapy prior to allowing a Part B drug therapy. Given the difference in cost-sharing requirements between Parts B and D, The Network is concerned that this may actually increase out-of-pocket costs for beneficiaries and further reduce access to vital cancer treatments.

Prohibition Against Gag Clauses in Pharmacy Contracts

The Network appreciates Congress' recognition of the need for increased transparency among Part D plan sponsors and Pharmaceutical Benefit Managers (PBMs) with the passage of the "Know the Lowest Price Act of

[4] 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.

[5] See "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials", available at https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf (last visited Jan. 8, 2019).

2018," and welcomes the administration's implementation of the prohibition on so called "gag clauses" in Part D pharmacy contracts. Previously, Medicare Part D plan sponsors and PBMs often restricted the ability of pharmacies to inform a plan enrollee when the cash price of their prescription was less than the enrollee's cost when obtaining the prescription through their insurance. Now, patients will have the information necessary to access their drugs with the lowest out-of-pocket costs possible.

Pharmacy Price Concessions to Drug Prices at the Point of Sale

CMS is also considering a proposal that would change the definition of negotiated price concessions, also known as direct and indirect remuneration or DIR fees. The policy would require Part D plan sponsors to include all pharmacy price concessions at the point of sale, exclude pharmacy incentive payments from the negotiated price at the point of sale, and prohibit plan sponsors from charging "pharmacy administrative service fees" to pharmacies. **The Network strongly supports this policy and encourages CMS to finalize it for the 2020 plan year.**

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. Practices with medically integrated pharmacy services have been shown to significantly improve patient adherence[6], ensure the timely receipt of prescribed drugs[7], and improve outcomes[8] at a lower cost[9]. This is particularly true in oncology, where complex cancer treatments with serious side effects require unabating skilled physician attention for regular visits and chemotherapy. Over the past decade, the availability and use of oral oncolytic medications (chemotherapy, biotherapy, and immunotherapy) has significantly increased. Payments for these medications are made under Medicare Part D through plan sponsors and PBMs.

While DIR fees were initially created to track manufacturer rebates and other price adjustments to plans and PBMs for Medicare Part D medications, over time they have morphed from a rebate the plan pays to CMS into a myriad of fees the participating pharmacy/dispensing physician pays the plan and PBM. This pharmacy price concession structure fails to allow for meaningful price comparisons, does not encourage price transparency, and is not optimal for producing the lowest overall prescription drug costs for beneficiaries.

The Network is particularly concerned that retroactive pharmacy price concessions act as a disincentive to practices operating medically integrated pharmacies. This is because pharmacy price concessions are calculated and applied retrospectively, forcing practices to guess the amount the plan and PBM will "clawback" after the point of sale. When DIR fees are percentage-based, they can have a particularly unfair negative effect on practices that dispense high-priced specialty medications through medically integrated pharmacies; DIR fees applied to specialty medications have often resulted in negative net cost recovery for disease-curing and life-sustaining cancer treatments. It is also difficult for practices to positively impact the level of DIR fees because they are often based on targets beyond practices' control, such as CMS MA star ratings. Similarly, DIR fees may

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[6] Pauline W. Chen, When Patients Don't Fill Their Prescriptions, N.Y. Times (May 20, 2010), available at: http://www.nytimes.com/2010/05/20/health/20chen.html?_r=0.

[7] Lee Schwartzberg et al., Abandoning Oral Oncolytic Prescriptions at the Pharmacy: Patient and Health Plan Factors Influencing Adherence (2010), available at: http://www.communityoncology.org/pdfs/asco-poster-handout.pdf.

[8] Michael A. Fischer et al., Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions, 25 J. Gen. Intern. Med. 284 (Apr. 2010), available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842539/pdf/11606_2010_Article_1253.pdf.

[9] See William Shell, The History of Physician Dispensing, Complete Claims Processing Inc., available at: http://www.ccpicentral.com/history-of-physician-dispensing.php (last visited Jan. 10, 2018).

be levied on a pharmacy based on certain quality measures targeted toward primary care rather than specialty medications. Should CMS decide to establish a standard set of performance metrics, The Network believes the metrics should pertain to the type of pharmacy, drug dispensed, and disease managed.

The Network agrees with CMS that pharmacy price concessions can lead to higher beneficiary cost-sharing. Beneficiaries typically pay their copay or coinsurance at the point of sale, based on the negotiated price of the medication. Several months later, when the DIR fees are levied on the pharmacy, the net payment to the pharmacy is reduced but the savings are not passed on to the beneficiary. This proposal would ensure patients benefit from the lowest negotiated price.

We previously commended CMS' proposal to include pharmacy price concessions at the point of sale in the CY 2019 proposed Part D rule. **We encourage the administration to finalize this change and continue to create transparency in DIR fees.**

Conclusion

The Network appreciates the administration's commitment to improving affordability of drugs and encourages CMS to collaborate with stakeholders to develop and implement value-based initiatives aimed at reducing patient costs while protecting access to safe and timely care. However, we remain concerned with the expanded use of step therapy for cancer patients, as well as DIR fees, which discourage the formation of medically integrated pharmacies better suited to monitor cancer patients on oral medication. Last, we are deeply concerned with the uncertainty of the International Pricing Index (IPI) model which would impose excessive risk and unpredictability on community-based practices and could result in providers closing their doors, pushing patients out of the community-setting and into less convenient, more costly settings of care. We urge CMS to abandon the IPI model and move forward with patient-centered policies that will result in demonstrable savings for patients and Medicare without jeopardizing access to timely, clinically-appropriate, community-based cancer care.

On behalf of The US Oncology Network, thank you for the opportunity to provide our comments on Proposed Rule CMS-4180-P. We welcome the opportunity to discuss the issues outlined 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.

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