PATIENTS RISING

Putting patients at the center of health policy

August 17, 2026

The Honorable Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via www.regulations.gov

RE: Comments on CMS–4215–P, Medicare Drug Price Negotiation Program Proposed Rule for Initial Price Applicability Year 2029

Dear Administrator Oz,

Patients Rising is a national nonprofit that represents patients living with chronic and life-threatening conditions. We appreciate the opportunity to comment on the proposed rule for Initial Price Applicability Year (IPAY) 2029 under the Medicare Drug Price Negotiation Program.

Patients Rising supports Medicare's authority to negotiate drug prices. We fight for lower out-of-pocket costs for the patients we serve. We comment as one of many patient voices in the room — with the hope that, as CMS finalizes the rules that will govern this program for years, patients are the ones who actually benefit.

Medicare drug price negotiation was put forth as a program to lower costs for patients. But *how* CMS sets and implements these prices — and *how* it listens to patients along the way — will decide whether the program keeps that promise. A negotiated price is not the same thing as a lower cost at the pharmacy counter or in the infusion suite. Coverage on paper is not the same thing as access. And a public engagement process is not the same thing as patients actually being heard.

Our comments are organized around three questions we believe CMS should ask of every policy in this rule:

- **Does the savings actually reach the patient?**
- **Does the patient's access — and stability on a working therapy — hold?**
- **Does the patient's voice actually count?**

I. Does the savings actually reach the patient?

The entire justification for this program is patient affordability. So the first test of any implementation policy is simple: when Medicare negotiates a lower price, does the patient pay less?

The early evidence says: not always, and not automatically. Independent analysis of Medicare claims data has found that when negotiated prices fell steeply, patients' out-of-pocket costs frequently fell

far less — in some cases only marginally.[1] Treated cautiously, as that analysis itself urges, the gap is exactly the point. A lower price on the government's ledger can coexist with a patient who sees little or no relief at the counter, because fixed copays don't fall when a price falls, because a drug can be moved to a worse tier or buried behind prior authorization, and because savings on one medicine can be quietly offset by higher costs elsewhere in a patient's benefit.

This is the "ripple effect beyond the price tag" we warn about constantly: a single price does not stay on the page. It moves through what pharmacies stock, what plans cover, what tier a drug sits on, and what a patient ultimately owes. A program measured only by the price Medicare pays can look like a success on paper while patients experience no change — or, in the worst case, pay more as costs are shifted onto them through premiums, deductibles, or cost-sharing on their other medicines.

We therefore urge CMS to measure and publicly report whether savings actually reach patients — not just whether Medicare or Part D plans pay less. That means tracking patients' real out-of-pocket costs and total financial liability across the whole benefit, standardized and reported transparently, so that a negotiated price cut that does not reach the patient is visible rather than hidden. Put plainly: if Medicare's price for a medicine drops by half and a patient's cost barely moves, the program has not yet done its job for that patient, and CMS should be able to see that and say so.

II. Does the patient's access — and stability on a working therapy — hold?

A lower price is worth little to a patient who loses access to the treatment that works for them, or who is pushed into a more burdensome, more costly way of receiving it. As CMS implements this program, protecting access and treatment stability has to sit alongside the price itself.

We are especially concerned about one provision in this proposed rule: the modification to the fixed combination drug policy. CMS proposes to treat a newer subcutaneous version of a medicine as the *same* qualifying single-source drug as its original intravenous form for price-setting purposes.

We understand what CMS is trying to prevent. The agency describes this as a "narrow modification" meant to address "a program integrity risk in which a manufacturer may avoid selection" or "avoid the application of the MFP."[2] We share the goal that a negotiation program that can be sidestepped through trivial, evasive reformulations does not serve patients. If a manufacturer is identified as having changed a product for no reason other than to reset the negotiation clock, patients gain nothing and this should be prevented if it happens.

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[1]See Pioneer Institute, Comments on CMS–4215–P (Aug. 2026) (analysis of licensed IQVIA Medicare prescription claims data, Q1 2024–Q1 2026, finding, for example, that for one selected medicine the maximum fair price represented roughly a 66% reduction from the reference list-price benchmark while average out-of-pocket costs for prescriptions with patient liability fell by roughly 2%). Pioneer cautions that these findings are preliminary and directional, and that the published difference between a maximum fair price and CMS's reported 2023 list price is not equivalent to the change in a plan's net drug cost after rebates, fees, and other concessions.

[2]Centers for Medicare & Medicaid Services, *Medicare Drug Price Negotiation Program Proposed Rule (CMS–4215–P) Fact Sheet* (June 2026), describing a "narrow modification to the general fixed combination drug policy" to address "a program integrity risk in which a manufacturer may avoid selection" or "avoid the application of the MFP." Comments due August 17, 2026, via https://www.regulations.gov.

But as written, the provision is not drawn narrowly enough to tell an evasive tweak apart from a genuine advance that patients depend on — and patients are the ones who absorb the difference. Some newer subcutaneous therapies are not paperwork variations on an IV drug; they are separately approved medicines, reviewed by the FDA under their own applications and their own clinical trials, that a patient experiences in a completely different way.[3] For a patient, an IV infusion can mean a surgically implanted port with its own risks, and a full day organized around the infusion chair. A subcutaneous injection can take minutes and be delivered closer to home. When a pricing rule treats those two things as identical, the incentives across the system can quietly tilt back toward the setting that is easiest to bill — the hospital infusion center — and a patient who was stable on a therapy they could receive close to home may find that option deprioritized or gone.

Here again, the affordability math can invert: a negotiated price that pushes a patient back into a hospital infusion setting can *raise* that patient's real, total cost of care — travel, days of lost work, caregiver time, facility fees, and the cost-sharing that attaches to provider-administered drugs. The burden falls hardest on the patients already carrying the most: those in rural and medically underserved areas who drive hours for specialty care, working-age adults on Medicare through disability for whom a full-day appointment means lost income, and homebound patients who depend on a caregiver to get anywhere.

We ask CMS to withdraw the fixed combination drug modification as currently written; and if it proceeds, to narrow the policy so it targets only genuine attempts to avoid selection or the MFP — not FDA-approved products with their own applications and trials — and to first assess and publish the proposal's effect on site of care, treatment stability, and patients' total cost of care. More broadly, we urge CMS to build access and treatment-stability safeguards into implementation across the program, recognizing that a drug on a formulary is not the same as a drug a patient can actually get, and that patients doing well on a therapy should not be forced off it by a pricing technicality.

III. Does the patient's voice actually count?

CMS has taken real steps to invite patients into this process, and we appreciate that. But inviting patients to speak is not the same as ensuring they are heard, or that their input shapes decisions. We join other patient organizations in urging CMS to strengthen its patient engagement process and to close the loop between patient input and decision-making. Patients who live with these conditions — and the organizations that represent them — repeatedly tell us the current engagement process asks a great deal of them and returns very little in the way of preparation, access, or evidence that their voices mattered. Several concrete improvements would close that gap.

Make participation workable and meaningful. Patients invited to CMS's roundtables often arrive unsure what CMS is asking or what information would be useful. A plain-language briefing sent in advance — with sample questions and suggestions for what to gather beforehand — would let patients prepare thoughtful answers and use the limited time well. Just as important, CMS should let patients speak to how *they* define a medicine's value. The agency rightly asks about clinical

[3]For example, the FDA approved a subcutaneous formulation of nivolumab (Opdivo Qvantig, nivolumab and hyaluronidase-nvhy) on December 27, 2024, under its own Biologics License Application on the basis of the dedicated CHECKMATE-67T trial (NCT04810078), which compared it to intravenous nivolumab. U.S. Food and Drug Administration, *FDA Approves Nivolumab and Hyaluronidase-nvhy for Subcutaneous Injection* (Dec. 27, 2024).

benefit, but patients experience value more broadly: whether they can access and afford the treatment, whether care is continuous, and whether they can stay on a therapy that works without disruption. Those factors are inseparable from clinical outcomes in a patient's real life and should be squarely within scope.

Be transparent about who is chosen, and how. Because seats at roundtables and town halls are limited, CMS effectively decides which patient and caregiver perspectives enter the official record. CMS should publish the criteria it uses to select participants before applications open, so patients and patient organizations can understand whether they are a fit and recruit the right voices — or, if the goal is the broadest possible range of experience, expand participation so fewer qualified patients are turned away.

Meet patients where they are on written comments. An individual patient should not be expected to navigate the same federal rulemaking submission process built for manufacturers and trade associations. CMS should create a separate, plain-language patient submission pathway with clear instructions and questions written for patient experiences — and a distinct pathway for patient organizations, which speak for whole communities and should be able to submit narrative letters and the survey and research evidence they already collect, rather than being forced into standardized text fields written for an individual's personal story. CMS should also schedule the written comment period *after* the roundtables and town halls, so patients can respond to what was discussed and those who applied but weren't selected still have a meaningful way to contribute.

Close the feedback loop. Every cycle, patients and patient organizations invest significant time preparing submissions, applying, and sharing deeply personal experiences — and then hear essentially nothing about what CMS took from it. Beyond a redacted transcript, there is no account of the themes CMS identified, how patient input informed the negotiation, or why some recommendations were not adopted. We urge CMS to publish a **Patient Engagement Summary** after each cycle that names the major themes raised, explains how patient perspectives informed the agency's deliberations, and describes where patient input made a difference. Without that, patients understandably conclude their participation is a formality — and disengage.

Use the patient research that already exists. Patient organizations have spent years developing rigorous methods for collecting patient-reported evidence on affordability, access, and treatment experience. Rather than building engagement tools from scratch, CMS should collaborate with patient organizations and experienced patient-research partners on question design and meaningful endpoints, so the evidence it gathers is both more usable and less burdensome to provide.

Recommendations

Consistent with our support for a negotiation program that genuinely lowers costs for patients, we urge CMS to:

1. **Measure and publicly report whether negotiated savings reach patients** — tracking real out-of-pocket costs and total beneficiary liability across the full benefit, not just the price Medicare or plans pay — so that savings that fail to reach the patient are visible rather than hidden.

2. **Withdraw the proposed fixed combination drug modification as currently written,** because it is too broad to distinguish evasive reformulations from genuine, separately approved therapies patients rely on.

3. **If CMS proceeds, narrow the policy — aggregating products only where FDA confirms the added component has no independent therapeutic or delivery role — and first publish a patient-impact assessment** covering site of care, treatment stability, access for rural, homebound, and working-age patients, and patients' total cost of care.

4. **Build access and treatment-stability safeguards into implementation across the program,** recognizing that formulary coverage is not the same as real access, and that patients stable on a working therapy should not be displaced by a pricing technicality.

5. **Strengthen and make workable the patient engagement process** — advance briefing materials, a broader definition of value, reasonable accommodations, and transparent participant-selection criteria.

6. **Create patient- and patient-organization-specific written comment pathways** in plain language, permit narrative submissions from organizations, and schedule the written comment period after roundtables and town halls conclude.

7. **Publish a Patient Engagement Summary each cycle** that shows patients how their input was used — and collaborate with patient organizations and patient-research partners to improve how patient evidence is gathered.

Patients Rising believes Medicare drug price negotiation should deliver real relief to patients. That is precisely why implementation matters so much. A program that lowers a price on paper — while patients see little savings, lose access to the therapy that works for them, or never learn whether their voices mattered — will not keep the promise it was built on. We urge CMS to keep patients, and their real-world experience of care, at the center of every decision in this rule.

We thank CMS for its work to make medicines more affordable, and we welcome the opportunity to bring patient voices directly into it.

Sincerely,

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