The US Oncology Network

May 25, 2022

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Lina Kahn
Chair
U.S. Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, D.C. 20580

Re: Solicitation for Comment Concerning the Business Practices of Pharmacy Benefit Managers (FTC-2022-0015)

Dear Chair Kahn:

On behalf of The US Oncology Network (The Network), which represents more than 10,000 oncology physicians, nurses, clinicians, and cancer care specialists nationwide, thank you for the opportunity to provide feedback on the issues raised in the Federal Trade Commission's (FTC) Request for Information on the business practices of pharmacy benefit managers (PBMs) and their impact on independent pharmacies and consumers (FTC-2022-0015).

The Network is one of the nation's largest and most innovative networks of independent, 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.

As community cancer providers, we are dedicated to ensuring our patients receive access to timely and personalized care. Unfortunately, we find ourselves repeatedly stymied in the pursuit of these two goals by constant interference from pharmacy benefit managers. These challenges have only increased as the nation's largest insurers, PBMs, and specialty pharmacies have consolidated and grown. Today, the three largest PBMs process nearly 80 percent of all prescription claims,[1] and CVS Health (aligned with Aetna), Express Scripts (Cigna), Optum Rx (United Healthcare), and AllianceRx Walgreens Prime comprise 75 percent of the specialty drug market.[2] These large PBMs act with impunity, determining pharmacy networks, establishing utilization management policies, setting reimbursement rates, and then presenting independent community cancer practices with a "take it or leave it" approach to contracting. While the PBM industry claims they maximize negotiated savings for their covered beneficiaries and plan sponsors, the real-world evidence suggests PBMs interfere with the doctor-patient relationship, drive up healthcare costs, and delay delivery of life-saving treatments.

Dozens of states have passed legislation focused on improving transparency and reining in PBMs to improve patient access and support community pharmacies. Often this legislation has followed investigations confirming the PBM practice of spread pricing, in which PBMs charge state Medicaid plans a higher amount for a prescription drug than they are reimbursing pharmacies and then keep the difference, to the tune of millions of dollars. This patchwork approach to regulation, however, typically does not extend to Medicare, Medicare Advantage, or employer-sponsored coverage. While the decision in *Rutledge v. Pharmaceutical Care Management Association* clarifies that states can regulate PBM reimbursement to pharmacies in ERISA-

[1] https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html
[2] [2] The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute, 77.

based plans, much more oversight and reform is needed. **The Network appreciates the Federal Trade Commission's interest in this issue and urges the agency to move forward with a study examining PBM pricing and contractual practices.**

Our comments will focus on the following topics in the RFI:

- PBMs' use of methods to steer patients away from unaffiliated pharmacies and toward PBM-affiliated mail order and specialty pharmacies, including:
    - Narrow networks and steerage to affiliated specialty pharmacies for oral oncolytics, including the use of DIR fees; and
    - Steerage to affiliated specialty pharmacies for physician-administered drugs (white bagging)

- The impact of PBM rebates on formulary design and patients' ability to access prescribed medications without endangering their health, creating unnecessary delay, or imposing administrative burdens for patients or prescribers, including:
    - Prior authorization; and
    - Step therapy, including whether patients are being forced to substitute different prescription drugs to maximize PBM rebates

<u>PBM Steerage in Oral Oncolytics</u>

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. A cancer patient sees their oncologist frequently and in-person, creating a close relationship that allows them to feel comfortable asking questions, sharing side effects, and easily communicating with practice staff. Practices with medically integrated pharmacy services have been shown to significantly improve patient adherence[3], reduce time to treatment[4], and improve outcomes at a lower cost.[5] Just-in-time dose adjustments frequently occur in cancer clinics, and steering the script to be filled at a PBM-affiliated specialty pharmacy prohibits timely filling that leads to patients having to waste medication delivered to them before a dose adjustment has been made, or a delay in initiation of new therapy.

In contrast to a community cancer practice with MID capabilities, PBMs do not have access to a patient's full medical records or lab results and cannot answer a patient's questions about their medical condition. Patient reports of delays in prescription delivery, mix-ups at the PBM-owned pharmacy, endless phone tag with PBM representatives, and bureaucratic red tape abound. Calls to confirm information may go unanswered because the patient may not answer the unknown number and then have difficulty returning the call and speaking with a live person who is familiar with their case. For example, an 85-year-old patient with liver cancer in Nevada reported a nearly 3-week delay in starting her oral chemotherapy regimem due to back and forth with the nurse at the patient's health plan. With cancer treatments, every day is critical and delays not only impact treatment efficacy but create stress for the patient and their caretakers.

Additionally, the disconnect between the PBM, the patient, and their care team can create waste. PBM mail order pharmacies regularly refill prescriptions with no awareness that the drug may no longer be appropriate because of the patient's disease progression, or the dose needs modification because of changes in the patient's liver or kidney function. A recent American Society of Clinical Oncology (ASCO) analysis[6] of data

[3] https://www.ajmc.com/view/medically-integrated-dispensing-an-alternative-to-how-oral-drugs-get-dispensed
[4] https://www.targetedonc.com/view/the-benefits-of-medically-integrated-dispensing-for-cancer-drugs
[5] https://ascopubs.org/doi/abs/10.1200/JCO.2018.36.15_suppl.e18916
[6] https://ascopubs.org/doi/full/10.1200/OP.22.00022?bid=169320226&cid=DM10426

from NCODA's Cost Avoidance and Waste Tracker Tool quantified this waste. Among 37 onology practices who submitted data over a 4.5 year period, $8.9 million in waste was attributed to external mail order pharmacies, compared to $2.4 million from practices with MID.

To articulate how this waste can be generated, consider a patient with metasatatic breast cancer started on hormone blockade with a targeted therapy called CDK4/6 inhibition. This therapy is an effective combination that has tripled progression free survival in this patient population, but this success in therapy is predicated upon compliance and appropriate management. Patients are seen frequently when starting treatment to anticipate the need for dose reduction, as more than 40 percent of patients will require dose reduction over the course of treatment. Patients with therapy filled at external specialty pharmacies have frequently been mailed the higher dose when dose reduction is required, causing a waste of medication that costs >$10,000 in a month. This occurs because there is no communication between the PBM, specialty pharmacy, and treating office. In addition, the patient is delayed in receiving the new dose for several weeks when filled externally. The natural consequence can be suboptimal therapy leading to early progression and even death.

As the nation's largest insurers and PBMs consolidated, it became increasingly common for commercial health plans or plan sponsors to *require* their members to use the mail order or specialty pharmacy that the plan or its PBM owns and operates. As payers, they control where patients can get their prescription filled. This means that while patients may have higher adherence if they were able to fill their prescription at their oncologist's office, their insurance likely forces them to obtain their medication elsewhere. In fact, only 48 percent of patients are able to fill their first prescription by a dispensing physician and this drops to 41 percent for ongoing refills.[7] This is particularly common for oncology medications. As of 2016 (the most recent year for which data is available), 71 percent of managed care plans mandated that patients use insurance-designated specialty pharmacies for some or all oral oncology drugs. Nearly 90 percent of these plans contract exclusively with a single specialty pharmacy for oncology services.[8] Restrictive networks not only hurt patients by preventing them from taking full advantage of an integrated care team but they also hurt practice viability.

Even further, some PBMs have shown a willingness to misinterpret Medicare Part D's "any willing pharmacy" requirement and define pharmacy too narrowly in order to exclude MID and physician-owned pharmacies from their networks. In 2016, one PBM also went so far as to issue notices to MID physicians of the same, alerting that the physician dispensing class of trade would no longer be included in the PBM's Part D network. Though the PBM reversed its decision after strong backlash, additional regulatory guidance is needed to strengthen their inclusion as in-network Part D providers.

Direct and Indirect Remuneration Fees

Another anticompetitive tactic employed by PBMs is the growing use of retroactive pharmacy price concessions, also known as direct or indirect remuneration (DIR) fees. DIR fees have grown exponentially over the past decade and threaten the success of practice-based pharmacies. According to the Centers for Medicare and Medicaid Services (CMS), 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.

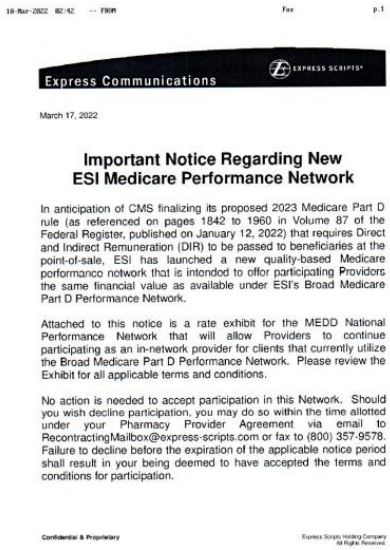
According to PCMA, the trade association for PBMs, "PBMs, working on behalf of Medicare Part D plan sponsors, may enter into value-based network agreements with pharmacies that include performance standards designed to improve patients' health and lower out-of-pocket costs. Often, the agreements assume pharmacies will meet or exceed performance standards, thus resulting in either no change in reimbursement or bonuses paid to the pharmacy. When pharmacies do not meet performance standards, pharmacies must

[7] The 2019 Genentech Oncology Trend Report, Genentech, 2019, 32.
[8] The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute, 220.

return overpayments." In reality, PBMs benefit from pharmacies' failure to meet mismatched performance standards. For example, adherence is critically important to the oncology specialty and has a strong correlation with better outcomes.[9] 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. Again, there is no way to negotiate alternative metrics given PBM's "take it or leave it" approach to contracting. There is also no transparency into whether similar metrics are applied to specialty pharmacies owned by PBMs that are competing for the same business.

DIR fees serve as a disincentive to practices wishing to establish or expand MID platforms and practice-based pharmacy operations, impeding the growth of integrated care models that have been proven to improve patient outcomes. The Network applauds CMS' recently finalized proposal to require Part D plans to apply all price concessions they receive from network pharmacies to the point-of-sale price. While The Network agrees with CMS that the new policy will lower patient out-of-pocket costs and increase transparency for practice-based pharmacies, we are disappointed CMS did not address pharmacy quality metrics and are concerned that this policy will ultimately, and unfairly, lower pharmacy reimbursement.

These concerns are not unfounded. On March 17, 2022, Express Scripts Inc. informed pharmacies via fax that it was amending its pharmacy provider agreements "in anticipation of CMS finalizing its proposed 2023 Medicare Part D rule that requires DIR to be passed to beneficiaries at the point-of-sale." The amendment lowers reimbursement to pharmacies and institutes a "Network bonus pool" which charges participants "up to a $0.75 per claim fee," to be pooled and distributed according to performance, which again, is based on quality measures that assess adherence for diabetes medications, hypertension medications, and cholesterol-lowering medications and are not related to cancer care. As further evidence of the "take or leave it" approach, the notice (shown below) informs pharmacies that "no action is needed to accept participation in this Network. Should you wish to decline participation, you may do so within the time allotted under your Pharmacy Provider Agreement…Failure to decline before expiration of the applicable notice period shall result in your being deemed to have accepted the terms and conditions for participation." Community cancer clinics that participate in ESI's network have no opportunity to negotiate the terms of this contract.



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Express Communications

EXPRESS SCRIPTS®

March 17, 2022

Important Notice Regarding New ESI Medicare Performance Network

In anticipation of CMS finalizing its proposed 2023 Medicare Part D rule (as referenced on pages 1842 to 1960 in Volume 87 of the Federal Register, published on January 12, 2022) that requires Direct and Indirect Remuneration (DIR) to be passed to beneficiaries at the point-of-sale, ESI has launched a new quality-based Medicare performance network that is intended to offer participating Providers the same financial value as available under ESI's Broad Medicare Part D Performance Network.

Attached to this notice is a rate exhibit for the MEDD National Performance Network that will allow Providers to continue participating as an in-network provider for clients that currently utilize the Broad Medicare Part D Performance Network. Please review the Exhibit for all applicable terms and conditions.

No action is needed to accept participation in this Network. Should you wish decline participation, you may do so within the time allotted under your Pharmacy Provider Agreement via email to RecontractingMailbox@express-scripts.com or fax to (800) 357-9578. Failure to decline before the expiration of the applicable notice period shall result in your being deemed to have accepted the terms and conditions for participation.

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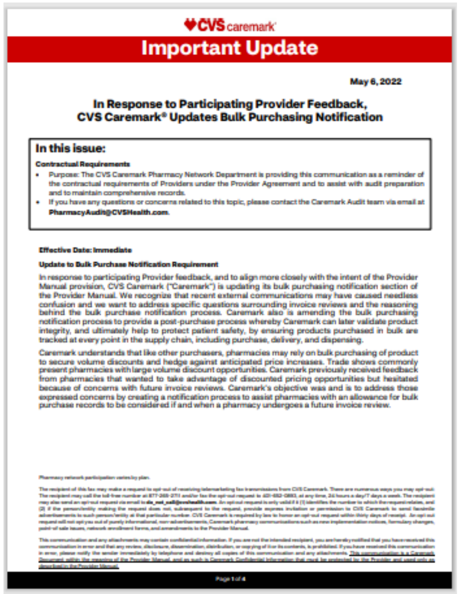
[9] https://pubmed.ncbi.nlm.nih.gov/34784654/

PBM Overreach
Another example of PBM overreach is the recent notices (shown below) Network practices have received from CVS Caremark demanding data on the bulk purchase of oral drugs. This data request is wholly unrelated to the management of member prescription drug benefits and yet was included in contracts that independent pharmacies have no leverage to amend. It is yet another example of PBM mandates that will require staff at community cancer clinics to take time away from patients with no benefit to the patient.


CVS caremark

Important Update

May 6, 2022

In Response to Participating Provider Feedback,
CVS Caremark® Updates Bulk Purchasing Notification

In this issue:

Contractual Requirements

- Purpose: The CVS Caremark Pharmacy Network Department is providing this communication as a reminder of the contractual requirements of Providers under the Provider Agreement and to assist with audit preparation and to maintain comprehensive records.
- If you have any questions or concerns related to this topic, please contact the Caremark Audit team via email at **PharmacyAudit@CVSHealth.com**.

Effective Date: Immediate

Update to Bulk Purchase Notification Requirement

In response to participating Provider feedback, and to align more closely with the intent of the Provider Manual provision, CVS Caremark ("Caremark") is updating its bulk purchasing notification section of the Provider Manual. We recognize that recent external communications may have caused needless confusion and we want to address specific questions surrounding invoice reviews and the reasoning behind the bulk purchase notification process. Caremark also is amending the bulk purchasing notification process to provide a post-purchase process whereby Caremark can later validate product integrity, and ultimately help to protect patient safety, by ensuring products purchased in bulk are tracked at every point in the supply chain, including purchase, delivery, and dispensing.

Caremark understands that like other purchasers, pharmacies may rely on bulk purchasing of product to secure volume discounts and hedge against anticipated price increases. Trade shows commonly present pharmacies with large volume discount opportunities. Caremark previously received feedback from pharmacies that wanted to take advantage of discounted pricing opportunities but hesitated because of concerns with future invoice reviews. Caremark's objective was and is to address those expressed concerns by creating a notification process to assist pharmacies with an allowance for bulk purchase records to be considered if and when a pharmacy undergoes a future invoice review.

Pharmacy network participation varies by plan.

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<u>PBM Steerage in Physician-Administered Drugs</u>
The PBM and payer consolidation that led to patient steering in oral drugs is now threatening to expand into physician-administered (infusion) drugs. Each of the largest health insurers now owns and operates its own specialty pharmacy and we are beginning to see similar requirements for patients to obtain physician-administered drugs exclusively through their insurer's specialty pharmacy, instead of through their physician's office. This complex requirement can interrupt the course of care and contribute to the progression of disease. It is exponentially more problematic than steerage in oral drugs as the patient population receiving physician-administered drugs is more vulnerable and the drugs themselves are more sensitive.

The longtime standard of care for cancer treatment is for oncologists to maintain their own inventory and provide point-of-care dose adjustments. In cancer care, dose adjustments to accommodate fluctuations in a patient's weight, laboratory values, toxicities, or other clinical considerations are common. This ensures patients get the optimal dose with the least amount of side effects. Under a white bagging requirement, oncologists are required to procure patient-specific cancer medications through a health insurer's specialty pharmacy, which prevents providers from making changes to a patient's treatment at the point-of-care. Relatedly, if a patient's medication is not delivered on time or arrives damaged or the dose needs to be adjusted, treatment may be delayed as providers are not able to source products from their own inventory.

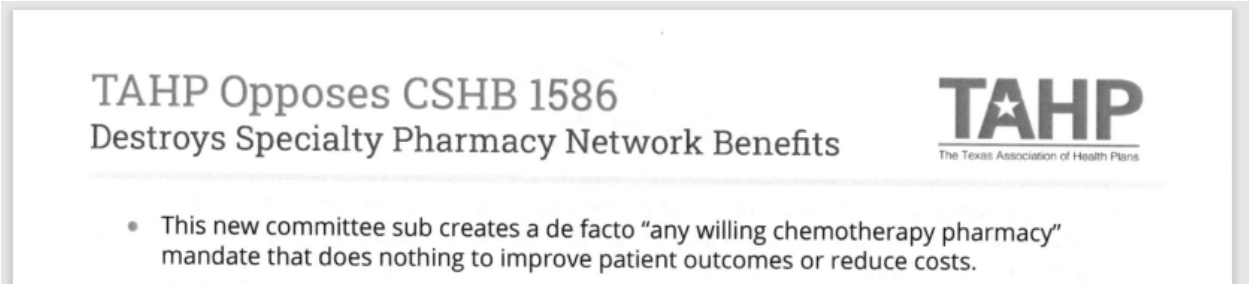
For example, a patient returning for their third round of chemotherapy to prevent cancer from returning may discover that they have a low white blood count necessitating a dosage adjustment. If the patient's drug was white bagged and is a higher dose than needed, the physician's options are to overdose the patient or to delay treatment until the appropriate dose is sent; neither of which is optimal for the patient. If the patient has to come back another day, they may have to miss work or find childcare and arrange transportation. Additionally, medications received for a specific patient that cannot be used are unable to be re-dispensed to

another patient. This causes unnecessary drug waste and can cost the plan and patient potentially tens of thousands of dollars.

White bagging makes it more expensive for physician practices to provide care by requiring extra storage and labor and increasing liability. The complexity increases as multiple payers require separate procurement from their affiliated specialty pharmacy for each individual patient. At the same time, white bagging decreases payment from the health plan to the physician for the same amount of care. Ultimately, the increased financial and administrative burden may result in care shifting to the more expensive hospital outpatient department setting, increasing costs to both the patient and the health care system, and reducing access to convenient, high-quality, community-based cancer treatment.

PBMs claim white bagging is a cost saving tool but, again, there is no evidence that any savings, to the extent they exist, are passed on to the patient. In fact, when a patient is required to obtain their infused drug through their insurer's specialty pharmacy, this often has the result of switching the coverage from their medical benefit to their pharmacy benefit, which may have its own separate deductible and will typically increase the patient's copay or coinsurance.

In 2021, providers sought to pushback against these white bagging mandates and in Texas HB 1586 was introduced. This bill aimed to prohibit insurance companies and PBMs from mandating the practice of white bagging. This bill would have simply maintained the status quo, allowing the provider to decide if white bagging made sense for their patient rather than having it forced upon them by the payer at the expense of both the patient and the practice. In response, we saw health plans wage a widespread disinformation campaign, including a mass text message campaign, alleging the bill would create "a de facto 'any willing chemotherapy pharmacy' mandate," that it would "destroy specialty pharmacy networks," and "would allow any physician or hospital outpatient infusion center to act as an unlicensed and unregulated specialty pharmacy."



PBM consolidation and subsequent steerage in both oral oncolytics and physician-administered drugs has led to specialty pharmacy dispensing becoming a larger share of PBM gross profits. In 2021, PBMs earned 35 percent of their gross profits from specialty pharmacy dispensing, up from just 17 percent in 2015.[10] No wonder PBMs and health plans are fighting competition so fiercely.

Burdensome Utilization Management Protocol

With the growth in the number of new cancer treatments available, cancer care has become both more complex and more tailored to the individual patient. Oncologists work closely with their patients to develop personalized treatment plans 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. As explained above, access to timely and individualized care is paramount for cancer patients.

[10] The 2022 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers, Drug Channels Institute, 299.

Unfortunately, this timely, personalized care is often disrupted by PBM prior authorization requirements. Prior authorization burdens physicians and clinical staff, increases practice operating costs, and delays time-sensitive care for patients. Prior authorization requirements 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. A patient may experience irreversible disease progression as they wait to receive the intended drug or treatment protocol initially prescribed by their oncologist.

Practices often employ multiple full-time employees devoted to navigating utilization management protocols across multiple payors, requiring significant investment in both human capital and infrastructure. A 2021 survey by the American Medical Association found that more than 93 percent of surveyed physicians reported care delays as a result of prior authorization, 34 percent reported prior authorizations lead to a serious adverse event and 82 percent reported that the burden associated with prior authorizations led to treatment abandonment.[11]

According to a study published in 2021 by ASCO, 72.3 percent of oral anticancer drugs received by patients required prior authorization. The median time to receipt of drugs was 7 days (range 0 – 142 days) with a quarter of patients (25 percent) waiting more than 14 days for their medication, and 5 percent waiting more than 30 days.[12] The patients in this study ultimately received the medication, meaning the prior authorization only served to delay necessary treatment. Prior authorization policies with appeal procedures that are deliberately difficult appear to be driven by cost containment goals rather than patient outcomes.

Step Therapy

Community oncologists aim to prescribe the drug that is the most effective at treating cancer, the least toxic, and the lowest cost to the patient. Oftentimes, however, PBMs interfere with this goal by requiring patients to try a drug that is preferred by their insurance plan before they can proceed to the drug prescribed by their physician—even if the patient has tried and failed on a drug while covered under a previous health plan. While PBMs claim step therapy encourages patients to try the least expensive drug first, these policies vary widely by payer, and we have observed step therapy policies that require patients to try a more expensive drug or even a brand drug before the generic or biosimilar version. For example, Anthem recently implemented a step edit for a drug used to treat non-Hodgkins lymphoma that would require cancer patients in its commercial plans to try the more expensive brand version of the drug before the less expensive biosimilar.

The likely explanation for this type of policy is that PBMs are maximizing rebates from drug manufacturers for their own gain at the expense of patients. Policymakers have long raised concerns that PBMs' reliance on drug manufacturer rebates to determine formularies is contributing to higher list prices. This expense is passed on to patients in the form of higher cost sharing or deductibles and to employers who provide employer-based insurance. We encourage the FTC to examine how PBMs are using these rebate dollars.

The Network believes that providers are best suited to direct treatment to less expensive medications without compromising clinical efficacy. Step therapy ignores and devalues this expertise. These burdensome policies divert critical time physicians could spend with patients and instead force them to dedicate their attention to a lengthy, bureaucratic, opaque appeals process. They also infringe upon the doctor-patient relationship that lies at the core of our health care delivery system by allowing insurance plans to decide which medicines a patient should take. Step therapy policies force patients into a one-size-fits-all model of care that prioritizes the illusion of cost savings over individualized treatment and patient health outcomes. Again, to the extent these policies create savings, there is no evidence it is passed to the patient.

[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5885220/
[12] https://www.asco.org/about-asco/press-center/news-releases/prior-authorizations-linked-delayed-receipt-oral-anticancer

Conclusion

The lack of transparency into PBM practices makes it nearly impossible to determine whether they are truly lowering costs for patients and the health care system. Based on our experience, we can attest that PBMs delay necessary care for cancer patients with tangible effects on their health. Both of these areas deserve more investigation and sunlight.

On behalf of The US Oncology Network, thank you for the opportunity to provide feedback on the impact of PBM practices and vertical integration on community cancer practices and our patients. 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,

Debra Patt, MD, PhD, MBA
Chair, Public Policy & Reimbursement Committee
National Policy Board
The US Oncology Network