June 30, 2023

# Rx Negotiation Rules Friendlier to Industry

Our Take: Top 10 Drugs Still Expected on Sept 1, 2023 as Lawsuits Mount

Relevant Companies

## Our Take & Next Up

**CMS final negotiation guidance here is incrementally more positive for biopharma co's, but the changes are mainly around the edges. The selected drug list for 2026 is still expected to be released by Sept 1.** In today's CMS final drug negotiation guidance for 2026, CMS (1) eases up on secrecy provisions (and removes gag clause) (2) clarifies fixed combo drug negotiation treatment (3) reaffirms QALY won't be used (4) no major changes to orphan drug policies, which is unhelpful (5) provides more avenues for the public to provide input. CMS announced insulin $35 cap applying to MA and Part B. As a reminder, four IRA lawsuits have been filed and we expect more to come in the following weeks. None of them ask for a preliminary injunction that would immediately halt implementation, likely because plaintiffs do not yet have standing. The IRA cases could go all the way to the Supreme Court.

## Key Points

**CMS reaffirms that fixed combination drugs will not be included in the same negotiation category as drugs with one active ingredient, a positive for industry.** This means, for instance, a fixed combination inhaler would be considered separately from a long-acting corticosteroid inhaler. CMS intends to negotiate one price for drugs that have the same active moiety/ingredient. All dosage forms of the same active ingredient will be treated as a single drug for purposes of negotiations. BLAs and NDAs will be grouped together if they represent different dosage forms or formulations of one active moiety/active ingredient with CMS noting this will likely discourage "product hopping".

However, if a drug is a fixed combination drug with two or more active moieties / ingredients, every distinct combination will be considered as a separate entity from the individual single source drugs.

**CMS largely removes gag clause provisions, likely in reaction to lawsuits, which is more reasonable to industry.** CMS will not publicly discuss ongoing negotiations prior to the release of the explanation of the maximum fair price (MFP) unless a manufacturer publicly discloses information regarding the negotiation process. CMS notes that manufacturers may choose to publicly disclose information regarding ongoing negotiations at its discretion. If a manufacturer chooses to publicly disclose material that CMS has previously deemed to be proprietary information, CMS will no longer consider that material proprietary. CMS removed the data destruction requirements under the confidentiality policy pertaining to manufacturers. d.

**Orphan drug exclusion criteria remains the same as proposed as CMS notes it is a statutory requirement (unhelpful for industry).** Drugs with more than one rare disease designation will not qualify even if the drug has not been approved for any indication in the additional designations. Once a drug loses its orphan exclusion, CMS will use the initial FDA approval date not the loss of eligibility date. As a result, drugs and biologics will not be able to increase exclusivity period with an orphan drug exclusion. But CMS has also provided additional details that CMS will not consider withdrawn orphan designations (or withdrawn approvals) as additional designations.

**CMS clarifies "bona fide" marketing for generics and biosimilars for brand drug removal from the list.** The IRA allows drugs to be removed from the selected drug list if there is a generic or biosimilar on the market. And a selected drug will stop being subject to the negotiated price at the start of the year that beginsat least 9 months after a generic/biosimilar comes to market. Selected drugs for 2026 will have until August 1, 2024, for CMS to determine if an FDA approved generic or biosimilar is engaging in "bona fide" marketing. If a generic or biosimilar launches between 2024 and 2026, the drug would still be subject to the initial year of negotiations. CMS will now consider both Prescription Drug Event (PDE) data and Average Manufacturer Price (AMP) data to determine "bona fide" marketing when deselecting a selected drug. CMS also notes they will consider the totality-of-the-circumstances. This is much broader than the initial guidance where CMS only listed Part D Prescription Drug Event (PDE) as a data point to determine "bona fide" marketing.

**CMS will not use comparative effectiveness (QALY) data (unchanged but clarified).** CMS reaffirmed that it will not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an individual who is elderly, disabled, or terminally ill as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill.

**CMS will not create a dispute resolution process for the Small Biotech exemption as suggested by guidance comments (unhelpful for industry).** For 2026 through 2028, "small biotech" drugs will be exempt from negotiation. The revised guidance notes for 2026 all information to determine Small Biotech Exemption will be collected on the small biotech exception ICR Form. CMS will collect information on 2021 total expenditures under Part D for all covered Part D drugs, total expenditures for the qualifying single source drug under Part D, and Total Expenditures under Part D for all covered Part D drugs for which the manufacturer that had a Coverage Gap Discount Program .

**CMS clarifies Medicare termination if manufacturers pull out of program, and addresses when drug ownership is transferred**. If a negotiated price can't be agreed upon, a manufacturer is expected to face the excise tax or leave the Medicare & Medicaid program. A manufacturer that is unwilling to enter into an agreement will have an expedited termination process from Medicare and CMS notes that a manufacturer is free to terminate its

agreement at any time after it goes into effect. If the ownership of a selected drug is transferred to another entity, the original manufacturer will remain responsible for providing the negotiated price until all the NDAs / BLAs of the selected drug are transferred. The transferring manufacturer must provide CMS at least 30 days written notice before the effective date of any such transfer.

**CMS responds to criticism on transparency by adding patient-focused listening sessions for fall and another CMS-manufacturer meeting during the negotiation process**. CMS will be holding patient-focused listening sessions in Fall 2023, after October 2. These meetings will be open to the public and will collect patient-focused input on therapeutic alternatives and other data considerations for selected drugs. Another CMS-Manufacturer meeting will also be added to the overall negotiation process in Fall 2023 after the October 2nd manufacturer data submissions. As a reminder, the lack of opportunity for input was highlighted as supporting evidence in PhRMA's litigation for their claim of a "due process" violation from the negotiation process.

**In legal news, four (4) lawsuits have been filed so far which challenge the Drug Negotiation Program, including PhRMA.** This includes MRK's lawsuit filed in the District Court for DC, BMY's lawsuit filed in a District Court for New Jersey, the Chamber of Commerce's lawsuit filed in a District Court for the Southern District of Ohio, and now PhRMA's lawsuit filed in District Court for the Western District of Texas. We expect more litigation to come from trade associations, individual drug companies, and potentially patient advocacy groups. MRK is up first with a briefing schedule set through November 21, 2023. There are overlapping arguments on the 5th amendment with MRK & BMY alleging a "just compensation" violation and PhRMA & Chamber of Commerce alleging violation of due process.

**HHS today also announced that the cap on insulin costs at $35 per month will go into effect ASAP for people who get their insulin through Medicare Part B and Medicare Advantage (MA)** with use of a traditional pump starting tomorrow, July 1. Millions of people with Medicare Part D are already benefiting from the IRA's $35 monthly cap on insulin costs.

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