PATIENTS RISING

Putting patients at the center of health policy

August 15, 2026

Submitted electronically to drugs@finance.senate.gov

The Honorable Ron Wyden Ranking Member Committee on Finance United States Senate
Washington, DC 20510

RE: Request for Information — Commonsense Policy Options to Lower Drug Prices for Patients (June 16, 2026)

Dear Ranking Member Wyden:

Patients Rising is a national patient education and advocacy organization representing Americans living with chronic and life-threatening illness. We appreciate the Committee's willingness to put detailed policy options in writing and invite scrutiny of them.

We also write to raise a structural concern about the document as a whole.

This RFI runs to forty-two pages and canvasses nearly every price in the pharmaceutical supply chain: the price the manufacturer charges, the price Medicare negotiates, the price the plan books, the price the wholesaler marks up, the price the private labeler assigns, the price the pharmacy is reimbursed. It is, in that sense, comprehensive.

But a price is not a cost. The patients we represent do not pay any of the prices this RFI discusses. They pay a coinsurance percentage, a copay tier, a deductible, or a share calculated off a benchmark that bears no reliable relationship to what anyone in the chain actually paid. Between every price in this document and the number on the receipt sits a benefit design that the price reform does not touch — and that is where savings are most often absorbed.

That is not a theoretical concern. It is documented in this RFI. The Committee notes that Part D rebates reached an estimated $77 billion in 2024, and cites JAMA research finding that rebate growth was associated with a $13 *increase* in average beneficiary cost-sharing per prescription. Rebates went up. Patient costs went up with them. That is the mechanism problem in a single sentence, and it will repeat itself with every price reform in this document unless Congress builds a delivery mechanism alongside it.

The test we apply

We evaluate every policy instrument in this RFI against two questions:

1. **Does it lower what the patient pays at the pharmacy counter?**
2. **Does it make that cost clearer and more predictable?**

We apply this test without regard to which party proposes a policy, which industry supports or opposes it, or how it is framed politically. Applied to this RFI, the test sorts the proposals into three groups, and we have organized our comment accordingly: proposals that reach the counter directly, proposals that will not reach the counter unless a delivery mechanism is attached, and the patient-facing problems this RFI does not address at all.

I. Proposals that reach the counter

Five proposals in this RFI change what a patient actually pays. If the Committee's legislative capacity is finite, these should be first in the bill, not traded away for the price provisions.

1. Base coinsurance and deductible-phase cost-sharing on net price — and do not limit it to a subset

This is the single most consequential patient-affordability proposal in the RFI, and we urge the Committee to treat it that way.

The Committee has already assembled the case. Rebates in Part D are large and growing. Cost-sharing in the deductible and coinsurance phases is calculated on benchmarks that approximate list price. And Part D benefit design is moving *toward* coinsurance and away from fixed copays — the RFI cites analyses showing standalone PDP use of coinsurance for preferred brand drugs rising from 9.9 percent in 2020 to 71.9 percent in 2024, and 83 percent of standalone PDPs carrying three coinsurance tiers in 2025.

That trend matters enormously for patients, and it cuts in a direction the Committee should name. Under a fixed copay, a patient is insulated from list price but also insulated from any savings — the copay does not fall when the price does. Under coinsurance, the patient is exposed to the full inflated benchmark. The market is moving patients from a design where

price reform does not help them to a design where price inflation actively hurts them. Net-price cost-sharing is the only structural answer to both.

The RFI references the bipartisan proposal the Committee approved unanimously in 2023, which would have applied net-price coinsurance to a subset of highly rebated chronic-condition drugs in Part D, and correctly observes that a broader application would reach more patients. We urge the Committee to go further than referencing it. **Cost-sharing in the deductible phase and wherever coinsurance applies should be calculated on a net price basis for all covered Part D drugs, with point-of-sale application, and the Committee should pursue the same standard in the commercial market.**

We recognize the objections. Plans will argue that redirecting rebate value to the patients who generate it raises premiums. That is a real trade-off and we address it in Section IV. But we would ask the Committee to hold the objection to its own logic: a system in which the sickest enrollees overpay at the counter so that all enrollees underpay at the premium is not risk pooling. It is a transfer from the chronically ill to everyone else, administered without their knowledge and without their consent.

2. Cap out-of-pocket costs for chronic care drugs — and close the Part B gap

We support extending cost-sharing caps beyond insulin, and we support the Committee's separate proposal for an out-of-pocket cap in Traditional Medicare. Two design points:

Structure the chronic-care cap as an aggregate monthly cap, not a set of per-drug caps. The RFI asks which approach is preferable. The patient the Committee should picture is not the one taking a single chronic medication — it is the beneficiary managing four or five conditions simultaneously, which the RFI correctly identifies as the norm in Medicare. A series of $35 per-drug caps leaves that patient with a monthly bill that is the sum of her diagnoses. An aggregate monthly cap on qualifying chronic-care medications is more protective for the patients most at risk, is far easier for a patient to understand in advance, and does not invite plans to game which products fall inside a category-by-category definition. It is better on both halves of our test.

The Part B out-of-pocket cap is overdue and should not be treated as a secondary item. Traditional Medicare remains the only major form of coverage in the United States with no annual limit on what a patient can be asked to pay. A Part B beneficiary on an infused therapy faces open-ended 20 percent coinsurance on a drug priced in the hundreds of thousands of dollars, with the exposure compounded by hospital outpatient markups. Every negotiation and

rebate reform in Section I of the RFI touches Part B drugs. None of them caps what the patient owes.

3. Expand the Low-Income Subsidy — and fix enrollment, not just eligibility

We support raising LIS eligibility to 200 percent of the federal poverty level and eliminating the asset test, and we support aligning Medicare Savings Program thresholds.

The asset test as it currently stands deserves to be retired on its own merits. A program that conditions prescription drug affordability on holding less than roughly $18,000 in savings tells low-income seniors and people with disabilities that modest financial resilience and access to medication are mutually exclusive choices. That is a policy actively working against every other thing we ask people to do.

We would add two items the RFI does not raise:

- **Enrollment is the binding constraint, not eligibility.** Expansion delivers nothing to a person who never enrolls. We urge the Committee to pair expansion with automatic enrollment through existing federal data matching for beneficiaries whose eligibility is already determinable from Social Security and IRS records, with an opt-out rather than an application.

- **Benchmark plan availability is collapsing, and it is a patient cost problem.** The number of premium-free LIS benchmark plans has fallen from 191 in 2023 to 88 in 2026. In several states, LIS beneficiaries now choose from one or two no-premium options or pay a premium out of a fixed income. Expanding subsidy eligibility into a market with no subsidized plans left to enroll in is an incomplete reform. We ask the Committee to address benchmark plan adequacy directly in whatever Part D stabilization package it develops.

4. Bring cost-plus pricing to generics — and give patients the benefit directly

The Committee's account of generic markups in Part D is accurate and, from a patient standpoint, indefensible. Part D plans reimbursed generics at a mean of 5.4 times acquisition cost. Medicare paid billions more than cash prices available at retail. Roughly ten percent of generic prescriptions in the United States are now filled outside of insurance entirely.

That last figure is the one we ask the Committee to sit with. Patients are paying monthly premiums for coverage and then walking past it, because their insurance costs more than not using it. Whatever else that is, it is a coverage failure, and it is invisible in every metric the program currently reports.

We support a NADAC-plus-dispensing-fee benchmark as a ceiling on Part D generic pricing. We also urge the Committee to adopt the patient-facing option it raises in passing and then leaves undeveloped:

No patient should ever pay more using their insurance than they would pay in cash, and cash purchases of covered generics should count toward the deductible and out-of-pocket maximum. Congress banned pharmacist gag clauses in 2018 so patients could learn when the cash price was lower. The natural completion of that reform is to stop penalizing them for acting on what they learn. A patient who finds a $2 cash price for a drug her plan prices at $100 should not have to choose between paying less today and making progress toward her out-of-pocket cap.

5. Hold plans and PBMs accountable for inappropriate pharmacy rejections

We appreciate that the Committee included this, and we urge it to expand rather than shrink the provision. The evidence in the RFI is damning: the HHS Office of Inspector General found 73 percent of appealed Part D rejections were overturned, and IQVIA found that patients who ultimately overcame a denial waited an average of 14 to 24 days, with 10 to 19 percent delayed five weeks or longer.

A 73 percent overturn rate is not a close-call rate. It describes a system in which denial is a first-line cost control applied to clinically appropriate prescriptions, with the cost of correcting it borne by patients in the form of untreated weeks.

Answering the Committee's specific questions:

- **Yes, CMS should develop a Part D Star Ratings measure** on rejection and overturn rates, weighted meaningfully enough to affect plan behavior.
- **Yes, rejection rates should be public and plan-specific in Plan Finder**, alongside overturn rates and average time to resolution. A patient choosing a plan during open enrollment can currently compare premiums and formularies but has no way to learn that one plan denies far more often than another.
- **On appeals efficiency:** the burden should shift off the patient. We urge automatic approval when a plan misses a statutory response deadline; continuation of coverage

during appeal for a therapy the patient is already stabilized on; a prohibition on re-authorizing a chronic therapy the same plan has already approved absent a change in clinical circumstances; and a requirement that the rejection reason and the appeal pathway be delivered to the patient in plain language at the counter, not mailed later.

We would add one item: **plans should not be permitted to remove a drug from the formulary or move it to a less favorable tier mid-plan-year for a patient already stabilized on it.** Enrollment is an annual commitment made on the basis of a published formulary. Patients cannot change plans in June when the formulary changes underneath them.

II. Proposals that will not reach the counter unless you attach a mechanism

The proposals in this section may be sound program policy. We take no position on several of them as fiscal or industrial matters, because that is not our test. Our concern is narrower and, we think, unanswered in the RFI: as drafted, none of them has a mechanism that carries the savings to the patient.

Expanded negotiation, international reference pricing, and earlier negotiation

Patients Rising supports Medicare's authority to negotiate drug prices. Our concern is with realization, not authority.

The Committee's own data illustrates the point. For the first negotiation cycle, the RFI reports roughly $6 billion in savings to taxpayers and $1.5 billion in out-of-pocket savings to beneficiaries — a ratio of about four to one. For the 2027 cycle, the figures cited are $12 billion for taxpayers and $685 million for beneficiaries — roughly seventeen to one. We do not question the estimates. We ask the Committee to notice the trend: as the program scales, the share reaching patients is shrinking.

There are structural reasons. A fixed copay does not fall when a negotiated price falls. A drug can be moved to a worse tier. Savings can be recaptured elsewhere in the benefit. None of these are arguments against negotiation. There are arguments that negotiation without a cost-sharing mechanism is a program that lowers government spending and is described to patients as though it lowered theirs.

International reference pricing illustrates the same gap in its starkest form. An Avalere Health analysis of a Most Favored Nation-style Medicare payment model found that only approximately 0.3 percent of fee-for-service beneficiaries would experience any change in cost-sharing liability — more than 99 percent would see no out-of-pocket reduction at all, because supplemental coverage insulates beneficiaries from changes in Medicare payment benchmarks. A policy can cut the reference price dramatically and still change nothing on a patient's receipt. Whatever the Committee concludes about incorporating international prices into negotiation, that finding should discipline every claim made about what the policy will do for patients: absent a cost-sharing mechanism, the honest answer is very little.

Whatever expansion the Committee pursues — more drugs, earlier selection, international reference points — it should be paired with the net-price cost-sharing reform in Section I. Absent that, expanding negotiation multiplies a savings stream that patients experience only indirectly, through premiums, if at all.

On **earlier negotiation timelines**, we raise one patient-side caution that we believe is distinct from the industry's argument. Generic and biosimilar entry remains the most reliable mechanism ever devised for lowering what patients pay, delivering price declines of 70 to 90 percent, permanently, without a program to administer. The RFI itself notes that only about 10 percent of biologics losing protection in the next decade have a biosimilar in development. If accelerated negotiation timelines further weaken the business case for biosimilar entry, patients could trade a durable structural price collapse for an administered price that applies to Medicare only. We do not claim to know where that line falls. We do urge the Committee to treat the biosimilar incentive package it floats as a companion requirement rather than an optional add-on, and to model patient out-of-pocket effects — not just program savings — under each timeline it considers.

On the small-molecule/biologic disparity, we do take a position — a patient's position. Under current law, a pill becomes eligible for negotiation four years before an infused biologic does. This disparity is usually debated as an investment question, with industry on one side and payers on the other. We come at it from a different direction, because the difference between a pill and an infusion is not an abstraction to the people we represent.

An oral therapy is taken at home, on the patient's schedule, without help. An infused biologic means travel, hours in a chair, IV access or a port, caregiver time, and time away from work — and in Medicare it frequently means moving from Part D, where the patient's annual out-of-pocket exposure is now capped, to Part B in a hospital outpatient department, where facility fees inflate the bill and, as we note above, no out-of-pocket cap exists at all. When development shifts from the pill to the infusion, the patient does not merely lose convenience. She is moved to the setting where her cost exposure is greatest and least limited. Nor is the

shift reversible after the fact: converting an approved infusion into an oral therapy — or even into a single subcutaneous injection — is genuinely difficult science, as our recent comments to CMS on fixed-combination and reformulated products discuss in detail. Modality is chosen early, and patients live with the choice for the life of the product.

That is what a four-year differential does at the margin. A developer weighing a small-molecule program against a biologic program sees two additional years of pre-negotiation revenue on one side of the ledger. These are for-profit enterprises, and we do not fault them for responding rationally to incentives Congress wrote; wishing otherwise is not a policy. Our objection is to the incentive itself, because the party who ultimately pays for it — in the infusion chair, in the hospital outpatient bill, in uncapped Part B coinsurance — is the patient, who was never consulted on the distinction and derives no benefit from it.

The disparity is sharper than the headline numbers suggest, because of how each clock interacts with the competitive timelines the IRA left in place. Biologics carry twelve years of BPCIA market exclusivity, so a thirteen-year negotiation timeline lands roughly where biosimilar competition could begin anyway — the negotiation clock and the natural competitive clock coincide. Small molecules, by contrast, typically face generic entry at 12.5 to 13.5 years, per the research this RFI itself cites. A nine-year negotiation clock therefore bites three to four years *before* the market would have disciplined the price on its own. One modality's clock runs alongside competition; the other runs ahead of it. That is not parity with an asterisk. It is a structural penalty on the pill.

It also carries a second-order consequence for the mechanism patients depend on most. This RFI candidly acknowledges that accelerated negotiation timelines could weaken the business case for biosimilar entry, and proposes an incentive package to compensate. We agree with that analysis — and we ask the Committee to notice that the identical mechanism already operates against generics under current law. A generic developer sizing an opportunity looks at the brand's price in the years after entry; when an MFP has been in effect for three or four years before the generic could launch, the reference price the generic would undercut has already been administratively lowered, and the return shrinks accordingly. Generic entry is the most reliable patient-savings mechanism ever devised — price declines of 70 to 90 percent, permanent, requiring no program to administer. A policy that quietly erodes the incentive to produce it, for small molecules specifically, deserves the same scrutiny and the same corrective attention this RFI already extends to biosimilars.

We also acknowledge the countervailing evidence honestly, because the Committee presents it: studies cited in this RFI find R&D investment increased following the IRA, and small-molecule acquisitions grew from $23 billion in 2024 to $38 billion in 2025. We will not overclaim, and we would caution every party in this debate against doing so — because the honest answer is that

the observation window is far too short to support anyone's conclusion. Drug development runs ten to fifteen years from discovery to approval, by the Committee's own account in Section III. Portfolio decisions being made in response to the IRA in 2023 through 2026 will surface as approvals — or absences — in the mid-to-late 2030s. Investment data from the first three years of a policy cannot capture a pipeline effect whose lag exceeds a decade; it can only capture activity already committed before the incentive changed. Neither we nor the industry nor the Committee will know the true effect for years. What can be evaluated today is the structure of the incentive itself — and structurally, the asymmetry is directional, deliberate, and supported by no patient-based rationale that anyone has offered. No one argues patients are better served by fewer oral options.

Our recommendation is that negotiation eligibility timelines be modality-neutral. Where Congress sets the number — nine years, eleven, thirteen — is a fiscal and innovation-policy judgment that belongs to Congress, and our patient-cost test speaks to the structure of the incentive rather than to the number. What that test tells us, unambiguously, is that the clock should not depend on whether a medicine is a pill or an infusion. That distinction is precisely the one patients experience most concretely and pay for most directly, and it should be the last thing federal law puts a thumb on.

Inflation rebates: re-basing, MA units, commercial extension

The Committee should be clear-eyed about who these rebates currently benefit. Inflation rebates are paid to the Treasury. They lower federal spending. They do not, by themselves, lower a patient's cost-sharing.

Congress already knows how to fix this, because it did it once. Under the IRA, beneficiary coinsurance for Part B rebatable drugs is calculated on the inflation-adjusted payment amount, so a manufacturer's excessive price increase does not flow into the patient's 20 percent. That is exactly the kind of delivery mechanism this RFI is otherwise missing.

If the Committee re-bases the penalties, extends them to Medicare Advantage units, or extends them to the commercial market, it should extend the beneficiary coinsurance protection in parallel each time. Otherwise the reform's entire patient-facing value is a premium effect the patient will never perceive.

Subscription models for GLP-1s and other population-health drugs

We are open to subscription models, and the Australian and Louisiana hepatitis C experiences the RFI cites are genuinely encouraging on access. But note what those examples have in common: the payer bought unlimited supply, and the patient's barrier disappeared. A

subscription model that fixes the *payer's* cost while leaving the patient with coinsurance on an unchanged list price would reproduce the exact failure this letter is about.

If the Committee pursues a subscription model, we ask that it condition participation on patient-facing terms:

- **A fixed, low, predictable patient cost-sharing amount** — a flat dollar copay, not a percentage of anything — as a condition of the model.
- **No enrollment caps, waiting lists, or step-therapy queues** used to ration a supply the payer has already purchased in full.
- **A medical-necessity exception pathway** allows a patient to access a non-contracted agent when the contracted one fails, is not tolerated, or is contraindicated. Subscription economics push hard toward single-product formularies; patients who do not respond to that product must not become the model's cost-control valve.
- **Continuity protection** for patients already stable on a therapy when a model takes effect. Forced switching for contracting reasons is a clinical event, not an administrative one.
- **Renegotiation cycles that account for new indications and new clinical evidence**, so a model priced for one population does not become the reason coverage is denied to another.

Answering the Committee's question about what else might suit a subscription approach: the strongest candidates from a patient standpoint are therapies where the clinical case is settled, utilization is currently suppressed by cost rather than by evidence, and the primary access barrier is payer budget exposure. Beyond GLP-1s, that description fits several vaccine and prevention categories and some high-prevalence chronic disease therapeutics.

PBM, private label, vertical integration, and dispensing fee reforms

We support the direction of these proposals. We ask the Committee to add one requirement that runs across all of them.

The 2018 Committee investigation, the FTC's findings, and the RFI's own account of private-label markups all describe the same pattern: dollars extracted between the manufacturer's price and the patient's counter. But the reforms as drafted return those dollars to plans and to the Medicare program. **Unless Congress specifies otherwise, PBM reform savings stop at the plan level.** Patients Rising asks that every supply chain reform in this section carry an explicit patient pass-through requirement — that recovered value be applied to reduce cost-sharing at the point of sale, and that plans report annually on whether it was.

Three specifics:

- **Private label markups are directly patient-facing.** When a PBM's private label acquires a biosimilar and resells it at roughly two and a half times what another payer pays, and a patient's coinsurance is calculated on that marked-up figure, the patient is personally financing the markup. We support the disclosure approach the RFI describes and would go further: cost-sharing on a private-label product should be calculated on the label's acquisition cost.
- **Exclusive negotiation and non-solicitation clauses should be prohibited.** Congress banned pharmacist gag clauses in 2018 for precisely this reason. A contract term that forbids a plan from talking to a manufacturer about price cannot be reconciled with a program built on price competition.
- **On dispensing fees, we support adequate cost-based compensation with one guardrail.** Patients Rising has supported reducing pharmacies' reliance on drug margin, including in our position on the Pharmacists Fight Back Act, and we agree that pharmacy closures — one in three retail pharmacies open in 2010 closed by 2021, concentrated in Black and Latino communities — are a patient access emergency. But a dispensing fee is only a patient benefit if it is paid by the plan and not passed through to the patient as higher cost-sharing. We ask that any minimum dispensing fee requirement expressly exclude the fee from the patient's cost-sharing calculation.

Launch prices

Transparency into launch price decisions is worth having, but it does not change what a patient pays. If the Committee legislates here, we ask for one patient-facing addition: **at launch, manufacturers *and* plans should be required to disclose what a patient with typical coverage will actually owe** — not the list price, not the net price, but the expected out-of-pocket cost under standard benefit designs. Patients are currently told a headline number that has no relationship to their obligation, and then discover the real one at the counter.

III. What this RFI leaves out

Four patient-facing problems of the same magnitude as the ones addressed here appear nowhere in forty-two pages.

1. 340B — a $100 billion program with no requirement that any of it reach a patient

340B appears once in this RFI, in a parenthetical about biosimilar discount modifications. That omission is difficult to justify on the numbers.

HRSA reported in July 2026 that 340B covered entity purchases reached $100 billion in calendar year 2025, a 23 percent increase over 2024 and more than double the 2021 figure. Disproportionate share hospitals accounted for roughly 80 percent of purchases, at $79.2 billion; federally qualified health center programs accounted for $5.9 billion. Independent analysis places the value of the underlying discounts at approximately $79.5 billion for 2025. By purchase volume, 340B is now second only to Medicare Part D among federal drug programs and exceeds net Medicaid and Medicare Part B drug spending.

This RFI proposes to require PBMs to disclose the spread between acquisition cost and the price charged to clients. We agree with that principle. We ask the Committee to notice that it applies with at least equal force to a program of this size in which the discount is mandatory, the beneficiary is a covered entity rather than a patient, and there is no statutory requirement that any portion of the discount reach the patient whose prescription generated it — nor any reporting that would let Congress find out.

Patients in our community routinely receive full-price bills, and are pursued by collections, for medications their hospital purchased at a deep statutory discount. Our own state-level research connects program opacity to documented patient financial harm, including medical bankruptcy. We would welcome the opportunity to brief Committee staff on that work.

We ask the Committee to apply its own transparency standard here: **require public reporting of 340B savings and their use, pilot point-of-sale patient notification so a patient can see when a discounted drug was dispensed to her, and require covered entities to document how the program benefits the vulnerable patients it was created to serve.** This is not an attack on the safety net. Documentation of benefit is the only mechanism that can actually enforce a safety-net mission.

2. Copay assistance, accumulators, maximizers, and alternative funding programs

The RFI states that Democrats intend to explore commercial market reforms. When the Committee does, this should be on the list.

Copay accumulator and maximizer arrangements collect assistance dollars intended to defray a patient's cost-sharing and decline to credit them toward that patient's deductible or out-of-pocket maximum. The patient's obligation is effectively paid twice, once by the manufacturer and once by the patient. Alternative funding programs go further, steering patients out of their own coverage toward charity assistance or foreign importation, with the patient bearing full cost if they decline. Federal regulation already defines cost-sharing as expenditures made "by or on behalf of" an enrollee, and a federal court held in September 2023; the decision remains substantially unenforced nearly three years later.

We urge the Committee to support enactment of the HELP Copays Act, to press for enforcement of the existing definition, and to direct investigation of alternative funding programs. These arrangements fail both halves of our test at once: they raise the patient's real cost, and they make her plan documents incapable of telling her what anything will cost or what will count.

3. Predictability infrastructure

The second half of our test — clarity and predictability — is largely absent from this RFI, and it is not a soft concern. A patient who cannot find out what a prescription will cost before she reaches the counter cannot plan, budget, or make an informed choice among plans.

Three concrete items:

- **Fix the Medicare Prescription Payment Plan.** Congress created a smoothing mechanism precisely for patients facing large costs early in the year, and it is barely being used: participation in 2025 ran at roughly 0.6 percent of Part D beneficiaries and under 7 percent even among those most likely to benefit. The 2026 automatic re-enrollment provision is a step forward, but it only helps people who already found the program. **Enrollment should be automatic and opt-out for beneficiaries a plan can identify as likely to incur a large early-year out-of-pocket obligation** — plans already run this identification and are already required to notify. Notification is not enrollment.
- **Require accurate, real-time, patient-facing benefit information** — the patient's actual cost, at her pharmacy, under her plan, at the point of prescribing, available to the patient and not only to the prescriber's software.
- **Publish plan-level out-of-pocket outcomes in Plan Finder** so patients can compare what enrollees like them actually paid, rather than only premiums and formulary listings.

4. No proposal in this RFI measures whether savings reach patients

This is the omission that concerns us most, because it is the one that makes the others self-correcting or permanent.

Every price reform in this document will be evaluated by CBO scores, program savings, and net spending — all measured at the government or plan level. None of them will be evaluated by what happened to beneficiary out-of-pocket costs, because no one is required to report it.

We ask the Committee to require CMS to publish an annual savings realization report: for drugs subject to negotiation, inflation rebates, or any new pricing mechanism Congress enacts, the change in the price paid alongside the change in average and median beneficiary out-of-pocket cost, reported by drug and by plan type. Where a price fell substantially and patient costs did not, that should be visible on the record rather than discoverable only by outside researchers years later.

This costs almost nothing, and it is the only way Congress will ever know whether any of this worked for the people it was written for.

IV. Guardrails and honest trade-offs

We would not ask the Committee to accept our recommendations without acknowledging their costs.

Premiums are a patient cost too. Directing rebate value to the point of sale will put upward pressure on premiums, and a reform that lowers a patient's counter cost while pricing her out of coverage entirely fails our test. We support pairing net-price cost-sharing with the Part D stabilization measures the RFI discusses, and we think the Committee should be candid that this is a redistribution — from healthy enrollees toward enrollees who use expensive medications — rather than a costless efficiency. We believe it is the right redistribution. Insurance is supposed to work this way.

Pharmacy access is a patient cost too. Aggressive generic pricing reform and adequate pharmacy compensation must move together. A cost-plus ceiling that closes the pharmacy in a rural county has not saved that county's patients anything.

Biosimilar and generic entry is the most powerful patient savings mechanism we have. Reforms that inadvertently suppress it should be modeled against patient out-of-pocket outcomes before enactment, not after.

Recommendations

1. **Base cost-sharing on net price** in the deductible phase and wherever coinsurance applies, for all covered Part D drugs, applied at the point of sale — and pursue the same standard in the commercial market.
2. **Cap chronic care drug cost-sharing as an aggregate monthly amount**, not per-drug, and **enact an out-of-pocket cap in Traditional Medicare Parts A and B.**
3. **Expand LIS to 200 percent FPL, eliminate the asset test, align Medicare Savings Programs, add automatic enrollment through federal data matching, and address the collapse in benchmark plan availability.**
4. **Adopt NADAC-based cost-plus pricing for Part D generics**, and guarantee that no patient pays more using insurance than the cash price, with cash purchases of covered generics credited toward the deductible and out-of-pocket maximum.
5. **Hold plans and benefit managers accountable for inappropriate rejections** through a Star Ratings measure, plan-level public reporting in Plan Finder, deemed approval on missed deadlines, continuity of coverage during appeal, no re-authorization of already-approved chronic therapies, and a prohibition on adverse mid-year formulary changes for stabilized patients.
6. **Attach a patient delivery mechanism to every price reform** — pair negotiation expansion with net-price cost-sharing; extend beneficiary coinsurance protection alongside every inflation rebate expansion; require patient pass-through of PBM and supply chain reform savings; and exclude minimum dispensing fees from patient cost-sharing.
7. **Make negotiation eligibility timelines modality-neutral.** End the disparity between small-molecule and biologic drugs, so federal law stops placing a development penalty on the form of medicine — the pill — that patients can take at home, on their own schedule, in the setting where their costs are capped. Where parity is set is a fiscal judgment for Congress; our test speaks to the structure of the incentive, not the number.
8. **Condition any subscription model** on fixed low patient cost-sharing, no rationing of purchased supply, a medical-necessity exception pathway, and continuity protection for stabilized patients.
9. **Apply the Committee's own transparency standard to 340B**: public reporting of savings and their use, point-of-sale patient notification pilots, and documentation of benefit to vulnerable patients.
10. **Address copay accumulators, maximizers, and alternative funding programs** in the commercial market reform agenda, including enactment of the HELP Copays Act.
11. **Require an annual CMS savings realization report** comparing changes in prices paid to changes in beneficiary out-of-pocket costs, by drug and plan type.

We are grateful for the Committee's work and for the opportunity to comment. Patients Rising would welcome the opportunity to brief staff on our 340B research, our state-level medical bankruptcy data, and the patient experience evidence underlying this letter.

Respectfully submitted,

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Patients Rising is a national patient education and advocacy organization. Our funding sources are disclosed on our website at patientsrising.org.