

ALSTON & BIRD



Health Care Legislative Update and Outlook

NCCMP Interim Annual Conference

Wednesday, September 13, 2023

Fairmont Chicago Millennium Park

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Legislative environment

September 2022

- Funding for the federal government runs out on September 30
- Possible lame duck legislation
- Impact of 2022 elections and possible new composition of the House and Senate

September 2023

- Funding for the federal government runs out on September 30
- Possible government shut down
- Potential for end of year legislation
- Impact of 2024 elections and possible new composition of the House and Senate, White House



PBM Legislation



Bi-partisan concerns

“For too long, pharmacy benefit managers have operated without accountability or scrutiny, and the results have been higher drug prices for taxpayers and Americans picking up their prescriptions at the pharmacy counter.” Senate Finance Committee Chair Ron Wyden (D-OR)

“PBM compensation is a blind spot for the American public. We know they leverage their market power to extract rebates from drug makers. We know they leverage their relationships with health insurers to decide which drugs should be covered.” House Education & Workforce Committee Chair Virginia Foxx (R-NC)

“The top three PBMs are each part of a corporate structure that also includes an insurer, specialty pharmacy and healthcare provider. Some include retail pharmacies as well. Those three companies ranked #4, #5 and #12 on Fortune’s list of the largest public companies in America last year. Using a different yardstick, the top three PBMs handle 80% of all US prescription volume.” Testimony of Karen Van Nuys, Ph.D., Executive Director, Value Of Life Sciences Innovation, Leonard D. Schaeffer Center For Health Policy & Economics, University of Southern California, before the U.S. Senate Committee on Finance (March 30, 2023)



Legislative process

- 5 Committees of Jurisdiction
- 3 in the House
 - Ways & Means
 - Education & Workforce
 - Energy & Commerce
- 2 in the Senate
 - Finance
 - Health, Employment, Labor & Pensions (HELP)



COMMITTEE JURISDICTION

Law	Plans	House Committee	Senate Committee
ERISA	Private sector group health plans	Education & Workforce	HELP
Internal Revenue Code (IRC)	Private sector group health plans Church plans	Ways & Means	Finance
Public Health Service Act (PHSA)	Insurers (including both group and individual market) Public plans	Energy & Commerce	HELP



PBM Legislation -- House

- Education & the Workforce
 - [H.R. 4507 - Transparency in Coverage Act of 2023](#) (reported favorably by a vote of 38-1 on July 12, 2023)
 - [H.R. 4508 - Hidden Fee Disclosure Act of 2023](#) (reported favorably by a vote of 38-1 on July 12, 2023)
- Energy & Commerce
 - [H.R. 3561 - Promoting Access to Treatments and Increasing Extremely Needed Transparency \(PATIENT\) Act of 2023](#) (reported favorably by a vote of 49-0 on May 24, 2023)
 - [H.R. 3285 - Fairness for Patient Medications Act](#) (reported favorably by voice vote on May 17, 2023)
- Ways & Means
 - [H.R. 4822 - Health Care Price Transparency Act of 2023](#) (reported favorably by a vote of 25-16 on July 26, 2023)

House Committees on Education & the Workforce, Energy & Commerce, and Ways & Means

- [H.R. _____ - The Lower Costs, More Transparency](#) (introduced September 8, 2023)



PBM Legislation – Senate

- Senate HELP Committee
 - [S. 1339 - Pharmacy Benefit Manager Reform Act](#) (reported favorably by a vote of 18-3 on May 11, 2023)

- Senate Finance Committee
 - Modernizing and Ensuring PBM Accountability Act (reported favorably by a vote of 26-1 on July 26, 2023)
 - Addresses Medicare Part D only



PBM Legislation - Key Topics*

- PBM transparency
 - PBMs are required to report detailed information to plan sponsors
 - Contracts between plans and PBMs cannot limit disclosure of information necessary to make the reports
- PBM compensation disclosure
 - Amends the ERISA compensation disclosure provisions added by CAA 2021 to clarify the PBM compensation that must be disclosed to plan fiduciaries
- Prohibition on gag clauses that would prevent pharmacists from communicating lower cost drug options to patients
- Disclosure of common ownership information to plan sponsors
- Cost-sharing restrictions for “highly rebated drugs”
- Rebate pass through
- Prohibition on PBM spread pricing
- Amendments to health coverage transparency requirements (for plans)

*Not all provisions are in all bills.



PBM Legislation – Key issues for multiemployer plans

- Appropriate drafting to ensure that multiemployer plans receive PBM reports
 - Certain bills provide for a higher level of disclosure to plans maintained by large employers
- Preemption issues
 - More states are enacting PBM legislation that could impact plan design
- Cost concerns for any additional requirements



Other legislation

- Cap on insulin cost-sharing
 - Extend Medicare Part D \$35 limit on cost-sharing for insulin to the commercial market
 - For example:
 - Affordable Insulin Now Act of 2023, S. 954, introduced by Raphael Warnock (D-GA)(bi-partisan)
 - Affordable Insulin Now Act, HR 1488, introduced by Angie Craig (D-MN)
- Extend Medicare Part D inflation rebates to commercial market
 - Inflation Reduction Act provides that HHS will negotiate prices for certain prescription drugs, and that drug manufacturers must pay a rebate to the federal government if drug price increases exceed inflation
 - Both of these provisions apply only to Medicare Part D
 - Lower Drug Costs for Families Act, S. 1139, introduced by Catherine Cortez Masto (D-NV) would take into account commercial sector drug sales in calculating inflation rebates



Health Savings Accounts (HSAs) and High Deductible Health Plans (HDHPs)

- Telehealth Expansion Act of 2023, HR 1843
 - Would permanently extend the ability of HSA compatible HDHPs to pay for telehealth and other remote services before the deductible is met
 - The current temporary provision expires for plan years beginning after Dec. 31, 2024
 - Approved by House Ways & Means Committee on June 7, 2023, by a vote of 30-12 (with 5 Democrats voting in favor)
 - The bill is estimated to lose \$5 billion over the 10-year budget window
 - Companion Senate bill is S. 1001
- Chronic Disease Flexible Coverage Act, HR 3800
 - Would codify the IRS guidance regarding preventive services in Notice 2019-45
 - The Notice expanded the list of permitted preventive services to include certain treatments for chronic conditions
 - Approved by House Ways and Means Committee on June 7, 2023 (by a vote of 34-6)
 - Estimated to have a minimum impact on federal revenues



Legislative Outlook

- Funding for the federal government runs out on September 30
- Possible government shut down
- Possibility of health care legislation
- Possibility of year end legislation
- Impact of 2024 elections



Thank you!