WHG Chart

May 19, 2023

Following the Senate Health, Education, Labor & Pensions (HELP) Committee markup (WHG summary) and the Energy & Commerce Health Subcommittee markup (WHG summary), we provide the following updated chart of PBM legislation.

Bill	Transparency Requirements	Banning Certain Practices	Rebate Passthrough to Plan	Improved Beneficiary OOP Costs	PBM Delinking
S. 1339, The Pharmacy Benefit Manager Reform Act **Advanced by Committee**	Yes	Yes	Yes	Yes	No
The SFC PBM Legislative Framework	Yes	Yes	Yes	No	Yes
H.R. 3281, the Transparent PRICES Act includes: • H.R. 2679, the PBM Accountability Act (commercial); • H.R. 3282, the Promoting Transparency and Healthy Competition in Medicare Act; (Medicare), and • H.R. 1613, the Drug Price Transparency in Medicaid Act of 2023 (Medicaid). **Advanced by Subcommittee**	Yes	Yes	No	No	No
H.R.3285 the Fairness for Patient Medications Act) **Advanced by Subcommittee**	No	No	No	Yes	No
H.R. 2816, the PBM Sunshine and Accountability Act	Yes	No	No	No	No
H.R. 830 and S. 1375 the Help Ensure Lower Patient (HELP) Copays Act	No	No	No	Yes	No
H.R. 2880, Protecting Patients Against PBM Abuses	Yes	Yes	No	No	Yes

1301 K St., NW – Ste. 300 | Washington, DC 20005
(202) 309-0796 | administrator@wynnehealth.com

WHG Chart

May 19, 2023

Transparency Requirements	
S. 1339, 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. For plan years beginning on or after the date that is 30 months after the date of enactment, 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 each of the 50 prescription drugs with the highest gross spending under the group health plan: 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; and iii. Any change in formulary placement compared to the prior plan year. C. The list of each therapeutic category or class of drugs for which a claim was filed under the health plan during the reporting period and with respect to each therapeutic class: a. Total gross spending before manufacturer rebates, fee, or other remuneration; b. The number of participants and beneficiaries who filled a prescription for a drug in that category or class;

1301 K St., NW – Ste. 300 | Washington, DC 20005
(202) 309-0796 | administrator@wynnehealth.com

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;
H. An explanation of any benefit design parameters that encourage or require participants to fill prescription at mail order, specialty, or retail pharmacies that are affiliated with the PBM, including
    a. The percentage of total prescription charged to the plan that were dispensed by mail order, specialty, or retail pharmacies that are affiliated with the PBM;
    b. A list of all drugs dispensed by such affiliated pharmacy and with respect to each drug:
        i. The amount charged, per dosage unit, per 30-day supply, and per 90-day supply to the plan;
        ii. The amount charged, per dosage unit, per 30-day supply, and per 90-day supply to beneficiaries;
        iii. The median amount charged to the plan or issuer per dosage unit, per 30-day supply, and per 90-day supply when the same drug is dispensed to non-affiliated pharmacies;
        iv. The interquartile range or costs, per dosage unit, per 30-day supply, and per 90-day supply, including amounts paid by beneficiaries
        v. The lower cost, per dosage unit, per 30-day supply, and per 90-day supply, including amounts charged to the plan and beneficiaries;
        vi. The net acquisition cost per dosage unit, per 30-day supply, and per 90-day supply, if the drug is subject to a maximum price discount; and

vii. Other information with respect to the cost of the drug, as determined by the Secretary, such as ASP, WAC, national average drug acquisition cost

I. A summary document that includes information described in a-h 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; and

J. A summary document for participants or beneficiaries, which will made available to participants and beneficiaries upon request to the plan sponsor that contains information in d-g.

No later than 2 years after the date of enactment, HHS will promulgate regulations to implement these requirements.

Reporting with Respect to Group Health Plans by Small Employers – For plan years beginning on or after the date that is 30 months after the date of enactment and annually after, 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 information required in (d), (e), (f), and (g) above, as well as the following:

- 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; and
- A summary document that includes the above information as the Secretary determined to be useful for plan sponsors for the purpose of selecting PBM services.

Opt-In for Group Health Insurance Coverage – For plan years beginning on or after the date that is 30 months after the date of enactment, 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 “Reporting with Respect to Group Health Plans by Small Employers” 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. In addition to the PBM reporting requirements, the Assistant Secretary for Planning and Evaluation (ASPE) is required to conduct or commission a study on how the US health care market would be impacted by the regulatory changes that would disallow manufacturer rebates under this bill. The Government Accountability Office (GA) would also be required to submit a report to Congress pharmacy networks. Amendments to increase transparency include the following: **Mullin Amendment #1:** The amendment that would require group health plans to make available to patients and providers health claims, network, and cost information on Application Programming Interfaces (APIs). **Braun Amendment #4:** The amendment would require the Department of Labor to conduct a study on imposing fiduciary duties on PBMs. **Marshall Amendment #3:** The amendment that would require PBMs to disclose information on prescription spending by the plan and its beneficiaries, as well as rebates, discounts, and other remuneration received by the plan.
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. 3281, the Transparent PRICE Act includes: • H.R. 2679, the PBM Accountability Act; • H.R. 3282, the Promoting Transparency and	**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;

Healthy Competition in Medicare Act; and • H.R. 1613, the Drug Price Transparency in Medicaid Act of 2023	○ 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). **Drug Price Transparency in Medicaid Act:** 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.

Promoting Transparency and Healthy Competition in Medicare Act:

1) 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:

- 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.

2) 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.

3) 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 establish a process in which non-specified pharmacy can report such information.
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
H.R. 2880, Protecting Patients Against PBM Abuses	PBMs are required to report the following to Part D sponsors: • The aggregate dollar amount of all rebates that the PBM received from drug manufacturers; • The aggregate dollar amount of all administrative fees that the PBM received from drug manufacturers; • The aggregate dollar amount of all rebates that the PBM did not pass through to the plan sponsor; • The percentage of aggregate dollars amount of all rebates that the PBM did not pass through to the plan sponsor; and • With respect to all plans for which the PBM manages prescription drug coverage, the highest percentage and lowest percentage of aggregate dollars amount of all rebates that the PBM did not pass through to the plan sponsor. The HHS Secretary will annually publish the above information in a form that does not disclose the identity of a specific plan, the prices charges for specific drugs and classes, or the amount of any rebates.
Banning Certain Practices, Including Spread Pricing	
S. 1339, The Pharmacy Benefit Manager Reform Act	**Spread Pricing:** For plan years beginning on or after the date that is 30 months after the date of enactment, 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. **Markey Amendment #2:** The amendment would incorporate the Patient Right to Shop Act (S. 1374), which would prohibit the use of gag clauses between PBMs and health plans so that beneficiaries have all the necessary information within consumer decision-support tools. The amendment was approved by voice vote.

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. 3281, the Transparent PRICE Act includes 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: • Payment made by the PBM is limited to the ingredient cost and a professional dispensing fee that is not less than the professional dispensing fee that the State plan or Waiver would pay if the plan was making the payment directly; and • Is passed through in its entirety to the pharmacy or provider who dispenses the drug
H.R. 2880, Protecting Patients Against PBM Abuses	The bill requires that Part D sponsor ensure that PBMs acting on behalf of the plan comply with the following provisions: • With respect to a covered part D drug dispensed by a pharmacy, the PBM may not charge such sponsor a different amount for such drug's ingredient cost or dispensing fee than the amount the pharmacy benefit manager reimburses such pharmacy for such drug's ingredient cost or dispensing fee. • With respect to a covered Part D drug dispensed by a network pharmacy, the PBM may not reimburse such pharmacy in an amount less than the amount the PBM would reimburse an affiliated pharmacy for such drug; • With respect to each covered Part D drug included on formulary of such a plan for which there is a drug that is not included on such formulary with therapeutic equivalence rating of AB in the same therapeutic class or category, the PBM shall submit to the plan a report specifying the difference between the national average drug acquisition costs for such a drug not included in such formulary and negotiated prices for such drug.
Rebate Passthrough	
S. 1339, The Pharmacy Benefit Manager Reform Act	For plan years beginning on or after the date that is 30 months after the date of enactment, 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 on a quarterly basis to the group health issuer, no later than 90 days after the end of each quarter; • In the case of an underpayment in a remittance for a prior quarter, as soon as practicable, but not later than 90 days after notice of underpayment is given; • Fully disclosed and enumerated to the group health plan sponsor; • 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	
S. 1339, The Pharmacy Benefit Manager Reform Act	Murkowski Amendment #1: The amendment that would incorporate the Safe Step Act (S. 652), which requires health plans to establish an exemption process for patients that face step therapy protocols. Markey Amendment #2: The amendment would incorporate the Patient Right to Shop Act (S. 1374), which would prohibit the use of gag clauses between PBMs and health plans so that beneficiaries have all the necessary information within consumer decision-support tools.
H.R.3285 the Fairness for Patient Medications Act	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 and S. 1375 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.

WHG Chart

May 19, 2023

PBM Delinking	

H.R. 2880, Protecting Patients Against PBM Abuses
 	
Rep. Carter (E&C)
	The bill requires that Part D sponsor ensure that PBMs acting on behalf of the plan comply with the following provisions:
	• The PBM derives no income with respect to any services provided in connection with covered Part D drugs other than flat dollar amount service fee;
	• The PBM receives such fees only pursuant to a written agreement between the PBM and the sponsor that sets forth the amount of any such fees. Any such fees may not be directly or indirectly based on or contingent upon:
	  ○ The price of any covered Part D drug;
	  ○ Discounts, rebates, fees, or other remuneration with respect to drugs; or
	  ○ Any other circumstance specified by the Secretary.
	
	Each Part D sponsor and PBM is required to provide the HHS Secretary an annual certification of compliance with these requirements. Additionally, PBMs are required to disgorge to the Secretary any payment in violation of the bill.
	.

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.

1301 K St., NW – Ste. 300 | Washington, DC 20005
(202) 309-0796 | administrator@wynnehealth.com