Grassley #1

Grassley Amendment #1 to the modification of the Chairman's Mark

Short Title: Grassley #1

Description of Amendment: To be supplied

Grassley #2

Grassley Amendment #2 to the modification of the Chairman's Mark

Short Title: Grassley #2

Description of Amendment: To be supplied

Roberts Amendment #1 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: This amendment may be cited as the "Using Market Forces to Keep Drug Prices Low"

Description of Amendment: This amendment prohibits mandatory rebates on covered Part D drugs with list price increases above inflation if the manufacturer enters into one or more price protection rebate agreements, or similar contracted agreements, for covered Part D drugs with plan sponsors and/or Pharmacy Benefit Managers.

Roberts Amendment #2 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: This amendment may be cited as the "Encouraging Stable Premiums for Medicare Part D Beneficiaries"

Description of Amendment: This amendment requires all mandatory rebates for covered Part D drugs with list price increases above inflation to be sent to Part D plans. It also requires that Part D plans demonstrate that these additional rebates were applied to benefit improvement or Part D premium reduction for the following benefit year.

Roberts Amendment #3 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: This amendment may be cited as the "Three Rationers Repeal"

Description of Amendment: Repeals the Center for Medicare and Medicaid Innovation (CMMI), the Community Preventive Services Task Force, and the Patient-Centered Outcomes Research Institute (PCORI).

Roberts Amendment #4 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: This amendment may be cited as the "Improving Metrics for Price Reporting for Orphan Drugs Act"

Description of Amendment: This amendment strikes reporting requirement #3 from Section 141 of this Act.

Cornyn-Cardin Amendment #1 to the Chairman's Mark

Short Title: Preventing Fraud in Medicare Part D

Description of Amendment: This policy 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.

Offset: To be provided.

Cornyn Amendment #2 to the Chairman's Mark

Short Title: Improving Innovation in Dialysis Treatment

Description of Amendment: This policy would authorize the Secretary of Health and Human Services to create a temporary add-on payment adjustment for a new medical device approved by the Food and Drug Administration that provides meaningful clinical improvement for the diagnosis, treatment, or management of end stage renal disease. The adjustment would be implemented in a nonbudget neutral manner under Section 1881(b)(14) of the Social Security Act (42 U.S.C. 1395rr(b)(14)) and take effect on January 1, 2020.

Offset: To be provided.

Cornyn Amendment #3 to the Chairman's Mark

Short Title: Clarification of Negotiated Price Definition

Description of Amendment: This policy would amend Section 123 to change the definition of negotiated price to require that a substantial percentage of price concessions that are determinable at the time and point of sale (e.g., price concessions that are often referred to as formulary tier rebates) are included in the negotiated price so that patient payments in the Part D deductible and co-insurance payments are based on this more accurate price.

Offset: To be provided.

Cornyn Amendment #4 to the Chairman's Mark

Short Title: Expanding Access to Generics and Biosimilars

Description of Amendment: This policy would require automatic Part D plan formulary coverage of generic drugs and biosimilars for which the wholesale acquisition cost (WAC) is lower than the WAC of the reference product.

Additionally, this provision would require that Part D plan formularies place generic drugs and biosimilars (other than specialty drugs) on a designated generic tier with cost-sharing that is meaningfully lower than the cost-sharing associated with the lowest cost-sharing tier that includes brand drugs.

This provision would establish a specialty tier designated for generic drugs and biosimilars that are considered specialty drugs with cost-sharing that is meaningfully lower than the cost-sharing associated with the brand drug specialty tier.

The term 'specialty drug' is defined as a covered Part D drug that exceeds a wholesale acquisition cost threshold established by the Secretary.

These provisions would take effect in Plan Year 2021 and subsequent years.

Offset: To be provided.

Cornyn Amendment #5 to the Chairman's Mark

Short Title: Protecting Seniors from High Drug Prices

Section 128 shall not go into effect until the Secretary of Health and Human Services certifies that it will not lead to higher launch prices.

Offset: To be provided.

Thune Amendment #1 to the Chairman's Mark of the Prescription Drug Pricing Reduction Act of 2019

Short Title: To lower prescription drug costs and support competition and free market principles

Description of the Amendment: This amendment would strike all after the table of contents and re-insert the table of contents and text of the Chairman's mark, except for Section 128 to impose an inflation cap in the Medicare Part D program.

Offset: To be provided

Thune/Enzi Amendment #2 to the Chairman's Mark of the Prescription Drug Pricing Reduction Act of 2019

Short Title: To support reducing beneficiary out of pocket costs and premiums and deficit reduction

Description of the Amendment: This amendment would direct any reductions in spending to the federal government that are not used to reduce beneficiary out of pocket prescription drug costs or premiums to deficit reduction.

Offset: To be provided

Thune Amendment #3 to the Chairman's Mark of the Prescription Drug Pricing Reduction Act of 2019

Short Title: TBD

Description of the Amendment: TBD

Offset: TBD

Thune Amendment #4 to the Chairman's Mark of the Prescription Drug Pricing Reduction Act of 2019

Short Title: TBD

Description of the Amendment: TBD

Offset: TBD

Thune/Carper Amendment #5 to the Chairman's Mark of the Prescription Drug Pricing Reduction Act of 2019

Short Title: To further promote value-based insurance design in Medicare Advantage and Part D

Description of the Amendment: This amendment would direct the Secretary of Health and Human Services (HHS) to promulgate regulations to expand the principles of value-based insurance design. Specifically, it would direct HHS to issue regulations to expand flexibility under the reinterpretation of the Medicare Advantage uniformity requirements as described in CMS' April 16, 2018 final rule, to include Medicare Advantage Prescription Drug Plans (MA-PD) and prescription drug plans under Part D.

CMS fact sheet: https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-policy-changes-and-updates-medicare-advantage-and-prescription-drug-benefit-program

Regulation: https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare

Offset: n/a

Thune/Carper Amendment #6 to the Chairman's Mark of the Prescription Drug Pricing Reduction Act of 2019

Short Title: Chronic Disease Management Act

Description of the Amendment: This amendment would ensure high-deductible health plans (HDHPs) that are used with health savings accounts (HSAs) can opt to cover care related to chronic disease management prior to a beneficiary reaching their plan deductible.

Background: https://www.thune.senate.gov/public/index.cfm/press-releases?ID=59C2BE3A-ECD2-45E2-BC60-F62A0CDD341A

Offset: To be provided

Burr-Bennet-Scott-Carper Amendment #1

Purpose: To improve the coordination between the U.S. Food and Drug Administration and the Centers for Medicare and Medicaid Services (CMS)

Description: This amendment would require a public meeting between FDA and CMS to discuss the challenges associated with the next generation of treatments and therapies that will be available to seniors. It also allows for certain novel medical products to receive a code in advance of FDA approval in order to streamline coverage determination, and provides for a specific coverage with evidence development pathway at CMS for these products. These coding and coverage changes are designed to encourage CMS to provide a more transparent and predictable path to help seniors access cutting-edge treatments and cures.

Offset to be provided.

Portman Amendment #1

Portman Amendment #1 to the Prescription Drug Pricing Reduction Act of 2019-

Description of Amendment: Portman #1 would require that Prescription Drug Plans to pass along an increased amount of rebates to patients at the point of sale. Increased amounts of rebates would be defined as the greater of either 20% of all total rebates collected or 20% more rebates than a Prescription Drug Plan had passed along to patients at the point of sale in plan year 2019.

In order to mitigate premium increases, the amendment would establish an additional a 5% manufacturer liability that runs through the entirety of the initial coverage phase, thus reducing liability for plans by 5% in the initial coverage phase.

Portman-Carper Amendment #2

Portman-Carper Amendment #2 to the Prescription Drug Pricing Reduction Act of 2019-

Description of Amendment: Portman-Carper #2 would require HHS to 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.

Toomey Amendment #1

Toomey Amendment #1 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Co-Sponsor: Roberts

Short Title/Purpose: To strike section 128 from the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Description of Amendment: Toomey Amendment #1 would strike the following provision:

- **Section 128:** Medicare Part D Rebate by Manufacturers for Certain Drugs with Prices Increasing Faster than Inflation

Offset: To be provided if necessary

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #2

Toomey Amendment #2 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose: To strike Section 107 of the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Description of Amendment: Toomey Amendment #2 would strike the following provision:

- **Section 107:** Medicare Part B Rebate by Manufacturers for Drugs or Biologicals with Prices Increasing Faster than Inflation

Offset: To be provided if necessary

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #3

Toomey Amendment #3 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose: To strike Section 209 of the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Description of Amendment: Toomey Amendment #3 would strike the following provision:

- **Section 209:** Modification of Maximum Rebate Amount under Medicaid Drug Rebate Program

Offset: To be provided if necessary

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #4

Toomey Amendment #4 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose: To prevent drug prices from increasing as a result of this legislation

Description of Amendment: Toomey Amendment #4 would prevent section 128 of the PDPRA from taking effect unless certified by the Secretary of Health and Human Services that it will not lead to higher launch prices nor result in higher beneficiary cost sharing due to the higher launch prices.

Offset: N/A

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #5

Toomey Amendment #5 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose: To ensure transparency and a robust fiscal analysis of the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Description of Amendment: Toomey Amendment #5 would require that the legislative text of the PDPRA be posted to the Senate Finance Committee website for no less than three full calendar days before the Committee can report the PDPRA to the full Senate.

Additionally, the amendment would require that Senate Finance Committee members have a final fiscal analysis, including behavioral assumptions, impacts on commercial payers and the uninsured, and other findings from the Congressional Budget Office for no less than three days before the Committee can report the PDPRA to the full Senate.

Offset: N/A

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #6

Toomey Amendment #6 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose: To prohibit the International Pricing Index Model for Medicare Part B Drugs subject to Section 107 of the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Description of Amendment: Toomey Amendment #6 would amend Section 107 of the PDPRA to prevent the Secretary of Health and Human Services from finalizing, implementing, or administering an International Pricing Index Demonstration, or any substantially similar regulation, for Medicare Part B drugs meeting the definition of "rebateable" under Section 107 of the PDPRA.

The International Pricing Index Demonstration refers to the proposed rule published by the Centers for Medicare & Medicaid Services on October 30, 2018, and entitled "Medicare Program; International Pricing Index Model for Medicare Part B Drugs."[1]

Offset: N/A – Amendment does not have a cost.

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

[1] 83 Fed. Reg. 54546

Toomey Amendment #7

Toomey Amendment #7 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose: To increase accountability and transparency in the Federal regulatory process by applying the provisions of the Regulations from the Executive in Need of Scrutiny (REINS) Act (S. 92) to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Description of Amendment: Toomey Amendment #7 would amend the relevant provisions of the Social Security Act to apply the following to any major rulemaking that occurs due to the enactment of the PDPRA.

Specifically, Toomey #7 would require that major rules that are promulgated pursuant to the enactment of the PDPRA be subject to Congress enacting a joint resolution of approval prior to taking effect. Such joint resolutions would be privileged in both the House and Senate.

Major rules are defined as any final or interim final rule with the following effects, as certified by the Office of Management and Budget:

- An estimated annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions;
- Significant adverse effects on competition, employment, investment, productivity, innovation; or
- The ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export market

Offset: N/A

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #8

Toomey Amendment #8 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose: To amend the Internal Revenue Code of 1986 to restore incentives for investments in qualified improvement property.

Description of Amendment: Makes technical amendments from the 2017 tax reform law to allow qualified improvement property to be immediately expensed instead of depreciated over 39 years. Additionally, clarifies that qualified improvement property has a 20-year depreciable life for purposes of the Alternative Depreciation System.

Offset: N/A – Amendment has no cost.

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #9

Toomey Amendment #9 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: The Empowering State Medicaid Programs to Lower Drug Prices Act

Description of Amendment: Toomey #9 would strike section 209 of the PDPRA and amend section 1927 of the Social Security Act to create a 10-state demonstration program empowering participating states to negotiate supplemental rebates through the use of formularies comparable to Part D and commercial insurers. The demonstration program would begin on January 1, 2022, and last for five years. Participating states would have the ability to petition the federal government to end their participation if the state determines, and the Secretary certifies, that further participation would result in immediate harm to beneficiaries or increased costs to the federal government.

Participating states would be required to cover at least two drugs per therapeutic class, with classes determined by the Secretary and informed by a public comment period. Drugs indicated to treat a rare disease or condition as defined in section 5(b)(2) of the Orphan Drug Act would be prohibited from being excluded with respect to the treatment of those rare diseases or conditions. Participating states would also be required to have processes approved by the Secretary for manufacturers and beneficiaries to appeal the exclusion of drugs.

Participating states would have the option to create separate formularies for covered outpatient drugs dispensed to individuals through a Medicaid managed care organization and drugs dispensed to individual on a fee-for-service basis.

Offset: To be provided if necessary.

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #10

Toomey Amendment #10 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose: To preserve state flexibility in contracting.

Description of Amendment: Toomey Amendment #10 would strike the following provision:

- **Section 206:** Improving Transparency and Preventing the Use of Abusive Spread Pricing and Related Practices in Medicaid

Offset: To be provided if necessary.

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #11

Toomey Amendment #11 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose:

Description of Amendment: To be supplied by sponsor

Offset:

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #12

Toomey Amendment #12 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose:

Description of Amendment: To be supplied by sponsor

Offset:

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #13

Toomey Amendment #13 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose:

Description of Amendment: To be supplied by sponsor

Offset:

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey Amendment #14

Toomey Amendment #14 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose:

Description of Amendment: To be supplied by sponsor

Offset:

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey/Crapo Amendment #15

Toomey/Crapo Amendment #15 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019 Act

Purpose: To allow for the offering of additional standalone Medicare prescription drug plans and increase the availability of plans offering point-of-sale rebates.

Description of Amendment: Toomey/Crapo #15 would increase the number of plan choices available to beneficiaries by requiring CMS to issue new guidance increasing the number of plans a Part D sponsor may offer in a region.

Toomey/Crapo #1 would allow a plan sponsor to offer up to two additional prescription drug plans in a region provided that one such plan offers certain price concessions to beneficiaries at the point-of-sale.

Offset: To be determined

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Toomey/Enzi Amendment #16

Toomey/Enzi Amendment #16 to the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title/Purpose: To require the Medicare Payment Advisory Commission (MedPAC) submit to Congress a report on shifting coverage of certain Medicare Part B to Medicare Part D.

Description of Amendment: Toomey/Enzi Amendment #16 requires MedPAC to issue a report no later than June 30, 2021, with a description of the differences in reimbursement for drugs under Parts B and D, including:

- Per-capita spending on Medicare-covered drugs;
- Utilization management techniques used with respect to Medicare-covered drugs; and
- Beneficiary cost-sharing with respect to Medicare-covered drugs.

Additionally, the report will include an analysis of the feasibility of moving coverage of such drugs currently reimbursable under Part B into such Part D, including recommendations regarding:

- Therapeutic categories and drug classes;
- Formulary flexibility;
- The ability of the benefit structure under Part D to control total spending on drugs and biologicals currently reimbursable under Part B;
- What, if any, changes to the bidding process under Part D may be necessary to integrate coverage of drugs and biologicals currently reimbursable under Part B into Part D; and
- Other changes to the program under Part D that the Commission finds necessary to facilitate the addition of drugs and biologicals currently reimbursable under Part B into Part D.

Offset: N/A – No additional funds are authorized for purposes of the report.

[NOTE – Amendment sponsor reserves the right to modify the amendment for technical, germaneness, or other purposes.]

Cassidy Amendment #1 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: To ensure providers and Medicare are appropriately paid under the Average Sales Price (ASP) formula

Description: This amendment would create a new formula separate from ASP, under which Medicare Part B claims are excluded from the ASP calculation, and the difference between traditional ASP and the new ASP would be paid to the HHS Secretary on a quarterly basis.

Offset: N/A

Cassidy Amendment #2 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: To study the difference between price reported for Average Sales Price (ASP) purposes in commercial and Medicare claims.

Description: This amendment would ask GAO to study the difference between price reported for Average Sales Price (ASP) purposes in commercial and Medicare claims.

Offset: N/A

Cassidy Amendment #3 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: To allow Medicare and Medicaid to better avoid duplicate discounts

Description: This amendment would direct the Secretary to establish a drug claims modifier in Medicare and Medicaid for the purpose of more effectively avoiding duplicate discounts.

Offset: N/A

Cassidy Amendment #4 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: To allow for innovation to be appropriately assessed under the Part D inflation rebate

Description: For a drug or biologic for which a sponsors has filed an additional application under section 505(b) or (j) of the Food, Drug, and Cosmetics Act or under section 351(k) of the PHSA for a change to a drug previously approved in another application under section 505(b) that results in a new indication, route of administration, dosing schedule, dosing form, delivery system, delivery device, or strength, such inflationary penalty may not apply.

Offset: N/A

Cassidy Amendment #5 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: To Ensure Equity for Rare Disease Patients

Description: This provision allows an addition to Sec. 208 to amend the requirements for reporting Medicaid best price and average manufacturer price (AMP). As part of a time-limited demonstration project, this provision would allow an exemption to both Medicaid best price and AMP for value-based arrangements that are for payments over a period of time not to exceed 5 years and will condition payment or nonpayment on meeting specified outcomes. The demonstration authority would reside in 1927(l), the initial year of a value-based arrangement would be limited to the five years following FY2021 (once the provisions in Sec. 208 are in place), and the demonstration must have a cost neutrality requirement that the costs to Medicaid under this exemption are not worse than if the exemption did not apply.

CBO score to be provided.

Offset: N/A

Cassidy-Menendez Amendment #6 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: To add a new measure set to the Medicare Star Ratings Program encouraging biosimilar uptake

Description: This amendment would direct the secretary to create a Star Ratings measure set based on Medicare patients' access to biosimilars. The elements of this assessment would be:

- Is a biosimilar on formulary in lieu of or in addition to its originator product
- Tier placement/cost-sharing relative to the originator product
- Utilization management tools
- Biosimilar utilization by enrollees when the biologic is also available

In developing such measures, the Secretary shall ensure that each measure developed to address coverage, preferencing, and utilization management is constructed such that patients retain equal access to appropriate therapeutic options without undue administrative burden.

Offset: N/A

Cassidy-Menendez Amendment #7 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: To provide relief for Medicare patients with chronic conditions

Description: The annual out-of-pocket threshold, or any amount incurred short of such threshold that is more than 1/12 of the amount specified in Section 121 of the PDPRA, may be paid by the beneficiary each month in equal installments up to the total amount specified in that section. A prescription drug plan or an MA-PD plan sponsor shall invoice a beneficiary in equal installments per month over the remaining benefit year for annual out-of-pocket expenses incurred by the beneficiary that are in excess of 1/12 of the amount specified in Section 121 of the PDPRA. Provided, however, that in no event shall the cost-sharing owed for the annual out-of-pocket threshold exceed the total amount specified in that section

Offset: N/A

Cassidy-Brown-Lankford-Menendez-Daines Amendment #8 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: To establish pharmacy quality metrics in Medicare Part D

Description: This this amendment would require the Secretary to establish a standardized quality metrics program in Medicare Part D

Offset: N/A

Cassidy-Brown-Lankford-Daines Amendment #9 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: Technical Update to Bona Fide Fees Definition

Description: this amendment would require PBMs to count bona fide fees (e.g. administrative fees) as part of their rebate calculation so that they are included in the amount that is required to be passed along to Medicare.

Offset: N/A

Wyden Amendment #1 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: Placeholder/TBD

Description of Amendment: Placeholder/TBD

Offset: TBD

[Note: Amendment sponsor reserves the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Wyden Amendment #2 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: Placeholder/TBD

Description of Amendment: Placeholder/TBD

Offset: TBD

[Note: Amendment sponsor reserves the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Stabenow Amendment #1 to The Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Cosponsors: Wyden, Brown, Cantwell, Cardin, Bennet, Casey, Warner, Whitehouse, Hassan, Cortez Masto

Short Title: Medicare Drug Price Negotiation

Description of Amendment: Amend the Social Security Act to allow the Secretary of Health and Human Services to leverage the bargaining power of Medicare Part D enrollees to lower prescription drug prices.

[Note: Amendment sponsor reserves the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Stabenow Amendment #2 to The Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: TBD

Description of Amendment: TBD

[Note: Amendment sponsor reserves the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Stabenow Amendment #3 to The Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: TBD

Description of Amendment: TBD

[Note: Amendment sponsor reserves the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Stabenow Amendment #4 to The Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: TBD

Description of Amendment: TBD

[Note: Amendment sponsor reserves the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Cantwell Amendment #1 to the Chairman's Mark of the Prescription Drug Pricing Reduction Act of 2019 (co-sponsored by Senators Stabenow, Cardin, Brown, Hassan)

Short Title: Requiring a report by the Secretary of Health and Human Services related to drug shortages in the Medicare program

Description of Amendment:

At the appropriate place in the Chairman's Mark, the amendment would require the Secretary of Health and Human Services to issue a public report to Congress related to shortages of generic drugs within the Medicare program. The report shall be issued no later than January 1, 2021. The report shall include an analysis of:

a) The effect of generic drug shortages on Medicare beneficiary access, quality, safety, and out-of-pocket costs;

b) The effect of generic drug shortages on health providers, including hospitals and physicians, across the Medicare program;

c) The current role of the Centers for Medicare and Medicaid Services (CMS) in addressing generic drug shortages, including CMS's working relationship and communication with other federal agencies and stakeholders;

d) The role of all actors in the generic drug supply chain (including drug manufacturers, distributors, wholesalers, secondary wholesalers, group purchasing organizations, hospitals, and physicians) on generic drug shortages within the Medicare program;

e) Medicare Part A and Part B reimbursement structures and incentives and their effect, if any, on generic drug shortages;

f) Whether shortages may be addressed by the establishment of an emergency supply program for generic drugs similar to the Strategic National Stockpile operated by the U.S. Department of Health and Human Services Assistant Secretary for Preparedness and Response.

The report shall provide relevant findings and recommendations to Congress. Such report shall include consultation with the Food and Drug Administration's Drug Shortages Task Force.

Offset: To be provided, if necessary

Cantwell Amendment #2 to the Chairman's Mark of the Prescription Drug Pricing Reduction Act of 2019

Short Title: Lymphedema Treatment Act

Description of Amendment:

At the appropriate place in the Chairman's Mark, insert the *Lymphedema Treatment Act of 2019* (S. 518)

Under current law, Medicare Part B does not provide coverage or reimbursement for compression therapy products used to treat lymphedema. Lymphedema is a chronic and debilitating health condition resulting in swelling in the lymphatic system.

The *Lymphedema Treatment Act* would amend Section 1861 of the Social Security Act (42 U.S.C. 1395x) to require that Medicare Part B cover physician-prescribed compression therapy items that are used to treat lymphedema. The legislation defines compression therapy items to include multi-layer compression bandaging systems; custom or standard fit gradient compression garments; non-elastic and low-elastic compression garments and compression wraps and directional flow pads; and any other compression items determined by the Secretary of Health and Human Services to be effective in treating lymphedema. The legislation requires coverage to begin on January 1, 2021.

Offset: To be provided

Cantwell Amendment #3 to the Chairman's Mark of the Prescription Drug Pricing Reduction Act of 2019 (co-sponsored by Senator Lankford)

Short Title: To amend title XI of the Social Security Act to strengthen and expand pharmacy benefit manager transparency requirements

Description of Amendment:

Current law (Section 1150A of the Social Security Act, 42 U.S.C. 1320b-23) requires that pharmacy benefits managers (PBMs) report certain confidential information about their business practices to the Secretary of Health and Human Services. These transparency requirements apply to PBMs that contract with Medicare Part D plans; Medicare Advantage plans offering a prescription drug plan; and qualified health plans offered on the Affordable Care Act (ACA) exchanges. Under current law, PBMs are required to report (a) the percentage of all prescriptions managed by the PBM that are provided through retail pharmacies compared to mail order pharmacies, and the generic dispensing rate, (b) the aggregate amount and type of rebates, discounts, or price concessions that the PBM negotiates, and the aggregate amount passed through to the plan sponsor, and (c) the difference between the amount the health plan pays the PBM and the amount the PBM pays pharmacies (also known as the "spread"). Under current law, the Secretary may use the transparency information collected in Section 1150A (in a manner that does not reveal the identity of a specific PBM or plan) in carrying out the Medicare Part D program. The Secretary may also share the reported information with the Government Accountability Office, the Congressional Budget Office, and to state exchanges under the Affordable Care Act.

At Section 1150A of the Social Security Act, the amendment would strengthen and expand these requirements by:

1. Including PBMs contracting with state Medicaid programs in the types of PBMs required to report information to the Secretary;

2. Expanding the information PBMs are required to report, to include:
   a. The percentage of rebates, discounts and price concessions passed on to the plan sponsor;
   b. The percentage of the "spread" between the price the health plan pays the PBM and the price the PBM pays pharmacies for drugs;
   c. The aggregate amount of bona fide service fees the PBM received from Medicare Prescription Drug Plan (PDP) sponsors, qualified health benefit plans, Medicaid managed care entities, and drug manufacturers.

3. Allowing more uses of the reported information, to include allowing the Secretary to disclose the information to:

    a. States in carrying out their administration and oversight of state Medicaid programs;
    b. To the Federal Trade Commission to carry out section 5(a) of the Federal Trade Commission Act (15 U.S.C. 45) and any other relevant consumer protection or antitrust authorities enforced by such Commission, including reviewing proposed mergers in the prescription drug sector.

    c. To assist the Department of Justice to carry out its antitrust authorities, including reviewing proposed mergers in the prescription drug sector.

Offset: To be provided if necessary

Menendez – Lankford- Cardin-Daines Amendment 1

Incentivizing Generic and Biosimilar Use in Medicare Part D

This provision would require Part D plan formulary coverage of generic drugs and biosimilars for which the wholesale acquisition cost is lower than the wholesale acquisition cost of the reference product.

This provision would require that Part D plan formularies place generic drugs and biosimilars (other than specialty drugs) on a designated generic tier with cost-sharing that is meaningfully lower than the cost-sharing associated with the lowest cost-sharing tier that includes brand drugs.

This provision would establish a specialty tier designated for generic drugs and biosimilars that are considered specialty drugs with cost-sharing that is meaningfully lower than the cost-sharing associated with the brand drug specialty tier.

The term 'specialty drug' is defined as a covered Part D drug that exceeds a wholesale acquisition cost threshold established by the Secretary.

These provisions would take effect in Plan Year 2022 and subsequent years.

Menendez –Lankford – Cardin --Daines Amendment 2

Incentivizing Generic Use in Medicare Part D

This provision would require Part D plan formulary coverage of generic drugs for which the wholesale acquisition cost is lower than the wholesale acquisition cost of the branded product.

This provision would require that Part D plan formularies place generic drugs (other than specialty drugs) on a designated generic tier with cost-sharing that is meaningfully lower than the cost-sharing associated with the lowest cost-sharing tier that includes brand drugs.

This provision would establish a specialty tier designated for generic drugs that are considered specialty drugs with cost-sharing that is meaningfully lower than the cost-sharing associated with the brand drug specialty tier.

The term 'specialty drug' is defined as a covered Part D drug that exceeds a wholesale acquisition cost threshold established by the Secretary.

These provisions would take effect in Plan Year 2022 and subsequent years.

Menendez –Carper Amendment 3

Where appropriate in the Chairman's mark update section 105 to add language to ensure that a biosimilar product's total payment including with add-on does not exceed the total payment of the reference product.

Carper Amendment #1 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: GAO report reviewing representation on patients in Medicare local coverage determination (LCD) and national coverage determination (NCD) processes

Description: The comptroller-general will review Medicare local coverage determinations (LCDs) and national coverage determinations (NCDs) from the last five years to make the following assessments related to the inclusion of patients in these Medicare coverage decisions:

- how often and to what extent patient perspectives were considered in the public comment periods associated with local and national coverage decisions?

- what barriers and challenges do patient and disability groups raise with regard to participating in the comment periods associated with local and national coverage decisions?

- are there geographic or policy variations in the level of interaction by patient and disability groups with local and national coverage decisions?

- what barriers or challenges to including patient perspectives in LCDs and NCDs are cited by patient and disability groups, CMS, and Medicare Administrative Contractors?

Offset: No offset needed.

Carper Amendment #2 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: Medicare Advantage Insurer Pharmacy and Therapeutics (P&T) Committee Improvements

Description: Under current law, Medicare Part D P&T committees are required to base clinical decisions on the strength of scientific evidence and standards of practice and take into account therapeutic advantages in terms of safety and efficacy. Also, under current law in Section 1182 of the Social Security Act (42 U.S.C. 1320e–1(e)), Medicare is prohibited from using a dollars-per-quality adjusted life year or similar measure that discounts the value of a life because of an individual's disability as a threshold to determine coverage, reimbursement, or incentive programs in order to prevent discrimination in access to care.

However, the scientific evidence considered by Part D P&T committees is not required to be publicly available to determine the validity of the scientific evidence or whether the scientific evidence used meets meaningful standards, especially evidence from organizations that may assess the clinical or cost effectiveness of a treatment based on averages without appropriate consideration of patient subpopulations.

Provision

This section would amend Section 1860D–4 of the Social Security Act to improve engagement of patients related to the work of Part D insurers' P&T committees making recommendations for formulary development and revisions by PDP sponsors. It would also ensure that differences among patient subgroups are considered, and that the scientific evidence referenced by the P&T committees is transparent to the public.

To ensure input from impacted beneficiaries and their providers, this provision would add a patient representative and a person with a disability to the P&T committee. It would also create expert advisory panels that would be consulted by the P&T committee when considering the formulary placement of treatments within the panel's expertise, one for rare diseases and others for high burden diseases.

The nation has made a commitment to personalized medicine and to the development of patient-centered outcomes research and other tools that help patients and their providers make improve personal health decisions. Often, different people respond differently to the same drugs. Therefore, in developing the formulary, the P&T committee would be required to take into account the needs of patient subgroups, including people with co-occurring conditions, racial and ethnic minorities, children, older adults and other populations likely to possess atypical medication responses.

The P&T committee would also be required to disclose scientific evidence referenced that may employ a dollars-per-quality adjusted life year or similar metric as described in 42 U.S.C. 1320e–1(e) and solicit input from appropriate expert advisory panels.

Offset: No offset needed.

Carper Amendment #3 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: GAO report reviewing representation on patients in Medicare local coverage determination (LCD) and national coverage determination (NCD) processes

Description: At the appropriate place in the Chairman's Mark, insert section 3 and section 5 (the Medicare Part D section) of the Insulin Price Reduction Act (Shaheen/Collins/Carper/Cramer).

The "Insulin Price Reduction Act" would prohibit PBMs and insurers in Medicare Part D from receiving rebates or other remuneration for insulin products for which the manufacturer has complied with the bill's list price reduction requirements. Specifically, insulin manufacturers that reduce the 2020 list price of their insulin product to a level no higher than the 2006 list price will be eligible for these rebate restrictions. To retain the rebate restriction treatment for the following year, any increases in the list price for the insulin product must be limited to no more than the increase in medical inflation for the year.

The bill would also require that PBMs and insurers waive the deductible for any insulin product that meets these list price reduction requirements each year.

Offset: No offset needed.

Carper Amendment #4 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: Providing Access to Medicare Part D for Medicare-only PACE enrollees

Description: Under current law, PACE program enrollees must obtain their Medicare Part D outpatient drug benefits through the Part D plan that is offered by the PACE provider. PACE program enrollees who are Medicare-eligible beneficiaries, but who are not eligible for benefits under the State's Medicaid program, must pay a premium for the Part D outpatient drug benefit.

This amendment would permit Medicare-only PACE program enrollees to purchase a standalone Part D prescription drug plan (PDP) policy from a PDP sponsor outside the PACE program. If a Medicare-only enrollee elects to purchase a standalone policy from a PDP sponsor outside the PACE provider, the enrollee would be responsible for premiums and cost-sharing imposed under that PDP plan. Total premiums and cost-sharing under a PDP policy from a PDP sponsor outside the PACE program could be substantially less than the premium that applies under the Part D plan offered by the PACE program.

Offset: To be provided at a later date

Carper Amendment #5 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: GAO report on effect of Medicaid inflation cap on generic drugs

Description: The comptroller-general will conduct a study examining the impact of the current Medicaid rebate cap of 100 percent and increasing the Medicaid rebate cap to 125 percent on generic medicines. GAO should consider how the policy impacts the pricing decisions of generic manufacturers, the potential for shortages, and the benefit provided to patients in the form of lower out-of-pocket costs.

Offset: No offset needed.

Cardin Amendment #1 to the Chairman's Mark the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: To address drug shortages.

Description of Amendment: This policy allows the HHS Secretary to reimburse Part A and Part B drugs that are in shortage at wholesale acquisition cost (WAC) or an alternate amount, instead of the manufacturers average sales prices (ASP) or current payment for the drug until the drug or biological is removed from the Food and Drug Administration (FDA) drug shortage list.

A drug only qualifies for this payment increase if the manufacturer reports 1) the shortage 6 months in advance, 2) the cause or causes of the shortage and 3) the expected length of the shortage.

Offset: To be provided, as needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Cardin-Cornyn Amendment #2 to the Chairman's Mark the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: Streamlining the Part D Appeals Process

Description of Amendment: This policy streamlines the Part D appeals process for beneficiaries by allowing a refusal at the pharmacy counter to function as the Part D plan's initial coverage determination.

Offset: To be provided, as needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Cardin-Cortez Masto-Hassan Amendment #3 to the Chairman's Mark the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: Empowering States to Address Prescription Drug Costs

Description of Amendment: This policy allows the HHS Secretary to confidentially share Medicaid drug price and rebate data, including best price information, with state affordability boards for purposes of advancing state prescription drug cost containment measures.

Offset: To be provided, as needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Cardin-Whitehouse Amendment #4 to the Chairman's Mark the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: International Price Indexing

Description of Amendment: This policy phases in by 2024 the Medicare payment amount for selected Part B drugs to an amount that more closely aligns with prices in countries with similarly developed economies compared to the United States.

Offset: To be provided, as needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Cardin-Hassan-Brown Amendment #5 to the Chairman's Mark the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: Civil Monetary Penalties for Not Reporting Drugs in Shortage

Description of Amendment: This policy imposes new civil monetary penalties on pharmaceutical manufacturers who participate in the Medicare and Medicaid programs when manufacturers do not provide information to the Food and Drug Administration on 1) reasons for a drug shortage, 2) estimated duration of the drug shortage, and 3) actions taken by the manufacturer to address the drug shortage.

Offset: To be provided, as needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Cardin Amendment #6 to the Chairman's Mark the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: Tax Credit For Increased Production of Drugs on the Drug Shortage List.

Description of Amendment: This policy creates a new tax credit for an eligible pharmaceutical manufacturer's qualified production expenses associated with a drug that is on the Food and Drug Administration's drug shortage list.

Offset: To be provided.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Brown Amendment #1 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Short Title: Medicare Negotiations and Competitive Licensing Act (S. 377)

Description: this amendment would authorize the Secretary of Health and Human Services (HHS) to negotiate drug prices and, if drug companies refuse to negotiate in good faith, it would enable the Secretary to issue a competitive license to another company to produce the medication as a generic.

Offset: to be provided (if necessary, as this is expected to be a saver).

Brown Amendment #2 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Cosponsors: Hassan

Short Title: Stop Price Gouging Act (S. 378)

Description: this amendment establishes excise tax on pharmaceutical companies that sell prescription drugs that are subject to price spikes that exceed the annual percentage increase of CPI-U.

Offset: to be provided (if necessary, as this is expected to be a saver).

Brown Amendment #3 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Short Title: Medicare Out of Pocket Cap

Description: based on sections from the Medicare Affordability and Enrollment Act of 2016 (S. 3371), this amendment would 1) establish an annual limit on out-of-pocket expenditures for traditional Medicare beneficiaries, 2) expand income-eligibility for cost-sharing, 3) with respect to beneficiaries consequently eligible for cost-sharing, establish an FMAP percent of 100% under Medicaid, and 4) allow beneficiaries residing in U.S. territories to be eligible for certain premium and cost-sharing subsidies available to other beneficiaries under Part D.

Offset: to be provided.

Brown Amendment #4 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Cosponsors: Hassan

Short Title: Reinstatement of Rebates into Part D for LIS Beneficiaries

Description: based on last Congress' *Medicare Drug Savings Act*, this amendment would require drug manufacturers to issue rebates to CMS for prescription drugs dispensed to eligible low-income individuals under Part D or an MA PDP. The Congressional Budget Office (CBO) has estimated in the past that this provision would save $141 billion over 10 years.

Offset: in past years, the Congressional Budget Office (CBO) has estimated that this provision would save $141 billion over 10 years.

Brown Amendment #5 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Short Title: Biologics Exclusivity

Description: based on the bipartisan PRICED Act in prior Congresses, this amendment would update the exclusivity period for biologics, lowering it from 12 years to 7 years, and ban the inclusion of intellectual property provisions related to biologics exclusivity in future trade agreements.

Offset: to be provided (if necessary, as this is expected to be a saver).

Brown Amendment #6 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Cosponsors: Stabenow

Short Title: Rebate Requirement for High Initial Launch Price

Description: this amendment would require drug manufacturers to pay additional rebates if they launch a new prescription drug product that has an initial price of $10,000 or more per year or course of treatment. All rebates would go back into the Medicare trust fund.

Offset: to be provided (if necessary, as this is expected to be a saver).

Brown Amendment #7 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Cosponsors: Cardin, Hassan

Short Title: Reduced Part D Premiums

Description: this amendment would lower the Part D out-of-pocket maximum set in section 121 of the Chairman's mark from $3,100 to $1,500 and make the other necessary adjustments to plan and manufacturer financing mechanisms in the benefit redesign (while retaining 20% government reinsurance in the catastrophic portion of the benefit) to keep premiums the same.

Offset: to be provided.

Brown Amendment #8 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Cosponsors: Cardin, Hassan

Short Title: Reduced Out of Pocket Cap in Part D

Description: this amendment would adjust the plan and manufacturer financing mechanisms in the benefit redesign (section 121 of the Chairman's mark) while retaining 20% government reinsurance in the catastrophic portion of the benefit to reduce the average Medicare Part D premium by 20%.

Offset: to be provided.

Brown Amendment #9 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Cosponsors: Cortez Masto, Whitehouse, Hassan

Short Title: End Taxpayer Subsidies for Drug Ads Act (S. 73)

Description: this amendment would amend the Internal Revenue Code of 1986 to deny the deduction for advertising and promotional expenses for prescription drugs.

Offset: to be provided.

Brown Amendment #10 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Cosponsors: Cassidy, Carper, Lankford, Hassan, Daines

Short Title: Phair Relief Act

Description: this amendment, identical to the introduced *Phair Relief Act*, would increase PBM transparency measures, require the Secretary to set a minimum percent of rebate that must be passed through back to the consumer, prohibit PBMs from retroactive DIR fee clawbacks for a period of 5 years, establish a standardized quality metrics system in Medicare Part D, and establish an audit system for pharmacies to report when they are reimbursed below cost.

Offset: to be provided.

Brown Amendment #11 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Cosponsors: Carper

Short Title: Part D Negotiated Prices Required to Take Into Account All Price Concessions at the Point-Of-Sale

Description: Amend SSA Section 1860D-2(d)(1)(B) to provide the negotiated price, including all price negotiated concessions, at the point-of-sale for covered Part D drugs, as is done in Section 4 of S. 476. If it is not possible to calculate all negotiated price concessions at the point-of-sale, an approximated negotiated price, as established by the Secretary, would be used. The approximate negotiated price would reflect the estimated negotiated price based on the previous year's negotiated price concessions under the plan for all or similar Part D drugs or be based on other factors determined appropriate by the Secretary. The use of the approximate negotiated price would not prevent the use of value-based contracts between drug manufacturers, prescription drug plan sponsors, Medicare Advantage organizations, and pharmacies. The effective date would be as soon as practicable.

Offset: to be determined.

Bennet-Burr-Carper-Scott-Brown-Cassidy Amendment #1 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Short Title: Improve Coordination between the U.S. Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS)

Description: This amendment would require the Secretary of Health and Human Services 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.

Offset: Not applicable.

Casey Amendment #1 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Cosponsors: Cortez Masto, Brown, Stabenow

Short Title: Medicare Extra Rx HELP (Higher Eligibility Limits in Part D) Act

Description of Amendment: This amendment would expand the Medicare Part D Low-Income Subsidy (commonly known as Extra Help) and simplify program administration by eliminating the program's asset test, increasing its income threshold and extending full cost-sharing protections to all program participants.

Casey Amendment #2 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Short Title: Prescription Drug Pricing Dashboard Act

Description of Amendment: This amendment would codify and build on the Medicare Part B, Medicare Part D and Medicaid drug spending dashboards.

Casey Amendment #3 to the Chairman's Mark, the Prescription Drug Pricing Reduction Act (PDPRA) of 2019.

Cosponsors: Brown, Stabenow, Hassan

Short Title: Protecting Married Seniors from Impoverishment Act

Description of Amendment: This amendment would make permanent protections that prevent the spouse of a person receiving Medicaid-covered home and community-based services from fully depleting his or her financial resources.

Warner Amendment #1 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: Reducing Prescription Drug Costs for Children's Health Insurance Program

Description of Amendment: This amendment would amend SSA 1927 to provide states with the option to apply the Medicaid Drug Rebate Program to standalone CHIP programs to help provide coverage of and improve access to prescription drugs. This option would allow states to align prescription drug coverage across programs, reduce prescription drug costs for states, and expand access to prescription drug coverage for children in CHIP.

Offset: N/A. Produces budgetary savings.

Warner/Carper/Bennet Amendment #2 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: Providing for Independent Clinical Valuation of New and Existing Therapies

Description of Amendment: This amendment authorizes the Centers for Medicare and Medicaid Services (CMS) to request independent third-party assessments of the clinical value of new and existing therapies. Such an assessment shall include metrics and criteria determined as necessary by affected patient groups and shall be prohibited from using metrics referenced in 42 U.S.C. 1320e–1(e). Medicare and Medicaid may prioritize such assessments to help make coverage decisions for Medicare and Medicaid beneficiaries with regard to advanced biological and gene therapies. In cases where a manufacturer challenges coverage decisions by Medicare and Medicaid, the Secretary may provide for independent and transparent assessments of claims and clinical evidence put forward by both the manufacturer and CMS to resolve disputes over coverage.

Warner/Bennet Amendment #3 to the Prescription Drug Pricing Reduction Act of 2019

Short Title: Technical Assistance to States Seeking to Implement Value-Based and Other Innovative Payment Arrangements

Description of Amendment: This amendment would require the CMMI/CMCS Medicaid Innovation Accelerator Program to provide technical assistance to state Medicaid programs seeking to implement innovative payment models such as the "Netflix" model or other value-based arrangements in Medicaid under supplemental rebates and other options.

Offset: N/A

Whitehouse Amendment #1 to the Chairman's Mark

Short Title: Tax Treatment of Patient Assistance Programs

Description of Amendment: This amendment prohibits pharmaceutical manufacturers from claiming tax deductions for amounts paid or incurred relating to manufacturer patient assistance programs for individuals with comprehensive health insurance.

Offset: Not needed.

Whitehouse Amendment #2 to the Chairman's Mark

Co-sponsor: Senator Brown

Short Title: Vaccine cost-sharing under Medicare Part D

Description of Amendment: This amendment would ensure treatment of cost sharing for Part D vaccines is consistent with treatment of vaccines under Medicare Part B. Under the amendment, the following would not apply to an adult vaccine recommended by the Advisory Committee on Immunization Practices that is covered under Medicare Part D: deductible, coinsurance, initial coverage limit, cost sharing above the annual out-of-pocket threshold.

Offset: To be provided.

Whitehouse Amendment #3 to the Chairman's Mark

Short Title: International Pricing Index

Description of Amendment: This amendment directs CMS to establish a "target price" for drugs reimbursed under Medicare Part B, based on an international price index of Organization of Economic Cooperation and Development countries. CMS would reimburse these drugs based on the target price.

Offset: Not needed

Whitehouse Amendment #4 to the Chairman's Mark

Short Title: International Pricing Index Start Date

Description of Amendment: Requires the Administration's International Pricing Index model to begin January 1, 2020.

Offset: Not needed

Hassan Amendment #1 to the Chairman's Mark

Short Title: Inflationary Rebate Multiplier for Price Spikes in Medicare Part B

Description of Amendment: This would amend the inflationary rebate provision in the Chairman's Mark to subject the manufacturer rebate obligation to a multiplier in instances where the ASP of a Medicare Part B drug increases at a rate substantially above inflation. The manufacturer rebate obligation, based on the inflationary rebate calculation methodology set forth in the Chairman's Mark, would be multiplied by two if the increase to the ASP rises at or above 2 times inflation, by 3 if the increase to ASP rises at or above 3 times the rate of inflation, and so on.

Offset: Not needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Hassan Amendment #2 to the Chairman's Mark

Short Title: Inflationary Rebate Multiplier for Price Spikes in Medicare Part D

Description of Amendment: This would amend the inflationary rebate provision in the Chairman's Mark to subject the manufacturer rebate obligation to a multiplier in instances where a manufacture increases the price of a drug substantially above inflation. The manufacturer rebate obligation, based on the inflationary rebate calculation methodology set forth in the Chairman's Mark, would be multiplied by two if the price of a Part D drug rises at or above 2 times inflation in a given period, by 3 if the increase to ASP rises at or above 3 times the rate of inflation in a given period, and so on.

Offset: Not needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Hassan Amendment #3 (offered with Senators Brown and Cortez Masto) to the Chairman's Mark

Short Title: Extending the Part D Rebate Liability to Reformulated and Repackaged Products

Description of Amendment: This amendment would extend the inflationary rebate obligation in Medicare Part D to include line extension drugs, which would include but not be limited to reformulations, changes in color, added inactive ingredients, and changes to packaging size of the same drug. This will address the concern that companies may choose to reformulate existing drugs in order to increase prices while avoiding their rebate obligations.

Offset: Not needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Hassan/Whitehouse Amendment #4 (offered with Senator Brown) to the Chairman's Mark

Short Title: GAO Study on Increases to Medicare Spending due to Pharmaceutical Manufacturer Contributions to Copay and Patient Assistance Organizations

Description of Amendment: This amendment directs the Government Accountability Office to study the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expenditures within the Medicare and Medicaid programs. This analysis shall include the extent to which copayment coupons and patient assistance programs contribute to inflated prescription drug prices; the impact these programs have on utilization of higher-cost brand drugs in the Medicare Part D program and lower utilization of generic drugs in the Medicare Part D program; the extent to which manufacturers offering copayment coupons and other patient assistance programs, or sponsoring manufacturer patient assistance programs report or obtain tax deductions for offering or sponsoring such assistance (either as business expenses or charitable deductions); and the extent to which manufacturers paying for sponsorships at outreach and advocacy events organized by patient assistance programs report or obtain tax deductions for offering or sponsoring such events.

Offset: Not needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Hassan Amendment #5 (offered with Senator Whitehouse) to the Chairman's Mark

Short Title: Requiring Patient Assistance Programs to Report Medicare Data

Description of Amendment: This amendment would require patient assistance programs as defined by the HHS Office of the Inspector General to report annually to CMS the total dollar amount of copayment assistance received by drug manufacturers, the total dollar amount given to Medicare beneficiaries, and the specific drugs for which the copayment assistance dollars were provided.

Offset: Not Needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Hassan Amendment #6 (offered with Senators Cortez Masto and Whitehouse) to the Chairman's Mark

Short Title: Adding Samples to the Medicare Open Payments Database

Description of Amendment: This amendment would require that drug and device manufacturers report annually to the Medicare Open Payments Database the value of any product samples distributed to physicians or hospitals. Such manufacturer reporting shall include the aggregate monetary value of each type of sample provided.

Offset: Not Needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Hassan Amendment #7 (offered with Senator Whitehouse) to the Chairman's Mark

Short Title: Mandatory Reporting of Charitable Contributions by Opioid Manufacturers

Description of Amendment: This amendment would require that any manufacturer of opioids report annually to the Medicare Open Payments Database the dollar amount of any charitable contributions to patient advocacy organizations, patient assistance programs, and other healthcare professional associations and organizations that engage in lobbying or advocacy activities before Congress or the Department of Health and Human Services. Such reporting shall include the dollar amount provided to each recipient organization.

Offset: Not Needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Hassan Amendment #8 to the Chairman's Mark

Short Title: Mandatory Reporting of Charitable Contributions by Drug Manufacturers

Description of Amendment: This amendment would require that drug manufacturers report annually to the Medicare Open Payments Database the dollar amount of any charitable contributions to patient advocacy organizations, patient assistance programs, and other healthcare professional associations and organizations that engage in lobbying or advocacy activities before Congress or the Department of Health and Human Services. Such reporting shall include the dollar amount provided to each recipient organization.

Offset: Not Needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Hassan Amendment #9 (offered with Senator Brown) to the Chairman's Mark

Short Title: Requiring Manufacturer Compliance with Post-Market Reporting Requirements

Description of Amendment: This amendment would require that pharmaceutical manufacturers that fail to adhere to existing post-market reporting requirements for products that receive accelerated approval be subject to civil monetary penalties as determined by the Secretary. This would allow the federal government to evaluate the safety and efficacy of expensive drugs, and ensure that pharmaceutical manufacturers are complying with existing laws that are in place to protect patients.

Offset: Not Needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Hassan Amendment #10 (offered with Senators Cortez Masto and Brown) to the Chairman's Mark

Short Title: Ensuring Beneficiary Certainty In Part D During the Benefit Redesign

Description of Amendment: In order to ensure certainty for Part D beneficiaries during the benefit redesign phase, this amendment would require that prior authorizations approved by a Part D plan for a beneficiary during the 2019 plan year be considered approved in subsequent plan years until the Part D benefit redesign is fully implemented, so long as the beneficiary does not voluntarily switch to a new Part D plan during that time.

Offset: Not Needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Hassan Whitehouse Amendment #4 (offered with Senator Brown) to the Chairman's Mark

Short Title: GAO Study on Increases to Medicare Spending due to Pharmaceutical Manufacturer Contributions to Copay and Patient Assistance Organizations

Description of Amendment: This amendment directs the Government Accountability Office to study the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expenditures within the Medicare and Medicaid programs. This analysis shall include the extent to which copayment coupons and patient assistance programs contribute to inflated prescription drug prices; the impact these programs have on utilization of higher-cost brand drugs in the Medicare Part D program and lower utilization of generic drugs in the Medicare Part D program; the extent to which manufacturers offering copayment coupons and other patient assistance programs, or sponsoring manufacturer patient assistance programs report or obtain tax deductions for offering or sponsoring such assistance (either as business expenses or charitable deductions); and the extent to which manufacturers paying for sponsorships at outreach and advocacy events organized by patient assistance programs report or obtain tax deductions for offering or sponsoring such events.

Offset: Not needed.

[Note: Amendment sponsor(s) reserve the right to modify this amendment for technical, revenue-related (if applicable), germaneness, or other purposes.]

Cortez Masto/Stabenow/Hassan/Brown Amendment #1 to the *Prescription Drug Pricing Reduction Act (PDPRA) of 2019*

Short Title: Reporting Government Contributions to Research and Development

Description of Amendment: This amendment would require drug manufacturers to report to the Centers for Medicare and Medicaid Services any financial or technical assistance provided by federal or state government entities, including but not limited to the National Institutes of Health and the Defense Health Program, to support the research and development of any drug for which the manufacturer is required to report pricing information under Sec. 141 of this bill.

Cortez Masto/Stabenow/Hassan/Brown Amendment #2 to the *Prescription Drug Pricing Reduction Act (PDPRA) of 2019*

Short Title: Understanding Government Contributions to Research and Development

Description of Amendment: This amendment would require the Government Accountability Office to conduct a study of financial or technical assistance provided by federal or state government entities, including but not limited to the National Institutes of Health and the Defense Health Program, to the research and development of the 10 highest cost drugs in Medicare Parts D and B by both program spend and unit price.

Cortez Masto/Stabenow/Hassan Amendment #3 to the *Prescription Drug Pricing Reduction Act (PDPRA) of 2019*

Short Title: Ensuring a Fair Deal for States

Description of Amendment: This amendment would prohibit the application of any interest charges in any contract between state Medicaid agencies and drug manufacturers to facilitate the long-term financing of drugs under Section 208 of this bill.

Cortez Masto Amendment #4 to the *Prescription Drug Pricing Reduction Act (PDPRA) of 2019*

Short Title: Protecting Patients

Description of Amendment: This amendment would prohibit the consideration of patient behavior in a determination of drug efficacy or the application of risk adjustment (such that would allow a manufacturer to collect payments despite diminished efficacy among riskier populations) for the purposes of satisfying the value component of a contract between state Medicaid agencies and drug manufacturers to facilitate the long-term financing of drugs under Section 208 of this bill.

Cortez Masto/Hassan/Brown Amendment #5 to the *Prescription Drug Pricing Reduction Act (PDPRA) of 2019*

Short Title: Ensuring Manufacturer Compliance with FDA Efficacy Safeguards

Description of Amendment: In cases where a state Medicaid program enters into a long-term financing contract with a manufacturer under Section 208 of this bill for the procurement of a drug that has received accelerated approval from the Food and Drug Administration (FDA), the contract will only remain valid so long as the manufacturer is in compliance with FDA's requirements for timely post clinical review (including any required post approval confirmatory studies), or the drug is deemed effective by FDA. Manufacturers whose drugs fail to meet this criteria cannot be reimbursed using federal Medicaid dollars.

Cortez Masto/Hassan Amendment #6 to the *Prescription Drug Pricing Reduction Act (PDPRA) of 2019*

Short Title: Ensuring a Fair Price for State Medicaid Agencies

Description of Amendment: In cases where a state Medicaid program enters into a long-term financing contract with a manufacturer for the procurement of a drug under Section 208 of this bill, the manufacturer must first receive approval of the price of the drug from an independent third party that would determine whether the reimbursement rate for the drug is appropriate based on factors including but not limited to: efficacy relative to therapeutic alternatives, manufacturing costs, and state budget impacts. The independent third party must include consumer groups, disability groups, and patients.

Cortez Masto/Hassan Amendment #7 to the *Prescription Drug Pricing Reduction Act (PDPRA) of 2019*

Short Title: Estimating the Impact of Unforeseen Circumstances on State Medicaid Agencies

Description of Amendment: This amendment would require the Government Accountability Office to conduct a study to understand the impact of significant changes in a state's Medicaid cost liabilities (e.g. through increased enrollment) or state or federal Medicaid funding (e.g. from cuts proposed in the President's budget) on state Medicaid agencies engaged in long-term financing contracts with drug manufacturers under Section 208 of this bill. GAO should explore the impact of outstanding payment obligations to drug manufacturers under the above circumstances on factors including but not limited to coverage of optional benefits, coverage of optional populations, and provider reimbursement rates.

Cortez Masto/Warner/Hassan Amendment #8 to the *Prescription Drug Pricing Reduction Act (PDPRA) of 2019*

Short Title: Understanding the Impact of the Act on List and Launch Price over Time

Description of Amendment: This amendment would require the Government Accountability Office to conduct a study of the impact of the policies in this legislation on the list and launch price of drugs covered under Medicaid, and Medicare Parts B and D over the decade preceding and following enactment.

Cortez Masto/Brown Amendment #9 to the *Prescription Drug Pricing Reduction Act (PDPRA) of 2019*

Short Title: Enhancing the Public Benefit of Direct to Consumer Advertising

Description of Amendment: This amendment would eliminate the full tax deduction for all direct-to-consumer prescription drug advertising, including traditional TV, print and radio, as well as all digital ads (including social media and mobile and web apps) when the ad pictures or mentions the specific name of the drug.

Cortez Masto Amendment #10 to the *Prescription Drug Pricing Reduction Act (PDPRA) of 2019*

Short Title: Taking Steps to Fulfill Treaty Obligations to Tribal Communities

Description of Amendment: This amendment 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;
- any instances where tribal communities (including but not limited to patients in Indian Health Service, Tribal, and urban Indian (I/T/U) health systems) struggle with access to prescription drugs and recommendations to address those barriers;
- recommendations to address gaps and barriers in Indian Health Service, Tribal, and urban Indian (I/T/U) health systems' access to the VA Prime Vendor Program and federal drug discount program;
- 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.