COALITION AGAINST SOCIALIZED MEDICINE

a Project of THE CONSERVATIVE POLITICAL ACTION COALITION

To:	**Hon. Robert F. Kennedy, Jr., Secretary, US Department of Health and Human Services** **Hon. Mehmet Oz, Administrator, Centers for Medicare and Medicaid Services**
From:	**Andrew Langer, Executive Director, Coalition Against Socialized Medicine**
Date:	**August 17, 2026**
Re:	**Comments from the Coalition Against Socialized Medicine on the Centers for Medicare and Medicaid Services Notice of Proposed Rulemaking, "Medicare Program: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program," Docket #CMS-2026-2080, File Code CMS-4215-P, Published June 16, 2026**

The Coalition Against Socialized Medicine (hereafter "CASM") respectfully submits the following comments in response to the Centers for Medicare and Medicaid Services Notice of Proposed Rulemaking, "Medicare Program: Medicare Drug Price Negotiation Program and Medicare Prescription Drug Benefit Program," Docket #CMS-2026-2080, File Code CMS-4215-P, Published June 16, 2026

CASM is a coalition of allied free-market limited-government policy research, education, and advocacy organizations, and is led by the Conservative Political Action Coalition ("CPAC"), a non-profit, non-partisan 501(c)(4) research, education, and advocacy organization based in Alexandria, Virginia.

Our coalition is dedicated to defending the free-market principles that uphold America's healthcare system. We support reforms that protect and promote biopharmaceutical innovation and ensure our foreign allies pay their fair share by rejecting foreign government price controls that distort competitive markets and undervalue critical American medicines. CASM champions patient-centered, market-based solutions that expand access to care, improve outcomes, and reduce costs for both patients and taxpayers.

INTRODUCTION

The Coalition Against Socialized Medicine ("CASM") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") proposed regulations governing the Medicare Drug Price Negotiation Program for initial price applicability year ("IPAY") 2029 and subsequent years. CASM recognizes the importance of making medicines affordable, protecting Medicare beneficiaries, and maintaining access to effective treatment. These objectives, however, cannot be evaluated solely by examining near-term government expenditures. Policies intended to reduce current prices must also account for their effects on future treatment options, patient choice, and medical innovation.

CASM is a nationwide coalition dedicated to protecting patients from government-controlled healthcare and opposing price controls that interfere with competition, innovation, and individualized medical decision-making. CASM supports market-based policies that expand access, encourage competition, and reward the development of safer, more effective, and more convenient treatments. These comments focus specifically on CMS's proposed treatment of certain fixed-dose combination ("FDC") drugs and other follow-on medicines when identifying qualifying single-source drugs ("QSSDs") for purposes of the Negotiation Program.

Congress created the Negotiation Program through the Inflation Reduction Act of 2022 ("IRA"). An initial price applicability year is the year in which a negotiated maximum fair price takes effect for a selected medicine. The proposed rule would codify CMS's implementation of the IRA program for IPAY 2029 and subsequent years, following implementation of earlier years largely through program guidance. Those implementation decisions matter. CMS can administer the statute narrowly, or it can magnify the IRA's adverse effects on innovation by extending price controls to additional patient-benefiting therapies.

CMS proposes to aggregate certain separately approved FDC drugs and follow-on formulations with an original medicine when identifying a potential QSSD. The proposal would apply when products held by the same New Drug Application or Biologics License Application holder share an active moiety, active ingredient, or antigen component, and an additional component creates a new formulation and enables an alternative route of administration. CMS could consequently treat dosage forms and strengths associated with separately approved products as parts of a single drug for negotiation purposes.

Separate approval by the Food and Drug Administration may reflect distinct clinical evidence, trials, scientific review, safety considerations, manufacturing requirements, formulations, labeling, and patient benefits. A shared active ingredient does not make complete therapies clinically or practically identical. By aggregating these products, CMS would disregard the regulatory and real-world significance of their differences for negotiation purposes. The newer therapy could inherit the expenditure history, negotiation timeline, and pricing treatment of an older medicine, substantially reducing the incentive to undertake the research and investment necessary to develop meaningful improvements.

Accordingly, CASM urges CMS to withdraw or substantially revise the proposed QSSD aggregation policy for FDC and follow-on medicines. Separately approved products should

remain distinct when they provide clinically or practically meaningful differences, including improved safety, effectiveness, tolerability, adherence, convenience, or administration. The discussion below explains how the proposal could discourage continuing innovation, distort development incentives, reduce patient choice, and harm rural and underserved communities. It also recommends a more targeted response to legitimate program-integrity concerns that preserves competition and protects patient-benefiting innovation.

EXECUTIVE SUMMARY

CASM's comments address CMS's proposal to aggregate certain separately approved fixed-dose combination drugs and follow-on therapies with older medicines when identifying qualifying single-source drugs. CMS should not magnify the Inflation Reduction Act's price-control effects by treating meaningful, independently approved improvements as mere extensions of earlier products. Although CMS may appropriately address genuine attempts to circumvent the Negotiation Program, its proposed approach risks sweeping legitimate medical advances into an overbroad aggregation policy and discouraging the development of better treatment options for patients.

Our comments address the following:

- **The Inflation Reduction Act established the Medicare Drug Price Negotiation Program, but CMS should not use implementation decisions to enlarge its practical reach.** Aggregating additional, separately approved medicines would compound the IRA's effects by extending an older product's negotiation treatment to newer therapies that required additional research, development, and regulatory approval.
- **Separately approved FDC and follow-on products may require distinct development programs, clinical evidence, FDA applications, and independent regulatory review.** A shared active ingredient does not establish that two complete therapies are scientifically, clinically, or practically identical. CMS should account for the significance of separate approval when identifying a QSSD.
- **Aggregation would disregard meaningful distinctions between an original medicine and a newer therapy for Medicare negotiation purposes.** Different formulations, combinations, dosing schedules, and delivery systems may present distinct considerations involving effectiveness, safety, tolerability, adherence, administration, and patient experience.
- **Medical innovation continues after a medicine receives its initial approval.** Continued research may yield improved formulations, combinations, dosing schedules, delivery technologies, and routes of administration. Medicare policy should reward this continuing development rather than create a structural preference for older, potentially more burdensome versions of a treatment.
- **Follow-on innovation can materially transform how patients receive care.** A medicine previously administered through a lengthy infusion may be improved and offered as a subcutaneous injection. Such advances can reduce treatment time, simplify administration, improve adherence, lessen demands on healthcare facilities, and expand the settings in which patients can receive treatment.

- **Applying an older medicine's negotiation history to a newer, separately approved therapy would change the economics of developing that improvement.** Aggregation could shorten the effective period available to recover the costs and risks associated with additional research, clinical development, regulatory review, manufacturing, and market introduction.
- **Research and development decisions are made prospectively and often years before a product reaches patients.** If developers expect a successful follow-on therapy to inherit the pricing treatment of an older medicine, promising projects may be narrowed, delayed, or abandoned before their potential clinical and practical benefits can be realized.
- **Rural and underserved communities may bear disproportionate consequences.** Patients in these communities frequently face long travel distances, limited specialist availability, transportation barriers, and fewer infusion facilities. Therapies that simplify administration or permit treatment outside specialized settings may therefore provide especially important access benefits.
- **Fewer formulations and delivery options would weaken competition and patient choice.** Patients differ in their health, mobility, treatment tolerance, work obligations, caregiving support, and access to medical facilities. Multiple treatment options allow patients and clinicians to select the therapy best suited to those individual circumstances.
- **CMS should distinguish genuine circumvention from meaningful follow-on innovation through objective, patient-centered criteria.** Shared ingredients, common ownership, a new formulation, and an alternative route of administration should not automatically establish that a product is merely an attempt to avoid negotiation.
- **The final rule should recognize separately approved products as distinct medicines when they provide material patient benefits.** Relevant considerations should include clinical outcomes, safety, tolerability, adherence, dosing, treatment time, administration burdens, site-of-care flexibility, healthcare-resource use, access, and convenience.
- **Market competition and continued innovation provide a more durable path to better outcomes and lower costs than expanding government price controls.** Additional therapies can create competition among formulations, delivery methods, treatment settings, and care regimens while reducing costs and burdens beyond the acquisition price of the medicine itself.

Patient-benefiting improvements should not be presumed to be attempts to evade negotiation merely because they share an active ingredient with an older medicine. CMS should revise the proposal so that the Negotiation Program does not discourage continued development after initial approval or deprive patients of better future treatments. Preserving meaningful distinctions among separately approved medicines would advance affordability, expand access, protect patient and clinician choice, and sustain the long-term innovation necessary to improve healthcare outcomes.

I. THE PROPOSED RULE IMPLEMENTS THE INFLATION REDUCTION ACT'S PRICE-NEGOTIATION PROGRAM

Congress created the Medicare Drug Price Negotiation Program through the Inflation Reduction Act of 2022. The program authorizes CMS to negotiate maximum fair prices for selected high-expenditure, single-source medicines covered under Medicare Parts B and D. An initial price applicability year identifies the year in which an agreed maximum fair price becomes effective. IPAY 2029 is particularly significant because CMS may select up to 20 qualifying medicines for negotiation, including both Part B and Part D products, with the resulting prices taking effect during 2029.

For IPAYs 2026 through 2028, CMS implemented the Negotiation Program primarily through program instructions and other forms of guidance, as directed by the IRA. The present proceeding would move major elements of the program into formal regulations governing IPAY 2029 and subsequent years. These rules will therefore shape recurring selection, negotiation, renegotiation, and price-effectuation decisions well into the future. Codification makes it especially important for CMS to evaluate how its definitions and classification policies will affect long-term research incentives, treatment availability, and patient access.

The IRA's negotiation requirements changed the expected economic return from medicines that may become subject to government-negotiated prices. Developing a medicine requires substantial investment undertaken amid scientific, regulatory, manufacturing, and commercial uncertainty. Decisions about which projects to pursue depend partly on the expected opportunity to recover those costs and risks when research succeeds. Not every reduction in expected revenue will eliminate a particular development program. Nevertheless, diminished returns can influence which projects receive funding, how broadly they are pursued, and whether promising improvements advance to patients.

Against that statutory background, CMS now proposes its own method for identifying certain QSSDs, including the aggregation of some separately approved FDC and follow-on products with older medicines. This implementation choice is distinct from the IRA's underlying creation of the Negotiation Program. By causing a newer therapy to inherit the negotiation history and pricing treatment of an earlier product, the proposal would compound the statute's existing effects on development incentives. CMS should avoid classification policies that unnecessarily extend those disincentives to continued, patient-benefiting innovation.

II. CMS PROPOSES TO AGGREGATE CERTAIN SEPARATELY APPROVED FOLLOW-ON MEDICINES

Identifying a QSSD is a foundational step in administering the Negotiation Program. That classification affects which products CMS evaluates together, how it calculates total Medicare expenditures, whether a medicine becomes negotiation-eligible, and which dosage forms and strengths are ultimately subject to an agreed maximum fair price. CMS generally proposes to aggregate dosage forms and strengths that share specified ingredients and application holders.

Because each subsequent determination builds on the initial classification, the method CMS uses to define a single drug carries significant consequences throughout the negotiation process.

Fixed-dose combination medicines generally contain two or more active ingredients or components combined within a single product. Under CMS's general FDC policy, products containing distinct combinations of active ingredients have previously been evaluated separately from medicines containing only one of those ingredients or a different combination. That approach appropriately recognizes that adding an active component can produce a therapy with different clinical properties, dosing requirements, safety considerations, methods of administration, and patient benefits. Separate treatment can therefore reflect substantive differences rather than superficial distinctions in packaging or marketing.

CMS now proposes a modification under which it would aggregate certain combination products or new formulations with an earlier medicine. The policy would apply when products belonging to the same New Drug Application or Biologics License Application holder share an active moiety, active ingredient, or antigen component, while an added component creates a new formulation and enables an alternative route of administration. CMS would then identify the potential QSSD using the dosage forms and strengths containing the shared component, including applicable products approved through separate applications.

Aggregation could combine expenditures associated with older and newer products when CMS determines negotiation eligibility and ranks eligible medicines for potential selection. It could therefore affect whether and when the combined QSSD becomes subject to negotiation. Once selected, CMS could apply the agreed maximum fair price across the products treated as dosage forms or strengths of the same selected drug. A separately approved follow-on therapy could consequently inherit the expenditure history, negotiation timetable, and pricing consequences associated substantially with a medicine that entered the market years earlier.

CASM opposes treating shared ingredients as sufficient grounds to erase meaningful distinctions among separately approved medicines. Products containing the same active ingredient are not necessarily identical in their complete clinical profiles, administration requirements, patient experiences, development costs, or practical value. CMS should preserve separate treatment for follow-on therapies that provide genuine improvements in safety, effectiveness, tolerability, adherence, convenience, access, or delivery. A properly targeted policy can address functionally duplicative products without discouraging innovations that produce better treatment options for patients.

III. SEPARATE FDA APPROVALS REFLECT MEANINGFUL PRODUCT DISTINCTIONS

A separate FDA approval is not merely a marketing distinction or a different label attached to an existing medicine. Depending on the product and application, a follow-on therapy may require its own development program, application, supporting evidence, clinical trials, manufacturing information, proposed labeling, and regulatory review. The precise requirements vary according to the nature of the product and the basis for approval. Nevertheless, separate approval ordinarily

reflects an evaluation of the complete therapy rather than the shared active ingredient considered in isolation.

Different formulations, combinations, and routes of administration may produce distinct considerations involving safety, effectiveness, dosing, tolerability, adherence, storage, administration, and clinical monitoring. The same active ingredient can appear in therapies that impose materially different demands on patients, caregivers, clinicians, and healthcare facilities. A product delivered through a lengthy infusion, for example, may create a very different treatment experience from one administered through a subcutaneous injection. Active-ingredient overlap is therefore an incomplete measure of whether two therapies are medically or practically distinct.

FDA bears responsibility for scientifically evaluating whether a product satisfies the applicable standards for approval, while CMS administers Medicare coverage, payment, and negotiation policies. Those responsibilities are different but intersect when CMS classifies separately approved products for negotiation. CMS should account for product distinctions recognized through FDA's review rather than treating separate approvals as irrelevant whenever therapies share an ingredient and application holder. Disregarding those approvals without a careful, evidence-based assessment risks substituting an administratively convenient pricing classification for a more complete understanding of the products involved.

Accordingly, CMS should treat separately approved therapies as distinct medicines when the evidence demonstrates meaningful clinical or practical differences. The final policy should examine the complete product and its benefits for patients, including improvements in safety, effectiveness, tolerability, adherence, dosing, administration, treatment time, convenience, and access. Shared ingredients and common ownership should not control that determination. Respecting meaningful distinctions would preserve incentives for patient-benefiting innovation while leaving CMS able to address products that are functionally duplicative and offer no material improvement.

IV. MEDICAL INNOVATION CONTINUES AFTER A MEDICINE'S INITIAL APPROVAL

Initial FDA approval is often one stage in a medicine's development rather than the endpoint of innovation. Researchers may continue studying improved formulations, new combinations, more manageable dosing schedules, better delivery technologies, and alternative routes of administration. This work can make an established therapy safer, more effective, more accessible, or easier to use. Valuable medical progress does not always require discovering an entirely new active ingredient. It can also result from improving how an existing medicine reaches patients and performs under real-world conditions.

Follow-on innovation can reduce dosing frequency, eliminate administration steps, provide more predictable delivery, improve tolerability, simplify storage, or lessen monitoring requirements. These changes may appear incremental when considered separately, but they can determine whether patients begin treatment, follow the prescribed regimen, or complete a necessary course

of therapy. Product design affects real-world performance because medicines provide little benefit when patients cannot obtain, tolerate, or use them consistently. Improvements that reduce practical barriers can therefore produce meaningful clinical value even when the underlying active ingredient remains unchanged.

Consider a medicine initially administered through a lengthy infusion that is later developed as a subcutaneous injection. The improved version may substantially reduce treatment time, reliance on infusion facilities, patient travel, clinical staffing demands, and disruption to work or family responsibilities. It may also permit treatment in additional settings or make care more manageable for patients with mobility or transportation limitations. Although the therapies share an active ingredient, their administration requirements and effects on patients' daily lives may differ materially.

Healthcare progress frequently occurs through a succession of meaningful refinements rather than a single transformative discovery. No individual improvement must revolutionize treatment to deliver substantial benefits when applied across a large patient population. Shorter appointments may improve adherence; simpler administration may reduce errors; better tolerability may prevent discontinuation; and greater site-of-care flexibility may expand access. These advantages can reinforce one another, converting what appears to be a modest formulation or delivery change into a significant improvement in patients' ability to receive and sustain effective treatment.

The Negotiation Program should not create a structural preference for first-generation formulations over improved versions of the same medicine. If CMS causes a newer therapy to inherit the negotiation treatment of an older product, developers may have less incentive to pursue improvements that require additional research, clinical evaluation, and regulatory approval. Patients could consequently remain dependent on more burdensome treatment methods even when better alternatives are scientifically possible. CMS should preserve incentives for continued development whenever an improved therapy offers identifiable clinical, practical, or access-related value.

V. THE AGGREGATION POLICY WOULD WEAKEN INCENTIVES FOR FOLLOW-ON RESEARCH

Research decisions are made years before a medicine reaches patients and often before its prospects can be predicted with confidence. Developers must account for scientific uncertainty, clinical-testing costs, regulatory review, manufacturing development, potential safety or effectiveness failures, and the risk that an approved product will not achieve broad adoption. Before committing personnel and capital, they necessarily compare those costs and risks with the expected opportunity for a successful therapy to earn a return. Government pricing policy becomes part of that prospective calculation.

Aggregating a newer therapy with an older medicine could cause the follow-on product to inherit the original product's negotiation timeline and pricing treatment. The improvement may therefore have substantially less time to recover its distinct research, clinical, regulatory,

manufacturing, and introduction costs than it would receive if evaluated separately. This is not merely the ordinary commercial risk that accompanies product development. It is an additional policy-created risk arising because CMS would base consequential aspects of the newer therapy's treatment on the history of a medicine approved years earlier.

The proposal would influence projects still being considered, not only therapies that have already received approval. If developers expect a successful follow-on product to receive no distinct treatment under the Negotiation Program, they may narrow its development program, postpone investment, or abandon the project entirely. These decisions generally occur outside public view and long before CMS could measure their effects through claims or expenditure data. Patients cannot benefit from improved formulations, combinations, or delivery methods that never progress beyond the planning stage.

Resources may also shift away from improving established medicines and toward projects less exposed to CMS's aggregation policy. Follow-on development can sometimes reach patients more quickly or with less scientific uncertainty than research involving an entirely new therapeutic approach, while still producing meaningful improvements in safety, tolerability, adherence, administration, or access. Government policy should not artificially make this form of innovation less attractive merely because it builds upon an existing active ingredient. Research priorities should respond to patient needs and medical opportunity rather than avoidable regulatory distortions.

Over time, the cumulative result could be fewer formulations, fixed-dose combinations, delivery systems, dosing options, and routes of administration. Because pharmaceutical development pipelines extend across many years, these losses may emerge gradually and prove difficult to trace to any single regulatory decision. An exclusive focus on immediate negotiation expenditures would overlook treatments that were delayed, narrowed, or never developed. CMS should evaluate these dynamic effects and recognize that preserving incentives for continued improvement is essential to future access, competition, and patient welfare.

VI. PATIENTS WOULD BEAR THE CONSEQUENCES OF REDUCED FOLLOW-ON INNOVATION

The value of a follow-on medicine should be assessed by its effects on patients, not solely by whether it shares an active ingredient with an earlier product. A treatment's effectiveness in actual practice can depend on whether patients can access it, tolerate it, and realistically incorporate it into their lives. Improvements in formulation, dosing, delivery, and administration can reduce barriers that prevent patients from receiving the intended clinical benefit. Those practical differences are therefore relevant to health outcomes and should inform CMS's treatment of separately approved therapies.

Simpler dosing and administration can improve adherence by reducing missed treatments, incomplete courses, and avoidable discontinuation. A therapy that requires less time, causes less discomfort, or presents fewer logistical complications may be more sustainable for patients receiving long-term care. These improvements can also reduce opportunities for administration

errors and ease demands on caregivers. Their clinical importance does not disappear because the improved product shares an active ingredient with an earlier medicine. The complete treatment experience, rather than ingredient overlap alone, determines whether many patients can use a therapy successfully.

Patients also differ in age, health status, mobility, treatment tolerance, caregiving support, work responsibilities, and proximity to appropriate healthcare facilities. A formulation suitable for one person may be impractical or unnecessarily burdensome for another. Multiple formulations and administration methods allow patients and clinicians to choose among options based on individual clinical and practical circumstances. By weakening incentives to develop those alternatives, CMS could move treatment toward a one-size-fits-all model that fails to recognize meaningful differences among patients and the settings in which they receive care.

Rural and underserved communities may experience especially serious consequences. Patients in these areas can face long travel distances, limited specialist availability, unreliable transportation, and fewer infusion centers or other facilities equipped to administer complex treatments. A less burdensome route of administration may reduce dependence on scarce healthcare infrastructure and make treatment possible closer to home. When policy discourages those improvements, the resulting loss is not distributed evenly. It falls most heavily on patients who already encounter the greatest practical obstacles to obtaining necessary care.

Access must be understood to include the availability of better future treatments, not merely the current price of an existing medicine. A policy may appear to produce immediate savings while also discouraging improvements that would reduce treatment burdens, expand care settings, or help patients remain on therapy. Those foregone benefits may be difficult to observe, but they are no less important. CMS should incorporate long-term patient access into its final policy and avoid an aggregation standard that sacrifices future treatment options for short-term expenditure reductions.

VII. FOLLOW-ON INNOVATION PROMOTES COMPETITION, CHOICE, AND AFFORDABILITY

Competition in healthcare occurs not only among medicines with unrelated chemical compositions but also among formulations, delivery methods, treatment settings, and therapeutic regimens. A follow-on product may compete with an older therapy by offering shorter administration, greater convenience, improved tolerability, or more flexible sites of care. Those advantages can pressure existing options to improve their value and encourage further development throughout the market. Treating competition as limited to entirely different active ingredients overlooks important ways in which therapies compete to meet the needs of patients and clinicians.

The acquisition price of a medicine represents only one component of the total cost of treatment. A lengthy infusion may also require specialized facility time, clinical staffing, patient transportation, additional monitoring, time away from work, and assistance from family caregivers. An improved formulation or route of administration may reduce some of these

burdens even if its purchase price is not lower. CMS should therefore consider costs across the full course of care rather than assume that expanding negotiated pricing necessarily produces the greatest overall savings for patients or the healthcare system.

Additional treatment options allow patients and clinicians to make decisions reflecting individual medical needs and practical circumstances. One patient may prioritize a familiar administration method, while another may need a therapy compatible with limited mobility, employment, caregiving responsibilities, or distance from a treatment facility. Aggregating meaningfully distinct products under a single pricing treatment can weaken incentives to create and maintain those choices. A competitive, patient-centered healthcare system depends on preserving alternatives and allowing clinical value to emerge through the decisions of patients and their healthcare professionals.

Government price controls may reduce the prescribed price of selected products while simultaneously weakening incentives for future competition and improvement. Durable affordability depends on continued innovation, market entry, competing treatment alternatives, and pressure to deliver greater value throughout the course of care. Policies that suppress those forces can exchange visible short-term savings for less choice and higher burdens over time. CASM supports market-based healthcare policies that reward patient value, encourage better therapies, and allow competition to improve both outcomes and affordability.

VIII. CMS SHOULD DISTINGUISH PROGRAM INTEGRITY FROM GENUINE INNOVATION

CMS expresses concern that a manufacturer could introduce a new formulation to avoid or delay selection of an older medicine for negotiation or to shift utilization away from a product already subject to a maximum fair price. CASM recognizes that the agency may address genuine attempts to circumvent lawful program requirements. The possibility of abuse, however, does not establish that all follow-on development presenting similar structural features is abusive. CMS must distinguish strategies lacking meaningful patient value from legitimate efforts to improve treatment.

The proposed criteria risk treating patient-benefiting innovation as a threat to program integrity. CMS emphasizes shared active ingredients, common application holders, formulation changes, and alternative routes of administration. Yet those same characteristics may describe an important medical advance. A new component that permits subcutaneous administration, for example, may reduce treatment time, facility dependence, travel, and staffing needs. CMS should not presume circumvention from the very features that enable a follow-on therapy to provide meaningful clinical, practical, or access-related benefits.

A more appropriate policy would establish an objective meaningful-difference standard for separately approved products. CMS should consider differences in safety, effectiveness, tolerability, adherence, dosing frequency, treatment duration, administration requirements, site-of-care flexibility, healthcare-resource use, and patient access. No single factor must control every determination, but CMS should evaluate the product as a whole and identify whether it

offers material value beyond the earlier medicine. Such an inquiry would better separate functionally duplicative products from genuine innovations deserving distinct treatment.

CMS should explain what evidence would demonstrate a meaningful clinical or practical difference and apply that standard through consistent procedures. Manufacturers should have a timely opportunity to submit clinical findings, patient-experience information, administration data, healthcare-resource evidence, and other relevant material before CMS makes an aggregation determination. The agency should also consult FDA and appropriate clinical experts when scientific or therapeutic questions arise. Ad hoc or retrospective classifications would create uncertainty during development programs that require significant commitments years before approval.

A carefully limited anti-circumvention policy can protect program administration without suppressing legitimate follow-on innovation. Functionally duplicative products that offer no material improvement need not receive the same treatment as separately approved therapies delivering demonstrable patient benefits. The final rule should reflect that distinction and use the least restrictive approach capable of addressing CMS's stated concern. By narrowing its policy, CMS can preserve program integrity while reducing the risk that patients will be denied safer, more accessible, or less burdensome future treatments.

IX. CMS SHOULD REVISE THE QSSD/FDC POLICY BEFORE FINALIZING THE RULE

CMS should withdraw proposed § 429.125(b)(4)(i) in its current form and preserve separate QSSD treatment for independently approved FDC and follow-on products that provide meaningful clinical or practical differences. Sharing an active ingredient and the same application holder should not determine whether complete therapies are treated as a single drug. The final policy should instead recognize distinctions involving safety, effectiveness, tolerability, adherence, administration, treatment burden, and access. These considerations better reflect whether a newer product delivers value beyond the original medicine.

If CMS retains an aggregation policy, it should establish a clear exception for separately approved products that provide material benefits to patients. Aggregation should require an individualized, evidence-based determination addressing the newer therapy's complete clinical and practical profile. CMS should consider the product's effects on dosing, treatment time, administration setting, healthcare-resource use, travel, caregiving burdens, and continuity of care. A presumption based principally on ingredient overlap and common ownership would not adequately distinguish functionally duplicative products from meaningful improvements.

Developers also need objective criteria they can understand before committing resources to follow-on research. Development decisions often precede FDA approval and market entry by many years, making predictable classification essential to informed investment. CMS should publish sufficiently detailed standards, examples, evidentiary expectations, and decision procedures to reduce uncertainty. The agency should also create a timely process through which developers may obtain guidance concerning the anticipated treatment of contemplated FDC or

follow-on products before making irreversible research, clinical, and manufacturing commitments.

Finally, CMS should monitor the policy's effects on follow-on research, FDA approvals, available treatment options, administration settings, and patient access. Particular attention should be paid to therapies that reduce facility dependence and to consequences for rural and underserved communities. CMS should reconsider the policy if evidence shows reduced development of meaningful improvements, fewer treatment choices, or disproportionate access effects. Program performance should be measured through patient-centered outcomes and long-term innovation, not solely through immediate reductions in Medicare expenditures.

CONCLUSION

CASM appreciates CMS's consideration of public input as it establishes formal regulations governing the Medicare Drug Price Negotiation Program for IPAY 2029 and subsequent years. Making medicines affordable, protecting Medicare beneficiaries, and administering public programs responsibly are important objectives. Those goals, however, should not be pursued in a manner that sacrifices future treatment advances or restricts the options available to patients and clinicians. A durable policy must consider not only immediate expenditures but also its long-term effects on access, competition, and innovation.

Separately approved FDC and follow-on medicines may require independent research, clinical evidence, FDA applications, regulatory review, manufacturing development, and investment. They may also provide patient benefits that are not captured by examining a shared active ingredient in isolation. Ingredient overlap does not make complete therapies clinically or practically interchangeable. CMS should respect meaningful distinctions reflected through separate approval and evaluate whether a newer product improves safety, effectiveness, tolerability, adherence, administration, convenience, or access before treating it as part of an older medicine.

Medical innovation continues long after a medicine first enters the market. Continued research can produce better formulations, useful combinations, simpler dosing, improved delivery technologies, and less burdensome administration methods. Aggregating these products with older medicines can reduce the expected opportunity to recover the costs and risks of developing those improvements. Because research decisions are made years in advance, the consequences will extend throughout the future development pipeline and may appear as promising therapies that are narrowed, delayed, or never pursued.

Patients would ultimately bear those consequences through fewer treatment options, greater administration burdens, reduced adherence, and diminished access to care. Rural and underserved communities may be especially affected when lost innovations would have reduced travel or dependence on specialized facilities. Discouraging alternative formulations and delivery methods can also weaken competition, limit patient and clinician choice, and work against long-term affordability. Patient-centered innovation should be recognized and rewarded, not presumed to constitute circumvention merely because it builds upon an existing medicine.

Accordingly, CMS should withdraw or substantially revise its proposed QSSD aggregation policy for certain FDC and follow-on medicines. Separately approved products offering meaningful clinical or practical benefits should receive separate treatment under the Negotiation Program, supported by objective criteria and evidence-based determinations. Market-based healthcare policies that reward innovation, preserve patient choice, and encourage competition provide the strongest foundation for improved outcomes and lower healthcare costs over time. CMS should adopt a final rule that protects those forces rather than extending government price controls to additional patient-benefiting therapies.

Sincerely,

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