U.S. Drug Pricing Reform: Back in the Limelight Again (page 1 of 2)

Latest bill, now with support from Sen. Joe Manchin (D-WV), would allow Medicare to negotiate prices of some drugs - drugs with highest spend

CONTEXT

In the "Build Back Better Act" bill, the 117th Congress attempted to give the U.S. government a role in drug price negotiation. That effort failed.

This week, in what has been re-branded as "The Inflation Reduction Act" bill, U.S. Sen. Majority Leader Charles Schumer (D-NY) and Sen. Joe Manchin (D-WV) announced agreement – and the bill includes drug pricing reform.

This is still just a bill. It may fail on its way to becoming law. But Mr. Manchin's support points to potential passage as part of Budget Reconciliation (Democrats have 50 seats plus the tie-breaking vote of Vice President Kamala Harris). The key unknown: how Senator Kyrsten Sinema (D-AZ) will vote…

PROPOSED CHANGES

- Focuses on a small set of single source Part B / D drugs for which Medicare spending is highest
  - 10 such drugs in 2026
  - 15 in each of 2027 and 2028
  - 20 in 2029 and later
- The drugs selected for negotiation would be drawn from the 50 highest-expenditure Part B drugs (healthcare professional-administered drugs) and Part D drugs (self-administered drugs), defined as small molecules that have been approved for ≥ 7 years, and biologics that have been approved for ≥ 11 years, with exclusions from 2026-2028 for:
  - Drugs that account for ≤ 1% of Part B or Part D expenditures
  - Drugs that account for ≥ 80% of total Part B or Part D expenditures attributable to the manufacturer across all of its Part B or D drugs
- Also exempt from consideration:
  - Vaccines licensed under § 351 of the Public Health Service Act
  - A new formulation of an otherwise qualifying drug
  - Drugs approved for only a single orphan disease
  - Drugs for which Medicare spent < $200M in 2021 (increasing by Consumer Price Index-Urban for following years)
  - Biologics derived from whole blood or plasma

https://www.finance.senate.gov/imo/media/doc/070622%20Prescription%20Drug%20Pricing%20Reform%20Leg%20Text.pdf, accessed July 29, 2022

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PROPOSED CHANGES

- Factors which the government must consider in negotiating prices:
  - R&D costs
  - Extent to which manufacturer has recouped R&D costs
  - Sales data
  - COGS
  - Taxpayer funding that supported R&D
  - Patent information
  - Trial data
  - Incremental clinical benefit vs. alternatives
  - Costs of alternatives
  - Health economic modelling must not count additional life years differently based on quality of those years (i.e., an additional year of life for someone who is elderly, disabled, or terminally ill differently from an additional year of life for someone who is not elderly, not disabled, not terminally ill)

WHAT TO DO

- Monitor evolution of this bill, particularly how Senator Sinema (D-AZ) plans to vote…
- Study eligibility criteria for selection – it could be that your product would be ineligible for some time simply due to time since FDA approval. Or your product may be ineligible for selection due to other factors (e.g., if it treats only a single orphan condition).
- If drug may be eligible for selection, begin now to prepare for price negotiation.
- Specifically, prepare health economic modelling to support product value. This may include updating models used for submission so that they reflect real-world data.
- Ensure health economic modelling complies with U.S. government rules on modelling. For instance, if your product targets the elderly, disabled, and/or terminally ill, ensure use of a metric that is free of QOL weighting (e.g., Life Years gained, rather than Quality-Adjusted Life Years gained).

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