Written testimony for:

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Chairman Grassley, Ranking Member Durbin, and members of the Committee:

Thank you for the opportunity to testify today. My name is Sheetal Kircher, and I am a medical oncologist at Northwestern Medicine in Chicago where I treat patients with gastrointestinal cancers. I am the Clinical Practice Director and Medical Director of the Survivorship Institute of Northwestern. Back in my home state of Illinois, I am a board member of the Illinois Medical Oncology Society. I am also a fellow of the American Association of Clinical Oncology (ASCO). I am here to share my perspectives as an individual practicing physician.

If you ask my patients or colleagues what a pharmacy benefit manager (PBM) is, most will not know. But if you ask them about their experience with obtaining specialty drugs, like oral anti-cancer drugs, injectables like growth factors, you will get a strong response and probably a story about a recent patient who had a delay in their care or could not afford their medications. While I am writing from the perspective of an oncologist, patients with other complex conditions—such as those managed in rheumatology, gastroenterology, and other specialties that rely on specialty medications—face similar challenges.

Approximately 60% of the prescriptions I send to our hospital-based specialty pharmacy must be transferred to a *different* specialty pharmacy owned by a PBM. We are not given a choice. Although our hospital-based specialty pharmacy meets all available accreditations, we are frequently excluded from PBM networks. Even when included, we face unsustainably low reimbursement rates and are judged by quality metrics designed for retail pharmacies, not cancer care.

Why does it matter that patients have the option to receive their medications from their hospital-based specialty pharmacy instead of a PBM-owned alternative?
Because timing, coordination, and expertise in cancer care are not optional. They are lifesaving.

1. **Hospital-based specialty pharmacies provide critical expertise and unique support for complex therapies.**
   Cancer therapies demand precise handling, close monitoring, and disease-specific knowledge. Specialty pharmacies at cancer centers are staffed by oncology-trained clinicians who educate patients, track adherence, manage side effects, and coordinate directly with the care team. This integration improves safety, reduces hospitalizations, and helps patients stay on treatment when appropriate, all of which reduce overall cost and improve patient outcomes. In contrast, PBM-owned pharmacies often lack oncology expertise and real-time communication with clinicians, putting patients at risk for adverse events and fragmented care.

   Our specialty pharmacy is more likely to connect patients with financial assistance programs either through charitable foundations or manufacturer-sponsored copay support, reducing out-of-pocket burdens and improving adherence. They engage directly with patients to assess barriers to medication use and provide supportive care guidance, which traditional PBMs typically do not.

2. **PBMs impose utilization management practices and medication switches that delay care and increase cost.**
   Clinicians and patients recognize that some level utilization management, such as prior authorization, is necessary to help ensure that expensive and potentially toxic medications are used appropriately. But when PBM-owned mail-order pharmacies are the only option, those safeguards turn into major roadblocks. Complex approval processes and prior authorizations can drag on for days or even weeks, largely because PBMs are disconnected from the care team. Unlike hospital-based specialty pharmacies that have real-time access to the patient's clinical records and can process approvals efficiently, PBM pharmacies often don't have access to the very information they're requesting. That disconnect creates a frustrating cycle of back-and-forth that delays treatment and adds unnecessary stress for patients and clinicians.

   Additionally, PBM policies that allow unilateral substitutions can further disrupt care and increase costs. For instance, when my patient with rectal cancer developed severe neutropenia, putting him at risk of infection, I prescribed a biosimilar growth following my institution's guidance to minimize cost when we feel the biosimilar is equivalent in efficacy to the brand name. The PBM, without consultation with me, substituted it with a brand-name version, likely due to rebate incentives. While this substitution may offer savings for the PBM, it is unclear whether those savings are passed on to the payer or, most importantly, to my patient.

3. **PMB-owned specialty pharmacies can contribute to waste.**
   An often-overlooked advantage of hospital-based specialty pharmacies is their ability to reduce unnecessary waste of high-cost cancer drugs. These clinically integrated pharmacies allow pharmacists to receive timely updates when a patient's treatment plan changes—such as when a dose is adjusted, therapy is paused due to toxicity, or treatment is discontinued altogether. This real-time communication ensures that medications are not dispensed unnecessarily. In contrast, when such coordination is lacking, especially with external or PBM-owned pharmacies, we risk dispensing drugs that are no longer needed. When a single bottle of oral chemotherapy can cost thousands of dollars, this leads to avoidable waste with significant financial implications for the healthcare system, payers, and most importantly, patients.

Caring for patients with cancer is both complex and demanding. Few moments in medicine carry greater emotional weight than hearing and delivering the words, "You have cancer." It is a moment that marks the beginning of a journey defined by uncertainty, urgency, and the need for compassionate, coordinated care they can trust.

As clinicians, we are trained to recommend the most evidence-based treatments while guiding patients and their families through one of the most vulnerable times in their lives. This includes navigating difficult decisions about balancing quality and quantity of life, often under immense emotional and financial strain.

This Committee has a meaningful opportunity to reform the policies and processes that too often create delays, confusion, and unnecessary burdens

Thank you for the opportunity to share my perspective and for your commitment to ensuring that patients receive care that is timely and affordable.

As supplementary information, I have attached the following documents:

1. American Society of Clinical Oncology (ASCO) Position Statement: Pharmacy Benefit Managers and Their Impact on Cancer Care
2. Pharmacy Benefit Manager Reform: Lessons From Ohio (JAMA, 2018)
3. Impact of Pharmacy Benefit Managers on Oncology Practices and Patients (Journal of Oncology Practice, 2020)

American Society of Clinical Oncology Position Statement: Pharmacy Benefit Managers and Their Impact on Cancer Care

Introduction

Cancer drugs are a critical component of treatment for many cancer types as well as for the prevention and control of symptoms. They also represent an increasing component of cancer care cost. Prescription drugs now account for 10% to 17% of national healthcare spending.[1,2] Spending on cancer drugs in the United States has increased substantially over the last 5 years, from $28 billion in 2013 to $51 billion in 2017, and is expected to continue this upward trend.[3] The arrival of new, more expensive prescription drugs has contributed to this increase, a trend that is likely to continue. ASCO has weighed in on the rising cost of cancer care several times, including position statements on the affordability of cancer drugs and utilization management.[4,5]

With cancer care costs rising, new strategies have emerged in the public and private sectors to curb spending while also aiming to preserve and improve quality. One such strategy is utilization of pharmacy benefit manager companies (PBMs), third-party administrators of prescription drug programs used by a variety of sponsors including commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and others. The PBM industry has grown exponentially since its inception in the 1980s and has become highly concentrated. The three largest PBMs (Express Scripts, OptumRx, and CVS Caremark) collect more than $200 billion a year to manage prescription services for 266 million Americans in both public and private plans. They cover 85% of the market.[6] Additionally, each of these PBMs own a specialty pharmacy company.

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[1] Sood N, Shih T, Van Nuys K, Goldman D: The Flow of Money Through the Pharmaceutical Distribution System. USC Shaeffer – Leanord D. Schaeffer Center for Health Policy & Economics. June 2017. http://healthpolicy.usc.edu/documents/USC%20Schaeffer_Flow%20of%20Money_2017.pdf.

[2] National Academy of Sciences, Engineering and Medicine. 2017. Making Medicines Affordable: A National Imperative. Washington, DC: The National Academies Press. https://doi.org/10.17226/24946.

[3] IMS Institute for Healthcare Informatics. *Medicines Use and Spending in the US*. April 2018. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf.

[4] American Society of Clinical Oncology. American Society of Clinical Oncology position statement on addressing the affordability of cancer drugs. J Oncol Pract 14(3): 187–192, 2017.

[5] American Society of Clinical Oncology. American Society of Clinical Oncology policy statement on the impact of utilization management policies for cancer drug therapies. J Oncol Pract 13:758-762, 2017.

[6] National Academy of Sciences, Engineering and Medicine. 2017. Making Medicines Affordable: A National Imperative. Washington, DC: The National Academies Press. Available at https://doi.org/10.17226/24946.

PBMs were originally created to serve as third-party administrators of pharmacy claims, but now leverage their market power to obtain lower prices on drugs. Employers and other plan sponsors also use PBMs to outsource the complicated work of designing and maintaining formularies to those with more specialized expertise. Although PBMs have the potential to generate cost savings for payers and plan sponsors, it is not clear those savings necessarily accrue to patients.[7] Stakeholders have been challenged in achieving detailed understanding of this issue because of the proprietary and confidential environment in which PBMs operate.[8]

ASCO members and others in the oncology community have also shared experiences and voiced concerns about a potentially negative role PBMs can have on patient care. Members of ASCO's State Affiliate Council and other ASCO members have expressed concern that, while employing certain cost containing practices, PBMs may in some cases be interfering with the doctor-patient relationship and lowering the quality of care.

As the leading organization for physicians and oncology professionals caring for people with cancer, ASCO is committed to promoting access to high quality, high value cancer care. Given the enormous leverage PBMs have over the delivery of cancer care—and in view of concerns raised by leaders of state hematology oncology societies across the country—the ASCO Board of Directors has placed a priority on understanding and addressing the role of PBMs in oncology and its effect on patient care.

The purpose of this ASCO Position Statement is to provide a summary of issues our members have raised about the role of PBMs in oncology, to share questions that have surfaced about PBM practices and their impact on physicians and patients, to assert ASCO's immediate position on key issues, and to highlight areas of concern the Society plans to explore more deeply as part of a focused policy effort.

The recommendations put forth in this statement are as follows:

- PBMs and the payers with whom they work for should take immediate steps to address quality of care concerns related to the cancer patients they serve, including assuring that changes to prescribed therapy for patients with cancer are made only in the context of prior consultation and approval of their physician.

- Pharmacies should not be prevented from sharing with patients their most cost-effective option for purchasing needed medications (i.e., gag clauses). To this

[7] Robert Goldberg, Drug Costs Driven by Rebates, Center for Medicine in the Public Interest. http://bionj.org/wp-content/uploads/2015/11/drug-costs-driven-by-rebates.pdf.
[8] Centers for Medicare and Medicaid Services. Medicare Part D – Direct and Indirect Remuneration (DIR). 2017. https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html

end, CMS should eliminate contractual requirements that prevent pharmacists from sharing with patients their most cost-effective option for purchasing required medications.

- CMS should leverage its regulatory authority to: 1) require that PBMs provide detailed accounting of DIR fees, and 2) instruct contractors and PBMs to discontinue application of current Star performance ratings and related DIR claw backs on oncology dispensing physicians and practice-based pharmacies, instead relying on measures and standards that are more appropriate to the specialty.

- CMS should enforce its "Any Willing Provider" provision in Medicare Part D, preventing PBMs from excluding qualified in-office dispensing or provider led pharmacies from its networks.

- CMS should consider extending use of the JW modifier to better identify sources and cost of waste related to chemotherapy drugs in both Part B and Part D. Such data should be made public. Private payers should consider similar strategies.

- Pharmacy and Therapeutics committees should include full and meaningful participation by oncology specialists.

PBMs and Cancer Care: Overview of the Issues

PBMs are responsible for developing and managing prescription drug benefits in the public and private insurance sectors. Their role includes processing prescription drug claims and negotiating contracts with pharmacies and pharmaceutical manufacturers. The expansion of prescription drug benefits, particularly with implementation of Medicare Part D, has created a higher demand for management and administration of prescription drugs for health plans, employers, and government entities (referred to in this statement collectively as "plan sponsors"). PBMs also own and operate specialty and mail-order pharmacies.

Because PBMs now participate in plans that cover so many lives, they naturally have significant influence over the way patients access their medications.[9] Recently two major PBMs announced plans to merge with large insurers. Pending approval by the federal government, CVS Health is set to acquire Aetna Inc. and Cigna is set to acquire Express Scripts. If approved, this will lead to greater market integration and an ever-increasing role of PBMs.

As for-profit companies, PBMs generate revenue in various ways from pharmaceutical manufacturers, pharmacies and plan sponsors. PBMs obtain

[9] PBM DIR Fees Costing. Medicare and Beneficiaries: Investigative White Paper on. Background, Cost Impact, and. Legal Issues. Prepared by. Frier Levitt, LLC. Commissioned by the Community Oncology Alliance. January 2017

revenue from pharmaceutical manufacturers in the form of rebate payments for "preferred" formulary status, which results in increased market-share by encouraging utilization of the drugs chosen.

Negotiated contracts defining reimbursement to pharmacy network providers (including chain and community pharmacies, physician dispensers and physician practices with on-site pharmacies) also serve as a source of revenue for PBMs. The "spread" or price difference generated by what is charged to plan sponsors and reimbursed to pharmacies for the same prescription has resulted in significant revenue for PBMs.

From plan sponsors, PBMs generate revenue through contracts for administration of prescription drug benefits within the health plans. PBMs charge administration and service fees to plan sponsors for processing prescriptions, creating and managing formularies, and processing claims. These are often managed separately from the rest of an employer's health plan.

PBMs assert there is no link between drug price growth and the rebates they are receiving.[10] The lack of transparency around rebate arrangements prevents verification of such claims. Regardless, the impact of PBMs on oncology care providers and patient quality of care is increasingly apparent. The American Medical Association (AMA) has adopted Resolution 225-A—18 which asks the AMA to assess the impact PBMs have on patient's timely access to medications, patient outcomes, and the "erosion of physician-led medication therapy management."[11]

The Role of PBMs in Utilization Management

As PBMs have grown, so have their restrictions and requirements on pharmacies, providers and patients. ASCO previously identified concerns about certain utilization management practices, the burden they often represent to both physicians and patients, and their potential to erode access and quality of care. These include: (i) prior authorization requirements, (ii) restrictive formularies, (iii) step therapy (fail-first) requirements, (iv) and specialty tiers.[12] While PBMs are more of an intermediary or agent for payers, ASCO's concerns about—and opposition to—certain utilization management practices also apply to PBMs that employ these same policies. ASCO members have reported that some patients have had their medication or dosage changed by PBMs without prior approval by—or

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[10] Pharmaceutical Care Management Association. No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories. https://www.pcmanet.org/wp-content/uploads/2017/04/Visante-Study-on-Prices-vs.-Rebates-By-Category-FINAL-3.pdf.

[11] American Medical Association. House of Delegates Resolution 225-A-18. https://policysearch.ama-assn.org/policyfinder/detail/pharmacy%20benefit%20manager?uri=%2FAMADoc%2Fdirectives.xml-D-120.933.xml

[12] American Society of Clinical Oncology. American Society of Clinical Oncology policy statement on the impact of utilization management policies for cancer drug therapies. J Oncol Pract 13:758-762, 2017.

consultation with—the treating physician. They have also reported increasing administrative burdens that require additional staff and resources—solely to navigate prior authorization requirements and patient financial assistance programs. The issue has drawn attention across the medical community: the American Medical Association (AMA) has identified this as a priority and has issued prior authorization and utilization management principles, which broadly align with ASCO's recommendations.[13]

Restricted Networks and Distribution

ASCO has previously stated its concerns about payer policies that require oncologists to administer chemotherapy agents that have been prepared outside the physician's office by an entity under contract with the payer (so called "brown bagging" and "white bagging").[14] "Brown bagging" refers to arrangements in which the drug is purchased through a specialty pharmacy and shipped directly to the patient; the patient then takes the drug to the physician's office for administration. "White bagging" refers to arrangements in which the drug is purchased through a specialty pharmacy and shipped to the provider's office for administration. "Brown bagging" is especially concerning, as there is little control over how hazardous or unstable medications are stored and handled prior to administration in the physician's office. Concerns about "white bagging" and "brown bagging" carry the same concerns about medication access and quality whether they are used by payers or PBMs.

As well, PBMs increasingly are shifting drug dispensing away from physicians and toward pharmacies they own or with which they are affiliated, which can negatively impact patient care and access.[15] PBMs actively incentivize—and in some cases require—patients to use mail order or specialty pharmacies in lieu of a dispensing physician. Such actions are problematic, as it means PBMs are both competing and determining reimbursement rates for pharmacists.[16] Certain states do not allow in-office dispensing or provider-led pharmacies, and such arrangements may not be appropriate in every practice setting. However, some studies have suggested that

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[13] American Medical Association, 2016. Prior Authorization and Utilization Management Reform Principles. https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf.

[14] American Society of Clinical Oncology. "Brown Bagging" and "White Bagging" of Chemotherapy Drugs. 2016. https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2016-ASCO-Brown-Bagging-White-Bagging-Brief.pdf.

[15] Pharmacy Benefit Managers' Attack on Physician Dispensing and Impact on Patient Care: Case Study of CVS Caremark's Efforts to Restrict Access to Cancer Care Prepared by Frier Levitt, LLC Commissioned by the Community Oncology Alliance, August 2016. https://www.communityoncology.org/wp-content/uploads/2016/08/PBMs_Physician_Dispensing-WhitePaper_COA_FL.pdf

[16] National Community Pharmacists Association. Letter to Senate Judiciary Committee. April 4, 2018. https://www.ncpanet.org/newsroom/news-releases/2018/04/09/pharmacy-associations-urge-senate-judiciary-committee-to-hold-hearing-on-pbms

practices with medically integrated services may improve patient adherence to treatment regimens. [17]

Rebates & Discounts

The lack of transparency in which PBMs operate has caught the attention of many stakeholders in the healthcare community, including plan sponsors who are employers. The National Pharmaceutical Council (NPC) has affirmed that employers are increasingly concerned with pharmacy benefit transparency, complexity, and rebates. A recent NPC survey revealed that a large percentage of employers agree PBMs lack transparency and are overly complicated. Skepticism about the role of rebates in achieving an "aligned and effective health care supply chain" has also been expressed. More than 69% of large employers surveyed report their organizations would welcome an alternative to rebate-driven approaches to managing pharmacy benefit costs.[18]

Numerous states have passed bills requiring greater transparency from PBMs, including Maximum Allowable Cost (MAC) list mandates and more. Scarce information is available about the size and frequency of rebates PBMs receive from manufacturers, nor is it understood the extent to which patients experience actual benefits of these rebates and discounts.

At the federal level, several legislative proposals call for greater transparency. [19,20] The 2018 HHS *Blueprint for American Patients First* also addresses PBM transparency.[21] The Blueprint requests comments on different approaches to learning more about the complex financial dealings of the pharmaceutical industry at-large. In addition to elimination of gag clauses, it also suggests modification of the Anti-Kickback Statute (AKS) Safe Harbor that allows for rebates.

Gag Clauses

According to the National Conference of State Legislatures, at least 26 states have passed legislation that would prohibit a practice known as a "gag clause" on

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[17] Egerton, Nancy. In-Office Dispensing of Oral Oncolytics: A Continuity of Care and Cost Mitigation Model for Cancer Patients. American Journal of Managed Care, 22, 4.
[18] National Pharmaceutical Council. Toward Better Value: Employer perspectives on what's wrong with the management of prescription drug benefits and how to fix it. 2017. http://www.npcnow.org/system/files/research/download/npc-employer-pbm-survey-final.pdf
[19] Senate Bill 413/HR 1038, Improving Transparency and Accuracy in Medicare Part D Spending Act. https://www.congress.gov/bill/115th-congress/senate-bill/413
[20] House Resolution 1316, Prescription Drug Price Transparency Act. https://www.congress.gov/bill/115th-congress/house-bill/1316
[21] US Department of Health & Human Services, 2018. American Patients First Blueprint. https://www.hhs.gov/about/news/2018/05/11/trump-administration-releases-blueprint-lower-drug-prices-and-reduce-out-pocket-costs.html

pharmacists.[22] Gag clauses, increasingly used by PBMs, are contractual requirements that bar a pharmacist from informing patients about lower-cost drug options. These options could include simply purchasing the drug for cash, rather than using insurance. In these circumstances, patients could pay cash at the pharmacy, rather than go through their insurance coverage, thereby avoiding costs that may be solely due to the PBM payment structure. CMS recently issued a letter to Part D plan administrators, reminding them that such clauses are considered "unacceptable."[23] Patients with insurance coverage are still challenged by high co-pays for prescriptions and out-of-pocket deductibles. Pharmacies should not be prevented from sharing with patients their most cost-effective option for purchasing needed medications (i.e., gag clauses).

Direct and Indirect Remuneration Fees

As a means of setting drug reimbursement at the lowest price, CMS implemented direct and indirect remuneration (DIR) fees, which are intended to determine actual net cost of drugs covered under Part D. DIR fees were initially authorized as part of the Medicare Modernization Act of 2003. CMS defines DIR as additional compensation received after the point-of-sale that serves to change the final cost of the drug for the payer, or the price paid to the pharmacy for the drug.[24] Through DIR fees, plan sponsors and PBMs are required to report all "direct" and "indirect" remuneration received from third-parties, including drug manufacturers.[25] Because manufacturer rebates paid to PBMs are not known until a prescription has been dispensed to the patient and a claim processed at the point-of-sale, such remuneration is calculated and reconciled *after* Medicare pays the PBM. In this way, CMS ensures that taxpayers are only paying PBMs what the drugs ultimately cost. However, it can also mean that dispensing pharmacies discover—after reconciliation—they owe additional money to the PBM.

A 2017 CMS report found that DIR fees used by PBMs do not decrease point-of-sale cost for patients and can, in fact, increase patient out-of-pocket costs. Patients incur cost-sharing based on the price at their pharmacy, rather than the final, post-DIR reconciled price paid by CMS to the PBM. This can push a patient more rapidly into the "donut hole" where they have higher out-of-pocket costs. At the same time, DIR fees can reduce patient premiums and some government costs by shifting costs to

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[22] National Conference of State Legislatures. Prohibiting PBM "Gag Clauses" that Restrict Pharmacists from Disclosing Price Options: Recent State Legislation 2016-2018. http://www.ncsl.org/Portals/1/Documents/Health/Pharmacist_Gag_clauses-2018-14523.pdf

[23] Centers for Medicare and Medicaid Services. CMS Sends Clear Message to Plans: Stop Hiding Information from Patients. May 17, 2018. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-05-17.html

[24] Medicare Modernization Act of 2003. 42 CFR 423.308

[25] Centers for Medicare and Medicaid Services. Medicare Part D – Direct and Indirect Remuneration (DIR). 2017. https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html

the catastrophic phase of the benefit.[26] CMS has proposed several ways to improve the administration of DIR fees in the Medicare program, but has yet to implement significant changes.

Recently, PBMs have created a separate—and additional—DIR fee structure, known among pharmacists and physicians with in-office dispensing and pharmacies as "claw backs." This involves retroactive collection of fees by PBMs, the amounts of which are based on physicians' and pharmacists' performance according to certain metrics. PBMs justify imposition of these performance-based DIR fees by referencing CMS' Star Rating System. The Star Rating System is used by CMS in Medicare Advantage and Medicare Part D to measure performance on plans covering drug services. The Star Rating System measures relate largely to medication adherence for conditions such as diabetes, hypertension, and cholesterol; and was designed to apply to Part D plan sponsors, not pharmacies. No such measures exist for medication management in oncology.[27]

Despite lacking oncology measures and its misapplication on pharmacies instead of plan sponsors, these fees are nevertheless charged directly to oncology pharmacy providers, who assert this is done in a way that that lacks transparency and is highly profitable for PBMs. These performance-based fees are not required by HHS or CMS regulations, and appear to have no basis in statute.[28]

Addressing Key Concerns: Transparency, Drug Waste, and Benefit Design

Key concerns that impact ASCO members and their patients with cancer fall primarily into four categories:

- Quality and access to care
- Transparency of PBM operations and pricing
- Impact on drug waste and/or cost
- Benefit design

Quality and Access to Care

[26] Centers for Medicare and Medicaid Services. Medicare Part D – Direct and Indirect Remuneration (DIR). 2017. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html

[27] Centers for Medicare and Medicaid Services. 2018 Part C and D Star Ratings Measures. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2018MeasureList.pdf

[28] PBM DIR Fees Costing. Medicare and Beneficiaries: Investigative White Paper on. Background, Cost Impact, and. Legal Issues. Prepared by. Frier Levitt, LLC. Commissioned by the Community Oncology Alliance. January 2017.

ASCO members have expressed several concerns about PBMs and their impact on care. These include mistakes in filling prescriptions, altering treatment dosages for patients without consulting their oncology care provider, incomplete dispensing resulting in duplicate patient copays, and delays in treatment related to prior authorization demands and other problems.

Many of the practices employed by PBMs are utilization management strategies. ASCO has previously asserted its position against policies that attempt to incentivize, force, or coerce patients to accept anti-cancer therapy alternatives that are not recommended by their oncologist. Such practices can threaten both the outcomes for patients and the well-being of their families or care takers. Utilization management processes – whether directed by a health plan or PBM-- should result in timely and clear determinations that are consistent with the health insurer's coverage and other policies; decisions should reflect evidence-based practice; and payers should implement utilization management policies in a way that minimizes administrative burdens on both providers and patients.[29] Public and private payers should take immediate steps to assure that changes to prescribed therapy for patients with cancer are made only in the context of prior consultation and approval by their physician.

Timely access to therapies may be harmed by PBM-imposed network restrictions. Some PBMs require that patients use only their proprietary specialty pharmacy for certain drugs, despite the possibility that the patient could access the drug more cheaply and quickly from a different pharmacy. It is not uncommon that PBMs allow the first fill of an oral oncology drug to be carried out at the local or practice pharmacy. Thereafter, all other prescription refills are often required to go through the PBM-associated specialty pharmacy. Because the largest administrative burden and staff time commitment are attached to the first prescription—which includes preauthorization, peer-to-peer review, patient education, enrollment into copay assistance, and seeking foundation support to fill the financial gap—this puts the PBM-associated specialty pharmacy at an unfair advantage. ASCO is opposed to requirements that limit patients to exclusive use of PBM-owned or affiliated pharmacies.

Additionally, PBM accreditation standards required for participating pharmacies are costly and do not have relevance for oncology care. They often are applied in a manner that inappropriately limits the dispensing of specialty drugs. CMS has stated that it has received complaints from pharmacies that Part D plan sponsors have begun to require accreditation of pharmacies, including accreditation by multiple organizations or additional Part D plan-/PBM-specific credentialing criteria for network participation. In a final rule, CMS clearly stated that it does not support

[29] American Society of Clinical Oncology. American Society of Clinical Oncology policy statement on the impact of utilization management policies for cancer drug therapies. J Oncol Pract 13:758-762, 2017.

the use of a PBM-specific credentialing criteria that inappropriately limits dispensing of specialty drugs to certain pharmacies.[30]

Some oncology practices that provide in-office dispensing have been excluded from PBM networks entirely, despite Medicare's Any Willing Provider (AWP) requirements. CMS has received many complaints from pharmacies expressing concern with the process PBMs have adopted for complying with the AWP requirements. To address these concerns, CMS issued a final rule clarifying that Part D plan sponsors must contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation. They also may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network solely because they do not fit in a Part D plan sponsor's particular pharmacy type classification.[31] CMS should enforce its "Any Willing Provider" provision in Medicare Part D, preventing PBMs from excluding qualified in-office dispensing or provider led pharmacies from its networks. This enforcement would also prevent PBMs from enacting disproportionate incentives for patients to only access PBM-operated specialty pharmacies, thus preserving patients' ability to choose the most appropriate pharmacy that meets their needs.

Additionally, CMS should instruct contractors and PBMs to discontinue application of current Star performance ratings and related DIR claw backs on oncology dispensing physicians and practice-based pharmacies, instead relying on measures and standards that are more appropriate to the specialty. Star performance ratings were not intended for this purpose and, as currently structured, are not appropriate for oncology practice. Both flat and percentage-based fees unfairly disadvantage cancer care providers without demonstrably improving quality or patient outcomes.

ASCO remains committed to ensuring that patients are able to obtain timely, high-quality treatment and services at the lowest cost possible. Fragmentation of medication management, which occurs when cancer drug dispensing and distribution are operated by third parties such as PBMs, has the potential to place cancer patients at higher risk for errors and life-threatening toxicities unless additional steps are taken to ensure patient safety and quality standards are met. When managed at the clinic site, the pharmacy has direct access to the patient's electronic records. Forty-seven states offer some degree of in-office dispensing of drugs or provider-led closed pharmacies. In general, specialty pharmacy certifications are readily achievable and can be used to assure appropriate patient

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[30] Centers for Medicare and Medicaid Services. Contract Year 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.

[31] Centers for Medicare and Medicaid Services.
CMS Finalizes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS-4182-F).
https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02.html

safety standards in this setting. ASCO is opposed to increasingly narrow networks that limit patient choice by excluding pharmacy options such as in-office or provider-led closed pharmacies that are convenient, cost effective, and safe for patient care.

Transparency of PBM Operations and Pricing

In contrast to expanding efforts by the federal government to make healthcare prices more public, little is known about PBM financial arrangements.[32] Scarce information is available about the size and frequency of rebates PBMs receive from manufacturers, nor is it understood the extent to which patients experience actual benefits of these rebates and discounts. The ever-changing mix of rebates, discounts and performance-based DIR fees make it nearly impossible for cancer care professionals to anticipate how much prescribed treatments will cost their patients. New and different terms are introduced by PBMs to refer to the same financial arrangements, which adds to the confusion.

Numerous states have passed bills requiring greater transparency from PBMs, including Maximum Allowable Cost (MAC) list mandates and more. As mentioned earlier, 26 states have passed bills to prevent gag clauses, to encourage pharmacists and dispensing physicians to feel empowered to talk to patients about the best possible price for their drugs.

CMS, specifically the Medicare program, should build on these efforts by leveraging its regulatory authority. For example, CMS should make clear the prohibition on gag clauses and should require a more stringent and detailed accounting of DIR fees. Collecting and ultimately publishing such data would help plan sponsors, employers and providers understand the financial arrangements for which they are being asked to contract, ultimately helping to ensure patients are able to be fully informed about price differences and ways to obtain their drugs at the lowest cost.

Impact on Drug Waste and/or Cost

A 2016 article by researchers at Memorial Sloan Kettering Cancer Center found that nearly $3 billion was being lost annually in waste of cancer drugs.[33] Cancer care providers and patients have common interest in reducing the amount of waste in the healthcare system. Providers seek to restrain costs and growth in expenditures in their practice, through quality improvement and efficient scheduling practices

[32] Centers for Medicare & Medicaid Services, 2016. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html

[33] Bach, Peter et al (2016), Overspending driven by oversized single dose vials of cancer drugs BMJ 2016; 352 doi: https://doi.org/10.1136/bmj.i788

that help reduce waste.[34] Patients have a natural interest in reducing their out-of-pocket costs. There is growing concern that PBMs may be contributing to the costly waste in cancer care. ASCO members have described situations in which a PBM sent the wrong dosage or type of medication or sent medication directly to a patient's home, only to have it expire before they are able to get to their physician's office. Each mistake and wasted vial of cancer medication represents an important expense for a cancer patient and a lost opportunity for appropriate treatment.

Since January 2017, CMS has been requiring attachment of a "JW modifier" to Part B drug billing when an office is submitting a claim for waste.[35] Such claims are limited to times where a physician is required to discard an unused portion of a single dose vial or container, and do not include a patient who does not show up for an appointment. While these instances do not cover the full scope of waste that affects patients in the Medicare program, this is an area worth exploring to better identify cost and sources of waste. ASCO supports increased use of the JW modifier, along with similar mechanisms in commercial plans, to document waste in Part D and private plans. Making these data publicly available would highlight opportunities to reduce waste, lower costs, and enhance care. CMS should consider extending use of the JW modifier to better identify sources and cost of waste related to chemotherapy drugs in both Part B and Part D. Such data should be made public. Private payers should consider similar strategies.

Benefit Design

ASCO members have noted a variety of ways in which PBMs use of the benefit design process—including network size and formulary design—can increase cost for providers and patients. Increased costs have also resulted in oncology practice staff spending more time to locate co-pay assistance for patients. A recent Kaiser Family Foundation survey highlights the increasing role of separate prescription deductibles within employer plans. Fifteen percent of workers of workers in with employer-sponsored coverage now face separate prescription drug deductibles, which shift 100% of the prescription cost to the patient until the deductible is met.[36]

There are also growing concerns about novel strategies imposed by PBMs on benefit design plans, including a relatively new element known as "copay accumulator programs." These programs target specialty drugs for which manufacturers typically provide copay assistance. With a copay accumulator program in place, a manufacturer's assistance no longer applies to a patient's copay or out-of-pocket maximum. Therefore, while they are described as a benefit for patients, these

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[34] Leung, Caitlyn, Cheung, M.C, Charbonneau, L.F., Price, A., Ng, P., Chan, K.K.W. (2017) Financial impact of cancer drug wastage and potential cost savings from mitigation strategies. Journal of Oncology Practice, 13, 7. https://doi.org/10.1200/JOP.2017.022905

[35] Centers for Medicare and Medicaid Services, 2016. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf

[36] Kaiser Family Foundation. 2017 Employer Health Benefits Survey. https://www.kff.org/health-costs/report/2017-employer-health-benefits-survey/

programs in effect prevent patients from reaching their deductibles sooner. Copay accumulator programs generate large savings for employers and PBMs while increasing cost-sharing for patients. There is no standardized naming for these programs, and formal names created by payers can be ambiguous and confusing.[37] PBMs are using co-pay accumulator programs to shift more healthcare costs away from plan sponsors and employers, and onto patients.

At the heart of PBM administration of drug plans is formulary design, a process that is normally managed by Pharmacy and Therapeutics (P&T) Committees. Used by a range of organizations including PBMs, health plans, hospitals and other health systems, P&Ts develop and manage policies related to formulary management, including prior authorizations, step therapies, quantity limitations, generic substitutions, and other drug utilization management activities affecting access.[38] P&Ts are composed of physicians and pharmacists from a variety of different specialties, but may also include different healthcare practitioners as well as individuals with legal, contract, administrative, and ethics expertise. P&Ts review the strength of scientific evidence when making formulary management decisions. Plans are often designed with several tiers; the highest tier (with the highest copays) often include specialty drugs. The American Cancer Society has found that PBMs regularly place cancer drugs on the highest tier of their formularies, requiring the largest amount of cost-sharing from patients.[39] While CMS has public policy regarding the creation of Part D drug formularies, this same guidance is not necessarily followed in the private sector by all plan sponsors.[40] A lack of oncology specific specialization on a P&T committee can lead to mistakes and omissions for cutting-edge and complex cancer medications, leading to inferior care for cancer patients. Pharmacy and Therapeutics committees should include full and meaningful participation by oncology specialists.

Conclusion

Promoting delivery of high value care to every patient with cancer is central to ASCO's mission. ASCO understands and shares concerns about escalating costs and their impact on patients—and we have been actively engaged in addressing that

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[37] Drug Channels. Copay Accumulators: Costly Consequence of a New Cost-Shifting Pharmacy Benefit. January 3, 2018. http://www.drugchannels.net/2018/01/copay-accumulators-costly-consequences.html

[38] International Society for Pharmacoeconomics and Outcomes. *Drug Information Used in the Managed Care Pharmacy P&T Decision Making Process: Current Practice and Insights.* Retrieved from: https://www.ispor.org/meetings/baltimore0511/presentations/ISPOR-AMCP-presentation-FINAL-5-10-11.pdf

[39] American Cancer Society Cancer Action Network. ACS CAN Examination of Cancer Drug Coverage and Transparency in the Health Insurance Marketplaces February 22, 2017. https://www.acscan.org/sites/default/files/National%20Documents/QHP%20Formularies%20Analysis%20-%202017%20FINAL.pdf

[40] Centers for Medicare and Medicaid Services. Medicare Prescription Drug Manual. Chapter 6 – Part D Drugs and Formulary Requirements (v.01.19.16). https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html

issue. However, strategies for controlling cost must not compromise oncologists' ability to provide the right care, at the right time, for all their cancer patients.

ASCO remains committed to principles and recommendations previously conveyed in policy statements addressing utilization management. The opaque nature of PBM practices and policies—and their uncertain impact on cost and quality of cancer care—warrant special attention. ASCO has established a focused effort to obtain greater insight on specific PBM practices, their impact on patients and on cost, and appropriate remedies. A dedicated group of ASCO volunteers will pursue an in-depth analysis of PBM impact on cost and waste, their role and impact on quality of care, and the impact of benefit design on patients' ability to access the care they need.

In the meantime, ASCO is deeply concerned that the practices highlighted within this statement have the near-term potential to erode quality and access to care and should be addressed immediately.

Questions? Contact Allyn Moushey at Allyn.Moushey@asco.org or 571-483- 1738

VIEWPOINT

HEALTH POLICY

Pharmacy Benefit Manager Reform
Lessons From Ohio

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Supplemental content

Addressing soaring prescription drug prices is a health care reform priority in the United States.[1] While the pricing practices of pharmaceutical companies have been a subject of intense scrutiny and reform proposals, so have the practices of pharmacy benefit managers (PBMs), who are intermediaries in the drug supply chain.[2]

PBMs—third-party administrators of pharmacy benefits—arose in the 1980s to manage patient access to drugs through coverage and formulary designs on behalf of payers. The influence of PBMs on patients' access to drugs and the affordability of medications has increased substantially since then. The industry has also consolidated, with the 3 largest PBMs—Express Scripts, OptumRX, and CVS Caremark—accounting for more than 85% of the market.[3] In 2017, Express Scripts reported an annual revenue of $100 billion.[4] These revenues far exceed those of some of the highest capitalized pharmaceutical companies, such as Pfizer, with a reported annual revenue of $52 billion in 2017.[5]

PBMs are the focus of current proposed reforms from the White House and US Senate. They are also the subject of numerous new state statutory and legislative reforms of drug pricing. Recent reforms have taken place in Ohio. The state's approach to assessing whether and how current relationships between PBMs and Ohio Medicaid serve public interests provides an important window into PBM practices nationwide and also may have implications for other state and federal reform efforts.

> Ohio has pioneered regulatory efforts to increase PBM accountability, eliminate spread pricing in favor of more transparent pass-through pricing, and reduce the use of pharmacy gag clauses.

The Changing Ohio State Medicaid and PBM Relationship

In 2011, Ohio Medicaid, which spends an estimated $4 billion annually on prescriptions covering 3 million beneficiaries,[6] switched from a fee-for-service arrangement for its outpatient prescription drug benefit in favor of managed care. Ohio contracted with managed care plans that in turn contracted with the PBMs OptumRx and CVS Caremark to manage the state Medicaid beneficiaries' drug benefits. The PBMs managed the benefit using formulary design, pharmacy network access, and discounts and rebates off of the list price of drugs. The move to managed care appeared beneficial for the state, with an independent third-party analysis conducted in 2018 estimating $145 million in annual savings over the previous fee-for-service arrangement.[7] These savings were largely driven by the lower prescription claim prices billed to plans by PBMs relative to the Medicaid fee-for-service claims.[7]

However, Ohio pharmacists increasingly expressed concerns that PBMs were engaging in anticompetitive behaviors and taking advantage of opaque proprietary pricing practices. For example, PBMs were providing preferential pricing to affiliated pharmacies over independent pharmacies. Some PBMs also used a controversial technique, "spread pricing," charging Ohio Medicaid high prices while paying pharmacies lower prices for the same drugs and pocketing the difference.[7] Contracts between the PBM and the state specify how much Medicaid will pay when an insured beneficiary fills a prescription at a pharmacy.[8] The reimbursement the PBM pays to a pharmacy for a dispensed prescription and the payment the PBM receives from the state for the same prescription may differ, and when they do, PBMs profit from the transaction. For example, one Ohio Medicaid analysis found that the 2017 fourth-quarter cost to a pharmacy for a 30-day supply of the generic leukemia medication imatinib mesylate was $3859, with a cost to Ohio Medicaid of $7201, a difference of $3342.[9]

Moreover, some PBMs use "gag clauses," which prevent pharmacies from sharing with patients the most cost-effective option when purchasing medications. Gag clauses are contractual requirements, often used by PBMs, that would prevent a pharmacist from informing the patient if the out-of-pocket payment for a prescription would be less expensive than obtaining access to the drug through the patient's health insurance drug benefit coverage. Mounting public pressure and local media coverage led to Ohio Medicaid commissioning a third-party audit of PBM performance in the state.

The Ohio audit, released in June 2018, is to our knowledge the first comprehensive review of PBM practices by a government agency in any state. The audit incorporated 39 million drug transactions between March 1, 2017, and March 30, 2018. It reported that PBMs reimbursed independent pharmacies at a higher rate than their own proprietary pharmacies (eg, CVS Caremark PBM to CVS pharmacies). The audit also reported an 8.8% spread between the amount PBMs billed to Medicaid managed care plans and the amount paid to pharmacies; this spread amounted to $223.7 million in the

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audit year.[10] A subsequent report from the office of the Ohio Auditor of State found substantially higher spread pricing (31%) and associated revenue (93%) among generic drugs, which accounted for the highest volume dispensed (86% of claims), compared with branded drugs (13% of claims; spread pricing at 0.8%) and specialty drugs (0.5% of claims and spread pricing at 1%).[6]

The Intervention of State Regulators

In late summer 2018, Ohio Medicaid directed Ohio managed care plans to end their contracts with PBMs, effective January 2019. Plans were instead asked to adopt a transparent "pass-through" pricing model whereby the managed care plan would pay the PBM the exact amount paid to the pharmacy for the prescription drug, a dispensing fee, and, in lieu of spread-based revenue, an administrative fee. The dispensing fee payments are based on Ohio Medicaid's required survey of pharmacy dispensing costs. Further, Ohio Medicaid's largest managed care company, CareSource, is now contracting with PBMs to allow state officials and third-party auditors to see and monitor drug pricing.

Ohio policy makers also pursued the prohibition of gag clause use by PBMs via a bulletin issued by the Ohio Department of Insurance in April 2018. House Bill 479, prohibiting the same, was passed in June 2018 and introduced in the Ohio Senate on July 5, 2018, but failed by not coming to a vote by the end of the 2018 legislative session. However, in October 2018, the bipartisan federal Patient Right to Know Drug Prices Act and Know the Lowest Price Act were signed into law, banning gag clauses.

Lessons From Ohio

States have often been fertile testing grounds for health policy innovation and, as has been seen with states' efforts toward expanding insurance coverage, may act as leaders in improving patient access to, and affordability of, prescription drugs. Ohio has pioneered regulatory efforts to increase PBM accountability, eliminate spread pricing in favor of more transparent pass-through pricing, and reduce the use of pharmacy gag clauses.

Other states are increasingly active in considering and adopting some of these changes for their own state populations (eTable in the Supplement). As of March 5, 2019, state legislatures have filed approximately 233 bills referencing PBMs. With the passing of bipartisan federal anti-gag clause bills in October 2018, states have shifted the focus to other issues such as controlling pharmacy reimbursement rates (eg, via regulation of spread pricing [6 states], ensuring that patients' out-of-pocket costs better reflect actual acquisition costs by prohibiting PBMs from charging higher co-pays than the cost of the drug [2 states], or requiring rebates received by PBMs to be passed on to the enrollee [3 states]); increasing rebate transparency (eg, by mandating the reporting of rebate amounts [21 states]); instituting PBM licensure and registration processes (17 states); and regulating pharmacy networks and contracts (21 states).

What may be lacking from many of these efforts is Ohio's empirical approach to assessing the potential effect of these reforms on meaningful outcomes and the promise to evaluate gains, audit, and monitor after reform implementation. This is critical for establishing the direct benefits and costs of pursuing these reforms and understanding potential unintended consequences.

Ensuring patient access to affordable drugs is a national, bipartisan imperative. The empirical approach in Ohio to anticipating the effects of spread pricing reform is an encouraging sign of state leadership in this area. The effects of other state efforts on spending, patient out-of-pocket costs, and ultimately on patient outcomes, including regimen adherence and clinical response, deserve close observation and continued study.

ARTICLE INFORMATION

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STATE OF CANCER CARE IN AMERICA

ASCO special articles

Impact of Pharmacy Benefit Managers on Oncology Practices and Patients

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abstract

Pharmacy benefit managers (PBMs) are thoroughly integrated into the drug supply chain as administrators of prescription drug benefits for private insurers, self-insuring business, and government health plans. As the role of PBMs has expanded, their opaque business practices and impact on drug prices have come under increasing scrutiny. PBMs are particularly influential in oncology care because prescription drugs play a major role in the treatment of most cancers and an increasing number of patients with cancer are treated with oral oncology agents managed by PBMs. There is concern that some PBM practices may threaten access to high-quality cancer care and may increase the financial and administrative burden on patients and practices. In this article, we review the role of PBMs in prescription drug coverage and reimbursement, discuss the impact of PBMs on oncology care, and present data from the 2018 ASCO Practice Survey assessing the knowledge and attitude of oncology practices toward PBMs.

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INTRODUCTION

Pharmaceutical benefits managers (PBMs) develop and manage prescription drug benefits for private insurers, self-insuring businesses, and other entities, such as unions and government health plans (eg, Medicare Part D). They are influential in oncology care because prescription drugs play a major role in the treatment of most cancers and an increasing number of patients with cancer are treated with oral oncology agents managed by PBMs.[1] As intermediaries in the prescription drug supply chain, PBMs can affect both oncology patients and practices. For patients, PBMs can influence what drugs are covered by insurance, the size of copays and possible rebates, and where drugs can be purchased and administered. For providers, PBM policies can influence patient care delivery and practice administration demands.

Although ASCO and others have raised concerns about the effects of PBM practices on care delivery, there is limited literature about the impact of PBMs on cancer care.[2,3] In this ASCO 2019 State of Cancer Care in America article, we review the role of PBMs in prescription drug coverage and reimbursement, discuss the impact of PBMs on oncology care, and present data from the 2018 ASCO Practice Survey assessing the knowledge and attitude of oncology practices toward PBMs. The 2018 survey findings, discussed in more detail later in this article, suggested that many oncologists have a limited understanding of the role that PBMs play in cancer care delivery. In this review, we provide an educational overview of the current landscape for those involved in care of patients with cancer and oncology practice administration.

Overview of PBMs

PBMs first entered the prescription drug supply chain during the 1980s when private insurance companies began separating prescription drug coverage from other medical expenditures.[4,5] During this period, insurance companies turned to these third parties to process pharmacy claims and for help with administrative strategies, such as implementing drug identification cards, electronic records, drug formularies, and online processing.[4,5] Over the next 30 years, prescription drug coverage became increasingly complex, and the role of PBMs expanded to include contract and price negotiation with drug manufacturers, wholesalers, payers, and pharmacies.[3]

PBMs have consolidated significantly in the past decade. The three largest PBM companies—Express Scripts, OptumRX, and CVS Caremark—process 85% of all prescription claims and administer drug

ASSOCIATED CONTENT
See accompanying editorials on pages 270 and 273 and accompanying oncographic on page 275

Author affiliations and support information (if applicable) appear at the end of this article.

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benefits for > 266 million Americans in public and private insurance plans.[6,7] As PBMs' market share has grown, so has their influence on the drug delivery system.[8]

The sources of revenue for PBMs are unclear because their contracts are not transparent. PBMs generate revenue in part by negotiating prices and rebates with drug manufacturers, establishing formulary tiers, setting patient copays, setting clinical policies, creating pharmacy provider networks, and determining pharmacy reimbursements rates.[9,10] Most own and operate their own mail-order and specialty pharmacies.[11] PBMs also receive payments from plan sponsors (insurers) for processing prescriptions and managing formularies.[10,12] Revenue also comes from pharmaceutical manufacturers whose drugs are listed on formularies set by PBMs via manufacturer rebates (often calculated as a percentage of drug list prices).[7,8,10,13] Additional revenue is generated for PBMs on the margin between the amount charged to payers for a prescription drug and how much PBMs pay out to pharmacies for the same drug, also known as spread pricing.[7,10,14] Table 1 provides a glossary of select PBM-related terms and practices. The flow of money, products, and services in the drug supply chain is conceptualized in Figure 1.

Potential Value of PBMs

As intermediaries between payers, drug manufacturers, and pharmacies, PBMs potentially have the ability to lower prescription drug prices and promote value.[7] PBMs can leverage their market power to negotiate lower prices and rebates from drug manufacturers, resulting in savings that can be passed on to payers and patients.[13,15] For example, PBM advocacy organizations claim that PBM formularies lower medical costs while providing patients with access to more affordable drugs.[16,17]

PBMs claim to increase value by implementing formulary and utilization management strategies that promote evidence-based medicine and by encouraging the use of cost-effective medications and generic substitutions.[16-21] PBM-preferred specialty pharmacy networks are framed as an optimal model for managing cost and access.[22,23] Some PBM specialty pharmacies also provide clinical services designed to improve the quality of patient care, such as educational programs aimed at improving drug adherence or mitigating adverse effects.[23]

Although PBMs do not disclose information about the size of drug discounts and rebates,[13] some studies have found that PBM negotiations with manufacturers do result in lower drug prices for payers and insurers. For example, health plans that use PBM-preferred pharmacy networks have demonstrated lower pharmacy costs,[24,25] and formulary restrictions have been found to reduce the use of drugs and associated drug costs.[26] The Centers for Medicare and Medicaid Services (CMS) reports that PBM-negotiated rebates from manufacturers have lowered net prices and contributed to slowing drug-spending growth in public programs like Medicare and Medicaid in recent years, although the share of prescription drug costs lowered by rebates is projected to decrease.[27,28]

Challenges With PBMs

As prescription drug prices continue to rise, there is increasing concern among government agencies, policy makers, and medical groups that PBMs may not be delivering lower drug prices or improving value in drug spending.[27] For example, tying rebates to drug prices may incentivize PBMs to list higher-price drugs on formularies and discourage the use of lower-price or generic drugs,[13] with unintended and potentially negative consequences on patient outcomes.[26,29]

Critics of PBMs are concerned that consolidation in the industry, particularly PBM ownership of mail-order and specialty pharmacies, represents a conflict of interest that may lead to pharmacies switching patients to higher-cost, better-reimbursed medications.[10,13] Vertical consolidation is demonstrated by the fact that PBMs have affiliated insurers and specialty pharmacies. Horizontal consolidation is shown through the market share dominated by the three largest PBMs.[30] Both types of consolidation have further increased market share and the leverage that PBMs have in contract negotiations with payers, manufacturers, and pharmacies,[13] which the White House Council of Economic Advisors linked to rising drug prices in a 2018 report.[13,31]

The lack of transparency in PBM practices may have a negative impact on the cost of care. Many PBM transactions are contractually defined and opaque, making it difficult to track the true beneficiaries of cost savings. There are concerns about whether the discounts PBMs receive from drug manufacturers and pharmacies are passed on to patients.[13,32] Moreover, the current framework of formulary tiers, preauthorization requirements, and copayments may be creating cost and access issues for patients, as well as financial risk and administrative burden for practices.[8,33-37]

There are examples of legislative action to address these issues, including a recent federal law that prohibits PBMs and insurers from using gag clauses, a practice through which pharmacies are blocked from providing drug price information to patients and employers (Table 1).[38,39] Prior to the protransparency gag clause legislation, PBMs could contractually prevent pharmacies from informing patients if the out-of-pocket cash price of a medication would be less than their copay (ie, going through their health insurance drug benefit).

PBMS IN ONCOLOGY

The price of prescription drugs is a major concern in oncology. Prices are increasing in both inpatient and outpatient prescription settings,[40,41] and the costs of oncology drugs are growing at a faster rate than those of other prescription drug classes.[41,42] This rise in price is affecting

TABLE 1. Glossary of PBM-Related Terms and Practices

Practice	Description	Study
Rebates	After-the-transaction (ie, sale) discount payments from manufacturers redeemed by PBMs and passed on, in part, to the insurer or employer. Typically negotiated from the manufacturer's list price and influenced by factors such as sale volume, formulary placement, and copayment pricing.	Werble[7]
Spread pricing	The practice of billing the payer more for a drug than is being reimbursed to the pharmacy, thereby generating revenue for the PBM.	ASCO 2018[8]
Medically integrated dispensing	Drug dispensing by a practice- or hospital-owned, in-house pharmacy. Intended to reduce costs and may improve outcomes by integrating medical care, education, and coordination of drug delivery.	NCODA
Utilization management	Rules that may restrict or deny select therapies.	
Prior authorization	Requiring patients or prescribers to secure preapproval as a condition of payment or insurance coverage for their prescribed medication.	
Restrictive formularies	Limitations placed on the number of drugs included within a category or class on a drug formulary.	
Step therapy (ie, fail first)	The requirement to use a certain drug, and have it be proven to be unsuccessful, before another drug is allowed to be covered.	
Specialty tiers	A formulary tier that may shift a larger portion of the cost of care from the payer to the beneficiary.	
Restricted networks and distribution	Methods to incentivize or require the use of preferred drug distribution paths, such as mail order or selected specialty pharmacies.	ASCO 2018[8]
Direct and indirect remuneration fees	Additional compensation received after the point of sale that changes the final cost of the drug for the payer or the price paid to the pharmacy for the drug. DIR fees are required by CMS and were authorized by statute in 2003.	Frier Levitt, 2017[12] ASCO 2018[8]
Clawback	A retroactive collection of fees by a PBM from a pharmacy. The amount is based on physicians' and pharmacists' performance according to certain metrics as established by the PBM.	Van Nuys 2018[35] ASCO 2018[8]
Gag clause	A practice through which PBMs and insurers could prohibit pharmacies from providing transparent drug-price information to customers and employers (eg, whether a prescription would cost less when paid for out of pocket). Illegal as of the October 2018 passage of the Patient Right to Know Drug Prices Act.	Coppock 2018[38]

Abbreviations: CMS, Centers for Medicare and Medicaid Services; DIR, direct and indirect remuneration; PBM, pharmacy benefit manager.

older (generic) and newer cancer drugs, with the annual cost of new medications routinely exceeding $100,000.[43-45] At the same time, cancer drugs are increasingly targeted to specific molecules, making manufacturing more complex and not necessarily interchangeable or available in generic form.[34] Cancer drugs may also require special procedures for handling and administration.[11]

PBMs have implemented policies that may shift costs to patients (eg, specialty formulary tiers) and make it more difficult for patients to access prescribed treatments (eg, utilization management practices like prior authorization and step therapy; see Table 1 for a glossary of select PBM-related terms and practices).

Cost Challenges

ASCO and other oncology groups have documented how PBM and payer policies may increase costs of oral cancer drugs to patients.[8,12,46,47] As plan administrators, PBMs use a variety of cost-containment and cost-sharing strategies.[5] Cancer drugs are routinely on the highest formulary tier and a subset of plans place all cancer medications on a specialty tier.[34,48] Drugs on the highest or specialty tiers typically require cost sharing by patients of 30%-50% of drug costs.[34,47] For example, Medicare Part D beneficiaries are liable for 25%-33% coinsurance for cancer drugs on the highest specialty tier, and these out-of-pocket expenses drive Medicare beneficiaries quickly into the donut hole, a coverage gap where they are responsible for paying a high proportion of drug costs until their out-of-pocket spending qualifies them for catastrophic coverage.[49,50] Since the passage of the Affordable Care Act in 2010, the portion of the drug cost for which most Part D beneficiaries are responsible while they are in the donut hole has shrunk from 100% to 25%.[51] Even so, out-of-pocket spending for cancer drugs, particularly targeted oral anticancer medications, is financially burdensome.[52] One recent analysis estimated the average out-of-pocket spending for a patient with Medicare Part D who requires a 12-month prescription for their anticancer drug was $10,470 in 2019 (ranging from $7,220/y for lapatinib to $15,472/y for lenalidomide).[53]

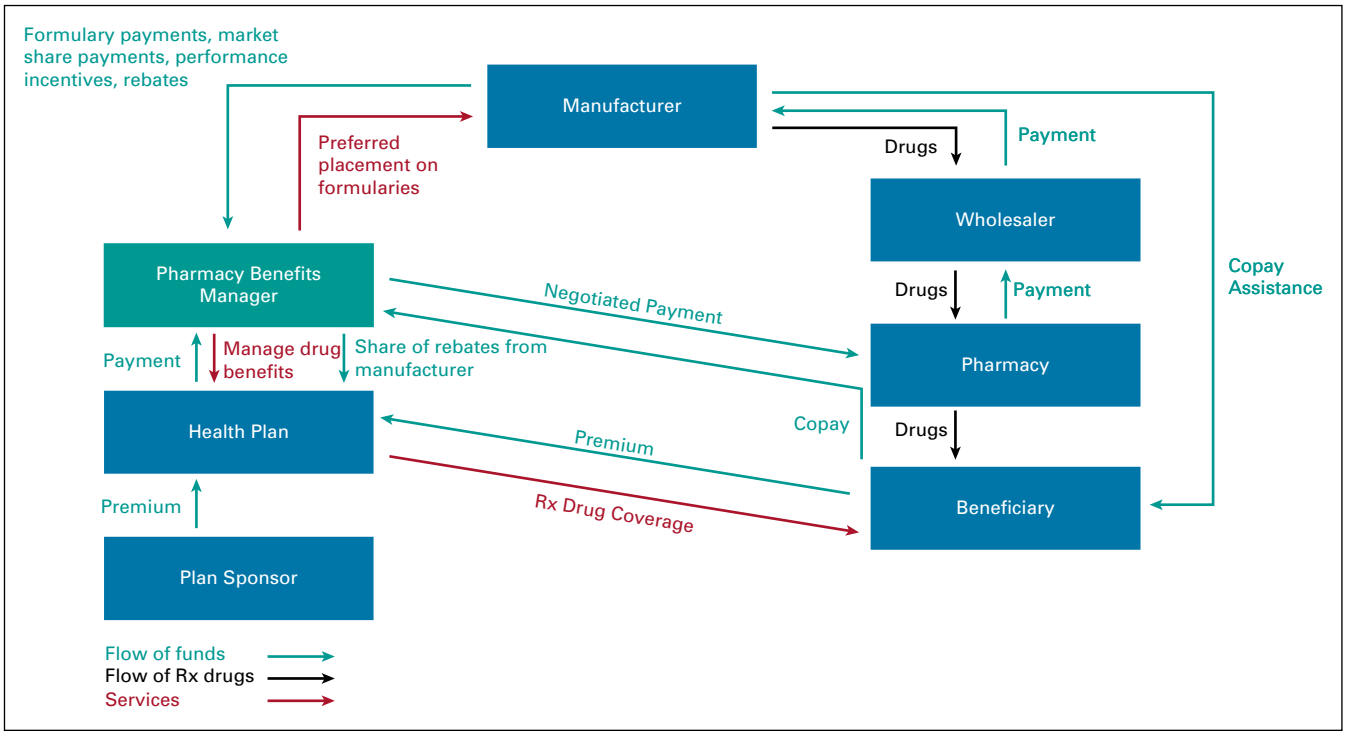

FIG 1. Conceptual diagram of the flow of products, services, and money in the drug supply chain. Rx, prescription. Adapted from Sood et al.[13]

Higher copays and large out-of-pocket costs have been shown to lead to drug noncompliance and drug abandonment and associated negative health outcomes.[26,35,49] Therapy noncompliance is price sensitive and patients enrolled in high-deductible plans are more affected than those with low deductibles.[5] In an analysis of a nationally representative pharmacy claims database, patients with cost sharing > $500 were four times as likely to abandon oral oncolytics compared with those with cost sharing of $100 or less.[54] The high costs of care, including prescription drug expenditures, are also a major cause of personal bankruptcy and financial and psychological distress in patients with cancer.[5,46]

Access Challenges

PBM practices can impede patients' access to cancer drugs. PBM utilization management approaches, for example, can include administrative rules that limit or restrict patient access to certain cancer treatments.[47] A 2019 survey of cancer patients by the American Cancer Society Cancer Action Network reported that 34% of patients had to wait for insurance approval of a treatment, and that utilization management policies result in treatment delays and increased stress for patients.[55] Treatment delays caused by utilization management policies can lead to patients discontinuing prescribed treatments and to poorer outcomes.[47,55,56] Delays in cancer care have previously been associated with worse outcomes,[57-59] and the adverse impact of cancer care delay caused directly by utilization management strategies (eg, prior authorization and step therapy) on outcomes deserves more investigation. Prior authorization is of particular concern to oncologists[47] and to the broader physician community: in a 2017 survey by the American Medical Association, 92% of physicians reported prior authorization can have a negative impact on clinical outcomes.[56]

Access may be affected by restrictive formularies that limit the number of drugs included in a class of drugs and by step therapy (sometimes called "fail first") policies that require use of the payer's preferred drug before coverage of the initial drug selected by the prescribing oncologist.[47] Restrictive formularies and step-therapy approaches are particularly problematic in cancer where drugs within a class may not be interchangeable and the exclusion of certain drugs from coverage could negatively affect outcomes.[47] In the era of precision therapy, it is plausible that a targeted agent's effectiveness could be compromised by first starting with step therapy–dictated, less-preferred medication. "Nonmedical switching," whereby a patient is required to change from a previously prescribed therapy to a different, less expensive therapy for no medically advantageous reason, is another utilization management practice that could impede patient access to optimal cancer care.[60,61] Currently, there are limited oncology- or PBM-specific data about the prevalence or impact of nonmedical switching.

PBM pharmacy requirements that shift drug dispensing away from oncologists can also introduce patient care and

cost issues. Practices with in-office dispensing are sometimes excluded from eligible pharmacy networks when they do not meet standards assigned by the PBM. Furthermore, PBMs may incentivize or require that patients fill prescriptions at PBM-owned or -affiliated pharmacies.[8] These practices diminish potential patient benefits of in-office dispensing, such as quicker access to medications and direct physician-patient communication about dosing and adverse effects, both of which can improve adherence.[62] Expensive waste of unused medication attributed to mail-order pharmacies, which are often incentivized or required by PBMs, is also a concern.[62]

ASCO PRACTICE SURVEY DATA

Measuring how oncologists view the role of PBMs in cancer care and how PBM policies influence patient care and practice management have been a major focus of ASCO. ASCO has used informal polling to document its members' impressions of the role of PBMs in care delivery and has been surveying oncology practices about overarching practice trends and pressures for nearly a decade through its annual practice survey. Practice survey methods were detailed previously in this *Journal of Oncology Practice* article series.[37] In 2017, oncology practices identified payers as their top pressure source, with prior authorization and coverage denials cited as specific payer strains.[46] In 2018, the ASCO practice survey included a series of PBM-related questions. The resulting data, described in detail in the following paragraphs, suggest many oncology practices perceive high levels of administrative burden resulting from PBM requirements, yet they have limited understanding of PBM activities and how PBM policies are affecting their patients.

ASCO received responses from 291 US clinical oncology practices to its 2018 survey, with 270 (92.8%) providing information on their experiences with PBMs. The survey respondents came from diverse geographies and settings and together represented > 8,400 oncologists (45%) who care for adult patients with cancer in the United States.[63] Half of the responding practices reported interacting with one (n = 11) or more (n = 123) PBMs, and another third (n = 86) were unsure of the number. Notably, the remaining 50 respondents (19%) were screened out of subsequent questioning because they reported interacting with no PBMs—an improbable finding given PBMs' high penetration of the prescription drug market. This section provides an overview of oncology practices' reported understanding of PBM practices, as well as the impact of PBM policies on drug accessibility, the provision of care, and practice administration.

Understanding of PBM Practices

Respondents to the 2018 practice survey were asked to assess their understanding of "PBM operations and negotiating tactics, including formulary development and management, different rebates and discounts PBMs receive, coupons, clawback amounts/Direct Indirect Remuneration (DIR) fees" (Table 1). A majority of respondents (55%; n = 109) had no to very little understanding of PBM operations and negotiating tactics. Understanding was particularly limited among hospital-owned practices (68.9% hospital-owned *v* 39.8% physician-owned practices reported no or very little understanding) and among practices without in-office dispensing of cancer treatments (66.3% without dispensing *v* 45.0% with dispensing), the latter of whom may stand to benefit from some PBM services. Survey respondents with patient care roles were more likely to report limited understanding than those with administrative roles (61.5% of clinical respondents *v* 51.1% of administrative respondents).

Despite limited understanding of PBM operations, responding oncology practices were largely familiar with PBM impacts on their administrative and patient care duties. Ten percent of practices (n = 20) reported benefits to working with PBMs, with written comments noting improvements to patient access (n = 8), reduced patient costs (n = 2), and reduced financial burden (n = 2), among other benefits. Overall, a low acknowledgment of benefits corresponded with high levels of perceived interruptions to practice administration and patient care activities .

PBM Policies and Drug Accessibility

In the 2018 practice survey, three-quarters of practices reported that PBMs interfered with patient care and/or made it difficult to get their work done (Fig 2). In addition, 186 of 200 respondents (93%) encountered PBM utilization management policies, with prior authorization delays, step therapy/fail-first requirements, noncoverage of drugs recommended/required for treatment, and placement of cancer drugs on highest formulary tiers cited as common experiences (Fig 3). Physician-owned practices reported that these policies had a greater negative impact than health system–owned practices. It is clear that for any policies aimed at addressing the PBM-related issues described in this review, the differential impact on physician-owned practices versus health system–owned practices should be considered.

PBMs and Issues With Providing Care

PBMs may directly contact some patients to initiate and manage their prescriptions. ASCO's data reveal that this has introduced disruptions, waste, and errors into the drug prescription process for oncologic treatments (Fig 4). More than 60% of responding practices reported that PBMs had contacted their patients without notifying their providers (62%; n = 123). Mail-order shipments were a major concern for these oncology practices, with nearly half reporting drug waste resulting from unwanted drug refills (42%) and 24% noting the shipment of premixed medications to patients without

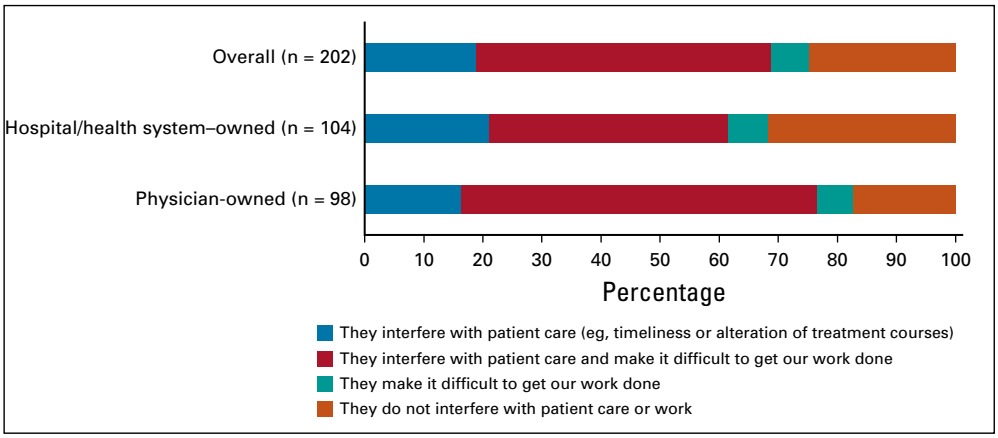

FIG 2. Impacts of pharmacy benefit manager policies on oncology practices.[8]

appropriate safeguards. Errors in the form of incorrect medications or dosages and unprompted mid-regimen changes were also reported.

PBMs and Practice Administration

In addition to influencing patient care, PBM policies can result in uncompensated costs and administrative work for practices. A majority of practices responding to ASCO's survey reported that PBMs interfered with their practice administration (n = 114; 56%; Fig 2). To handle PBM-related work, practices reported hiring staff (n = 50; 25%), shifting responsibilities among existing staff (n = 47; 24%), or both (n = 15; 8%). A majority of practices allocated staff time to handle PBM paperwork (n = 108; 54%), with time spent on activities including prior authorizations (n = 96; 89%), seeking copay assistance on behalf of patients (n = 86; 80%), and addressing PBM-related medication errors and patient complaints (n = 40; 38%).

To conclude, as the role of PBMs in the administration of prescription drug benefits has expanded, their opaque business practices and impact on drug prices have come under increasing scrutiny. PBMs are thoroughly integrated into the drug supply chain, and it is difficult to isolate PBM actions from those of insurers, plan sponsors, and manufacturers. However, evidence suggests that PBM practices likely impact the cost of and access to care for patients. The ASCO 2018 practice survey begins to quantify the perceived impact of PBMs on cancer care delivery among oncology practitioners. A large proportion of survey respondents were not confident in their understanding of the complex role and impact of PBMs, but most respondents reported experiencing disruptions to patient care and uncompensated administrative burden resulting from interactions with PBMs. General familiarity with and negative impressions of PBM activities were both more prevalent among physician-owned than hospital-owned oncology practices, suggesting that practices that have closer interactions with PBMs are more likely to perceive a negative impact on oncology care. The survey findings underscore the need for greater system transparency and increased provider education so the actions and influences of PBMs are more widely understood.

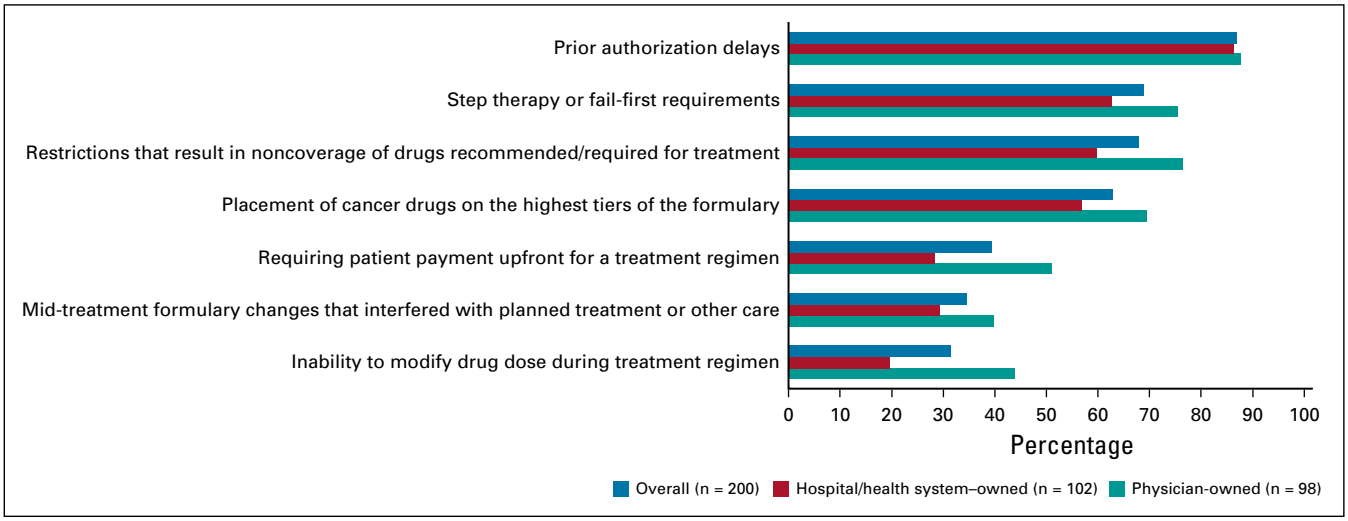

FIG 3. Consequences of pharmacy benefit manager utilization management and formulary policies.[8]

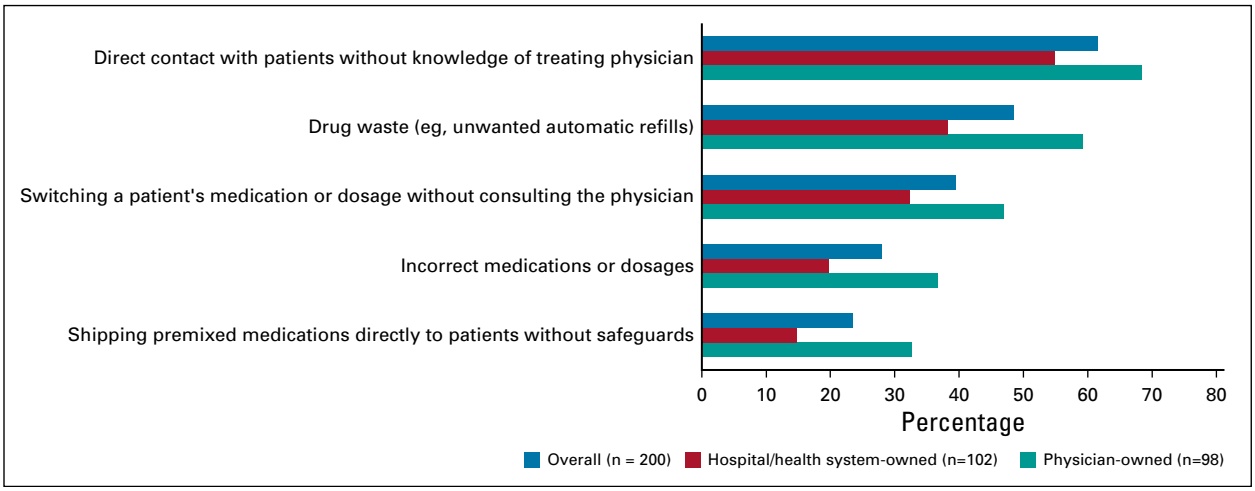

FIG 4. Results of pharmacy benefit manager interactions with patients with cancer.[8]

ASCO is committed to protecting oncologists' ability to provide the best treatment at the right time so patients have access to the most effective cancer treatments, and ASCO strongly supports efforts to control the costs of prescription drugs.[8,46,47] Some of the cost and access challenges associated with PBMs result from a lack of communication or coordination between PBMs and oncology practices. The high proportion of practices in the 2018 survey that reported errors and waste as a result of direct PBM contact with patients could be reduced, for example, by improving communication between the PBM and physician. At a minimum, the prescribing physician should always be consulted before any medication, regimen, or dosing changes. Addressing many of the challenges described in this article will require policy-based solutions. In comments responding to various CMS proposals, ASCO expressed its concerns regarding patient access and timely care and urged CMS to more carefully examine the impact of PBM practices on patient care and outcomes. ASCO is actively advocating on Capitol Hill and in states legislatures for reforms to many of the PBM practices described herein, such as utilization management, as well as for improvement in transparency. Moving forward, ASCO will continue to monitor the impact of PBMs on patients and practices and advocate for policies that ensure fair and transparent drug pricing, direct communication between patients and their oncology care providers, and oncology specialist representation in formulary design and other processes related to the delivery of cancer drugs.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST AND DATA AVAILABILITY STATEMENT

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Final approval of manuscript: All authors
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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Impact of Pharmacy Benefit Managers on Oncology Practices and Patients

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Open Payments is a public database containing information reported by companies about payments made to US-licensed physicians (Open Payments).

Sheetal Kircher
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