Modifications to the Chairman's Mark of the

Modernizing and Ensuring PBM Accountability Act

**Section 2**

**To accept Hassan-Lankford #1**

On page 5 of the Mark, in the third bullet under the subheading "PBM Data Reporting Requirements", following "access to generics and biosimilars", but before "if plans cover", insert: "including with respect to relative formulary tier placement of such generics and biosimilars,"

**To accept Tillis #1**

On page 5 of the Mark, in the second bullet at the bottom of the page, following "Congressional Budget Office (CBO)", insert: ", the HHS OIG".

**To accept Warner-Thune-Cortez-Masto-Tillis #2**

On page 6 of the Mark, at the bottom of the page following subsection VIII, insert the following new paragraph:

"*IX. MedPAC Reports on PBM-Reported Information*

The provision would require MedPAC to issue two reports and related recommendations to Congress on the information being reported by PBMs under this section, including: (1) an initial analysis of information reported by PBMs during the early years of implementation; and (2) a second analysis several years later analyzing changes in trends revealed in the information reported over time."

**Section 3**

**To accept Warner-Lankford #1**

On page 7 of the Mark, at the end of the first paragraph under heading Provision following "(2) relevant to the pharmacy", insert: "as determined by pharmacy type."

**Sections Added under the Modified Mark**

**To accept Carper-Grassley #2**

On page 12 of the Mark, after Section 8, insert the following:

"**SECTION 9. P&T COMMITTEE CONFLICTS OF INTEREST.**

This provision would amend Section 1860D-4 of the Social Security Act (SSA) to require that at least one practicing physician and one practicing pharmacist is independent and free of conflict with respect to any pharmacy benefit manager."

**To accept Cantwell-Grassley-Menendez-Daines #1**

On page 12 of the Mark, after Section 9, insert the following:

"**SECTION 10. ENHANCING PBM TRANSPARENCY REQUIREMENTS.**

This provision would amend Section 1150A of the SSA to expand the type of entities that must report data to the HHS Secretary to include certain PBM affiliates, to add data elements that would be required to be reported (to include fees received from manufacturers), and to add a requirement for CMS to produce an annual report with confidentiality protections."

**To accept Stabenow-Lankford #1**

On page 12 of the Mark, after Section 10, insert the following:

"**SECTION 11. FACILITATING MIDYEAR FORMULARY CHANGES FOR BIOSIMILARS.**

Beginning in plan year 2025, this amendment would allow PDP sponsors to change the preferred or tiered cost-sharing status of a reference biological product if such sponsor adds a biosimilar for such reference product to the formulary. The PDP sponsor would need to submit a request to the Secretary in order to make such a change."

**To accept Thune-Brown-Barrasso-Stabenow #1**

On page 12 of the Mark, after Section 11, insert the following:

"**SECTION 12. STRENGTHENING PHARMACY ACCESS FOR SENIORS.**

This provision would mitigate PBMs from steering patients to PBM-owned pharmacies for medicines that do not qualify as "limited access drugs" by codifying a portion of the Part D manual. The provision would also increase transparency of PBM practices in the prescription drug supply chain related to the dispensing of limited access drugs."

**To accept Scott-Warner #1**

On page 12 of the Mark, after Section 12, insert the following:

"**SECTION 13. INITIATING MEANINGFUL PATIENT REVIEW OF VARIOUS EXISTING PART D REGULATIONS.**

This provision would direct CMS to conduct beneficiary-focused listening sessions open to the public on potential Medicare Part D improvements."

**To accept Blackburn-Lankford #4**

On page 12 of the Mark, after Section 13, insert the following:

"**SECTION 14. REPORTING ON ENFORCEMENT AND OVERSIGHT OF PHARMACY ACCESS REQUIREMENTS.**

This provision would require the HHS Secretary to publish biennial reports on enforcement actions and oversight activities undertaken by the Department with respect to the pharmacy access requirements under section 1860D-4(b)(1) of the Social Security Act."

**To accept Bennet-Lankford #1**

On page 12 of the Mark, after Section 14, insert the following:

"**SECTION 15. STUDY ON PRICE-LINKED COMPENSATION ACROSS THE SUPPLY CHAIN.**

This provision would require GAO to complete a study of compensation and payment structures related to drug prices in the retail prescription drug supply chain."

**To accept Cortez-Masto-Young #1**

On page 12 of the Mark, after Section 15, insert the following:

"**SECTION 16. REPORTS ON INAPPROPRIATE PHARMACY REJECTIONS.**

This provision would require the Secretary to publicly post a biennial report related to preventing, identifying, or addressing inappropriate pharmacy rejections and inappropriate coverage denials under Part D."

**To accept Cardin-Cassidy #1**

On page 12 of the Mark, after Section 16, insert the following:

"**SECTION 17. STUDY ON DRUG SHORTAGES.**

This provision would require GAO to complete a study of factors across the outpatient prescription drug supply chain that influence prescription drug shortages."

**To accept Lankford-Menendez #3**

On page 12 of the Mark, after Section 17, insert the following:

“**SECTION 18. REPORT ON BIOSIMILAR AND GENERIC ACCESS UNDER PART D.**

This provision would direct HHS OIG to conduct a study and generate a report on biosimilar and generic drug access under Part D, including with respect to Part D plan features that discourage or encourage low-priced biosimilar and generic drug adoption and utilization under the program, along with trends in such adoption and utilization.”