CAPITOL STREET

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2027 Negotiated Drug Prices Potentially Start Lower?

More Mtgs w/ CMS, Data Exchange Contractor Introduced, 15 Patient Town Halls

Relevant Companies

Our Take & Next Up

Final 2027 drug negotiation rules provide more CMS meetings with manufacturers, guidance to pharmacies, but potentially lower initial prices give a wider array of data inputs as there will be 15 new town hall meetings (here). CMS introduces a third party data facilitator to the mix, incremental meetings and opportunities to exchange prices with manufacturers, along with more data points to consider in providing initial price offers, potentially pointing to lower (initial) prices in 2027. CMS wisely provides guidance for pharmacies whose cash flow may be materially affected by MFPs (maximum fair prices). CMS will rely on additional sources of info -- announcing 15 patient-centered roundtable meetings -- as it calculates an initial price for 2027, and a broader universe of therapies. Most of the other guidance (NDCs, therapeutic equivalents, timelines and so forth) are similar to year one guidance. The list for 2027 will be released by Feb 1, 2025.

CMS also issued the "Small Biotech Exception (SBE) and Biosimilar Delay Information Collection Request (ICR) for Initial Price Applicability Year 2027" (link) for a 30-day comment period. Comments are due Nov. 1, 2024. CMS believes all the information it currently collects is necessary to determine eligibility for the SBE. However, the ICR provides stakeholders with another opportunity to make suggestions on improving the agency's information collection process. According to the agency, interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information.

Key Points

We now know that Eliquis/Xarelto are not being compared to Warfarin. With year one in the rearview, manufacturers are gearing up for 15 in 2027 (Part D). See our take on 2026 prices (here) (released Aug 2024). We observed net price reductions of ~24%. There is a paucity of rebate data, so the mid-20s is an estimate.

Prices may be lower out of the gates from CMS as they incorporate additional data sources (NEW: 15 town hall meetings). The approach provides a pathway for CMS to consider the multitude of information expected from public input, including but not limited to peer-reviewed research, expert reports or whitepapers, clinician expertise, real-world evidence, and patient experience. CMS announces 15 town hall meetings (some virtual, some in person, none to be live-streamed) The agency will factor in additional company costs including

Phase IV post-marketing studies, post-IND costs for indications that did not receive FDA approval, and acquisition costs for failed or abandoned products. CMS will not use comparative effectiveness data or QALY.

We have said that 2nd generation combination products will be more appealing as companies navigate the complexities of the Medicare price negotiation program (think Darzalex Faspro). CMS will treat a fixed combination drug as distinct in its composition from the individual active moieties / active ingredients. CMS notes the following example in the final rule: A corticosteroid inhaler would not be aggregated with a fixed combination inhaler from the same NDA / BLA holder that contains the same corticosteroid combined with a long-acting beta agonist. In this example, the corticosteroid inhaler would be considered as a separate potential qualifying single source drug from the fixed combination inhaler.

Other notable policies that were in the final rule:

- **More patient focused meetings** – CMS will host up to 15 patient-focused roundtable events and a town hall meeting to receive patient-focused and clinically-oriented information on selected drugs for consideration in its initial offer development.
- **More optional meetings if CMS rejects price offer** – The first "optional" negotiation meeting will occur after the initial offer is issued and before the due date for drug companies that submit statutory written counteroffers. If CMS rejects a drug company's counteroffer, CMS will offer up to two more optional negotiation meetings.
- **Price exchanges can take place with more frequency** – Additional price exchange opportunities between CMS and drug companies that can occur during the period between CMS' rejection of the statutory written counteroffer, if applicable, and one week before final offers are due to be sent by CMS.
- **Data & payment facilitator (third party) contractor introduced in year two** – CMS provides requirements and parameters for exchange of data among dispensing entities (e.g., pharmacies), drug companies, and CMS via the Medicare Transaction Facilitator Data Module (MTF DM), to provide data needed to facilitate access to MFPs of selected drugs for dispensing entities, to provide claim-level data elements to participating drug companies where a selected drug was dispensed to a person who was verified to be MFP-eligible.
- **Pharmacy guidance & low cash flow signals** – Pharmacies, such as sole proprietor rural or urban pharmacies with high volume of Medicare Part D prescriptions dispensed, pharmacies that predominantly rely on prescription revenue to maintain business operations, long term care pharmacies, 340B entities with in-house pharmacies, or I/T/U pharmacies, may self-identify if they anticipate material cashflow concerns at the start of the initial price applicability year due to reliance on the retrospective MFP refunds within the 14-day prompt MFP payment window.

15 Part D drugs will be published by CMS by Feb 1, 2025: Our list is here. We note that CMS will use more recent data so our list is not apples-to-apples with the data CMS will use. See below for CMS selection criteria, which do not appear to differ from year one criteria in any major way.

- An eligible drug for initial price applicability year 2027 is a qualifying single source drug that is among the 50 single source drugs with the highest total expenditures (Part D).
- If a drug is a fixed combination drug with two or more active moieties/active ingredients, the distinct combination will be considered as one active moiety /active ingredient for the purpose of identifying potential single source drugs.

- All dosage forms and strengths of the drug with the same active moiety and the same holder of a NDA or BLA will be considered. Multiple NDAs with the same active moiety with non-identical names may be identified as potential qualifying single source drugs.
- To be considered a qualifying single source drug, at least 7 years (drugs) or 11 years (biologics) must have elapsed between the FDA date of approval or licensure, as applicable, and the selected drug publication date.
- CMS will consider a generic drug or biosimilar to be marketed when the totality of the circumstances reveals that the manufacturer of that approved generic drug or licensed biosimilar is engaging in bona fide marketing of that drug or biosimilar

Exclusions for small biotech and orphan are identical to 2026 qualifications (no CMS leniency here). We think the orphan fix could happen legislatively, but 9-13 parity is a heavier lift given CBO scoring.

- CMS will exclude low-spend Medicare drugs or biological products with less than $200 M (increased by CPI-U).
- CMS will still exclude a drug or biologic that is designated as a drug for only one rare disease or condition, and for which the only approved indication (or indications) is for such disease or condition.
- CMS will exclude plasma-derived products when identifying qualifying single source drugs as described.

IRA "fix" bills are unlikely to pass in 2024, with the orphan "fix" being more palatable to members of Congress than the 9-13 pill penalty. We believe legislation to "fix" the orphan exemption is a common sense fix, and while it won't pass this Congress it could in the future.

Timeline and requirements by March 1, 2025 are below, then the Summer of 2025 will be spent on negotiation back-and-forth. CMS outlines the following data to be required to be reported by the Primary Manufacturer to CMS by March 1, 2025:

- Research and development (R&D) costs of the primary manufacturer for the selected drug and the extent to which the manufacturer has recouped those costs
- Current unit costs of production and distribution of the selected drug, averaged across the primary Manufacturer and any secondary manufacturer(s)
- Prior federal financial support for novel therapeutic discovery and development with respect to the selected drug (**NOTE**: this reminds us of March-In)
- Data on pending and approved patent applications, exclusivities recognized by the FDA, and applications and approvals; and
- Market data and revenue and sales volume data for the selected drug in the US for the Primary Manufacturer and any Secondary Manufacturer(s).

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