

May 11, 2023

## Senate Health, Education, Labor and Pensions Committee Advances 4 Bills Addressing Generic Drug Access and PBMs

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On Thursday (May 11), the Senate Health, Education, Labor and Pensions (HELP) Committee resumed marking up a package of four bills aimed at increasing access to generic drugs and prohibiting certain pharmacy benefit manager (PBM) practices, such as spread pricing and pharmacy clawbacks, as well as enhancing transparency.

The markup took place after a May 2 session was cut short following concerns raised about moving forward with consideration of the bills and related amendments without first receiving cost estimates from the Congressional Budget Office (CBO) or hearing testimony from leaders of insulin manufacturers and pharmacy benefit managers at a May 10 hearing, among other concerns. At the start of the markup, HELP Committee Chair Bernie Sanders (I-VT) said that he and HELP Committee Ranking Member Bill Cassidy (R-LA) agreed in advance of the markup not to support amendments that 1) do not have a CBO score, and 2) have not received technical assistance.

The committee ultimately advanced all four measures with most of the debate and amendments focused on the Pharmacy Benefit Manager Reform Act. Committee members offered more than a dozen amendments to the bill of which eight were adopted. Much of the markup's debate centered on the bill's provision to ban spread pricing in PBM-insurer contracts, with several Republicans instead favoring guardrails on spread pricing, raising concerns that a complete ban limits plans' contracting options.

- For more information: <https://www.help.senate.gov/hearings/continuation51123>

### Mark-up details

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#### S. 1067, Ensuring Timely Access to Generics Act of 2023

- *High-level summary:* The bipartisan bill introduced by Sens. Michael Bennet (D-CO), Jeanne Shaheen (D-NH) and Susan Collins (R-ME) would give the Food and Drug Administration the authority to reject citizen petitions if they believe the petition is being filed to delay competition in the market.
- *Outcome:* Ordered to be favorably reported, as amended, in a 21-0 vote. The bill was unanimously approved with no committee members offering amendments during the discussion.

#### S. 1114, Expanding Access to Low-Cost Generics Act of 2023

- *High-level summary:* The bipartisan bill introduced by Sens. Tina Smith (D-MN) and Mike Braun (R-IN) aims to address an anti-competitive prescription drug practice called "parking" wherein a brand name drug manufacturer agrees not to pursue legal action against a generic competitor in exchange for the generic delaying entry into the market. The bill would give generic companies that are not the first to market 180-day market exclusivity and change the incentive structure to discourage generic drug companies from delaying their products' market entry.
- *Outcome:* Ordered to be favorably reported, as amended, in a 20-1 vote. The Committee in a 19-2 vote adopted Sen. Maggie Hassan's (D-NH) amendment to incorporate her bipartisan bill with Sen. Rand Paul (R-KY), the Increasing Transparency and Generic Drug Applications Act, which aims to accelerate generic

drug market entry by giving generic drug manufacturers with a pending FDA drug application access to information around inactive ingredient amounts. In his comments, Sen. Cassidy acknowledged some Republican members expressed concerns with the amendment but noted overall he felt the final amendment struck the right balance to get generic drugs to the market faster.

#### **S. 1214, Retaining Access and Restoring Exclusivity (RARE) Act**

- *High-level summary:* The bipartisan bill introduced by Sens. Tammy Baldwin (D-WI) and Bill Cassidy (R-LA) would codify the FDA's interpretation that the seven-year market exclusivity period for drugs for rare diseases or conditions prohibits the approval of other drugs for the same approved use or indication with respect to the disease or condition, rather than only with respect to the same disease or condition.
- *Outcome:* Ordered to be favorably reported in a 21-0 vote. Sen. Hassan withdrew two amendments offered last week and the bill was unanimously approved without additional discussion.

#### **S. 1339, Pharmacy Benefit Manager Reform Act**

- *High-level summary:* A bipartisan bill introduced by Chair Sanders and Ranking Member Cassidy that would prohibit PBMs that do not pass on 100% of rebates from engaging in so-called spread pricing or charging the plan a different amount than the PBM reimburses the pharmacy, as well as from arbitrarily, unfairly, or deceptively clawing back reimbursement payments to pharmacies or increasing fees or lowering reimbursements to pharmacies to offset changes to federally funded health plans. The bill also would mandate that PBMs report annually to the Federal Trade Commission (FTC) certain information about payments received from health plans and fees charged to pharmacies.
- *Outcome:* Ordered to be favorably reported, as amended, in a 18-3 vote. During the session, lawmakers offered more than a dozen amendments, ultimately adopting eight amendments, including Chair Sanders' substitute amendment:
  - The committee in a 16-5 vote adopted Sen. Tammy Baldwin's (D-WI) amendment to require drug companies to provide a transparency and justification report before raising drug prices by certain thresholds. During discussion, Sen. Baldwin said she would continue to work with ranking member Cassidy to account for existing state laws.
  - The committee adopted by voice vote two amendments from Sen. Edward Markey (D-MA) to mandate a Government Accountability Office study on the affordability of Narcan and ban gag clauses from PBM and insurer contracts that block consumers' access to certain drugs and costs.
  - The committee in a 21-0 vote adopted an amendment from Sen. Lisa Murkowski (R-AK) to create exceptions to step therapy protocols.
  - The committee in a 21-0 vote adopted an amendment from Sen. Mike Braun (R-IN) requiring the Department of Labor to conduct a study on the fiduciary responsibilities of PBMs.
  - The committee in a 20-1 vote adopted an amendment from Sen. Markwayne Mullin (R-OK) to require group health plans and health insurers and issuers to make available information on health claims, network, and cost through patient and provider application programming interfaces (APIs).
  - The committee adopted via voice vote, with Sen. Paul voting no, an amendment from Sen. Roger Marshall (R-KS) that clarifies PBMs are covered service providers under current law and are required to disclose compensation they receive from health plans.

The committee discussed but ultimately did not vote on two amendments from Sen. Paul that would repeal the anti-trust law Robinson-Patman Act and empower independent pharmacies to ban together to negotiate with PBMs, ruling them non-germane; two amendments from Sen. Marshall on administrative fee de-linking and applying discounts to count toward patients' deductibles and out-of-pocket costs; and an amendment by Sen. Mitt Romney (R-UT) to require PBMs to offer plans at least one non-spread pricing contract option. During the discussion on Sen. Romney's amendment some Republicans raised concerns that the bill would completely ban spread pricing and limit employer and plan sponsor choice.

*If you have questions, please contact [Heather Meade](#) or [Heather Bell](#).*

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