March 7, 2022

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4192-P
P.O. Box 8013
Baltimore, MD 21244-8013

Re: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192-P)

Dear Administrator Brooks-LaSure:

On behalf of The US Oncology Network (The Network), which represents over 10,000 oncology physicians, nurses, clinicians and cancer care specialists nationwide, thank you for the opportunity to comment on the "Contract Year (CY) 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs" [CMS-4192-P] Proposed Rule.

The Network is one of the nation's largest and most innovative networks of community-based oncology physicians, treating more than 1.2 million 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, state-of-the-art care close to home and at lower costs for patients and the health care system. We are 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, affordable care in the most efficient manner.

Over the past decade, the availability and use of oral oncolytic medications (chemotherapy, biotherapy, and immunotherapy) has significantly increased. As a result, many community-based cancer clinics have established medically integrated dispensing (MID) platforms or practice-based 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[1], ensure the timely receipt of prescribed drugs[2], and improve outcomes at a lower cost.[3] This is particularly true in oncology, where complex cancer treatments with serious side effects require unabating skilled physician attention for regular visits and chemotherapy. Payments for these medications are made under Medicare Part D through plan sponsors and pharmacy benefit managers (PBMs).

Pharmacy price concessions, also known as direct and indirect remuneration or DIR fees, have grown exponentially over the past decade and threaten the success of practice-based pharmacies. Table 3 in the proposed rule shows that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 107,400 percent between 2010 and 2020. Network practices' experience mirrors this trend. In 2020, Network practices paid nearly $40 million in total DIR. That figure jumped to nearly $54 million in 2021. We applaud CMS for recognizing that Part D sponsors and PBMs have been recouping staggering sums from network pharmacies after the point-of-sale in the form of pharmacy price concessions.

[1] https://www.ajmc.com/view/medically-integrated-dispensing-an-alternative-to-how-oral-drugs-get-dispensed
[2] http://www.communityoncology.org/pdfs/asco-poster-handout.pdf
[3] https://ascopubs.org/doi/abs/10.1200/JCO.2018.36.15_suppl.e18916

The Network previously responded to CMS' Request for Information (RFI) Regarding the Application of Pharmacy Price Concessions to Drug Prices at the Point of Sale in the "CY 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P)" and the related proposal in the "CY 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS-4180-P)." We appreciate the agency's continued commitment to improving transparency and reducing out-of-pocket costs for Medicare beneficiaries and will focus our comments on *Section H. Pharmacy Price Concessions in the Negotiated Price*.

In the proposed rule, CMS proposes to amend the current definition of negotiated price concessions in Medicare Part D. The policy would redefine the term "negotiated prices" and require Part D plans to apply all price concessions they receive from network pharmacies to the point-of-sale price. **The Network commends CMS for taking this important first step to lower patient out-of-pocket costs, increase transparency, and provide greater predictability to practice-based pharmacies; however, we strongly recommend CMS consider the full range of the policy's effect on PBM behavior and implement guardrails to ensure the rule has the intended effect.**

Requirement to Include All Pharmacy Price Concessions in the Negotiated Price

The Network is generally supportive of CMS' proposed revision of the definition of negotiated price at §423.100 to remove the "reasonably determined" exception and require all price concessions from pharmacies to be reflected in the negotiated price at the point-of-sale. We agree with CMS that plan sponsors and PBMs have applied this exception in an overly broad and unintended fashion, resulting in higher profit margins for plan sponsors and PBMs with little to no reciprocal benefit to patients. 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. CMS' own calculations show that having all pharmacy price concessions reflected as part of the negotiated price will reduce net beneficiary costs by approximately $21.3 billion over 10 years.[4] **We fully support lower patient out-of-pocket costs at the point-of-sale.** We also encourage CMS to disclose the negotiated price to the patient and the pharmacy at the point-of-sale.

Requiring all price concessions to be reflected in the point-of-sale price will also make reimbursement per-claim more predictable for pharmacies. Currently, pharmacy price concessions are calculated and applied retrospectively, often many months after claims have been submitted and reimbursed. This forces community practices to guess the amount the plan and PBM will "claw back" after the point-of-sale.

However, the proposed rule will lower DIR payments to PBMs. As CMS notes, under Part D's risk corridors, any DIR a plan sponsor receives that is above the projected amount factored into its plan bids contributes to plan profits. PBMs will be highly incentivized to find ways to offset these losses. This could come in the form of narrower networks and increased steerage towards PBM-affiliated pharmacies. Over the past decade, as the nation's largest insurers and PBMs have consolidated and grown (only three PBMs processed nearly 80 percent of all prescription claims in 2020)[5], it has become increasingly common for plan sponsors to require their members to obtain their prescriptions through their own or affiliated PBM. Should this rule exacerbate this trend, it will actually hurt community practices and patients by lowering competition and reducing access to integrated care.

[4] Without application to applicable drugs in coverage gap

[5] https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html

Further, given the broad definition of “administrative services fees” in the proposed rule, The Network cautions that PBMs and plan sponsors may simply increase these fees to offset the loss of DIR. The Network recommends CMS narrow the definition of pharmacy administrative services to prevent PBMs from exploiting this ambiguity. The Network also encourages CMS to conduct a more stringent review of the DIR data it collects from PBMs and to collect additional information about the types of fees being assessed. This additional scrutiny may help disincentivize PBMs from this type of behavior.

CMS proposes not to apply the new definition of “negotiated price” to drugs in the coverage gap. Instead, plans would have the flexibility to determine how much of the pharmacy price concessions to pass through at the point-of-sale. This would create two different definitions of negotiated price and presents another opportunity for PBMs to take advantage of an asymmetric system. Practice-based pharmacies often do not know if a patient is in the coverage gap at the point-of-sale. Given the high cost of cancer treatment, their patients are more likely to be in the coverage gap, but pharmacies wouldn’t even know which plans are choosing to include or exclude this policy to drugs in the gap. Essentially, CMS would just be replacing one form of uncertainty with another. Therefore, The Network encourages CMS to apply this definition uniformly across all phases of the Part D benefit.

Redefining “Negotiated Price” as Lowest Possible Reimbursement

CMS proposes to redefine “negotiated price” as the lowest possible reimbursement a network pharmacy will receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or PBM. Under the proposal, if a performance-based payment arrangement exists between a sponsor and a network pharmacy, the point-of-sale price of a drug reported to CMS would need to equal the final reimbursement that the network pharmacy would receive for that drug under the arrangement if the pharmacy’s performance score were the lowest possible. **The Network agrees this policy will inject much needed clarity into the calculation of DIR fees but, absent further action from CMS, cautions it will likely result in an overall reduction in reimbursement to pharmacies.**

The Lowest Possible Reimbursement Model is intended to provide a standardized way for Part D sponsors to treat the unknown at the point-of-sale under a performance-based payment arrangement. If implemented as intended, this will remove one of the major disincentives for establishing or expanding medically integrated pharmacy services and practice-based pharmacy operations: economic uncertainty. Adding to the frustration caused by the retroactive nature of pharmacy price concessions, the calculation of the DIR fee itself is opaque. Practices, already operating on thin margins, are left to simply speculate the amount of PBM "claw backs" occurring months after the point-of-sale. This creates an accounting nightmare for practice-based pharmacies as it is impossible to know what they will be reimbursed for a drug they have already dispensed. DIR fees can also be percentage-based, magnifying the negative impact on practices dispensing high-priced specialty medications solely due to the types of patients they see and subsequent costs associated with their treatments. Redefining “negotiated price” as the lowest possible reimbursement from a Part D sponsor or PBM will increase transparency and provide greater predictability for community practices.

Proposal Will Lower Net Reimbursement to Pharmacies

In the proposed rule, CMS estimates “a modest potential indirect effect on pharmacy payment as a result of pharmacies’ independent business decisions.” Specifically, CMS estimates pharmacies will seek to retain 2% of the existing pharmacy price concessions they negotiate with plan sponsors and other third parties to compensate for pricing risk and differences in cash flow and CMS assumes that these business decisions will result in a slight *increase* in pharmacy payments of 0.1-0.2 percent of Part D gross drug cost. On the contrary, The Network cautions CMS that the financial squeeze to PBMs as a result of the rule is more likely to result in lower net reimbursement to pharmacies. This is because PBMs hold all the leverage, particularly for practice-based pharmacies, presenting a “take it or leave it” approach to contracting. The far more likely outcome is that PBMs will lean on this leverage and reduce reimbursement.

Relatedly, CMS provides three scenarios in the proposed rule to illustrate how performance-based arrangements between Part D sponsors and network pharmacies would work under the Lowest Possible Reimbursement Model. In the third scenario, CMS suggests a pharmacy would receive a net positive bonus of 1% for high performance. This implies that CMS believes positive payment to pharmacy is common and a likely result under the proposal. In reality, PBMs typically structure performance incentives as downside incentives for providers. Unlike other value-based care arrangements with "upside" models that provide bonus incentives for high performers and potential contract termination for low performance, PBM DIR "downside" models apply fees to providers. Providers are only afforded the opportunity to reduce DIR fees, not eliminate them entirely, even if they achieve high performance. CMS acknowledges that DIR data reported to CMS and stakeholder feedback has indicated most performance-based arrangements only provide the opportunity to reduce "the magnitude of the amount by which the original reimbursement is reduced," noting that "most pharmacies do not achieve performance scores high enough to qualify for a substantial, if any, reduction."

Practice-based pharmacies should not have to choose between more predictable but lower reimbursement and unpredictable but potentially higher reimbursement. This is why it is critical that high performing pharmacies maintain the opportunity to earn incentive payments based on quality metrics. As currently drafted, the proposed policy does not protect the ability to earn an incentive payment and we have no reason to believe that the proposed changes in this rule would create greater incentive for PBMs to provide bonus payments to pharmacies. Performance bonuses would be considered negative DIR, so the more likely outcome is that the opportunity to earn incentive payments is reduced.

Pharmacy Quality Metrics

The Network supports value-based care and performance incentives for pharmacies. We are deeply committed to value-based payments that promote advancement in quality of care through medication adherence, medication reviews, and preventive services. Adherence is particularly important to the oncology specialty and has a strong correlation[6] with better outcomes. While adherence is typically a component of pharmacy performance measures, the metrics are more likely to pertain to chronic conditions like diabetes, hypertension, and high cholesterol. As a result, community oncology practices have limited ability to positively impact the level of DIR fees assessed as they are frequently based on targets outside of the practice's control. If pharmacies are going to be evaluated on adherence and patient outcomes, those measures should be tailored to the pharmacy's specialty. This would ensure CMS is truly incentivizing value-based care for beneficiaries across the Part D program. **The Network urges CMS to establish a standard set of performance metrics that 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 PBMs that also own retail and/or specialty pharmacies competing for the same business.

Additional Recommendations

The Network encourages the agency to continue creating transparency in DIR fees. For example, we note Part D sponsors are required disclose to CMS the aggregate negotiated price concessions by manufacturers that are passed through in the form of lower subsidies, lower monthly beneficiary premiums, and lower prices through pharmacies and other dispensers. The Network encourages CMS to make this data available at the aggregate level to the public. As the steward of the largest prescription drug program in the country, it is important for taxpayers to understand how these funds are being used. At a minimum, we encourage CMS to release trends identified in its analysis of this data on an annual basis.

[6] https://pubmed.ncbi.nlm.nih.gov/34784654/

Conclusion

If finalized, the changes in this proposed rule will have significant, wide-reaching impacts on pharmacies and the industry as a whole. As described above, we believe this rule will have an outsized effect on practices with MID platforms or practice-based pharmacies. These changes will affect a practice's accounting and inventory management. **The Network applauds CMS for taking this important first step to lower patient out-of-pocket costs, increase transparency, and provide greater predictability to practice-based pharmacies, but cautions that without further refinement the proposal could simply shift PBM behavior and lower reimbursement to pharmacies.** We strongly encourage CMS to think carefully about the downstream effects of this proposal and implement guardrails to ensure it has the intended effect—lowering patient out-of-pocket costs and providing greater certainty and predictability for pharmacies.

On behalf of The US Oncology Network, thank you for the opportunity to provide our comments on Proposed Rule CMS-4192-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.

Sincerely,

Marcus Neubauer, MD
Chief Medical Officer
The US Oncology Network