Summary of Filed HELP Amendments
May 11, 2023

- **Braun #1 (PBM Fiduciary)**
  - Adds PBMs as fiduciaries under the ERISA definition and applies responsibilities and disclosure requirements for fiduciaries otherwise regulated under ERISA.
  - This new requirement would mean that a PBM can only contract with a service provider if the following conditions are met: (1) the contract is *reasonable*; (2) the services are necessary for the operation of the plan; and (3) reasonable compensation or fees are paid – per ERISA § 408(b)(2).
- **Braun #4 (DoL Study of PBM Fiduciary)**
  - Requires the Labor Secretary to submit a report to Congress on the impact of a change in policy as to whether (1) a PBM is considered a fiduciary under ERISA, and (2) a PBM is subject to requirements and disclosures under ERISA.
- **Marshall #1 (Limiting PBM Charges to Flat Service Fee)**
  - Only permits PBMs to charge flat service fees for any service.
  - Flat service fees may not be contingent on drug price or drug benchmark price, discounts, rebates, fees, remuneration, or any other amounts specified by the Secretaries.
  - Enforceable through civil monetary penalties ($10,000/day).
  - Implemented through interim final rules, which are not initially subject to notice and comment but may be revised after receiving comments.
- **Marshall #2 (Applying any Discounts to Beneficiary Cost Sharing and Deductible)**
  - Requires that third-party payments, financial assistance, discounts, product vouchers, and other reductions (presumably with respect to brand name drugs based on the rule of construction) be applied to a patient's out-of-pocket requirements.
    - Applies to group health plans, coverage offered by health insurance issuers. Extends to payments made by the (1) Ryan White program, (2) Indian Health Service, and (3) Local, State or Federal Programs.
  - Does not apply to drugs for which generic or biosimilar versions are available.
  - Does not impact utilization management tools (including prior authorization and step therapy).
- **Marshall #3 (Disclosure of PBM and TPA Broker and Consulting Fees to Employer-Sponsored Plans)**
  - Requires that covered service providers who offer pharmacy benefit manager services or third-party administration services to ERISA-covered group health plans to furnish written information about their fees and services to the responsible plan fiduciary.
    - Implemented through notice and comment rulemaking within 18 months after enactment.
  - The new disclosure requirements would apply to parties who expect to receive $1,000 or more in direct or indirect compensation related to these services, which would typically include PBMs and TPAs.

    - The written disclosures would need to include details about the compensation expected to be received from the contract or arrangement and other information about the service relationship. The purpose of these disclosures is to enable the responsible plan fiduciary to assess the fairness of the compensation and identify any potential conflicts of interest.
    - Non-compliance with these disclosure requirements would render the service arrangement a prohibited transaction, as the statutory ERISA § 408(b)(2) exemption would not apply.
- **Murkowski (with Hassan and Marshall) (Safe Step Act – Exceptions Process for Medication Step Therapy)**
    - Group health plans must create an exception to medication step-therapy protocols in specified cases.
    - If certain conditions are met, a request to deviate from the protocol must be approved. These conditions include: (1) the current treatment is ineffective, (2) the expected ineffectiveness of the treatment along with irreversible consequences from delaying effective treatment, (3) the likelihood of an adverse reaction caused by the treatment, (4) the interference of the treatment with the individual's daily activities or occupational duties, (5) the individual's stability with the current prescription drugs, or (6) additional circumstances as determined by the Employee Benefits Security Administration.
    - Requires a group health plan to implement and makes a clear process available for an individual to request an exception to the protocol, including required information and criteria for granting an exception.
    - Specifies timelines under which plans must respond to such requests.
- **Romney #2 (Spread Opt-In)**
    - Maintains the existing prohibition on spread pricing as outlined in the Manager's Amendment.
    - Introduces an option for all health plan sponsors to voluntarily choose to consider or engage in spread price contracts. If a plan sponsor decides to opt-in, the PBM must offer at least one non-spread pricing contract, in addition to any other proposed contracts.
    - PBMs must obtain written consent from the plan sponsor before renewing an existing contract or entering into a new contract.
- **Romney #3 (Spread Opt-In Limited to Fully Insured)**
    - Aligns with Romney #2 with two notable differences:
        - Limits the eligibility for plan sponsors to opt-in and consider entering into spread pricing contracts to solely fully insured plans, specifically referred to as "group health insurance coverage" within the amendment text.
        - Mandates that health plans must guarantee that enrollees under a spread pricing contract are not charged more for a prescription drug, covered by the plan, than what the PBM pays to the pharmacy.
- **Baldwin #1 (Justification of Manufacturer Price Increases)**
    - Drug manufacturers must inform HHS and submit a transparency and justification report 30 days before raising the price of certain drugs that cost at least $100 by more than 10 percent over one year or 25 percent over three years.

- If a drug's list price exceeds the median family income (which was $70,784 in 2021), manufacturers must also submit a transparency and justification report.
- These reports require manufacturers to justify each price increase and provide detailed information on manufacturing costs, research and development expenses, net profits, marketing and advertising spending, and other relevant data.
- Does not prohibit price increases but provides insight into determining drug prices. HHS would make this information publicly accessible within 30 days through an easily understandable online format and will present an annual report to Congress summarizing the data submitted by drug manufacturers.