

Modifications to the Chairman's Mark of
The Prescription Drug Pricing Reduction Act of 2019

Subtitle A – Part B

To accept Menendez-Carper #3

On page 6 of the Mark, in the last paragraph on that page, add the following after the first sentence: “This payment would not exceed the total payment amount for the reference biologic.”

To modify Section 108

On page 10 of the Mark, in the first paragraph on that page, modify the second sentence to strike “may” and insert “shall”.

To accept Cassidy #2

On page 12 of the Mark, after Section 112, insert the following:

“Section 113: Study of Average Sales Price (ASP)

This provision would require GAO to study the difference between commercial and Medicare prices reported for ASP.”

To add Section 114: Authority to Use Alternative Payment for Drugs and Biologicals to Prevent Drug Shortages

On page 12 of the Mark, insert the following:

“Section 114: Authority to Use Alternative Payment for Drugs and Biologicals to Prevent Drug Shortages

This provision would authorize HHS to use a WAC-based (or other reasonable drug price measure) payment methodology under Medicare Part B instead of an ASP-based methodology for drugs that are currently in shortage and are on the FDA shortage list or for drugs which have a declining number of manufacturers that may result in a shortage in the future.

This provision also requires the establishment of a modifier or other mechanism that hospitals would report to CMS on claims for inpatient services that would enable tracking of use of drugs and biologicals in shortage.

Further, it would require the HHS Secretary to issue a public report to Congress related to shortages of generic drugs within the Medicare program.”

Subtitle B – Part D

To modify Section 123

On page 18 of the Mark, before the last sentence in the first full paragraph under “Provision,” add the following sentence: “Data released under this provision will represent transactions that occurred two years prior to the plan year in which data is released.”

To modify Section 125

On page 21 of the Mark, in the first sentence of the first full paragraph, following “electronic transmission of” but before “formulary and benefit information” insert “eligibility and”.

On page 21 of the Mark, in the second sentence of the first full paragraph, following “formulary of such plan;” but before “pharmacy options” insert “information relating to cost-sharing;”

To create Section 129

On page 25, after Section 128, insert the following:

“Section 129: Prohibit Branding on Part D Benefit Cards

This section would prohibit Part D plan sponsors from including any pharmacy branding information on the cards provided to beneficiaries for the purpose of accessing Part D benefits.”

To accept Cornyn/Cardin #1

On page 25 of the Mark, after Section 129, insert the following:

“Section 130: Preventing Fraud in Medicare Part D

The Mark would implement HHS-OIG recommendations to require Part D plan sponsors to report suspected and substantiate cases of waste, fraud, and abuse. Plan sponsors would also have to report any corrective actions taken to address these instances.”

To accept Cassidy-Brown-Lankford-Menendez-Daines #8

On page 25 of the Mark, insert the following after Section 130:

“Section 131: To Establish Pharmacy Quality Metrics in Medicare Part D

This provision would require the Secretary to establish a standardized pharmacy quality metrics program in Medicare Part D.”

To accept Cassidy-Menendez #6, as modified

On page 25 of the Mark, insert the following after Section 131:

“Section 132: Star Rating Measures to Encourage Biosimilar Uptake

This provision would require Medicare quality measures for Part D plan sponsors in the Star Rating system to include assessments of plan benefit and formulary design in encouraging patient access to biosimilars.”

To accept Portman-Carper #2, as modified

On page 25 of the Mark, after Section 132, insert the following:

“Section 133: HHS Study and Report on the Influence of Pharmaceutical Manufacturer Distribution on Provider Prescribing Behavior

HHS would conduct a study on the influence of pharmaceutical manufacturer distribution models that provide third-party reimbursement hub services on health care providers who prescribe the manufacturer’s drugs. The report would seek to identify whether these hub services influence or incentivize a provider to prescribe a drug, thus mitigating the effectiveness of cost-control measures like prior-authorization and step therapy that a Part D plan may utilize. The report would also seek to identify whether these hub services violate any existing federal laws.”

Subtitle C – Miscellaneous

To modify Section 141

On page 27 of the Mark, substitute the fourth paragraph with:

“HHS would be prohibited from publicly posting any proprietary manufacturer information.”

To remove Section 142:

On page 28 of the Mark, strike all of Section 142.

To accept Cantwell/Lankford #3, as modified

On page 28 of the Mark, insert the following after Section 141:

“Section 142: Strengthen and Expand Pharmacy Benefit Manager Transparency Requirements

This provision would amend SSA Section 1150A, which requires health plans or PBMs that manage prescription drug coverage to report aggregate information on prescriptions, price concessions, and PBM payments to pharmacies, to include PBMs contracting with state Medicaid programs in the types of PBMs required to report.

It would remove the current exemption of reporting bona fide fees from the reporting of the aggregate amount of price concessions negotiated and reported by a PBM. This section would also permit the HHS Secretary to share the information submitted by a PBM with:

- States in carrying out their administration and oversight of state Medicaid programs;
- The Federal Trade Commission; and
- The Department of Justice.”

To accept Casey #2, as modified

On page 28 of the Mark, insert the following after Section 142:

“Section 143: Medicare and Medicaid Prescription Drug Pricing Dashboard

This provision would codify and build on the internet website-based dashboards that contain information on prescription drug and biological spending and utilization in Medicare Part B, Medicare Part D, and Medicaid.”

To accept Bennet-Burr-Carper-Scott-Brown-Cassidy #1

On page 28 of the Mark, insert the following after Section 143:

“Section 144: Improve Coordination between the US. Food and Drug Administration and the Centers for Medicare and Medicaid Services

This provision would require the Secretary of HHS to convene a public meeting to discuss the challenges associated with the next generation of treatments and therapies that will be available to seniors. It also requires the Secretary to publish a report on coding, coverage, and payment processes under Medicare for new medical products.”

To accept Carper #1, as modified

On page 28 of the Mark, insert the following after Section 144:

“Section 145: Patient Perspectives in Medicare Local Coverage Determinations and National Coverage Determinations

This provision would authorize the Secretary of HHS to include patient perspectives in Medicare local and national coverage determinations in order to mitigate barriers in obtaining and assessing perspectives from patient and disability groups in the determination process.”

To accept Hassan-Whitehouse #4, as modified

On page 28 of the Mark, after Section 145, insert the following:

“Section 146: GAO Study on Increases to Medicare Spending due to Pharmaceutical Manufacturer Contributions to Copay and Patient Assistance Organizations

This provision would require GAO to study the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expenditures within the Medicare and Medicaid programs.”

To accept Toomey-Enzi #16

On page 28 of the Mark, after Section 146, insert the following:

“Section 147: To Require MedPAC to Submit to Congress a Report on Shifting Coverage of Certain Medicare Part B Drugs to Medicare Part D

MedPAC would issue a report no later than June 30, 2021, describing the differences in reimbursement for drugs under Parts B and D and the feasibility of moving coverage of such drugs currently reimbursable under Part B into Part D, with recommendations.”

To accept, as modified, Cortez Masto #10:

On page 28 of the Mark, insert the following after Section 147:

“Section 148: Taking Steps to Fulfill Treaty Obligations to Tribal Communities

The Mark would require GAO to conduct a study of access to and cost of prescription drugs in Indian Country, including:

- a review of what tribal communities pay for drugs relative to other consumers;
- recommendations to align the value of discounts available to the Medicaid program and discounts available to tribal communities through the purchased and referred care program for physician administered drugs;
- and an examination of how tribal communities utilize the Medicare Part D program and recommendations to improve enrollment among these populations.”

Subtitle D - Medicaid

To modify Section 208: Risk-Sharing Value-based Agreements for Covered Outpatient Drugs under Medicaid

On page 38 of the Mark, in Section 208, to the first paragraph after "...trials for such drug."

Add: Manufacturers of such drugs that are beyond 90 days after the phase II clinical trial meeting at the FDA as of January 1, 2022 may also notify the Secretary of their interest in entering into a risk-sharing value-based agreement (but if already on the market, such a drug must be approved by the FDA).

Subtitle E – Technical Corrections

On page 30, in Section 202, make a technical correction to the citation in the first line from 1927(b)(3) to 1927(g)(3).

On page 10 of the Mark, following "Section" but before "109" strike "This provision".

On page 10, in the sixth line of the last paragraph, strike "prohibits" and replace it with "prohibit".

On page 10, in the last line, strike "result".

On page 11, in the first line of the last paragraph, strike "2005" and replace it with "2015".

On page 12, in the third line of the first paragraph, add "would" after "a Medicare Part B drug".

On page 18, in the sixth line of the second full paragraph, add "is" before "displayed".

On page 18, in the sixth line of the second full paragraph, strike "prevented" and replace it with "prevents".

On page 24, in the sixth line of the last paragraph, add "the" after "would be".

On page 27, under "2. Prescription drugs...", add bullets to the lines beginning with the following: "In 2020"; "During 2021"; "During 2022"; "During 2023"; "On or after January 1".

On page 30, in the third line of the fifth paragraph, strike "be" after "would".

On page 33, in the second line of the third paragraph, add "to" after "used".

On page 39, in the first line of the last paragraph, add "in" after starting.