

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 owns a specialty pharmacy company.

¹ Sood N, Shih T, Van Nuys K, Goldman D: The Flow of Money Through the Pharmaceutical Distribution System. USC Schaeffer – Leonard 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.^{7,8} Stakeholders have been challenged in achieving detailed understanding of this issue because of the proprietary and confidential environment in which PBMs operate.^{9,10}

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.

⁷ 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>

⁸ 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>.

⁹ 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>

¹⁰ 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>.

- Pharmacies should not be prevented from sharing with patients their most cost-effective option for purchasing needed medications (i.e., gag clauses). To this 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.¹¹ 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.

¹¹ 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

As for-profit companies, PBMs generate revenue in various ways from pharmaceutical manufacturers, pharmacies and plan sponsors. PBMs obtain 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.¹² 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.”¹³

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.¹⁴ While PBMs are more of an intermediary or agent for payers, ASCO’s concerns about—and

¹² 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>.

¹³ 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>

¹⁴ 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.

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 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.¹⁵

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").¹⁶ "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.¹⁷ 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.¹⁸ Certain states do not allow in-

¹⁵ 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>.

¹⁶ 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>.

¹⁷ 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

¹⁸ 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>

office dispensing or provider-led pharmacies, and such arrangements may not be appropriate in every practice setting. However, some studies have suggested that practices with medically integrated services may improve patient adherence to treatment regimens.¹⁹

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.²⁰ 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.²¹

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.^{22,23} The recently announced HHS *Blueprint for American Patients First* also addresses PBM transparency.²⁴ 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

¹⁹ 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.

²⁰ 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>

²¹ 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>

²² [Senate Bill 413/H.R. 1038, Improving Transparency and Accuracy in Medicare Part D Spending Act.](https://www.congress.gov/bill/115th-congress/senate-bill/413)
<https://www.congress.gov/bill/115th-congress/senate-bill/413>

²³ [House Resolution 1316, Prescription Drug Price Transparency Act.](https://www.congress.gov/bill/115th-congress/house-bill/1316)
<https://www.congress.gov/bill/115th-congress/house-bill/1316>

²⁴ 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>

According to the National Conference of State Legislatures, at least 22 states have passed legislation that would prohibit a practice known as a “gag clause” on pharmacists.²⁵ 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.”²⁶ Patients with insurance coverage are still challenged by high copays 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.²⁷ Through DIR fees, plan sponsors and PBMs are required to report all “direct” and “indirect” remuneration received from third-parties, including drug manufacturers.²⁸ 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

²⁵ 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

²⁶ 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>

²⁷ Medicare Modernization Act of 2003. 42 CFR 423.308

²⁸ 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>

fees can reduce patient premiums and some government costs by shifting costs to the catastrophic phase of the benefit.²⁹ 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.³⁰

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 lacks transparency and is highly profitable for PBMs.³¹ These performance-based fees are not required by HHS or CMS regulations, and appear to have no basis in statute.³²

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

²⁹ 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>

³⁰ 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>

³¹ 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. Available at https://www.communityoncology.org/wp-content/uploads/2017/01/COA_White_Paper_on_DIR-Final.pdf

³² 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.

Quality and Access to Care

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.³³ 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 of 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

³³ 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.

for network participation. In a final rule, CMS clearly stated that it does not support the use of a PBM-specific credentialing criteria that inappropriately limits dispensing of specialty drugs to certain pharmacies.³⁴

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.³⁵ 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 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

³⁴ 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.

³⁵ 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>

drugs or provider-led closed pharmacies. In general, specialty pharmacy certifications are readily achievable and can be used to assure appropriate patient 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.³⁶ 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, 14 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.³⁷ 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

³⁶ 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>

³⁷ 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.³⁸ 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.³⁹ 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 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 PBM 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.⁴⁰

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

³⁸ 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>

³⁹ Centers for Medicare and Medicaid Services, 2016. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf>

⁴⁰ Kaiser Family Foundation. 2017 Employer Health Benefits Survey. <https://www.kff.org/health-costs/report/2017-employer-health-benefits-survey/>

maximum. Therefore, while they are described as a benefit for patients, these 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.⁴¹ 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.⁴² 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 often are 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.⁴³ 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.⁴⁴ 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

⁴¹ 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>

⁴² 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>

⁴³ 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>

⁴⁴ 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>

their impact on patients—and we have been actively engaged in addressing that 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.

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