CAPITOL STREET

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CMS Addresses Combo Drug Gaming for 2029 (Part B)

2029-30 Pricing Floor Proposed as Small Biotech Exclusion Expires

Relevant Companies

Our Take & Next Up

To prevent drugmakers from adding a new ingredient, formulation or administration route to evade Medicare price negotiation, CMS proposes to change its 'fixed combination' drug policy in 2029+ (BMY, MRK, JNJ, HALO, others) as a program integrity move. CMS released (here) 2029 rules which codify the Medicare Drug Price Negotiation Program (as required by law). CMS says that fixed-dosed combos – including those with hyaluronidase – would be considered as negotiation eligible products if they share the same active ingredient and same NDA/BLA holder, but have different additives for route of administration. Previously, we projected that CMS was likely to revisit this 'gaming' policy. See our 2028 analysis here.

Incremental positive for small biotech as "small biotech exception" (SBE) sunsets. The small biotech exception (ending after 2028) will not be codified. However, small biotech drugs may apply to CMS for a temporary floor on their negotiated prices for 2029 and 2030. This policy supports continued innovation while maintaining fairness for small biotech companies, according to CMS. The definition of a "small biotech" remains consistent with the SBE: small-volume drugs that are (1) equal to or less than 1% of the total Part B or D drug spend; and (2) at least 80% of the manufacturer's Part B or D spend.

The 60-day comment period closes on August 17, 2026. The final rule will be released in Fall 2026 with 2029 selected drugs expected to be announced by February 2027. Additionally, 2028 negotiated prices will be released this Fall before November 30, 2026. Our take on the next round of pricing discounts can be found below.

Key Points

The 2029 Medicare negotiation program will be implemented via rulemaking (per statutory requirements). We note that most program requirements remain consistent with the 2028 final guidance.

- CMS will select 20 Part B & D negotiation-eligible drugs for the fourth cycle of Medicare negotiations.
- As required by law, the program is transitioning from being implemented through guidance to being codified via regulation.

- This transition to notice-and-comment rulemaking now requires CMS to formally respond to public feedback and industry concerns.

CMS proposes grouping certain combo products (with shared active ingredients and same NDA/BLA holder) if the difference is *only* intended for subcutaneous and other administration routes. The fact sheet is here. CMS intends to include different formulations in their definition of "qualifying single source drugs" if an active ingredient creates a new formulation that enables an alternative route of administration. This will impact hyaluronidase combo products such as: Keytruda (MRK), Opdivo (BMY), Darzalex (JNJ), Vyvgart (ARGX), and Tecentriq (Roche).

Policies are an incremental negative for these Part B medicines (oncology) and will likely receive pushback for inclusion in the final CMS rule (Fall 2026). The proposal says "the program integrity concerns this policy would address relate primarily to biologics that are more likely payable under Part B, and drugs were not selected based on total expenditures under Part B until initial price applicability year 2028. The program integrity concerns raised by fixed combination drugs that are new formulations have not yet impacted drug selection but may soon as more drugs with significant total expenditures under Part B become qualifying single source drugs and negotiation-eligible drugs."

We said this policy was likely (here) though drugmakers have argued that the proposal is illegal. CMS previewed their intent to revisit the combination policy in the 2028 final guidance, and may follow through on 2029 proposed changes this time as a part of their larger "program integrity" agenda. Drug companies have argued CMS lacks the authority to lump fixed-dose combination and single-active-ingredient medications together for negotiation purposes, and CMS punted on making the policy change in its guidance for the 2028 round of price negotiations.

One negotiated price would apply to all selected drugs (including fixed-dosed combos) under this policy. If a drug selected for negotiation for 2029 has a new formulation that is a fixed combination drug containing hyaluronidase, the new formulation containing hyaluronidase would be included with the selected drug. As a result, the negotiated price would apply to all dosage forms and strengths of the qualifying single source drug, including the new formulation containing hyaluronidase.

Separately, CMS is proposing to implement a Temporary Floor for Small Biotech Drugs (as required by law), as the small biotech exemption ends in 2028. This floor will apply for 2029 and 2030 negotiations. CMS will limit their maximum fair price (MFP) offers for small biotech drugs to to a minimum of 66% of the average non-FAMP for 2029 and 2030. This is intended to provide small biotechs some pricing certainty and may benefit companies that are scheduled to lose small biotech exclusion status (e.g., INCY, NBIX, EXEL).

CMS proposes codifying Part D coverage requirements on negotiated and the definition of a "negotiated price."

- Policies would include codification of Part D coverage requirements and that the negotiated prices paid to dispensing entities by Part D plans would not exceed the MFP plus any dispensing fees. As a reminder, Part D plans must include all forms and doses of negotiated drugs on Part D formularies, but CMS did not require specific tiering or utilization management for selected drugs in 2026-2028.
- Commercial payers have begun adjusting coverage in response to negotiated pricing with products such as Austedo XR losing preferred formulary placement on certain plans. CMS may be looking to enforce negotiated drug coverage for Part D plans due to similar formulary change concerns.

BACKGROUND & PRICING OUTLOOK

We expect CMS to seek steeper discounts for 2028 drugs with increased experience and the pressure of MFN. Negotiated price reductions for the 2027 cohort ranged from 38% to 85%, exceeding the discounts observed for the 2026 cycle (which were closer to net pricing). Discount levels are expected to increase further in 2028+, particularly for products facing significant therapeutic competition or demonstrating more modest clinical differentiation. CMS has experience and knowledge accumulation from the first two rounds of negotiations and this is the first year of domestic MFN pricing via TrumpRx. MFN could influence offers despite not being explicitly included in guidance.

2029 selected drug list (out by February 2027) is expected to include more Part B products. CMS intends to finalize 2029 rules after August and will release the 20 selected Part B&D drugs in early 2027. We note that the 2028 selected drug list (15) skewed toward Part D, with some high-spend Part B products avoiding this list due to the "orphan fix" or the combination product policy. See our analysis of the 2028 list here.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com

202.250.3741 I www.capitol-street.com

900 19th St NW 6th Fl
Washington, D.C. 20006

CAPITOL STREET
