WHG Chart

April 28, 2023

Recently, the Senate Health, Education, Labor, and Pensions (HELP) Committee, the Senate Finance Committee (SFC) and the House Energy & Commerce Committee (E&C) released a framework and legislation aimed at pharmacy benefit managers (PBMs). The first chart provides an overview of all PBM legislation currently under consideration, while the subsequent chart provides details of the provisions by reform area.

Bill	Transparency Requirements	Banning Spread Pricing	Rebate Passthrough	Improved Beneficiary Out-of-Pocket Costs	PBM Reimbursement
S____, The Pharmacy Benefit Manager Reform Act	Yes	Yes	Yes	No	No
The SFC PBM Legislative Framework	Yes	Yes	Yes	No	Yes
H.R. 2679, the PBM Accountability Act	Yes	No	No	No	No
H.R. 1613, the Drug Price Transparency in Medicaid Act of 2023	Yes	Yes	No	No	No
H.R. ___, patient protections for highly rebated drugs	No	No	No	Yes	No
H.R.___, to amend title XVIII of the Social Security Act to promote transparency of common ownership interests under parts C and D of the Medicare program	Yes	No	No	No	No
H.R. 2816, the PBM Sunshine and Accountability Act	Yes	No	No	No	No
H.R. 830, the Help Ensure Lower Patient (HELP) Copays Act	No	No	No	Yes	No

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(202) 309-0796 | administrator@wynnehealth.com

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Transparency Requirements	
S____, The Pharmacy Benefit Manager Reform Act	**Oversight of Entities that Provide PBM Services** – The following is applicable to health plans that are regulated by the Public Health Service (PHS) Act, the Employee Retirement Income Security Act (ERISA), and the Internal Revenue Code. Beginning January 1, 2025, entities that provide PBM services on behalf of a group health plan or health insurance issuer offering group health insurance coverage are required to submit the following information to the plan sponsor in a machine-readable format: A. Information collected from drug manufacturers by such issuer on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer; B. A list of each drug covered by the plan that was dispensed during the reporting period, including: a. The brand name, chemical entity, and NDC; b. The number of participants and beneficiaries for whom the drug was billed during the reporting period, the total number of prescription claims for the drug, and total number of dosage unites of the drug dispensed across the reporting period; c. For each claim or dosage unit, the type of distribution channel used, such as retail, mail order, or specialty pharmacy; d. The WAC, listed as cost per days supply and cost per pill; e. Total OOP spending by participant and beneficiaries on such drug after the application of any benefits under the plan or coverage, including spending through copayments, coinsurance, deductibles, but not including any amounts spent by beneficiaries on drugs not covered under the plan or for which no claim is submitted; f. For any drugs for which gross spending of the plan exceeded $10,000 and that is one of the 50 prescription drugs for which the group health plan spent the most on during the reporting period: i. A list of all other drugs in the same therapeutic category or class, including brand name drugs and biological drugs and generic drugs, or biosimilar products that are in the same therapeutic category or class; and ii. Rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable. C. The list of each therapeutic category or class of drugs that were dispensed under the health plan during the reporting period and with respect to each category or class: a. Total gross spending before manufacturer rebates, fee, or other remuneration;

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b. The number of participants and beneficiaries who filled a prescription for a drug in that category or class;
c. If applicable to that category or class, a description of the formulary tiers and utilization mechanisms;
d. Total OOP spending by beneficiaries through copayments, coinsurance, and deductibles; and
e. For each therapeutic category or class under which 3 or more drugs are included on the formulary:
    i. The amount received or expected to be received from drug manufacturers in rebates, fees, alternative discounts or other remuneration that has been paid or is related to the utilization of drugs;
    ii. The total net spending after deducting rebates, price concessions, and other remuneration; and
    iii. The net price per course of treatment or 30-day supply incurred by the health plan and its participants.

D. Total gross spending on prescription drugs by the plan during the reporting period, before rebates and other remuneration;
E. Total amount received or expected to be received in drug manufacturer rebates, fees, and other remuneration related to utilization of a drug or drug spending;
F. Total net spending on prescription drugs;
G. Amounts paid directly or indirectly in rebates, fees, or other remuneration to brokers, consultants, advisors, who referred the health plan to the PBM;
    a. A summary document that includes information described in a-g as the Secretary determines useful for plan sponsors for the purposes of selecting PBM services, such as an estimated net price to plan sponsor and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary.

Supplementary Reporting for Intra-company Prescription Drug Transactions – For PBMs providing services under a covered group health plan or covered group health insurance coverage, they must submit a supplementary report every 6 months to the plan sponsor that includes the following:

- An explanation of any benefit design parameters the encourage or require participants and beneficiaries in the plan to fill prescription at mail order, specialty or retail pharmacies that are wholly or partially-owned by plan issuer or PBM entity, including mandatory mail and specialty home delivery programs, retail and mail and auto-refill programs, and copayment incentives provided by the PBM entity;
- The percentage of total prescription charged to the plan that were dispensed by mail order, specialty or retail pharmacies that are wholly or partially-owned by plan issuer or PBM entity; and

- A list of all drugs dispensed by such wholly or partially-owned pharmacy and charged to the plan during the applicable quarter and, with respect to each drug:
  - The amounts charged per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, with respect to beneficiaries, including amounts charged to the beneficiaries;
  - The median amount charged per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply including amounts paid by beneficiaries, when the same drug is dispensed by other pharmacies that are not wholly or partially-owned by the issuer or PBM entity;
  - The interquartile range of the costs per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, including amounts paid by beneficiaries, when the same drug is dispensed by other pharmacies that are not wholly or partially-owned by the issuer or PBM entity;
  - The lowest cost, per dosage unit, per course of treatment, per 30-day supply, and per 90-day supply, for such drug, including amounts charged to the plan and beneficiaries, that is available from any pharmacy included in the network;
  - The net acquisition cost per dosage unit and for a 30-day supply and the acquisition cost per typical course of treatment, if the drug is subject to a maximum price discount; and
  - Other information with respect to the drug, as determined by the Secretary, such as average sales price (ASP), wholesale acquisition cost (WAC), and national average drug acquisition costs per dosage unit per typical course of treatment or per 30-day supply.

Reporting with Respect to Group Health Plans by Small Employers – For plan years beginning on or after January 1, 2025, health insurance issuers that offer group coverage for small employers that conduct transactions with a wholly or partially-owned pharmacy are required to submit the report required by the "Oversight of Entities that Provide PBM Services" section, as well as the supplementary report every 6 months to the plan sponsor.

Privacy Requirements – Nothing above prevents a health insurance issuer or PBM entity from placing reasonable restrictions on the public disclosure of the required reported information. However, health insurance issuers and PBM entities may not restrict disclosure of the required reports to HHS for enforcement purposes.

Opt-In for Group Health Insurance Coverage – For plan years beginning on or after January 1, 2025, plan sponsors may elect to require a health insurance issuer offering group health insurance coverage to submit to plan sponsors the following information:

- For covered group health insurance coverage, the information required by the "Oversight of Entities that Provide PBM Services" section; or

	• For other group health insurance coverage, the information required by points a-g of the "Oversight of Entities that Provide PBM Services" section. **Required Reporting for All Group Health Insurance Coverage** – Each health insurance issuer of health insurance coverage is required to annually submit the following information, regardless of whether the plan sponsor elected the report: • A summary document that includes information described in a-g as the Secretary determines useful for plan sponsors for the purposes of selecting PBM services, such as an estimated net price to plan sponsor and participant or beneficiary, a cost per claim, the fee structure or reimbursement model, and estimated cost per participant or beneficiary. **Submissions to the Government Accountability Office (GAO)** – A health insurance issuer offering group health insurance coverage or PBM entities are required to report the information required by the "Oversight of Entities that Provide PBM Services" section and the "Reporting with Respect to Group Health Plans by Small Employers" section. **Standard Formats** – No later than June 1, 2024, the Department of HHS, Labor, and the Treasury shall specify through rulemaking, standard formats for health insurance issuers and entities providing PBM services to submit the reports required by the bill. The Departments will also define through rulemaking a limited form of the report required to be submitted to plan sponsors who are also drug manufacturers, drug wholesalers, entities providing PBM services, or other direct participants in the drug supply chain, in order to prevent anti-competitive behavior.
The SFC PBM Legislative Framework	Provisions that would increase transparency to foster a better understanding of how financial flows across the prescription drug supply chain impact government health care programs.
H.R. 2679, the PBM Accountability Act	For plan years beginning on or after January 1, 2025, and annually thereafter, PBMs are required to submit the following information to plan sponsors and make such a report available in a machine-readable format: 1. Information collected from drug manufacturers by such issuer on the total amount of copayment assistance dollars paid, or copayment cards applied, that were funded by the drug manufacturer; 2. A list of each drug covered by the plan that was dispensed during the reporting period, including: ○ The brand name, chemical entity, and NDC; ○ The number of participants and beneficiaries for whom the drug was filled during the plan year, the total number of prescription fills for the drug, and the total number of dosage units of the drug dispensed across the plan year, including whether the dispensing channel was by retail, mail order, or specialty pharmacy; ○ The WAC, listed as cost per days supply and cost per pill;

	○ Total OOP spending by participant and beneficiary spending through copayments, coinsurance, and deductibles; and ○ For any drugs for which gross spending of the plan exceeded $10,000 during the reporting period: ▪ A list of all other drugs in the same therapeutic category or class, including brand name drugs and biological drugs and generic drugs, or biosimilar products that are in the same therapeutic category or class; and ▪ Rationale for preferred formulary placement of such drug in that therapeutic category or class, if applicable. 3. The list of each therapeutic category or class of drugs that were dispensed under the health plan during the reporting period and with respect to each category or class: ○ Total gross spending before manufacturer rebates, fee, or other remuneration; ○ The number of participants and beneficiaries who filled a prescription for a drug in that category or class; ○ If applicable to that category or class, a description of the formulary tiers and utilization mechanisms ○ Total OOP spending by beneficiaries through copayments, coinsurance, and deductibles; and ○ For each therapeutic category or class under which 3 or more drugs are included on the formulary: ▪ The amount received from drug manufacturers in rebates, fees, alternative discounts or other remuneration that has been paid or is related to the utilization of drugs; ▪ The total net spending after deducting rebates, price concessions, and other remuneration; ▪ The net price per course of treatment or single-fill. 4. Total gross spending on prescription drugs by the plan during the reporting period, before rebates and other remuneration; 5. Total amount received or expected to be received in drug manufacturer rebates, fees, and other remuneration related to utilization of a drug or drug spending; 6. Total net spending on prescription drugs; 7. Amounts paid directly or indirectly in rebates, fees, or other remuneration to brokers, consultants, advisors, who referred the health plan to the PBM. The bill also requires plans to submit the information required under points 1 through 4 above to the Government Accountability Office (GAO).
H.R. 1613, the Drug Price Transparency in Medicaid Act of 2023	To ensure accurate payments to pharmacies under Medicaid; the HHS Secretary will conduct a survey of retail community pharmacy drug prices to determine the national average drug acquisition cost. To accomplish this, the Secretary may require any retail community pharmacy that receives Medicaid payments to respond to the survey. Results of the survey will be made publicly available. No later than one year after the effective date, the Secretary will submit a report to Congress examining specialty drug coverage and reimbursement under Medicaid.
H.R.___, to amend title XVIII of the Social Security Act to promote transparency of	**Plan requirements:** For plan years beginning on or after January 1, 2025, a contract entered into with a Part D plan (PDP) sponsor shall require the sponsor to report the following information:

common ownership interests under parts C and D of the Medicare program.	• The negotiated price for each covered Part D drug for which benefits are available under the plan for each in-network pharmacy (including an identification of whether each such pharmacy is a specified pharmacy);
	• The average per-drug among of direct and indirect remuneration paid by specific pharmacies for such covered Part D drugs dispensed during the plan year; and
	• The average per-drug among of direct and indirect remuneration paid by non-specified pharmacies for such covered Part D drugs dispensed during the plan year.
	
	Specified pharmacy is to mean, with respect to a PDP a pharmacy in which the sponsor is a person with an ownership or control interest.
	
	PBM Requirements: For plan years beginning on or after January 1, 2025, Part D sponsors will be prohibited from contracting with a specified PBM, unless the PBM agrees to report the following information the HHS Secretary in a manner and at a time specified by the Secretary:
	
	• With respect to the total amount of pharmacy and manufacturers rebates collected by the PBM for all covered Part D drugs:
	  ○ The total amount of rebates pass through to the PDP sponsor; and
	  ○ The total amount of such rebates retained by the PBM.
	• The total amount paid by the PBM to pharmacies for drugs furnished under the PDP during a plan year;
	• The total amount of payments made by the PDP sponsor to the PBM as reimbursement for the PBMs payments to pharmacies;
	• The total amount of payment made by the sponsor to the PBM as fees for services furnished by the PBM with respect to a PDP for the plan year;
	• The total amount of administrative costs incurred by the PBM for furnishing PBM services;
	• A specification as to whether the PBM is a specified PBM to the PDP sponsor.
	
	A specified PBM is to mean a PBM in which a sponsor is a person with ownership or control interest.
	
	Pharmacy Requirements: For plan years beginning on or after January 1, 2025, Part D sponsors will be prohibited from contracting with a specified pharmacy, unless the pharmacy agrees to report the following information to the Secretary in a manner and at a time specified by the Secretary:
	
	• The negotiated price for each covered Part D drug dispensed by the pharmacy;
	• The average per-drug amount of direct and indirect remuneration paid by the pharmacy for covered Part D drugs dispensed by the pharmacy; and
	• A specification as to whether the pharmacy is a specified pharmacy with respect to the PDP sponsor.
	
	The Secretary will also established a process in which non-specified pharmacy can report such information.

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H.R. 2816, the PBM Sunshine and Accountability Act	The bill would require PBMs to publicly report additional information to HHS, including: ○ Aggregate dollar amount of all rebates, administrative fees, and other revenue the PBM receives from drug manufacturers and healthcare entities; ○ Highest, lowest, and total retained rebate percentages; and ○ Post-adjudication payments or clawbacks that PBMs extract from pharmacies
Banning Spread Pricing	
S ____, The Pharmacy Benefit Manager Reform Act	For plan years beginning on or after January 1, 2025, group health plans or health insurance issuers offering group or individual health insurance coverage and entities providing PBM services shall not charge participants and beneficiaries a price for a prescription drug that exceeds the price paid to the pharmacy for such drug, excluding penalties by the pharmacy to such plan, issuer, or entity.
The SFC PBM Legislative Framework	Addresses spread pricing an issue that the legislation will seek to solve, but did not provide details on the policy solution
H.R. 1613, the Drug Price Transparency in Medicaid Act of 2023	Prohibits spread pricing in Medicaid by requiring PBMs to make payments based on a pass-through pricing model under which:
Rebate Passthrough	
S ____, The Pharmacy Benefit Manager Reform Act	For plan years beginning on or after January 1, 2025, a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing PBM services are required to: • Remit 100 percent of rebates, fees, alternative discounts, and other remuneration received that are related to utilization of drugs under such health plan or health insurance coverage, to the group health plan; and • Ensure that any contract entered into by such third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing PBM services remit 100 percent of rebates, fees, alternative discounts, and other remuneration received. Such rebates, fees, alternative discounts, and other remuneration, shall be: • Remitted to group health plan or group health insurance coverage in a timely fashion after the period for which such rebates, fees, alternatives discounts, or other remuneration is calculated, and in no case later than 90 days after the end of such period; • Fully disclosed and enumerated to the group health plan sponsor; • Available for audit by the plan sponsor, or a third-party designated by a plan sponsor not less than once per year; and

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	• Returned to the issuer or entity providing PBM services by the group health plan if audits by the issuer or entity indicate that the amounts received are incorrect after such amounts have been paid to the group health plan. A third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing PBM services shall make rebate contracts with rebate aggregators or drug manufacturers available for audit by such plan sponsor or designated third party.
The SFC PBM Legislative Framework	Provisions could include policies to: • Ensure discounts negotiated by PBMs produce meaningful savings for seniors; • Address and mitigate practices that unfairly inflate the prices patients and government programs pay for prescription drugs.
Improved Beneficiary OOP Costs	
H.R. ___, patient protections for highly rebated drugs;	Beginning April 1, 2024, and annually thereafter, the HHS Secretary is to certify drugs that qualify as "highly rebated drugs," which are those drugs in which total rebates, reductions in price, and other forms of remuneration exceeded 50 percent of total annual spending on such drug. Beginning January 1, 2025, group health plans that provide coverage of highly rebated drugs are prohibited from imposing cost sharing for a 30-day supply that exceeds the quotient of the annual net price paid by the plan for the highly rebated drug divided by 12.
H.R. 830, the Help Ensure Lower Patient (HELP) Copays Act	The bill requires health insurance plans to apply certain payments made by, or on behalf of, a plan enrollee toward a plan's cost-sharing requirements. Specifically, plans must apply third-party payments, financial assistance, discounts, product vouchers, and other reductions in out-of-pocket expenses toward the requirements.
PBM Reimbursement	
The SFC PBM Legislative Framework	A provision that would delink PBM compensation from the drug price. This could be in the form of a flat rate for PBM services.

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