



COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

1225 New York Avenue, NW, Suite 600
Washington, DC 20005
(202) 729-8147 | communityoncology.org

President
Michael Diaz, MD
Florida

Vice President
Kashyap Patel, MD
South Carolina

Secretary
Miriam J. Atkins, MD, FACP
Georgia

Treasurer
Ricky Newton, CPA
Virginia

Executive Director
Ted Okon
Washington, DC

Directors
Lakshmi Aggarwal, MD
Indiana

Robert Baird, Jr., RN
Ohio

Harry (Mac) Barnes, MD
Alabama

Edward (Randy) Broun, MD
Ohio

Steve D'Amato, R. Ph., BSpHarm
Maine

Marsha DeVita, NP, AOCN
New York

Stephen (Fred) Divers, MD
Arkansas

Chancellor Donald, MD
Louisiana

David Eagle, MD
North Carolina

Stuart Genschaw
Michigan

Lucio Gordan, MD
Florida

Bruce Gould, MD
Georgia

Edwin Graham
New York

Robert Green, MD
New York

Anshu Jain, MD
Kentucky

Terrill Jordan
New Jersey

Dinesh Kapur, MD
Connecticut

Edward Licitra, MD
New Jersey

Joseph Lynch, MD
Pennsylvania

Barbara L. McAneny, MD
New Mexico

Mark Nelson, PharmD
Washington

Todd O'Connell
New York

Kathy Oubre, MS
Louisiana

Debra Patt, MD
Texas

Jeff Patton, MD
Tennessee

William (Bud) Pierce, MD
Oregon

Marissa Rivera, MBA
Oregon

Barry Russo
Texas

Jeff Vacirca, MD
New York

Seaborn (Donny) Wade, MD
Virginia

April 8, 2019

Submitted electronically to: <http://www.regulations.gov>

The Honorable Alex M. Azar II
Secretary
United States Department of Health and Human Services
Attention: OIG-0936-P
200 Independence Avenue, SW
Room 600E
Washington, DC 20201

Re: *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*

Dear Secretary Azar:

On behalf of the Board of Directors of the Community Oncology Alliance (“COA”), we are submitting this comment letter regarding the Proposed Rule titled *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (OIG-0936-P)* (the “Proposed Rule”).

As you know, COA is an organization that is dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. COA’s mission is to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work. For more than 16 years, COA has built a national grassroots network of community oncology practices to advocate for public policies to support patients with cancer.

COA is highly supportive of the proposal by the Department of Health & Human Services and its Office of Inspector General (collectively “HHS”) to remove the safe harbor protection from the Federal Anti-Kickback Statute (“AKS”) for pharmaceutical rebates to Medicare and Medicaid plan sponsors and pharmacy benefit managers (“PBMs”) and instead put in place new safe harbors to allow point-of-sale discounts and fixed compensation arrangements between PBMs and manufacturers. **The existing safe harbor protection has led to a system of perverse incentives in which widespread use of rebates between manufacturers and PBMs not only drives up drug prices and patient costs, but also creates inconsistent access to therapies.** We applaud HHS for proposing an appropriately direct and impactful policy change that will essentially eliminate rebating in Medicare and Medicaid Managed Care, thereby restoring transparency and accountability in the system and improving access and affordability for patients.

In this letter, we explain our support for the Proposed Rule, which we believe will:

- Lower out-of-pocket costs for patients with cancer;
- Rein in the unbridled destructive influence of PBMs;
- Lead to lower list prices for drugs; and
- Protect competitive dynamics that will continue to keep premiums affordable for beneficiaries.

However, while COA supports the Proposed Rule and its intended purposes, we acknowledge that its implementation in the proposed timeline could create operational difficulties for various stakeholders, potentially ultimately impacting patients. For this reason, in this letter, we urge HHS to contemplate the following considerations when finalizing the Proposed Rule and its implementation:

- HHS must consider the relevant implications of all retrospective price concessions to ensure that PBMs are precluded from inappropriately clawing back reimbursement for prescriptions filled for Medicare beneficiaries;
- The chargeback administration system described in the Proposed Rule should include guardrails to avoid burdening not just standalone pharmacies, but community oncology practice-affiliated in-house pharmacies and in-office dispensers (collectively “Community Oncology Pharmacies”) as well; and
- The effective elimination of rebates must be expanded to the commercial market to achieve the full intended impact of lower prescription drug list prices.

Areas of Support

The Proposed Rule will lower out-of-pocket costs for patients with cancer, address access issues created by PBMs, and lower prescription drug list prices while avoiding increasing premiums to an unreasonable extent.

COA supports the proposed transition from secretive retrospective rebates to upfront discounts that are passed on to the patient at the pharmacy counter because this change will directly benefit patients. Specifically, transitioning to point-of-sale discounts will improve transparency, predictability, and affordability for patients. In the current system, sicker patients, such as those with cancer, do not see sufficient benefit from the rebates negotiated on their prescriptions. Their out-of-pocket costs are based on list prices, which are not inclusive of rebates, and the vast majority of dollars negotiated between manufacturers and PBMs are *supposedly* channeled toward lowering premiums. The Office of the Actuary (“OACT”) at the Centers for Medicare & Medicaid Services (“CMS”) estimates that the transition to point-of-sale discounts would result in Medicare beneficiaries spending \$83 billion less on prescription drug cost sharing over 10 years.¹ This constitutes direct and significant savings for American seniors, including patients with cancer who are prescribed critical, but expensive oncology treatments. We applaud HHS for its determination to dismantle a flawed system in order to deliver on the promise of securing savings for beneficiaries on prescription drugs.

While the decrease in out-of-pocket costs may cause an increase in premiums, according to the OACT analysis, reductions in total cost sharing would exceed total premium increases.² Moreover, the need for health plans to compete based on premiums will align plans’ incentives with those of the government and beneficiaries and continue to keep

¹ CMS Office of the Actuary. Proposed Safe Harbor Regulation. August 30, 2018. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>

² CMS Office of the Actuary. Proposed Safe Harbor Regulation. August 30, 2018. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf>

downward pressure on premium costs. Additionally, a rise in premiums that corresponds with a reduction in cost sharing would balance out **the totally illogical and unfair situation in which sick beneficiaries paying high out-of-pocket costs for their drugs currently subsidize premiums for healthy beneficiaries.** We note that this is the exact opposite of the way that normal, healthy, and rational insurance markets should function whereby healthy individuals in essence subsidize sick individuals; not the other way around as currently exists.

The Proposed Rule may or may not result in very negligible premium increases for all beneficiaries. Given that Medicare Advantage plans compete on premiums, and also compete, in essence, with fee-for-service Medicare, a more rational, free market (devoid of rebates) will keep a lid on premium increases, regardless of the warnings by plan sponsors opposed to this Proposed Rule. However, at the same time, eliminating rebates will make a meaningful difference for sicker patients and their families by lowering drug list prices.

The excessive reliance on Direct and Indirect Remuneration (“DIR”) to reduce total plan liability and keep premiums down has also led to opaque calculations and incentives that ultimately drive up costs for the government and taxpayers. The growth of rebates and other price concessions not reflected at the point-of-sale places more of the burden on beneficiary cost-sharing. In turn, higher beneficiary cost-sharing results in the quicker progression of Part D enrollees through the Part D drug benefit phases to reach the catastrophic phase. In 2017, CMS revealed³ a growing disparity between gross Part D drug costs, calculated based on costs of drugs at the point-of-sale, and net Part D drug costs, which account for all retrospective rebates. Since 2010, CMS observed total DIR increase by 22% per year between 2010 and 2015, while total Part D gross drug costs only grew about 12% per year during the same period.⁴ High priced drugs, usually associated with high rebates, have been shifting more of the drug spend into the catastrophic phase, where plans are responsible for only 15% of costs, while Medicare’s liability is 80%. Eliminating rebates would realign incentives in a way that would thwart the plan and the PBM practice of preferring expensive drugs with high rebates over cheaper alternatives.

The transition away from rebates to upfront discounts passed to beneficiaries would also impact the business models of PBM in a way that restores some checks and balances on their unbridled influence on drug access for patients. In the current system, PBMs unduly complicate drug procurement by delaying and denying patients’ treatment and driving up costs. COA has written extensively about the negative effects on patients of PBMs’ consolidation and power.⁵ The 3 largest PBMs control about two-thirds of drug benefits for over 260 million Americans.⁶ The Altarum Institute estimates that PBMs received \$89 billion in rebates in 2016, including \$23 billion to private health plans, \$31 billion to Medicare Part D plans, \$32 billion to Medicaid, and \$3 billion to other payers.⁷ Due to the convoluted and opaque nature of PBM contracts, savings from rebates are not fully passed on to lower the price of prescriptions for patients but instead serve to increase PBM profit margins. The Proposed Rule would ensure that PBMs and plans would prefer a product with the lowest net price rather than the largest rebate, thus generating savings that really benefit patients and improve their ability to access their therapies.

³ CMS. Medicare Part D – Direct and Indirect Remuneration (DIR) <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>

⁴ Ibid.

⁵ Community Oncology Alliance. Pharmacy Benefit Manager Horror Stories- Part V. April 4, 2019. <https://www.communityoncology.org/pharmacy-benefit-manager-horror-stories-part-v>

⁶ Charles Roehrig. The Altarum Institute. The Impact of Prescription Drug Rebates on Health Plans and Consumers. April 2018. https://altarum.org/sites/default/files/uploaded-publication-files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf

⁷ Ibid.

Finally, we are confident that the Proposed Rule would lead to lower drug list prices. Point-of-sale discounts would require a new level of transparency into contractual arrangements among pharmaceutical manufacturers, PBMs, and insurance plans that would change the nature of pricing and negotiation dynamics. We believe this increased transparency into the rebates provided to PBMs and plans would place significant pressure on pharmaceutical manufacturers to lower list prices. Manufacturers would no longer be able to point to rebates as the reason for fueling high drug prices. In fact, during the recent Senate Finance Committee hearing on drug prices titled “Drug Pricing in America: A Prescription for Change, Part II,” executives from seven major pharmaceutical manufacturers stated that they would lower list prices if rebates were removed from the system, both government programs and the commercial market. According to Merck CEO Ken Frazier, *“We have lowered list prices in the past and found that it creates a financial disadvantage for the company, and it doesn't get us more volume because of the incentives in the system. So, if we change all the incentives at one time, then list prices can come down.”*⁸

Additionally, new dynamics at the pharmacy counter resulting from the point-of-sale discounts would place further pressure on manufacturers to lower prices. Because the elimination of gag clauses allows pharmacists to discuss various options for prescriptions and their different prices, manufacturers would need to compete based on discount amounts. Together, these competitive dynamics would place significant downward pressure on manufacturers to lower list prices.

For all of these reasons, we believe the much-needed Proposed Rule would correct misaligned incentives in the existing drug payment and delivery system and positively impact drug prices, patient costs, and patient access to drugs.

Areas of Caution

HHS must consider the relevant implications of all retrospective price concessions to ensure that PBMs are precluded from inappropriately clawing back reimbursement from Community Oncology Pharmacies for prescriptions filled for Medicare beneficiaries.

COA applauds HHS for looking at the impact of rebates and DIR incentives on drug prices and the Part D program. However, we also continue to urge HHS to examine the way plan sponsors and PBMs have exploited pharmacy price concessions at the expense of beneficiaries, pharmacies, oncology practices, and the government. The treatment of these pharmacy price concessions as DIR, rather than as reductions in the “negotiated price” of a drug, has had a similar impact as rebates on keeping cost-sharing high and potentially driving increased catastrophic spending.

DIR “Fees” have become an all-inclusive category increasingly exploited by PBMs to include various concessions, such as fees related to performance-based programs or fees for participation in a preferred network. DIR Fees are being misused to claw back reimbursement on Medicare scripts from retail pharmacies and Community Oncology Pharmacies. CMS has been aware of this problem for quite some time, but it has been reluctant to interfere. However, COA is optimistic that the recently proposed changes in Part D rulemaking and the elimination of rebates together should also catalyze a solution to the challenges with DIR Fees. We continue to urge CMS to redefine “negotiated price” in Part D in a way that is net of pharmacy price concessions to increase transparency and provide clarity on expected reimbursement for dispensed medications. However, we also caution that the elimination of rebates will result in new pressures for PBMs to make up for lost rebate revenue by seeking additional ways to claw back reimbursement from

⁸ United States Senate Committee on Finance. Drug Pricing in America: A Prescription for Change, Part II. February 26, 2019. <https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-ii>

Community Oncology Pharmacies. This is already happening but will worsen as PBM rebate revenue shrinks or disappears completely.

Over the past decade, oral cancer drugs have become more prevalent in treatment, including as part of combinations consisting of intravenous and oral chemotherapy. Because of this, oncologists' ability to dispense medications directly to their patients is critical and allows for close management of a patient's cancer therapy. Community Oncology Pharmacies contribute to better coordinated care, faster treatment time, and greater patient convenience, but they are also exposed to significant financial risks and penalties as a result of inappropriate quality performance measures that are better suited to retail pharmacies. DIR Fees charged under the guise of a PBM "quality improvement program" forced on Community Oncology Pharmacies by PBMs are solely based on primary care quality metrics that are irrelevant to oncology, setting Community Oncology Pharmacies up for failure.

Let us be abundantly, and frankly, clear about the current system with out-of-control manufacturer rebates and DIR Fees charged by PBMs to all types of pharmacy providers. **With both rebates and DIR Fees, PBMs have a vested financial interest in having drug list prices be as high as possible.** The focus on rebates in this regard is clear. However, with DIR Fees increasingly being *based on a percentage of drug list prices*, especially on expensive cancer drugs dispensed by Community Oncology Pharmacies, PBMs also have a vested interest in having drug prices be as high as possible. And these DIR Fees are literally "extorted" from pharmacies – they are backed out of reimbursement provided by PBMs and if pharmacies object they are thrown out of the PBM's network. With the inordinate market control by the largest PBMs, pharmacies have no recourse to pay this form of PBM "vig."

While the Proposed Rule is not the policy vehicle for ensuring upfront, reasonable, and relevant reimbursement for Community Oncology Pharmacies, we urge HHS to keep these dynamics in mind as it makes significant changes to the Part D program and the rebating system. Because the Proposed Rule would remove the safe harbor protection for rebates, it would eliminate a significant portion of the DIR negotiated today. COA believes that this necessitates a new definition of "negotiated price" in such a way that would reflect the lowest possible reimbursement, net of chargebacks and pharmacy concessions. **However, we think CMS should also promulgate rules requiring plan sponsors and PBMs to ensure that the lowest possible reimbursement is reasonable, relevant, and does not result in payment to pharmacies below available acquisition costs, especially for specialty medications.**

The chargeback administration system should include guardrails to avoid burdening not just retail pharmacies, but Community Oncology Pharmacies as well.

In the context of point-of-sale discounts, in which the full value of the price reduction offered by the manufacturer gets reflected in the plan's payment to the pharmacy at the point-of-sale, pharmacies would use a "chargeback" against manufacturers to ensure the total payment for a drug is at least equal to the price agreed upon between the plan and manufacturer. Under the current system, pharmacies collect payment from plans in the form of drug reimbursement and from beneficiaries in the form of copays or coinsurance. In the new system, pharmacies would have a third payment, which includes a chargeback made directly or indirectly by a manufacturer. The chargeback payment would introduce a need for an entirely new system to reconcile the difference between the pharmacy's acquisition cost and the price agreed upon between the plans and drug companies. COA is concerned that such a system would require significant investment in personnel, data, and technology, among other operational considerations. This could be burdensome for Community Oncology Pharmacies, especially small physician in-office dispensers with limited resources. Given the aggressive implementation timeline of January 1, 2020, we urge HHS to consider opportunities to minimize new

operational investments for oncology practices to protect patient access to oral oncolytics. COA stands ready to work with HHS in lending its pharmacy operations expertise to facilitate the efficient implementation of the Proposed Rule.

The new chargeback system would also increase the financial risk to Community Oncology Pharmacies if HHS does not define an appropriate timeframe for processing chargebacks to minimize payment lags. As noted in the above sections, COA fully supports the elimination of rebates, but in a manner that ensures adequate, accurate, and timely reimbursement to Community Oncology Pharmacies. Again, we would be happy to lend our expertise to HHS in further developing guidance and guardrails to ensure protections for any dispensing entity.

The effective elimination of rebates must be expanded to the commercial market to achieve the full intended impact of lower prescription drug list prices.

While COA believes the Proposed Rule is a critical step in correcting serious problems with the current drug pricing and delivery system, we firmly believe the proposed policies must be extended to the commercial market to achieve the promise of reduced list prices. Expansion to the commercial market will realign incentives and restore transparency in the drug supply chain. The OACT predicts eliminating rebates in Medicare will indirectly result in some savings for private health insurance enrollees. Much more significant savings could be achieved by Congressional action to effectively eliminate rebates in the commercial market. An analysis by Milliman found that patients in the commercial market with high deductible health plans would save from \$145 to more than \$800 annually from passing rebates directly to patients at the point-of-sale.⁹ Those savings would be very meaningful to patients with cancer covered under private insurance, which pays for 44% of total U.S. expenditures for cancer.¹⁰

We cannot simply assume that commercial plans will follow Medicare's lead and shift to new business models. *We call on Congress to expand the effective elimination of rebates to the commercial market through legislation, such as Senator Mike Braun's Drug Price Transparency Act.*

Pfizer's CEO Dr. Albert Bourla directly acknowledged the need for the policy's expansion to the commercial market in order to impact his industry's pricing decisions during his testimony at the Senate Finance Committee hearing on drug prices. He stated, *"Importantly, we believe any reform should apply to all market segments as this will also lead to further reduction in list prices. A bifurcated market in which we eliminate rebates in government programs but maintain rebates for commercial plans will make it difficult for manufacturers to reduce list prices because it applies to all markets."*¹¹

COA appreciates the opportunity to comment on this extremely important Proposed Rule. We truly believe it has the potential to address some of the most burdensome access issues facing vulnerable patients with cancer that have resulted from the seriously flawed drug rebating system.

⁹ Milliman. Point of Sale Rebate Analysis in the Commercial Market. February 26, 2019. <https://www.phrma.org/report/point-of-sale-rebate-analysis-in-the-commercial-market>

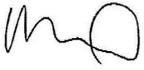
¹⁰ American Cancer Society Cancer Action Network. The Costs of Cancer. April 2017. <https://www.fightcancer.org/sites/default/files/Costs%20of%20Cancer%20-%20Final%20Web.pdf>

¹¹ Testimony of Dr. Albert Bourla, DVM, Ph.D. Chief Executive Officer, Pfizer. February 26, 2019. <https://www.finance.senate.gov/imo/media/doc/26FEB2019BOURLA-PFIZER.pdf>

COA is very willing to work with HHS to ensure that a final rule is operationally feasible and to develop appropriate guardrails for Community Oncology Pharmacies. We also support the expansion of the Proposed Rule to the commercial market through legislation currently under consideration in Congress.

Please do not hesitate to reach out to us with any questions.

Sincerely,



Michael Diaz, MD
President



Ted Okon
Executive Director