CENTER FOR INDIVIDUAL FREEDOM

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August 17, 2026

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comment of the Center for Individual Freedom in the Matter of Proposed Rule "Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program" (CMS-4215-P) Docket No. CMS-2026-CMS-2026-2080

To Whom It May Concern:

The Center for Individual Freedom (CFIF) hereby submits its Comment to the Centers for Medicare & Medicaid Services (CMS) regarding the above-referenced Proposed Rule.[1] Specifically, CFIF urges CMS to withdraw the proposed modification of § 429.125(b)(4)(i), which would change how the agency identifies a "qualifying single source drug" (QSSD) for purposes of the Medicare Drug Price Negotiation Program beginning with the initial price applicability year (IPAY) 2029.

As proposed, CMS would group an original biologic with a newer formulation of the same active ingredient into a single QSSD. For example, a medicine that was once administered as a lengthy infusion could be modified to allow for a new route of administration, such as a subcutaneous injection. Under the Proposed Rule, however, CMS would unjustifiably treat these medicines as the same product for drug pricing purposes, despite important differences between them.

Such a change would negatively impact innovation and consumer welfare. That's because follow-on innovations require additional research and clinical trials, and each product must receive separate Food and Drug Administration (FDA) approval via distinct applications to ensure that new routes of administration are safe and effective for patients. Continuing the example above, a subcutaneous injection, rather than an infusion, often means less time in the clinic and ultimately lower costs for the healthcare system, including reduced time for physicians and facilities. For patients in rural areas in particular, that can mean the difference between treatment at a local physician's office and a multi-hour drive to an infusion center that may not be readily accessible.

Bringing innovations such as that to patients requires significant time and is already extremely costly. If innovators cannot recoup their investment because the government artificially caps prices below market levels, their incentive to invest in improvements that make treatments easier and more accessible for patients will significantly weaken. Further, the development timelines of these therapies (including initiation of pivotal Phase 3 trials) predate the Inflation Reduction Act (IRA)

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[1] CFIF is a nonprofit organization established in 1998 with the mission of protecting individual liberties, rule of law, market innovation and consumer choice.

becoming law, demonstrating that the investments taken to develop these innovations were done to advance the science and patient benefit, not a means to circumvent negotiation selection as CMS claims in unfounded assertions of “program integrity” for the negotiation program.

That determination, moreover, is not CMS's to make. CMS has not been given authority to override the FDA's product-by-product determinations solely to bring more products into the negotiation program. Congress has routinely directed CMS to defer to the FDA on questions of drug identity, and the instant proposal would stretch CMS’s regulatory authority beyond what Congress has clearly authorized.

Accordingly, CFIF urges CMS to withdraw the proposed modification to § 429.125(b)(4)(i) and preserve the current framework, under which separately approved reformulated products are treated as distinct drugs. The FDA, not CMS, should determine drug product identity, and the negotiation program should reflect how the FDA has actually approved those products.

Patients benefit when companies continue investing in easier, safer ways to take their medicines, and the negotiation program should not penalize that investment before it ever reaches patients. Thank you very much for your attention to this important issue.

Sincerely,

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