August 17, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services

Re: Medicare Program: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program, CMS-4215-P— Qualifying Single Source Drug Classification
Submitted via Regulations.gov

Dear Dr. Oz:

The Partnership to Fight Chronic Disease (PFCD) and the other 50 undersigned organizations write to express our serious concerns about a proposed change to how the Centers for Medicare & Medicaid Services (CMS) identifies qualifying single source drugs (QSSDs) under the Medicare Drug Price Negotiation Program (MDPNP), and about the harms to patient access and innovation that would result. We share the goal of making prescription drugs accessible and affordable to Medicare beneficiaries but have serious concerns about the proposed treatment of fixed-dose combination therapies under the MDPNP. As described in more detail below, treating two separately approved FDA products as a single drug for MDPNP eligibility purposes, dismisses the value of scientific advancements that expand treatment options for people living with serious chronic diseases and discourages the development of new medicines that respond to unmet medical needs. We urge CMS to maintain separate QSSD classifications for FDA-approved fixed-dose combination therapies, including those in which an added active ingredient enables a different route of administration.

The proposed change is a significant departure from Medicare pricing policy to date.

Our concern begins at a broader level. From the MDPNP outset, CMS's working definition of a qualifying single source drug (QSSD) has been overbroad and the proposed change compounds that problem instead of fixing it. Since the first cycle of the MDPNP, CMS has recognized FDA-approved fixed-dose combination products as distinct qualifying single source drugs from their individual active ingredients.[1] The proposed policy departs from that approach, and singles out one narrow category of fixed-dose combination products, by failing to treat those separately approved combination products as separate QSSDs for purposes of the MDPNP.[2]

[1]Centers for Medicare & Medicaid Services. Medicare Drug Price Negotiation Program: Final Guidance for Initial Price Applicability Year 2028 (Sept. 30, 2025), § 30.1. https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf

[2]Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program, Proposed Rule, 91 Fed. Reg. (June 16, 2026) (CMS-4215-P). https://www.federalregister.gov/documents/2026/06/16/2026-12059/medicare-drug-price-negotiation-program-and-medicare-prescription-drug-benefit-program

As a practical example, the proposal would group a therapy administered by intravenous (IV) infusion together with a separately approved product that combines the same therapeutic active ingredient with an additional active ingredient that enables administration by subcutaneous (below-the-skin) injection. These are two different products, each reviewed and approved by FDA on its own record. CMS proposes to treat them as a single QSSD for the purposes of negotiation eligibility. While that may appear to be a technical classification change, it disregards both the innovation involved in developing each product and the substantial benefit patients receive from having more than one treatment option.

New products with new routes of administration are a lifeline for patients.

Single-ingredient products and fixed-dose combination products each play a distinct role in patient care, and patients benefit from having both available. For example, IV therapies allow for more tailored dosing and can be given in combination with other IV agents as part of a chemotherapy or other treatment regimens. An IV infusion typically requires travel to an infusion center or hospital outpatient facility, however, that requires a multi-hour commitment.[3] A new product that adds an active ingredient to enable, for example, subcutaneous administration offers something different and represents a significant advance for patients and their treatment options, since a subcutaneous injection can be administered in minutes, in a physician's office or even at home.[4]

These are not interchangeable experiences, and the availability of both has had a profound impact on treatment accessibility and choice. For patients living with chronic disease, the ability to choose *how* a treatment is administered can mean the difference between having access to treatment and not having access, or between staying on treatment and stopping or experiencing gaps. The availability of a new subcutaneous product makes treatment more accessible to people living in rural or other underserved areas in terms of limited access to infusion facilities as well as for people with challenges with access to transportation or personal or caregiver leave from work.

The people most affected by this distinction are often those least able to absorb additional burden: rural patients who may live hours from an infusion center, elderly patients, and family

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[3]Partnership to Fight Chronic Disease. *How a Proposed Rule Could Impact Treatment Options for Patients Living With Chronic Disease.* https://www.fightchronicdisease.org/post/how-a-proposed-rule-could-impact-treatment-options-for-patients-living-with-chronic-disease

[4]Bril V, et al. "Patient-reported preferences for subcutaneous or intravenous administration of biologic therapies." Journal of Patient-Reported Outcomes. 2024. https://pubmed.ncbi.nlm.nih.gov/39115099/

caregivers, and individuals without reliable transportation. When given the choice, **71% of patients prefer injection over IV administration** for a given therapy.[5]

Medical advancements that facilitate access, enable patient and provider treatment choice, and lessen the burden of treatment on patients and caregivers should be recognized and encouraged. CMS's proposed approach ignores both the innovation that new products with new routes of administration represent and their value to patients and should be rejected.

This proposal disregards FDA's scientific expertise and recognized distinctions between products.

A new product that combines a therapeutic active ingredient with an additional active ingredient that enables a new route of administration is not a reformulation of an existing drug. It is a distinct product with a different composition, developed over years of dedicated research. These therapies each require significant clinical investment and are approved only after an independent FDA review that assesses the combination, the delivery device, pharmacokinetics, and safety in the care setting intended for use.[6]

FDA's own regulations make this distinction clear. Under the agency's fixed-combination rule, two or more drugs may be combined in a single dosage form only where each component "contributes to the claimed effects." [7] That regulation includes the case in which a component is added to enhance the safety or effectiveness of the principal active component. An added ingredient that meets that standard is not incidental; it is an active component that FDA has evaluated on its own terms. Accordingly, a fixed-dose combination product is a distinct medicine as a matter of FDA's regulatory framework. CMS has relied on that same regulation in identifying qualifying single source drugs to date.

Whether two products are distinct medicines is a scientific and regulatory question that Congress assigned to FDA, and FDA has already answered it through separate approvals. We urge CMS to follow FDA's determination that these are distinct products and not change the current definition for QSSD.

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[5]Overton PM, et al. "Patient Preferences for Subcutaneous versus Intravenous Administration of Anti-Cancer Therapies." JTO Clinical and Research Reports, 2025; Article S2666-3643(25)00031-1. https://www.jtocrr.org/article/S2666-3643(25)00031-1/fulltext

[6] Badkar AV, Gandhi RB, Davis SP, et al. Subcutaneous Delivery of High-Dose/Volume Biologics: Current Status and Prospect for Future Advancements, Drug Des Devel Ther. 2021:159-170. https://pubmed.ncbi.nlm.nih.gov/33469268/; Bittner B, et al. "Advancing Subcutaneous Dosing Regimens for Biotherapeutics." Clinical Pharmacology & Therapeutics. 2023;114(4):620–632. https://pubmed.ncbi.nlm.nih.gov/37831325/

[7]21 C.F.R. § 300.50, Fixed-combination prescription drugs for humans. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-300/subpart-B/section-300.50

The consequences for patient-focused innovation are real and lasting.

The proposed change to the definition of a qualifying single source drug (QSSD) would have Medicare disregard exactly the kind of innovation that helps treatments benefit more patients: new products designed to expand where and how patients receive treatment. Medicare policy should recognize and protect patient access to innovative therapies, not discount their value, introduce new non-medical barriers to care, or worsen health outcomes. Medicare beneficiaries want the opposite. For example, in defining "unmet medical need", which is a key criteria for CMS during Medicare's Drug Price Negotiation process, people living with chronic conditions value innovations that from their perspective ease "treatment administration," have "similar outcomes but a superior mode of administration," or are able to be "taken at home."[8] CMS policy should recognize and value such innovation as well.

We urge CMS to:

1. **Maintain separate QSSD classifications for FDA-approved fixed-dose combination therapies,** including those in which an added ingredient enables a different route of administration, consistent with the approach CMS has applied since the program began.
2. **Protect patient access to innovative therapies** by ensuring that Medicare policy does not eliminate the incentive to develop new products that expand where and how patients can be treated.

Patients have fought hard for access to treatments that fit their lives and not just their diagnoses. Medicare policy should continue to honor that progress, not reverse it.

We appreciate the agency's consideration of these comments and welcome further dialogue on this critical issue.

Respectfully submitted,

AiArthritis
AIDS Delaware
Alabama Independent Pharmacy Alliance
Alliance for Aging Research
American Behcet's Disease Association (ABDA)
Biomarker Collaborative
Bioscience Association of West Virginia
Bleeding Disorders Council of California
Brain Injury Assoc. of NE

[8] Defining "Unmet Medical Need" in the Inflation Reduction Act for the Maximum Fair Price: Reflecting Patient Input. June 2023, available online at https://www.fightchronicdisease.org/_files/ugd/b11210_0315d9aea91749d685745c71c2fdf920.pdf.

Cancer Support Community
CancerCare
Capability Consulting
Chronic Care Policy Alliance
Combined Health Agencies Drive- Nebraska
Easterseals Iowa
Equitas Health
Exon 20 Group
H.E.A.L.S. of the South
ICAN, International Cancer Advocacy Network
Indiana Life Sciences Association
Infusion Access Foundation
Infusion Providers Alliance
International Association of Hepatitis Task Forces
Iowa State Grange
Kentucky Life Sciences Council
Latinos for Tennessee
LUNGevity Foundation
Lupus and Allied Diseases Association, Inc.
ManageHealthCareCosts.com
Melanoma Research Foundation
Men's Health Network
MET Crusaders
Michigan Biosciences Industry Association (MichBio)
National Grange
Nebraska State Grange
Neuropathy Action Foundation
No Bone Left Behind Alabama
North Carolina Grange
NRG1 Energizers
Ohio State Grange
Oncology Managers of Florida
Partnership to Fight Chronic Disease
Patients Rising
PDL1 Amplifieds
Prevent Blindness Wisconsin
Quality Connection
Schaefer Technologies, Inc.
Sickle Cell Disease Association of America-Mobile, Alabama
The Legacy Society
The Tanner Foundation for Neurological Diseases
Tigerlily Foundation