CAPITOL STREET

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Senate Bills Advance & CEOs Testify: PBM, Insulin, Generics & Biosimilars

Middleman Assault on All Fronts

Relevant Companies

In early May, the Senate Health Education Labor Pension (HELP) committee (Chair Sanders, I-VT) is expected to markup a package addressing drug supply chain (PBM) and drug pricing provisions on generics, biosimilars & insulin. The markup is part of a larger plan by Senate Majority Leader Chuck Schumer (D-NY) to package health care bills from the Health, Finance, Judiciary and Commerce committees for a floor vote in an effort to further lower healthcare costs. The House may acquiesce for policy passage in 4Q23.

⋙ Our Take & Next Up

Republicans and Democrats in the House and Senate are attacking PBMs on all fronts. The hope is to release myriad bills, launch investigations (House Oversight Investigation & FTC study announced) with the hope that industry cannot block & tackle. As a reminder the pharmaceutical industry *supports* supply chain reform and is indirectly influencing language that digs into the PBM business model.

LIKELY OUTCOME: The HELP Committee (Chairman Sanders, I-VT) is expected to mark up a bill in early May. Our preview is below; it will likely echo Sec 306 of the 2019 *Lower Healthcare Costs Act.* At the end of the year, we expect some generic and biosimilar and even PBM transparency provisions to pass muster. The more onerous anti-PBM provisions will encounter some House GOP pushback due to the impact on small PBMs and expanded oversight by the agencies, such as the FTC as the aggregator of data.

Energy & Commerce will debate a PBM-focused bill this week (4/26). We expect to see a HELP (Chair Sanders, I-VT) bill markup as soon as the first week of May with an Insulin CEO/PBM CEO hearing scheduled for May 10. PBM transparency and other provisions that pass markup may be included in a larger Senate healthcare bill (end of the year package) with overall passage likely.

Generic reforms are low impact reforms regarding approvals, patents & access. On PBM, the Senate Finance committee is also working on its own anti-PBM bills, a bipartisan goal for Chair Wyden (D-OR) and Ranking Member Crapo (R-ID). With the number of anti-PBM reforms being considered by committees in both chambers, and the bipartisan nature of transparency and oversight, we expect some

anti-PBM reform in 2023. Insulin reform – the Shaheen-Collins bill was updated last week -- also addresses rebating on insulin products, FDA review of biosimilars for biologics and CMS coverage of biosimilars.

Key Points

PHARMACY BENEFIT MANAGERS

Most PBM reform provisions are not brand-new policies. An updated Section 306 of the Murray-Burr 2019 *Lower Health Care Costs Act* (which later became the *Surprise Billing Act)* is expected to be reintroduced. A bipartisan House bill, the *Pharmacy Benefit Manager Accountability Act*, introduced by Reps. Ann Kuster (D-NH), Buddy Carter (R-GA), Anna Eshoo (D-CA), and Brett Guthrie (R-KY), echoes Section 306 policies and increases odds of passage as a House companion bill.

Transparency has remained a key priority & likely will be a part of the Senate HELP bill. These provisions could require PBM disclosure of rebate info and fees to plan sponsors or pharmacies, with additional reporting requirements for vertically integrated PBMs.

We may also see a ban on spread pricing, not just in Medicaid but also in commercial. Spread pricing is largely unpopular with stakeholders but large PBMs supported publicly banning the practice in prior Senate Finance hearing testimony. Overall, the Senate HELP committee's anti-PBM reforms may have a low-medium industry impact but other PBM legislation is also moving in tandem.

The *PBM Transparency* Act ($740 M in savings over 10) is a separate bill impacting commercial markets and passed the Senate Commerce Committee on March 22. The bill, sponsored by Cantwell (D-WA), Chair of the Commerce Committee, and Grassley (R-IA), attempts to regulate PBM conduct through FTC enforcement of unfair conduct and explicit requirement for PBMs to provide full disclosure of costs and fees. The bill bans spread pricing and DIR fees unless PBMs pass along 100% of rebates to the health plan or payer. PBMs would also be required to disclose the aggregate of the cost, price, and reimbursement of prescription drugs, all fees, markups, and discounts the PBM charges, and remuneration fees it receives from manufacturers.

Bipartisan PBM reform is expected from the Senate Finance Committee per its recent framework. The Finance committee will focus on delinking PBM compensation from drug prices (likely banning spread pricing), addressing the pharmacy fees and unclear quality measures, and increasing the transparency of PBM transactions (particularly for Part D plan sponsors). Other key issues the committee will look at include ways to modernize Medicare's "Any Willing Pharmacy" rules and address PBM market concentration.

GENERICS

Generic reforms from the HELP Committee are likely to focus on improving FDA approvals and addressing patent loopholes or administrative delays. Provisions are expected to be relatively low-impact and similar to past proposals. We largely expect generic provisions to pass on a bipartisan basis.

One provision is expected to address Q1/Q2 issue in generic approvals. This was a bipartisan provision that appeared in the 2022 House FDA user fees but failed to pass in the larger package. *The Increasing Transparency in Generic Drug Applications Act* ($414 M in savings over 10), reintroduced by Senators Paul (R-KY) and Hassan (D-NH), would direct the FDA to provide certain information on if the Q1 and Q2 (qualitative and quantitative) formulation of the proposed generic is the same as that of the reference listed drug. The current process of establishing Q1 and Q2 can require numerous controlled correspondences to the Office of Generic Drugs (OGD). If the FDA identifies an issue with a proposed generic drug's Q1/Q2 sameness, it will not disclose the direction or size of the deviation or the specific ingredient issue to the generic applicant. This a low impact reform that is expected to significantly improve the timing of the generic approval process without targeting brand manufacturers.

Closing patent loopholes may also be considered which negatively impacts brand manufacturers. Lawmakers have discussed the need to close patent loopholes and improve the generic process to market and, earlier this year, the Senate Judiciary passed 4 bills out of committee that address patent practices which delay generic access to market. We could see additional patent or FDA loophole reform included to build on the Judiciary committee's work. *Ensuring Access to Generic Medications Act*, reintroduced by Sens. Hassan

(D-NH) and Braun (R-IN), could be included, and would impact how brands protect exclusivity period. The bill will allow generic manufacturers to sue if manufacturers overstate the scope of their method of use patents to delay or stop FDA approvals.

A potential provision on increasing generic competition may do harm more than help generics. The *BLOCKING Act* ($406 M in savings over ten) would allow the FDA to approve subsequent generics, in certain situations before the end of the 180-day exclusivity period. It is intended to address situations where the first generic applicant delays marketing despite having FDA approval and market exclusivity. While the bill generated some savings when scored in the Senate User Fees, it is expected to negatively impact generic entry as it potentially decreases the exclusivity period which lower manufacturer incentives to make generic drugs. Generic drugs already have limited profitability and declining prices are a cause of drug shortages (according to the FDA), which run counter to the committee's goal of improving generic access.

Solutions addressing generic drug supply shortage are less likely but also possible due to high profile drug shortages of late in the US. A report commissioned by the Senate Committee on Homeland Security & Governmental Affairs found the FDA still lacks critical info to mitigate shortages while new drug shortages increased by ~30%. In the opposite chamber, the Essential Medicines Strategic Stockpile Act was recently introduced in the House by Reps. Carter (R-GA) and Blunt Rochester (D-IL). The bill would require the Department of Health and Human Services to establish a list of 50 generic medications that are essential in public health emergencies.

INSULIN CAPS

A commercial insulin cap is less likely to be included, but it will be revisited with a HELP hearing likely on May 10 on insulin pricing and rebating practices. In March, Sens. Kennedy (R-LA) and Warnock (D-GA) reintroduced a commercial insulin cap of $35 for a 30-day supply, which was left out of the *Inflation Reduction Act*. The *Affordable Insulin Now Act*, starting in 2024, would require private plans to cover one of each insulin dosage form for no more than $35 per month. The bill is currently being rescored and CBO costs are expected to be lower due to the recent lowering of commercial insulin prices.

CEOs to testify May 10 include David Ricks, Chair and Chief Executive Officer, Eli Lilly as well as the following.

- Lars Fruergaard Jørgensen, President and Chief Executive Officer, Novo Nordisk
- Paul Hudson, Chief Executive Officer, Sanofi
- David Joyner, Executive Vice President and President of Pharmacy Services, CVS Health
- Adam Kautzner, President, Express Scripts
- Heather Cianfrocco, Chief Executive Officer, OptumRx

A ban on collecting rebates on insulin products was recently introduced and is also expected to be rescored. The *INSULIN Act*, sponsored by Sens. Shaheen (D-NH) and Collins (R-ME) is a competing bill that placed a $35 monthly cap and requires PBMs to pass through 100% of the rebates they collect on insulin products starting in 2024. New to the bill are provisions that would create a new, expedited pathway for the FDA to consider biosimilars that would be alternatives to biologics without adequate competition and provision that allows Medicare to make mid-year formulary changes to put biosimilars on their formularies as soon as they come on the market.

The healthcare industry implements business reforms. With increasing oversight on the horizon, drug manufacturers and PBMs have announced reforms to avoid policymaking.

Starting in summer 2023, Express Scripts (CI) is launching a new "fully transparent" option that eliminates spread pricing and charges a flat monthly fee per client. The new pricing option will allow clients to receive 100% of the drug rebates. The company is also offering enhanced financial and fee disclosure for other clients who choose to use spread pricing and will report spread pricing arrangements in its Form 5500 reporting.

All 3 insulin manufacturers (LLY, NVO, SNY) will lower list price for some of its insulin products starting in late 2023/2024. Insulin is notoriously known for its high list prices despite stable or declining net prices. The price cuts have helped LLY avoid Medicaid inflationary rebates and come at a time when a commercial insulin pricing cap is being revisited.

- Starting in January 2024, SNY will lower the list price of *Lantus* by 78%, price of *Apidra* by 70%, and offer a $35 out of pocket cap for commercial.

- Starting in January 2024, NVO will lower the list price of several insulin products (*Levemir, Novolin, NovoLog*) by up to 75%.
- LLY now caps out of pocket costs for insulin at $35 for commercial insurance. Starting in Q4 2023, LLY will cut the list price of Humalog by 70%. LLY is also planning on cutting the list price of non-branded insulin to $25 a vial starting on May 1, 2023.

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