COMMUNITY ONCOLOGY ALLIANCE

Dedicated to Advocating for Community Oncology Patients and Practices

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

August 10, 2026

The Honorable Ron Wyden, Ranking Member
Senate Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Submitted via email to drugs@finance.senate.gov

RE: Request for Information (RFI): Commonsense Policy Options to Lower Drug Prices for Patients

Dear Ranking Member Wyden and Senate Finance Committee Minority Staff:

On behalf of the Board of Directors of the Community Oncology Alliance ("COA"), we are submitting this comment letter regarding the Request for Information: *Commonsense Policy Options to Lower Drug Prices for Patients* ("RFI").

COA is an organization 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 largest nonprofit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. Since its grassroots founding close to 25 years ago, COA's mission has been to ensure that patients with cancer receive quality, affordable, and accessible care in their own communities where they live and work. COA is committed to providing solutions to the challenges that community oncology patients and physicians face throughout the care journey. We seek to ensure that cancer care is delivered with the utmost quality and in an accessible and affordable manner.

Our COA *Prescription for Health Care Reform 2.0,* ("Prescription 2.0")[1] which we recently released and distributed to every member of Congress and staff, is a comprehensive five-part plan outlining targeted solutions to stabilize the health care system, prioritize patients, and protect access to high-quality, affordable care. Grounded in more than two decades of advocacy on behalf of independent community oncology practices, the plan reflects the collective expertise of oncologists, pharmacists, practice administrators, and other health care professionals working on the front lines of cancer care. Drawing on real-world experience and policy analysis, the *Prescription 2.0* identifies practical reforms designed to restore competition, reduce administrative burden, and strengthen patient access to community-based treatment.

COA's Philosophical Approach to the Senate Finance Committee Drug-Pricing RFI

Make no mistake about it—COA strongly supports lowering drug costs for people with cancer and for all Americans. We want to be clear at the outset about how much of this RFI issued by the Senate Finance Committee Minority Staff we support. The Committee's examination of vertical integration, pharmacy benefit manager ("PBM") private-label markups, exclusive-negotiator and non-solicitation clauses, inappropriate pharmacy

[1] Community Oncology Alliance. "COA Prescription for Health Care Reform 2.0." Available Here.

rejections, and inadequate dispensing fees identifies real distortions that harm patients with cancer every day. COA has documented these practices for years.[2,3] On these questions, we are aligned with the Committee, and our comments offer specific recommendations to strengthen the policies under consideration.

At the same time, COA urges the Committee to apply a broader framework to drug-pricing reform. Throughout our comments, "lower drug costs" means lowering the amount borne by patients and taxpayers and reducing total health care spending—not simply lowering one manufacturer price or statutory payment benchmark while leaving intermediary profits, institutional spreads, and higher site-of-care costs untouched. Price does not always equal cost. You can lower the underlying price of a drug and not reduce the cost to the patient.

Every proposal considered by the Committee should be measured against five basic questions:

- Does it lower what patients actually pay for their medications?
- Does it reduce total health care spending rather than merely shift costs among stakeholders?
- Does it preserve access to independent, physician-led community care and avoid unnecessarily shifting treatment into higher-cost hospital settings?
- Does it eliminate compensation derived from market power and arbitrage without undermining payment for legitimate clinical services, operating costs, and financial risk?
- Does it preserve incentives for meaningful innovation, including areas of unmet needs (e.g., pancreatic cancer[4]), new cellular therapies, and biosimilars?

Drug-pricing reform must confront the entire system that stands between a manufacturer's price and a patient's bill.

What follows are our overarching comments, followed by specific responses to the RFI.

Compensation for Leverage is Not the Same as Compensation for Function and Risk

That broader perspective requires a distinction that the RFI does not yet adequately draw. At page 30, the Committee groups physicians with PBMs and wholesalers under a single heading—"price-linked compensation"—and asks how to delink each form of payment from drug prices. That grouping assumes a resemblance that does not reflect the real world.

Both a PBM rebate and the Medicare Part B drug reimbursement add-on are calculated, at least in part, as a percentage. That is where the similarity ends.

A PBM rebate is commonly related to a drug's list price and can grow as the gap between list and net price widens. The PBM may therefore be compensated by the distortion itself and, through formulary placement, can influence which products receive favorable coverage. As the RFI documents, these arrangements can cause PBMs to prefer high-list-price, high-rebate products over lower-priced alternatives.

The Part B drug add-on, by contrast, is calculated from Average Sales Price ("ASP"), a benchmark that is already net of manufacturer discounts and rebates included in the ASP calculation. It is paid to the entity that acquires the drug, finances it, stores it, prepares it, administers it, and bears the associated operational and financial risks.

[2] Community Oncology Alliance. "PBM Horror Stories." Available Here.
[3] Community Oncology Alliance. "Comment Letters." Available Here.
[4] Cereda V and D'Andrea M. "Pancreatic cancer: failures and hopes—a review of new promising treatment approaches." *Exploration Target Anti-tumor Therapy.* 18 March 2025. Available Here.

The relevant test should not be whether compensation is expressed as a percentage. The question should be whether the payment reflects a legitimate function and genuine risk—or whether it reflects market leverage, steering power, or arbitrage.

Applied honestly, that test condemns PBM rebates paid for formulary placement. It condemns private-label markups, affiliate spreads among vertically integrated entities, and compensation shifted among vertically integrated entities to evade regulatory limits. It also requires close scrutiny of the spread generated by 340B drug discounts when those savings are not provided to patients. But it supports adequate payment to the independent practice, especially an independent community oncology practice, that buys the drug, which in most cases is very expensive, carries it, prepares it, administers it, and remains financially responsible for it.

The Part B Add-on Reflects Real Clinical and Financial Exposure

The percentage component of Part B reimbursement is not arbitrary. Many of a practice's most consequential financial exposures—including financing, inventory loss, wastage, bad debt, and acquisition above reimbursement—scale with the price of the drug. Other substantial clinical and operational expenses exist regardless of price.

An independent community oncology practice purchases the drug and may finance it for a month or longer before receiving reimbursement. It stores the product under applicable USP <797> and <800> standards, prepares it under pharmacy supervision, administers it under clinical monitoring, and remains financially exposed when a dose is wasted, a vial is broken, a claim is denied, a patient's coverage changes, or beneficiary cost-sharing is not collected.

Floating a $20,000 dose for sixty days presents a fundamentally different financial exposure from carrying a $200 product. The same is true when a high-cost dose is lost, wasted, or reimbursed below acquisition cost. A purely flat payment would sever reimbursement from a significant part of that financial exposure while leaving the exposure with the practice.

The practice's economics compound the problem. Sequestration reduces the effective statutory six-percent add-on to 4.3 percent. It is simply not realistic to talk about Part B reimbursement as ASP plus six percent because it is not. Additionally, ASP is calculated retrospectively, which means reimbursement may lag behind current acquisition costs when prices are increasing. Because ASP is a volume-weighted average across purchasers, independent practices without the purchasing scale, discounts, or group-purchasing advantages available to large hospital systems may acquire drugs above the published ASP. And we want to underscore that even at its current effective level of 4.3 percent after sequestration, ***the add-on does not fully compensate practices for the clinical, operational, inventory, financing, wastage, bad-debt, and reimbursement risks associated with furnishing modern cancer therapies.***

These are not theoretical concerns. They are real risks borne by the practice that takes title to the product and remains responsible for delivering treatment.

If the Committee intends to target compensation untethered from value, it should focus on spreads generated through discounts, affiliate transactions among vertically integrated entities, steering, and market leverage.

The Part B add-on is fundamentally different. It helps compensate the practice that acquires the drug, finances it, prepares it, administers it, and bears the associated clinical, operational, and financial risks.

COA therefore opposes replacing ASP plus six percent with a flat or capped payment unless Congress first establishes an independently validated replacement that guarantees acquisition-cost coverage and fully compensates practices for the clinical, operational, inventory, financing, and reimbursement risks of furnishing physician-administered therapies.

This does not mean COA is rigidly tethered to the existing payment system. COA has explored tiered ASP methodologies and is now working on bundled approaches to cancer care. But any alternative must begin with the economic realities of delivering treatment—**not with the unsupported assumption that the physician add-on is equivalent to a PBM rebate.**

PBMs do not bear the acquisition, inventory, wastage, or patient-specific reimbursement risk borne by an oncology practice. They receive rebates and fees associated with drugs purchased or dispensed by others. That is fundamentally different from a medical practice that purchases the drug, finances it, stores and prepares it, delivers the treatment, and remains financially liable when reimbursement fails.

Discounts Must Benefit the Patients Who Generate Them

Discounts do not automatically become patient savings. This is a central failure of the current system, and it is not confined just to PBMs.

When a rebate, discount, or markup is captured by an intermediary or institution while the patient's cost-sharing is calculated from a substantially higher price or payment benchmark, the patient may effectively be charged based on savings someone else received.

The Committee identifies this problem in Part D and asks how cost-sharing during the deductible and coinsurance phases could be based on net price. COA supports that objective. Its logic should be applied consistently across federal drug programs: when a discount is generated by a patient's prescription or treatment, that patient should receive a direct and measurable benefit.

For Part D drugs, beneficiary cost-sharing should reflect actual net cost rather than an inflated list-price benchmark. For Part B drugs, Congress must consider not only the drug-payment benchmark but also whether a policy shifts treatment into a hospital outpatient department, where the total allowed amount and beneficiary liability is substantially higher.

A Drug-Pricing Framework Cannot Ignore 340B

The clearest example of discounts failing to reach patients is the 340B Drug Pricing Program ("340B").

According to Health Resources & Services Administration data, covered entities purchased more than $100 billion in drugs at 340B prices in 2025, including approximately $79 billion purchased by disproportionate share hospitals ("DSH").[5] Based on available estimates, the market value of those drugs is upwards of $200 billion.[6] Oncology drugs administered in hospital outpatient departments are one of the fastest-growing purchase segments in 340B.[7]

These amounts document the extraordinary scale of 340B and the enormous difference between 340B acquisition prices and the reimbursement benchmarks used elsewhere in the health care system.

For comparison, the RFI cites approximately $77 billion in Part D manufacturer rebates in 2024. Congress cannot credibly examine rebates of that magnitude while excluding another discount system that involves an even greater gross difference between acquisition price and market value.

Unlike Part D rebates, 340B discounts generally carry no comprehensive federal requirement that a defined portion directly reduces the cost borne by the patient whose prescription or treatment generated the discount. Numerous studies have found that patients frequently do not receive those discounts and, in some cases, are charged amounts many times greater than the hospital's acquisition cost.

[5] Health Resources & Services Administration. "2025 340B Covered Entity Purchases." Available Here.
[6] Martin R, Karne H, Zeng Shanyue. "The Size and Growth of the 340B Program in 2025." IQVIA. 4 June 2026. Available Here.
[7] Health Resources & Services Administration. "2025 340B Covered Entity Purchases." Available Here.

COA does not raise this concern principally with respect to federally qualified health centers, grantees, or genuine safety-net providers whose 340B savings support essential services in underserved communities. Our principal concern is the expansion of 340B through large DSH systems and their child sites and contract-pharmacy arrangements into affluent and well-insured markets, where discounts may be generated by insured patients, retained as institutional revenue, but never reflected in what those patients pay.

That is no longer simply safety-net financing. It is a form of arbitrage that can also facilitate hospital acquisitions of independent physician practices and accelerate the movement of care into higher-cost settings.

Even where elements of 340B administration fall outside the Senate Finance Committee's principal jurisdiction, the Committee has direct authority over Medicare and Medicaid policies that determine how 340B discounts affect beneficiary cost-sharing, duplicate discounts, site of care, and federal spending.

The Committee's relevant policy levers include:

- Medicare reimbursement for 340B-acquired products;
- The benchmarks used to calculate beneficiary cost-sharing;
- Medicaid duplicate-discount protections;
- Site-of-service payment differentials; and
- Policies that affect hospital consolidation and physician-practice viability.

A comprehensive drug-cost strategy cannot ignore these effects!

Prior Federal Policy has Already Shifted Care into the More Expensive Hospital Setting

Congress must also consider the cumulative and unintended consequences of prior policy choices that have increased health care costs.

For years, inadequate physician reimbursement, hospital-favorable site-of-service differentials, 340B drug acquisition advantages, and broader payment policies that reward hospital ownership have contributed to the migration of cancer care and other medical services out of independent practices and into hospital outpatient departments, where patients' costs are much higher.

That migration is not incidental to the drug-cost problem. It is one of its principal drivers!

For example, when a policy causes an infusion of chemotherapy to move from a community oncology practice to a hospital outpatient department, Medicare and the beneficiary pay substantially more for the same drug administration and clinical care, even though the price has not changed. A reform that lowers one payment benchmark but accelerates that migration may increase, rather than reduce, total spending and beneficiary liability.

As a result, every major drug-payment proposal should be evaluated for its likely effect on:

- Independent practice viability;
- Hospital acquisition and consolidation;
- Site-of-care migration;
- Beneficiary cost-sharing;
- Rural and underserved access;
- Treatment delays; and
- Total Medicare spending.

The United States has a Uniquely Layered Drug-Pricing System

U.S. launch prices are formed within a uniquely distorted and regulated market. Pharmaceutical manufacturers anticipate PBM rebate demands, Medicaid rebates, 340B discounts, wholesaler and Group Purchasing Organizations ("GPOs") fees, and other statutory or negotiated concessions that do not exist in the same combination or at the same scale in any other country. These dynamics are not the sole cause of high United States's launch drug prices, but they most certainly fuel them. Market exclusivity, clinical value, competition, anticipated demand, shareholder expectations, and willingness to pay also influence launch pricing.

We are not defending the pharmaceutical industry. We are acknowledging the reality of the factors that influence drug launch prices in the United States.

Congress cannot ignore the role that overlapping rebate and discount systems play in widening the gap between gross and net prices.

The United States has created a system in which:

- PBMs demand rebates and fees tied to formulary access;
- Vertically integrated entities can retain revenue at several points in the supply chain;
- Medicaid imposes statutory rebates;
- 340B DSH hospitals acquire drugs at deeply discounted prices;
- Wholesalers and GPOs receive additional fees and compensation; and
- Patients may still owe cost-sharing calculated from gross prices or reimbursement benchmarks that bear little relationship to the net amount retained by the manufacturer or the acquisition cost of the dispensing or administering entity.

No other country layers this degree of intermediary extraction, statutory discounting, and institutional arbitrage onto the price of prescription drugs.

International Reference Pricing Cannot Substitute for Domestic Reform

The RFI's international price comparisons therefore measure only part of the problem.

International reference pricing may reduce manufacturer revenue and Medicare spending. However, it does not, by itself, eliminate PBM rebates, affiliate spreads among vertically integrated entities, private-label markups, 340B arbitrage, or hospital site-of-care differentials.

The RFI also acknowledges that foreign reference-price data may not reflect true net prices because other countries increasingly use confidential rebates. Comparing gross prices in the United States with foreign prices that may themselves exclude confidential discounts can therefore produce an incomplete or misleading result.

For Part B drugs, the operational consequences are especially important. ASP is already a net benchmark. If an international reference-price provision lowers the Part B reimbursement benchmark without guaranteeing that independent community practices can acquire the drug at or below that amount, it could increase the number of products that practices must purchase above Medicare reimbursement.

The PBM rebate layer, private-label markup, 340B acquisition spread, and hospital site-of-care advantage may remain untouched. Meanwhile, the add-on payment falls because it is calculated from the reduced benchmark.

COA is not arguing that Americans should continue paying the highest drug prices in the world. We are arguing that international reference pricing cannot substitute for reforming the domestic supply chain and must include explicit protections for provider acquisition, patient access, and community-practice viability.

Innovation Must Remain Part of the Analysis

Lower costs and continued innovation are not mutually exclusive goals.

COA supports preserving strong incentives for clinically meaningful innovation, especially in pediatric cancers, rare cancers, and areas of unmet clinical need. At the same time, exclusivity and orphan-drug protections should not be manipulated to block competition or permanently shield mature, high-revenue products from appropriate scrutiny.

The relevant policy question is not whether all innovation incentives should be preserved unchanged. It is whether a proposal appropriately distinguishes genuine development risk and unmet need from strategies designed primarily to extend market protection or avoid negotiation.

COA's Recommended Framework

COA urges the Committee to pair the reforms in this RFI with measures that:

- Require drug discounts, including 340B discounts, to produce direct and measurable benefits for eligible patients;
- Base beneficiary cost-sharing on prices that reflect actual net cost;
- Eliminate PBM steering, private-label markups, affiliate spreads among vertically integrated entities, and compensation generated through market leverage rather than legitimate services;
- Address 340B-driven and other institutional arbitrage;
- Equalize Medicare payment for the same service across sites of care where clinically appropriate;
- Guarantee that independent practices can acquire physician-administered drugs at or below Medicare reimbursement;
- Preserve adequate reimbursement for the clinical, operational, inventory, and financial risks of furnishing cancer treatment;
- Evaluate every policy for its impact on consolidation, community access, rural patients, and site-of-care migration; and
- Preserve incentives for meaningful innovation while preventing abuse of statutory protections.

The appropriate measure of reform is not simply whether a statutory benchmark falls. It is whether patients pay less, taxpayers spend less, competition is strengthened, innovation is preserved, and patients can continue receiving high-quality treatment close to home.

We implore the Committee to recognize that a policy that lowers one price while increasing total health care costs, accelerating hospital consolidation, or making community-based cancer treatment economically impossible is not meaningful drug-cost reform.

If the Committee seeks a realistic and lasting reduction in what Americans pay for medicines, it must take a genuinely holistic approach—one that confronts every source of cost, distortion, and unintended consequence across the drug supply chain and sites of care.

COA's specific recommendations and answers to questions posed in the RFI are summarized below.

Policies that COA Supports

I. Delivering Lower Negotiated Drug Prices to Patients Faster (Section I.I – Lowering Drug Prices, pages 9-11)

While COA does not support expanding the Medicare Drug Price Negotiation Program, we do support efforts to boost the biosimilar market. The increased adoption and appropriate utilization of biosimilars is a key mechanism to reduce drug costs, enhance access to life-saving treatments, and alleviate the financial toxicity experienced by patients undergoing cancer care. COA fully supports and advocates for policies that advance biosimilar development and uptake while maintaining rigorous clinical standards and remains committed to collaborative engagement with public and private stakeholders to promote biosimilar acceptance and market sustainability.[8]

We suggest Congress consider incentives to boost biosimilar adoption independently of the negotiation program and that adoption efforts expand beyond biosimilar development. Although biosimilar adoption has grown rapidly in the oncology space, with oncology achieving the fastest adoption rates,[9] biosimilar uptake still faces challenges. Payer policies, including anti-competitive rebate structures favoring reference products and formulary restrictions, and reimbursement instability, remain significant barriers to broader biosimilar adoption.[10,11] We expand on these considerations to inform biosimilar adoption policy below:

- **Payer Policies:** COA supports prohibiting insurers and PBMs from restricting biosimilar access via unfavorable formulary placement or utilization management policies. Currently, PBMs may favor more expensive originator biologics compared to lower-cost biosimilars due to rebates, and biosimilars preferred by PBMs vary across payers. Inconsistent payer policies force clinics to stock multiple versions of the same therapeutic class, inflating inventory costs and administrative complexity. COA strongly believes that biosimilar selection should fall to the treating clinic, not the payer, which would promote efficiency, reduce waste, and control costs.

- **Reimbursement:** Rapid declines in ASP across biosimilar categories must also be addressed to reduce market destabilization. Otherwise, manufacturers may choose to exit the biosimilar market due to destabilized ASPs or choose not to develop biosimilars altogether. Providers also face challenges in dispensing biosimilars; in some instances, reimbursement is less than the acquisition cost, leading them to dispense these products at a loss. The payer policies noted above compound this issue further, as the drug a patient receives is determined by PBM-defined formularies rather than by provider and patient decision-making. An ASP floor for biosimilars that would provide a guaranteed minimum reimbursement for providers, combined with the removal of non-provider discounts from the ASP calculation, is one solution that may address reimbursement challenges.[12]

  Community oncology practices often prefer biosimilars because their lower acquisition costs can reduce inventory and working-capital exposure. However, rapid ASP erosion, inconsistent payer preferences, and inventory purchased before a reimbursement decline can leave practices underwater and discourage substitution even when use of the biosimilar is clinically appropriate.

Operationally, COA also supports the prompt issuance of temporary biosimilar Healthcare Common Procedure Coding System ("HCPCS") codes and permanent J-codes by the Centers for Medicare & Medicaid Services ("CMS") in order to facilitate streamlined billing and coding of new products. Plans should be required to cover new biosimilars promptly upon launch, PBMs should be prohibited from using rebate bundling, affiliated private labels, or formulary exclusions to favor a higher-cost product, and Congress should also consider a temporary and narrowly tailored reimbursement floor or transition protection that protects reimbursement from falling below reasonable acquisition cost because of ASP lag, without establishing a permanent price floor that impedes manufacturer competition. In all cases, the

[8] Community Oncology Alliance. "COA Position Statement on Biosimilars." 7 November 2025. Available Here.
[9] Cardinal Health. 2026 Biosimilars Report. Available Here.
[10] Community Oncology Alliance. "COA Position Statement on Biosimilars." 7 November 2025. Available Here.
[11] IQVIA Institute. "Modeling Policy Proposals for Medical Benefit Biosimilar Reimbursement in the U.S." February 2026. Available Here.
[12] Ibid.

physician's clinical judgment must remain paramount, and patients should not be subjected to inappropriate medical switching.

Recommendations

- Support clinically backed, collaborative provider and patient educational efforts to promote confidence in biosimilar use.
- Prohibit insurers and PBMs from restricting biosimilar access via unfavorable formulary placement or utilization management policies.
- Allow provider- and patient-driven decision-making surrounding biosimilar use, rather than payer-driven decision-making.
- Address ASP destabilization, where reimbursement for biosimilars falls below ASP. An ASP floor for biosimilars that would provide a guaranteed minimum reimbursement for providers, combined with the removal of non-provider discounts from the ASP calculation, is one potential solution.[13]
- Require CMS to promptly issue biosimilar HCPCS codes in order to facilitate streamlined billing and coding of new products.
- Assign permanent biosimilar J-codes on an accelerated schedule and require prompt plan coverage of new biosimilars upon launch.
- Prohibit PBMs from rebate bundling, private labeling products with vertically integrated entities, and formulary exclusions designed to favor a higher cost reference product over a biosimilar.
- Protect physician clinical judgment and prohibit inappropriate medical switching of stable patients between clinically similar products.

II. Enhancing Manufacturer Accountability for Price Gouging (Section I.II – Lowering Drug Prices, pages 13-14)

COA supports applying Part B inflation-rebate liability consistently to Medicare Advantage ("MA") units so that manufacturers do not avoid rebate obligations solely because a beneficiary receives treatment through MA rather than fee-for-service Medicare. Implementation must use reliable encounter data, prevent duplicate liability, establish clear rules for discarded units and replacement products, and place all reporting and reconciliation duties on manufacturers and plans. Community oncology practices should be protected from clawbacks, recoupments, payment reductions, or other financial liability resulting from incomplete MA encounter data, plan reporting failures, or manufacturer rebate calculations.

Recommendations

- Apply Part B inflation-rebate liability consistently across MA and fee-for-service Medicare, with all reporting and reconciliation duties on manufacturing and plans.
- Protect community oncology practices from repayment demands or reimbursement reductions caused by incomplete plan data or manufacturer calculations.

III. Out-of-Pocket Caps (Section II.I – Lowering Patient Out-of-Pocket Costs, page 19)

COA supports applying out-of-pocket caps to more chronic care drugs in Medicare beyond insulin. Priority categories should include oral cancer drugs and supportive care medications, and an aggregate monthly cap covering all qualifying chronic-care medicines would better protect patients than separate caps. COA also strongly supports establishing an annual out-of-pocket maximum in fee-for-service Medicare, including Part B drug coinsurance. To further strengthen patient protection against high out-of-pocket costs, we recommend banning copay accumulator or maximizer programs and alternative funding programs that prevent patient assistance from counting toward out-of-pocket costs. While direct manufacturer copay

[13] Ibid.

assistance is not permitted in Medicare Part D, we believe it is important for the Senate to consider options to lower drug prices that expand beyond Medicare.

Recommendations

- Ban copay accumulator or maximizer programs and alternative funding programs that prevent patient assistance from counting toward out-of-pocket costs.
- Extend out-of-pocket caps and establish a fee-for-service Medicare annual out-of-pocket maximum that protects against Part B coinsurance.

IV. Generic Drug Price Markups (Section II.I – Lowering Patient Out-of-Pocket Costs, pages 22-23)

COA supports efforts to address market distortions for generic drugs. COA supports National Average Drug Acquisition Cost ("NADAC")-based cost-plus reimbursement for commoditized Part D generics when paired with mandatory NADAC reporting, audit authority, appeal processes, and protections for medically integrated oncology dispensing. Additionally, although the RFI focuses on Part D drugs, we believe that addressing dynamics in the generic sterile injectable ("GSI") market is vital.

Recommendations

- Exempt low-cost GSI drugs from 340B discounts and Medicaid inflation rebates.
- Align reimbursement for GSIs, such as by changing reimbursement from ASP to Average Wholesale Price ("AWP").
- Use NADAC-based cost-plus reimbursement for commoditized Part D generics, paired with mandatory NADAC reporting.
- Create market incentives for manufacturers with three or fewer active manufacturers.

V. Games and Abuses Due to Vertical Integration (Section II.II – Addressing Perverse Dynamics in the Supply Chain, pages 24-25)

COA appreciates that Congress is considering ways to address gaming and abuses due to vertical integration by seeking feedback on whether Congress should require CMS to develop a new standard for how margin is considered for vertically integrated sponsors in the Part D bidding process to prevent program abuses and put downward pressure on drug costs. COA supports requiring CMS to evaluate the full enterprise margin of vertically integrated Part D sponsors—including PBM revenue, specialty/mail pharmacy spread, private-label profits, GPO fees, wholesaler compensation, and affiliate transfers—and to have full audit authority to reject bids that shift profits to vertically integrated affiliates.

PBMs are adept at finding ways to profit, and while the Consolidated Appropriations Act, 2026 ("CAA") takes meaningful steps in reining in abusive PBM practices, COA knows there is more to be done, particularly as the CAA provisions do not take effect until 2028 and 2029. As the HHS Office of Inspector General recently found, enrollees in plans offered by vertically integrated Part D sponsors paid lower monthly premiums but substantially higher out-of-pocket drug costs. If implemented, we encourage a data-driven approach. Some of the data that PBMs will be required to report to CMS under the CAA may be useful in developing a potential standard.

Recommendations

- Require CMS to evaluate the full enterprise-wide margin for vertically integrated Part D sponsors and grant audit/rejection authority for bids that distort costs.
- Utilize a data-driven approach leveraging CAA reporting to prevent profit shifting among vertically integrated entities.

VI. PBM Private Label Drugs (Section II.II – Addressing Perverse Dynamics in the Supply Chain, pages 26-27)

COA supports the proposals to require PBMs to disclose the spread between their private labeler's acquisition cost on private label drugs and the price PBMs charge their Part D and other clients for the same drugs. COA supports mandatory transparency, auditable cost-plus requirements, the prohibition of preferential formulary placement for private-label drugs over lower-net-cost alternatives, and the barring of Medicare use of non-transparent private-label drugs.

Recommendations

- Require PBMs to disclose the spread between their private labeler's acquisition cost on private label drugs and the price PBMs charge their Part D and other clients for the same drugs.
- Prohibit preferential formulary treatment for PBM private-label products and enforce auditable cost-plus standards in Medicare.

VII. Increasing PBM Accountability for Rising Drug Costs (Section II.II – Addressing Perverse Dynamics in the Supply Chain, page 28)

COA supports replacing rebate guarantees with comprehensive net-effective-cost accountability that includes all rebates, admin fees, spread pricing, GPO revenue, affiliate pharmacy profits from vertically integrated entities, private-label margins, and related-party transfers. Cost targets must be paired with access and quality metrics (rejection rates, time to therapy, treatment abandonment, steering) to prevent PBMs from meeting financial targets by denying clinically appropriate care. Furthermore, COA supports prohibiting exclusive-negotiator and non-solicitation clauses that prevent plans, manufacturers, and practices from exploring direct arrangements that lower costs.

Recommendations

- Replace PBM rebate guarantees with net-effective-cost accountability paired with strict access and quality metrics.
- Ban exclusive-negotiator and non-solicitation clauses to enable direct contracting models that lower drug costs.

VIII. Pharmacy Dispensing Fees in Part D (Section II.II – Addressing Perverse Dynamics in the Supply Chain, pages 28-29)

Addressing below-cost underwater reimbursement is vital to protect patient access to independent community oncology. A recent study confirmed that community oncology practices deliver high-quality cancer care, finding longer survival rates for certain metastatic cancers than those observed in industry benchmarks.[14] Patients receiving treatment at a community oncology practice with medically integrated dispensing may also be able to access their treatments more quickly and easily, and receive coordinated care between their oncologist and the practice's own pharmacists. Underwater reimbursement threatens this care by eroding the coordinated relationship between prescribing clinicians and integrated pharmacies.

As such, COA appreciates Congress's consideration of changes to pharmacy dispensing fees in Medicare Part D to improve predictability and expand pharmacy access. As Congress considers changes, we urge Congress not to take a one-size-fits-all approach. We support adequate dispensing fees based on documented costs and the type of pharmacy service being provided, rather than one national amount designed around traditional retail dispensing. CMS should distinguish among retail, specialty, and mail-order pharmacies, and medically integrated dispensing practices.

[14] Flatiron Health. "COA Quality of Care Study: Phase 1 Report on Overall Survival." April 2026. Available Here.

Community oncology practices with medically integrated dispensing incur high costs, including for clinical review, coordination with the treating oncologist, dose changes, treatment holds, toxicity and adherence monitoring, patient education, financial navigation, Risk Evaluation and Mitigation Strategies compliance, and avoided waste. These costs will differ from those that other types of pharmacies incur, such as retail pharmacies. Dispensing fees must account for these costs with a reasonable margin component. Otherwise, there is no financial incentive for independent pharmacies to enter or remain in the market, ultimately undermining patient access as closures of independent pharmacies have increased.[15]

Medically integrated dispensing has numerous benefits for patients, providers, and payers, including increased pharmacy oversight, increased savings from interventions that prevent unnecessary prescriptions from being filled and sent (referred to as cost avoidance), reduced waste for patients and payers, better patient compliance and satisfaction, and clinical benefit for patients.[16] Adequate reimbursement with a reasonable margin is essential for patients, providers, and payers to continue to access these benefits.

Recommendations

- Ensure that dispensing fees account for variations in site-specific costs. The costs incurred by a community oncology practice with medically integrated dispensing will differ from those of other pharmacies, such as retail and mail-order pharmacies.
- Differentiate dispensing fees by care setting and ensure reimbursement includes a reasonable operating margin to compensate for specialized clinical services, care coordination, financial navigation, and waste avoidance.

IX. Inappropriate Pharmacy Rejections (Section II.II – Addressing Perverse Dynamics in the Supply Chain, pages 31-32)

For patients with cancer, timely treatment initiation is particularly important, and pharmacy rejections delay their access to care. As such, COA supports policies that address inappropriate pharmacy rejections, including the Senate Finance Committee's considered policies of developing a Medicare Part D Star Rating metric related to inappropriate pharmacy rejections and increasing transparency regarding pharmacy rejection rates through Plan Finder. To further support timely patient access to clinically appropriate drugs, COA supports addressing the full range of PBM tactics that may lead to pharmacy rejections and limit patient access to medications.

Recommendations

- Address the burden of prior authorization and utilization management on patients and providers.[17,18] COA has championed the Improving *Seniors' Timely Access to Care Act* (S. 1816/H.R. 3514), which would streamline the prior authorization process in MA. COA has also supported the 2026 CMS *Interoperability Standards and Prior Authorization for Drugs Proposed Rule* (CMS-0062-P), which would improve the prior authorization process across plans, including MA plans, but the rule has not yet been finalized.[19]
- Limit the use of step therapy protocols and safeguard physician-patient decision-making, including banning "fail-first" step therapy and non-medical switching in cancer care, and ensuring a clear

[15] Qato D. "Nearly 1 in 3 Retail Pharmacies Have Closed Since 2010, Widening Health Disparities." *USC Leonard D. Schaeffer Institute for Public Policy & Government Service.* 3 December 2024. Available Here.
[16] Darling J, Starkey A, Nubla J, Reff M. "Financial Impact of Medically Integrated Pharmacy Interventions on Oral Oncolytic Prescriptions." *JCO Oncol Practice.* 13 May 2022. Available Here.
[17] American Medical Association. "2025 AMA prior authorization physician survey." 2026. Available Here.
[18] Community Oncology Alliance. "National Survey Shows Insurer Utilization Management Interferes with Cancer Treatment Decisions. 10 February 2026. Available Here.
[19] Centers for Medicare & Medicaid Services. "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges." 14 April 2026. Available Here.

exception process for patients and providers forced into step therapy. This could involve "gold carding," a mechanism exempting oncologists from burdensome prior authorization requirements once they meet a threshold approval rate.[20]

- Require detailed public reporting on rejections, denials, processing times, appeal overturn rates, and the use of AI, as providers and patients are often not aware of when insurers use AI.[21]

X. Other Part D Reforms

- **Improvements to Medicare Low-Income Assistance Programs (Section II.I – Lowering Patient Out-of-Pocket Costs, pages 19-20):** COA supports expanding eligibility for Part D low-income subsidies ("LIS") to 200 percent of the federal poverty level, eliminating or modernizing the asset test, aligning LIS with Medicare Savings Programs, and streamlining enrollment through automatic enrollment and multi-year eligibility.
- **Basing Part D Cost-Sharing on Net Price (Section II.I – Lowering Patient Out-of-Pocket Costs, pages 20-22):** COA strongly supports basing beneficiary deductible and coinsurance liability on prices that reflect the actual net cost of the drug rather than gross list price, passing through estimated rebates at point-of-sale, and prohibiting PBMs from penalizing list-price reductions.
- **Part D Market Impact (Section II.I – Lowering Patient Out-of-Pocket Costs, pages 23-24):** COA supports efforts to stabilize Part D market premiums, particularly in the standalone Prescription Drug Plan ("PDP") market. However, as Congress considers potential changes, we urge a careful assessment of the unintended consequences. For example, while findings suggest the Inflation Reduction Act ("IRA") has improved patient access to high-cost medications for Medicare patients,[22] it has also contributed to instability in the standalone PDP market and higher plan bids,[23] a situation that Congress is now looking to remedy, narrower formularies, including for protected class drugs,[24] and more utilization management due to increasing plan liability.[25]

XI. Supporting Biopharmaceutical Innovation and Clinical Research (Section III)

COA supports sustained increases in National Institutes of Health and National Cancer Institute funding for high-unmet-need areas (e.g., pancreatic, pediatric, and rare cancers, metastatic disease, cell/gene therapies). Congress should make expanding clinical trials into community oncology practices a national priority by providing infrastructure grants, adequate payment for screening/data collection, standardized contracts, central IRB reliance, and clear safe harbors for sponsor-provided patient travel, lodging, and logistics support.

XII. 340B Program Reform

The RFI does not address the 340B Drug Pricing Program, which is ripe for reform that would lower drug costs for patients. In our *Prescription 2.0,* we provide many policy recommendations to reform 340B to ensure that drug discounts benefit patients as Congress originally intended. We also recently released an updated position calling for patient-centered program reform.[26]

---

[20] Community Oncology Alliance. "Understanding Gold Cards: Making Prior Authorization Easier." 16 September 2024. Available Here.
[21] National Association of Insurance Commissioners. "Health Insurance Artificial Intelligence/Machine Learning Survey Results." 2025. Available Here.
[22] Cai C, Anderson K, Kesselheim A. "Changes in Medication Use After Medicare Part D Annual Out-of-Pocket Spending Caps. *JAMA Health Forum.* 18 June 2026. Available Here.
[23] Medicare Payment Advisory Commission. March 2026 Report to the Congress: Medicare Payment Policy. March 2026. Available Here.
[24] Anderson D, McEnany M, Petry S, Anderson K. "Inflation Reduction Act Changes To Part D Plan Design: Lower Premiums, Higher Deductibles, And Some Smaller Formularies." *Health Affairs.* 6 April 2026. Available Here.
[25] Fein A. "IRA Fallout: What 2025 Medicare Shifts Mean for Patient Access and Market Strategy. *Drug Channels Institute.* 25 April 2025. Available Here.
[26] Community Oncology Alliance. "COA 340B Drug Pricing Program Position Statement." 9 July 2026. Available Here.

COA supports the original purpose of 340B—improving access to affordable medications and ensuring care for uninsured, underinsured, indigent, and medically vulnerable patients. Unfortunately, the current 340B framework functions as an institutional financing mechanism, especially for large hospital systems, purchasing drugs at deep discounts and being reimbursed by Medicare and commercial payers at inflated prices. The program is plagued by insufficient transparency, little accountability, and growing evidence of unintended consequences across the health care system. These unintended consequences include higher costs for patients—***the exact problem the Senate Finance Committee is seeking to address***—as well as provider consolidation, site-of-care distortions, higher costs for employers and taxpayers, and reduced patient access to lower-cost community-based care settings. Most notably, patients in need are not universally receiving the drug discounts.

COA believes that 340B requires significant reform to realign it with its patient-centered purpose. Reform should include a clear and enforceable definition of the 340B patient, greater program transparency and accountability, strict limits on contract pharmacy arrangements, elimination of profit opportunities for for-profit intermediaries, such as PBMs, and an end to 340B drug arbitrage that allows entities to buy low and sell high without directly benefiting patients.

Fundamentally, COA believes 340B discounts should follow patients in need, not institutions. The program should ensure that vulnerable patients receive affordable medicines and that 340B savings are directly tied to measurable patient benefit.

Recommendations

At a minimum, COA supports the following elements of 340B reform:

- Clear and enforceable definitions of eligible patients, charity care, community benefit, direct patient support services, and contract pharmacy eligibility and oversight. Definitions would support accountability and make it easier to determine whether 340B savings are reaching vulnerable populations.
- Requiring covered entities to publicly report acquisition costs, reimbursement levels, contract pharmacy arrangements, administrative and third-party fees, use of 340B-derived revenue, and patient assistance and charity care metrics. Claims of community benefit should be supported by objective, measurable patient-level data rather than broad institutional spending categories.
- Sufficient regulatory authority, data transparency, audit capacity, and enforcement infrastructure to ensure compliance and prevent diversion, duplicate discounts, and misuse.
- Contract pharmacy reform limiting contract pharmacy arrangements to models that demonstrate improved patient access and affordability rather than primarily expanding institutional or intermediary revenue opportunities. PBM-owned and vertically integrated affiliated mail-order pharmacies should not be permitted to use 340B as a revenue-generating mechanism.

Policies that COA Does Not Support

I. Bolstering Medicare's Ability to Negotiate Lower Drug Prices (Section I.I – Lowering Drug Prices, pages 5-12)

Expanding the Medicare Drug Price Negotiation Program without addressing COA's existing concerns would exacerbate anticipated challenges. COA strongly urges Congress to pass the bipartisan *Protecting Patient Access to Cancer and Complex Therapies Act* (H.R. 4299), which legislates a technical fix to the IRA that removes providers and patients from the middle of price negotiations and is budget-neutral by

having drug manufacturers rebate the negotiated price difference directly to Medicare.[27] The time to act is now, before the negotiated prices for 2028 take effect.

The current Part B Maximum Fair Price ("MFP") effectuation process creates an additional and potentially severe cash-flow problem in Medicare Advantage. CMS reports that approximately 85 percent of MA encounter data is currently submitted within 60 days of the claim's "from" date, and the manufacturer's 14-day payment window does not begin until the Medicare Transaction Facilitator receives and transmits verified encounter information. As a result, practices may be required to finance the difference between acquisition cost and MFP for 74 days or longer, with still greater delays when encountering records containing errors or unresolved edits. Congress and CMS must require prompt MA encounter-data submission and establish an enforceable deadline for practices to be made whole.

Congress should also work directly with practices to address and understand the significant financial, operational, and administrative challenges providers face under the Medicare Drug Price Negotiation Program.

Recommendations

- Pass H.R. 4299 to remove practices from the middle of the negotiated-pricing transaction before expanding or altering negotiation mechanisms.
- Work with practices to address and understand the significant financial, operational, and administrative challenges providers face under the Medicare Drug Price Negotiation Program.
- Congress and CMS must require prompt MA encounter-data submission and establish an enforceable deadline for practices to be made whole.
- Congress must also prevent MFP from becoming a de facto commercial reimbursement ceiling that allows private plans to reduce provider payment without ensuring that practices can acquire the drug at or below the resulting reimbursement amount.

II. Factoring International Pricing into Negotiation (Section I.I – Lowering Drug Prices, pages 6-9)

COA agrees that Americans should not bear disproportionately high drug costs compared with patients in other developed countries. International pricing may therefore be considered as one informational factor in negotiation, but it should not be automatically imposed as a separate reimbursement ceiling unless manufacturers are required to make the drug available to community practices at or below the resulting Medicare payment amount.

Any international comparison must rely on credible estimates of actual net prices and appropriately account for confidential foreign rebates, product availability, indications, dosage, and comparable economic markets. It must also include safeguards against shortages, launch delays, and reduced investment in clinically meaningful therapies.

For Part B drugs, Congress must not reduce an already net ASP-based reimbursement benchmark while leaving community oncology practices responsible for purchasing the product at a higher commercial price. Nor should international reference pricing merely transfer savings to insurers. Any savings generated through such a policy should be demonstrably passed through to patients and Medicare beneficiaries rather than retained as insurer windfalls.

[27] H.R.4299 - Protecting Patient Access to Cancer and Complex Therapies Act. 7 July 2025. Available Here.

Recommendations

- Treat international reference pricing as an informational factor rather than an automatic reimbursement ceiling, and guarantee provider acquisition at or below the resulting Medicare payment amount.
- Protect Part B drugs from benchmark reductions that leave practices purchasing products at commercial prices above Medicare reimbursement.

III. Negotiating Lower Prices on More Drugs (Section I.I – Lowering Drug Prices, page 9)

COA does not support increasing the number of drugs selected for negotiation, or accelerating negotiation timelines, until Congress corrects the inherent mismatch issues in the current IRA MFP effectuation process.[28,29] Independent practices do not set the MFP and cannot compel manufacturers, wholesalers, or distributors to make drugs available at that price, yet practices may be forced to purchase a drug above the amount Medicare ultimately recognizes for reimbursement. Expanding the program before fixing that mismatch would multiply the risk to community practices and patient access. Congress should first enact H.R. 4299, which removes practices from the middle of the negotiated-pricing transaction.

Recommendations

- Do not expand the number of negotiated drugs or accelerate negotiation timelines until the MFP effectuation mismatch is corrected.
- Pass the *Protecting Patient Access to Cancer and Complex Therapies Act* (H.R. 4299) to address COA's key financial concern regarding the IRA.[30]

IV. Negotiating Drugs Earlier in Their Lifecycle (Section I.I – Lowering Drug Prices, pages 9-11)

Earlier negotiation timelines raise additional concerns specific to cancer care—they may discourage investment in additional indications, combination regimens, pediatric studies, rare cancers, and small-molecule oncology drugs whose clinical value continues to develop after initial approval. Any future change to negotiation timing should include protections for products undergoing substantial post-approval research, therapies for pediatric and rare cancers, cell and gene therapies, and products for which a generic or biosimilar is credibly expected to enter the market. For biosimilars, accelerating negotiation could reduce the commercial opportunity for these developers before they have an opportunity to enter the market and recover the hundreds of millions of dollars that biosimilar development may require. If the reference product's price is substantially reduced shortly before biosimilar launch, investment may be redirected away from products that would otherwise generate sustainable competition. Therefore, Congress should expedite FDA review and CMS coding, and prevent rebate bundling, exclusionary formulary practices, and 340B incentives from undermining the adoption of lower-cost competitors.

Recommendation

- Protect products undergoing substantial post-approval research, pediatric and rare cancer therapies, and cell and gene therapies.

V. Eliminating Blockbuster Bailouts (Section I.I – Lowering Drug Prices, pages 12-13)

COA opposes eliminating the blockbuster drug bailout included in the 2025 reconciliation package and replacing it with the *No Big Blockbuster Bailouts Act* (S. 3019) due to the potential adverse impacts on drug development. The legislation implemented via the *One Big Beautiful Bill Act* better incentivizes orphan

[28] Avalere Health Advisory. "Commercial Spillover Impact of Part B Negotiations on Physicians." 16 September 2024. Available Here.
[29] Avalere Health. Provider Perspectives on Medicare Drug Price Negotiation: Implications for Part B Beneficiary Access, Practice Operations, and Reimbursement. 9 September 2025. Available Here.
[30] H.R.4299 - Protecting Patient Access to Cancer and Complex Therapies Act. 7 July 2025. Available Here.

drug development, which is important for cancer patients' access to new therapies. Additionally, COA recommends that the exemptions to the negotiation process be expanded to drugs used for pediatric cancer treatment, to further incentivize pediatric cancer drug development.

Recommendations

- Maintain orphan drug development incentives and reject changes proposed under S. 3019.
- Exempt drugs with pediatric cancer indications from the Medicare Drug Price Negotiation Program.

VI. Enhancing Manufacturer Accountability for Price Gouging / Inflation Rebates (Section I.II – Lowering Drug Prices, page 13-14)

COA urges caution before rebasing inflation penalties to an earlier year and does not recommend a specific year without careful product-level modeling. A retroactive or poorly designed rebase could destabilize low-margin products, GSIs, and shortage-prone medicines without meaningfully improving patient affordability. If Congress proceeds, any rebasing policy should be prospective or phased in, account for legitimate manufacturing and supply-cost increases, protect products in shortage, and ensure all rebate liability remains with the manufacturer rather than being transferred to providers or reflected in reimbursement below acquisition cost.

In addition, COA is not prepared to endorse a broad federal extension of Medicare inflation rebates to all commercial-market units without further analysis. Such a policy could interact unpredictably with the *Employee Retirement Income Security Act of 1974,* state insurance requirements, commercial contracts, launch-price decisions, and the economics of small manufacturers and shortage-prone products. At a minimum, Congress should determine whether any savings would actually reduce patient cost-sharing and premiums rather than being retained by plans and PBMs. Providers must not be held liable for commercial rebate obligations or forced to accept reimbursement below their acquisition costs.

Recommendations

- If Congress rebases inflation penalties, do so prospectively or in a phased manner, with protections for shortage-prone products and legitimate cost increases.
- Ensure rebate liability remains with manufacturers and is never transferred to providers or reflected in below-acquisition-cost reimbursement.
- Do not extend Medicare inflation rebates to the commercial market absent further analysis confirming that savings would reach patients rather than be retained by plans and PBMs.
- Ensure providers are never held liable for commercial rebate obligations or forced to accept below acquisition cost reimbursement.

VII. Subscription Models for GLP-1s and Population-Health Drugs (Section I.III – Lowering Drug Prices, pages 14-17)

COA believes subscription models may warrant limited testing for population-health products that have large eligible populations, multiple competing manufacturers, scalable production, and relatively predictable clinical use, such as GLP-1 therapies. Medicare, Medicaid, and private markets should generally use separate models because their populations, legal requirements, and financing structures differ. Initial participation should be voluntary, agreements should be renegotiated at least annually or when new entrants, indications, or safety data emerge, and funding should come principally from negotiated manufacturer concessions rather than premium-increasing assessments. Most oncology therapies are poor candidates because treatment is individualized, biomarker-driven, frequently combination-based, and rapidly evolving.

Recommendations

- Limit subscription-model testing to population health products that meet appropriate criteria on a voluntary basis, with funding from negotiated manufacturer concessions rather than premium increases.
- Recognize that most oncology therapies are poor candidates for subscription pricing given their individualized, biomarker-driven nature.

VIII. Addressing Excessive Launch Prices (Section I.III – Lowering Drug Prices, pages 17-18)

COA supports greater transparency regarding exceptionally high launch prices but cautions against rigid price controls that fail to account for rare populations, high-risk science, and manufacturing complexity. Congress must recognize that launch prices are shaped by intermediary rebate demands, 340B obligations, and statutory concessions that widen the gross-to-net price gap.

Recommendation

- Avoid rigid price controls on initial launch prices and instead address the system of intermediary rebates and statutory concessions that drive gross launch prices upward.

IX. Addressing Price-Linked Compensation / Delinking Part B Physician Add-On (Section II.II – Addressing Perverse Dynamics in the Supply Chain, pages 29-30)

COA strongly opposes flat-fee, capped, or reduced-percentage alternatives to the Part B physician add-on. COA has significant concerns about the considered add-on payment changes for Part B drugs. For many independent community oncology practices, the suggested policies would be insufficient to cover the costs of administering Part B drugs, threatening the viability of such practices.

Independent community oncology practices rely on the add-on payment to cover—***although certainly not fully compensate for***—the costs associated with dispensing these drugs. For many high-cost oncology therapies, a flat fee or lowered add-on percentage with a flat fee would be inadequate for practices to cover the costs of administering Part B drugs, which extend beyond drug acquisition and include staffing, storage, and operations. The Part B add-on reflects real financial, inventory, wastage, and clinical risks borne directly by the acquiring practice.

While COA ultimately supports the current ASP-plus payment structure, given there is no appropriate, reasonable, and realistic alternative, if changes to this structure are proposed, they should vary based on expenditures associated with administering the drug and not be flat for all drugs. COA has previously suggested a tiered ASP approach in conjunction with clinically appropriate utilization management ("CAUM") as an alternative. COA's proposed tiers would vary according to certain thresholds based on drug prices and other considerations. CAUM is a voluntary system that would implement decision-support tools developed and managed by physicians rather than payers or third-party vendors, incentivizing appropriate utilization based on the latest scientific evidence and clinical guidelines, reducing suboptimal therapy use, while upholding the highest standard of patient care and eliminating waste.[31]

Recommendations

- Maintain the ASP plus six percent add-on payment.
- Reject flat-fee or capped payment models that sever reimbursement from real financial and clinical exposure.

[31] Community Oncology Alliance. "Re: Extending the Oncology Care Model." 15 November 2021. Available Here.

- If implementing ASP changes, work closely with independent physician practices to fully understand the scope of impacts and explore physician-led tiered ASP/CAUM approaches.

Conclusion

COA is committed to providing solutions to the challenges that community oncology patients and physicians face throughout the care journey. We seek to ensure that cancer care is delivered with the highest quality and in an accessible and affordable manner.

Thank you for your request for information and consideration of these comments. COA is available to discuss the concerns or recommendations in this letter and can be contacted at debra.patt@usoncology.com and tokon@COAcancer.org.

We look forward to working with you on promoting the health and well-being of Americans with cancer.

Sincerely,

Debra Patt, MD, PhD, MBA, FASCO
President

Ted Okon, MBA
Executive Director