NCPA's Analysis of the
The Prescription Drug Pricing Reduction Act (PDPRA) of 2019
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On July 25, 2019, the Senate Finance Committee held a markup on several proposals related to drug pricing, collectively known as the Prescription Drug Pricing Act (PDPRA) of 2019. The following are proposals that are important to community pharmacies. It should be noted that these proposals are only conceptual and actual language has not been made public at this time.

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

- **What does this provision do?**
  Manufacturers would be required to pay a rebate to CMS for the amount their Medicare Part B drug/biologic is above the inflation rate (CPI-U). This is only applicable to drugs/biologics sold in physician offices. The provision does not appear to include biosimilars or vaccines in Part B.

Section 121 – Medicare Part D Benefit Design

- **What does this provision do?**
  Starting January 1, 2022, the Part D benefit would:
  - Change beneficiary cost sharing in the initial gap to 25%.
  - Eliminate the coverage gap.
  - Cap enrollee cost sharing above the catastrophic out-of-pocket threshold to $3,100.
  - Lower federal reinsurance in the catastrophic phase to 20% for the government, 60% for insurers (brand) or 80% (generic), and 20% for manufacturers (brand) or 0% (generic).
  - Change the manufacturer discount program to operate in the catastrophic phase, which would require manufacturers to give a 20% discount off negotiated prices during catastrophic coverage, including for LIS beneficiaries.

Section 122 – Providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission with Access to Certain Drug Payment Information, Including Certain Rebate Information

- **What does this provision do?**
  CMS would be allowed to share with MACPAC and MedPAC any Medicare Part D and Medicaid drug price and rebate data for further analysis. Data would be barred from certain public disclosures.

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Section 123 – Public Disclosure of Drug Discounts and Other PBM Provisions

- **What does this provision do?**
  - Report of Drug Data: For CY 2022, HHS would be required to make available data on aggregate price concessions and/or aggregate amount of the difference between what an insurer pays a PBM, and what a PBM pays retail pharmacies and mail order pharmacies, and the number of prescriptions dispensed. Data released under this provision would represent transactions that occurred two years prior to the plan year in which data is released.
  - Plan Audits of PBMs: For CY 2022, Part D plan sponsors would be required to conduct financial audits of data related to their PBM contracts. Audits would be conducted every two years. Audit reports would be submitted to HHS so that HHS could review the "net price transparency" between insurers and PBMs.
  - DIR Reports to Pharmacies: For CY 2022, Part D insurers would be required to report to pharmacies, at least annually, any post-point-of-sale adjustments for price concessions or incentive payments for covered Part D drugs, including those made by a PBM. Reports would be done at the claims level, "or approximated, if applied at another level."
  - DIR Reporting in Bids: For CY 2022, plans would have to report in their bids actual and projected direct and indirect remuneration amounts in their bids for Part D coverage, including those related to pharmacies. The purpose of this provision is to ensure that projected remuneration related to pharmacies and manufacturers is based on actual remuneration in a prior year.

Section 124 – Public Disclosure of Direct and Indirect Remuneration Review and Audit Results

- **What does this provision do?**
  - Public Disclosure of DIR Discrepancies: HHS would be required to publicly report DIR discrepancies in a plan's bids and annual DIR report. The public report would include the number of potential errors CMS identified for plan review, the extent to which plans resubmitted reports making changes to past contract years, and the extent to which errors in DIR reports resulted in an increase or decrease in DIR for a past year.
  - Public Disclosure of Plan Audits: For 2020, HHS would be required to publicly report the results of the independent third party financial audits of plans, that includes DIR information, conducted under current law.

Section 125 – Increasing Use of Real-Time Benefit Tools to Lower Beneficiary Costs

- **What does this provision do?**
  - Plans would be required to use a RTBT that enables electronic transmission of eligibility and formulary and benefit information that integrates with clinicians' electronic prescribing and EHR systems. Information in the tool would include: list of any clinically-appropriate alternatives to a drug included on the formulary of such

plan; information relating to cost-sharing; pharmacy options (including the individual's preferred pharmacy and other retail pharmacies and a mail-order pharmacy, as applicable); the formulary status and any applicable prior authorization or other utilization management policies applied by insurers.
  - HHS would adopt the electronic standard for the tool.

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

- **What does this provision do?**
  For CY 2022, manufacturers would be required to pay a rebate to CMS for their Medicare Part D drug if the list price (WAC) of that drug is above the inflation rate (CPI-U). Rebate would be for every 6 months. The provision applies to only brand and biologics (not biosimilars).

Section 129 – Prohibit Branding on Part D Benefit Cards

- **What does this provision do?**
  Part D plan sponsors would be prohibited from including any pharmacy branding information on the cards provided to beneficiaries for the purpose of accessing Part D benefits.

Section 130 – Preventing Fraud in Medicare Part D

- **What does this provision do?**
  Per HHS-OIG recommendations, Part D plan sponsors would be required 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.

Section 131 – To Establish Pharmacy Quality Metrics in Medicare Part D

- **What does this provision do?**
  The HHS Secretary would be required to establish a standardized pharmacy quality metrics program in Medicare Part D.

Section 132 – Star Rating Measures to Encourage Biosimilar Uptake

- **What does this provision do?**
  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.

Section 142 – Strengthen and Expand Pharmacy Benefit Manager Transparency Requirements

- **What does this provision do?**

- PBMs contracting with state Medicaid programs would be required to report aggregate information on prescriptions, price concessions, and PBM payments to pharmacies under SSA Section 1150A.
- 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.
- HHS would be able to share such information submitted by a PBM with: states overseeing Medicaid programs; the FTC; and the DOJ.

Section 143 – Medicare and Medicaid Prescription Drug Pricing Dashboard

- **What does this provision do?**
  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.

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

- **What does this provision do?**
  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.

Section 201 – Medicaid Pharmacy and Therapeutics Committee Improvements

- **What does this provision do?**
  For states with state-run formularies, P&T committees would need to include pharmacists.

Section 204 – Ensuring the Accuracy of Manufacturer Price and Drug Product Information under the Medicaid Drug Rebate Program

- **What does this provision do?**
  This provision would require the HHS Secretary to audit the price and drug product information reported by COD manufacturers to ensure its accuracy and timeliness.

Section 205 – Excluding Authorized Generics from the Calculation of Average Manufacturer Price for Purposes of the Medicaid Drug Rebate Program

- **What does this provision do?**
  This provision would exclude authorized generic drugs from the calculation of AMP under the Medicaid drug rebate program and for other purposes. In addition, this provision would amend the statutory definition of wholesaler to exclude COD manufacturers.

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

- **What does this provision do?**
  - Prohibits Spread Pricing: Spread pricing would be unallowable for purposes of claiming federal matching payments under Medicaid.
  - PBM Administrative Fees: Any administrative service fees paid to PBMs would be limited to a reasonable administrative fees and such fees would be reported to Congress/state(s) upon request.
  - Reimbursement Benchmark: PBMs would be required to reimburse an ingredient cost and a professional dispensing fee, which must be no less that the professional dispensing fee under the fee-for-service program.
  - Pharmacies Penalized for Not Answering NADAC: All retail community pharmacies that receive payments under Medicaid would be required to respond to NADAC surveys. Penalties for pharmacies that did not respond would be assessed. Also, information collected from survey would be publicly available including "information on price concessions including on and off invoice discounts."
  - Report on Specialty Drugs: HHS Secretary would be required to issue a report to Congress examining specialty drug coverage and reimbursement under Medicaid, i.e. whether acquisition costs for specialty drugs are captured in the NADAC survey.
  - Publish WAC for Outpatient Drugs: The provision would also require manufacturers to report wholesale acquisition cost for covered outpatient drugs and for the Secretary to make such information available on a public website.