Wynne Health Group

Memorandum

September 26, 2019

SENATE FINANCE COMMITTEE RELEASES TEXT OF PRESCRIPTION DRUG PRICING REDUCTION ACT OF 2019

The Senate Finance Committee released legislative text of the **Prescription Drug Pricing Reduction Act of 2019 (S. 2543)**, which was advanced (19-9) by the Committee in July. A summary follows below.

The bill requires rebates for Medicare Part B and Part D drugs whose prices have increased faster than CPIU. It makes significant changes to the Medicare Part D benefit design, including capping beneficiary out of-pocket costs at $3,100 in 2022, decreasing federal liability for reinsurance costs to 20 percent by 2024, eliminating the coverage gap discount program, and implementing 20 percent manufacturer discounts in the catastrophic phase. It also includes manufacturer transparency requirements beginning July 1, 2022, among other provisions.

Medicare Part B

- **Manufacturer Reporting of ASP Data** – Sec. 101 requires manufacturers without a Medicaid rebate agreement to report average sales price (ASP) data to HHS beginning the first calendar quarter after enactment.
- **Inclusion of Coupons' Value in ASP Calculation** – Sec. 102 requires drug, biosimilar, and biologic manufacturer to include the value of coupons provided to privately insured patients in medications' ASP effective for calendar quarters beginning July 1, 2021. A coupon is defined to mean "any financial support that is provided to a patient, either directly to the patient or indirectly to the patient through a physician, prescriber, pharmacy, or other provider, under a drug coupon program of a manufacturer that is used to reduce or eliminate cost-sharing." This provision does not apply to contributions to patient assistance programs or foundations.
- **Payment for Biosimilars during Initial Period** – Sec. 103 provides for biosimilar reimbursement on or after July 1, 2020, at the lesser of the biosimilar's wholesale acquisition cost (WAC) plus a three percent add-on; or ASP plus six percent of the reference biologic.
- **Temporary Increase in Medicare Part B Payment for Biosimilar Biological Products** – Sec. 104 provides for an increased add-on payment for a biosimilar for five years: from six percent of the reference product's ASP to eight percent of the reference product's ASP. The five year period begins Jan. 1, 2020, for biosimilars paid by Medicare as of Dec. 31, 2019, and otherwise begins the first day of the calendar quarter in which the product is paid by Part B.
- **Improvements to Medicare Site-of-Service Transparency** – Sec. 105 requires the HHS Secretary to make available on a public website the Medicare estimated payments to physician offices under the physician fee schedule and the associated estimated beneficiary cost-sharing amount. This provisions intends to allow beneficiaries to compare costs across hospital outpatient departments, ambulatory surgical centers (ASCs), and physician offices.
- **Medicare Part B Rebate by Manufacturers for Drugs or Biologicals with Prices Increasing Faster than Inflation** – Under sec. 106, manufacturers would be required to pay a rebate to Medicare for the amount that their Medicare Part B drugs or biologicals increased above CPI-U. A "rebatable" drug is defined as a brand prescription drug or biological that is separately payable when furnished in a physician office, hospital outpatient department, and ASC setting, although the

definition would not include biosimilars or vaccines in Part B. HHS would provide specified information to manufacturers by Jan. 1, 202, including the total number of billing units for each rebatable drug for the quarter; the amount, if any, of the excess ASP increase for the quarter; and the rebate amount for the rebatable drug. Manufacturers would pay a quarterly rebate within 30 days. HHS would use the ASP for a rebatable drug in the calendar quarter beginning July 1, 2019, for determining the CPI-U change in subsequent quarters. Civil monetary penalties would apply for failure to pay the required rebate amount.

- **Required Refunds for Discarded Amounts of Certain Single-Dose Vials** – Sec. 107 requires manufacturers to pay refunds beginning July 1, 2021 if the unused portions of certain single-dose vials exceed a minimum threshold set at 10 percent, although the threshold could be increase through rulemaking. Civil monetary penalties would apply for failure to pay the required rebate amount. This provision does not apply to drugs or biologicals that serve as radiopharmaceutical or imaging agents.
- **Clarification of the Medicare ASP Methodology** – Sec. 108 creates a statutory definition of "bona fide service fees" that manufacturers do not have to include as a concession in the calculation and reporting of ASP. Specifically, it is defined as the "fair market value for a bona fide, itemized service that is actually performed on behalf of the manufacturer; and the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; is not passed on, in whole or in part, to a client or customer of the entity, whether or not the entity takes title to the drug or biological; is a fixed payment and not based on a percentage of sales; and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties." The definition would "narrow" the existing fees exempt from ASP reporting (i.e. fees based on a percentage of sales) and thus expand those that must be treated as a concession and included in ASP reporting.
- **Maximum Add-on for Drugs, Biologicals, and Biosimilars** – Sec. 109 establishes $1,000 as the maximum add-on amount a provider can be reimbursed for a drug, biological, or biosimilar beginning on Jan. 1, 2021. Providers would receive the lesser of that amount or the percentage based add-on through Dec. 31, 2028; the $1,000 max would be indexed in 2029 and beyond. The max applies to separately payable drugs in physician offices, hospital outpatient departments, and ASCs.
- **Treatment of Drug Administration Services Furnished by Off-Campus Outpatient Departments of Providers** – Sec. 110 requires that payment for the professional service of administering a Medicare Part B drug is made at the Medicare Physician Fee Schedule rate, not the Hospital Outpatient Prospective Payment System rate beginning Jan. 1, 2021. The provision would not be implemented in a budget neutral manner.
- **GAO Study and Report on ASP** – Sec. 111 directs the Government Accountability Office (GAO) to study spending on drugs and biologicals for which reimbursement is based on ASP and that account for the largest percentage of total spending on drugs under Part B. The study is required to analyze the extent to which the drugs and biologics are paid for under Part B or by private payers; changes in Medicare spending or beneficiary cost-sharing; and the extent to which manufacturers provide rebates, discounts, or other price concessions to private payers. The report, including recommendations, is due to Congress no later than two years after enactment.
- **Authority to Use Alternative Payment to Prevent Potential Drug Shortages** – Sec. 112 authorizes the HHS Secretary to use WAC or another "reasonable measure" instead of ASP to prevent a potential shortage of the drug or biological in response to a public health emergency.

<u>Medicare Part D</u>

- **Medicare Part D Benefit Redesign** – Beginning Jan. 1, 2022, sec. 121 implements significant reforms to Medicare Part D's benefit design, including:

- Eliminating the coverage gap and establishing 25 percent beneficiary cost-sharing between the annual deductible and catastrophic threshold;
- Capping enrollee cost sharing above the catastrophic out-of-pocket limit; and
- Establishing a new annual out-of-pocket spending amount needed to trigger the catastrophic coverage phase of $3,100 in 2022, indexed to the growth in Part D spending.

The provision would also:

- Lower federal reinsurance in the catastrophic phase, with Medicare ultimately paying 20 percent and insurers paying 60 percent for brand drugs and 40 percent for generic drugs in 2024 and subsequent years.
- Sunset the existing coverage gap discount program, where manufacturers are currently paying 70 percent discounts;
- Institute a new manufacturer discount program in the catastrophic phase through which brand manufacturers enter into agreements with HHS to provide 20 percent discounts off negotiated prices to applicable beneficiaries, including individuals who are enrolled in a Part D plan; are not enrolled in a qualified retiree prescription drug plan; and have not incurred costs for covert part D drugs in a year that are equal to exceed the annual out-of-pocket threshold.

- **MedPAC and MACPAC Access to Rebate Data** – Sec. 122 authorizes HHS to share Medicare Part D and Medicaid rebate data with the Medicare Payment Advisory Commission (MedPAC) and Medicaid and CHIP Payment and Access Commission (MACPAC), subject to limitations. Specifically, MedPAC and MACPAC are prohibited from disclosing information about "the specific amounts or identity of the source of rebates, price concessions, and other forms of direct or indirect remuneration under such prescription drug plan or such MA-PD plan" as well as "information submitted with the bid."
- **Public Disclosure of Drug Discounts and Other PBM Provisions** – Under sec. 123, HHS would be required to publicly disclose online data on aggregate price concessions, including rebates and discounts and as well as spread. Such information is required to be posted beginning July 1, 2022. Part D plans would also be required to audit data in their pharmacy benefit manager (PBM) contracts, including accounting for the net price of covered drugs, and would be subject to civil monetary penalties for non-compliance. Part D plans would be required to report to pharmacies at least annually on any post-point-of-sale adjustments for price concessions or incentive payments and at least annually to HHS on any conflicts of interest among P&T committee members. Part D plans would also be required to report beginning in plan year 2022 on projected and annual direct and indirect remuneration (DIR).
- **Public Disclosure of Direct and Indirect Renumeration Review and Audit Results** – Under sec. 124, HHS would publicly report on "discrepancies related to direct a summary and detailed DIR reports submitted by PDP sponsors." Such reports are required to include "the number of potential errors identified by the Secretary for PDP sponsors to review; the extent to which PDP sponsors resubmitted DIR report to make changes for previous contract years; and the extent to which resubmitted DIR reports resulted in an increase or decrease in DIR in a previous contract year."
- **Increased Use of Real-Time Benefit Tools (RTBTs)** – Sec. 125 requires Part D plans to implement RTBTs meeting specified criteria, though no sooner than standards are adopted by HHS. The provision would require qualified EHRs under ONC's Health IT Certification Program include RTBTs providing patient cost and coverage information and add use of RTBTs to improvement activities for purposes of the Merit-based Incentive Program.
- **Improvements to Provision of Parts A and B Claims Data to Drug Plans** – Sec. 126 provides for an exception to the current parameters for Part D plans' use of Parts A and B data, allowing

them to use such data for certain coverage determination purposes such as to improve therapeutic outcomes.

- **Permanent Authorization of Successful Pilot for Retroactive Part D Coverage for Low-Income Beneficiaries** – Sec. 127 permanently authorizes the Limited Income Newly Eligible Transition (LI NET) program beginning no later than 2022.
- **Part D Rebate by Manufacturers for Certain Drugs with Prices Increasing Faster than Inflation** – Sec. 128 requires a mandatory rebate if manufacturers increase list prices for Part D drugs above CPI-U. Manufacturers would be required to provide rebates to Medicare for each six month period beginning Jan. 1, 2022 for which the list price (defined as WAC) of a "rebatable" drug increased faster than CPI-U for that period. Rebatable drugs are brand medications (not a generic) or those that are licensed as a biologic (not a biosimilar). Rebates would be based on the quantity of each drug during the rebate period and the amount its average daily list price exceeded the inflation-adjusted list price. Manufacturers would have to enter into rebate agreements with HHS for their drugs to be covered by Part D.
- **Branding on Part D Benefit Cards** – Sec. 129 prohibits co-branded, co-owned, or affiliated network providers, pharmacies or PBMs on Part D benefit cards and will apply to plan years beginning on or after Jan 1, 2022.
- **Fraud, Waste, and Abuse in PDP and MA-PD Plans** – Sec. 130 requires PDPs and MA-PD plans to report potential fraud, waste, and abuse, including suspicious activities and steps made by the plans to take corrective actions, to HHS beginning Jan 1, 2021.
- **Pharmacy Quality Measures** – Sec. 131 directs HHS to establish a set of pharmacy quality measures for PDPs to implement in incentive payments to pharmacies or price concessions paid by a pharmacy based on quality measures. This shall take effect Jan 1, 2023.
- **Access to Biosimilar Biological Products Measure** – Sec. 132 establishes the inclusion of a set of measures based on access to biosimilar products to the 5-star rating system in Medicare. Effective in 2025, the measures will assess the impact a plan's benefit structure has on utilization or access to biosimilars.
- **Pharmaceutical Manufacturers Third-Party Reimbursement Hubs** Sec. 133 directs HHS to conduct a study on the influence of pharmaceutical manufacturers third-party reimbursement hubs on health care providers who prescribe their drugs and biologicals. HHS will submit a report to Congress no later than Jan. 1, 2021.

<u>Miscellaneous</u>

- **Drug Manufacturer Price Transparency** – Sec. 141, effective July 1, 2022, requires manufacturers to report to HHS information and supporting documentation needed to justify WAC price increases for prescription drugs and biological products in cases where the Secretary determines the price increase met or exceeded certain thresholds. HHS would then be required to publicly post the price justifications for applicable drugs under three categories: (1) drugs or biologics with list price of at least $10 per dose and price increase of at least 100 percent since the date of enactment during 2020; (2) drugs and biologics in the top 50 percent of net spending (per dose) in Medicare or Medicaid in at least one of the preceding 5 years and a list price increase; and (3) new drugs with a high launch price established for the first time, if the list price for a year supply or course of treatment exceeds the gross spending for covered Part D drugs necessary to meet the annual out-of-pocket threshold (about $10,000 in 2022). Drugs with a high launch price would be required to report annually until an equivalent is on the market. Failure to submit timely justification or false information will result in civil money penalties.
- **PBM Transparency Requirements** – Sec. 142 delineates information PBMs are required to submit, including aggregate amounts of service fees received from PDPs, qualified health plans, managed care entities, and drug manufacturers. No later than July 1, 2020, the Inspector General

of HHS will conduct an annual review of the information and evaluate PBM rebates, administrative fees, the difference between what plans pay PBMs and what PBMs pay pharmacies, and generic dispensing rates and submit a report to Congress.

- **Prescription Drug Pricing Dashboards** – Sec. 143 requires HHS to establish and annually update a website-based dashboard, beginning no later than Jan. 1, 2020. The dashboard would allow beneficiaries, clinicians, researchers, and the public to review information on spending and utilization of prescription drugs covered in Part B and D. The section also details what information will be included in the dashboard, such as brand-name and generic equivalents, manufacturer, use of drug, spending, change in spending, and out-of-pocket costs.
- **Improving Coordination Between the FDA and CMS** – Sec. 144 requires HHS to convene a public meeting to discuss ways to improve coordination between the FDA and CMS and prepare for the availability of novel medical products, no later than 12 months after the date of enactment. 18 months after the public meeting, HHS shall updated the final guidance "National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development," and the final guidance shall be issued 12 months after the update. Additionally, no later than 12 months after the date of enactment HHS shall publish a report regarding processes used for coding, coverage, and payment of novel medical products.
- **Patient Consultation in Medicare National and Local Determinations** – Sec. 145 permits HHS to consult with patients and organizations who represent patients in making national and local determinations.
- **GAO Study on Increased to Medicare and Medicaid Spending –** Sec. 146 directs GAO to conduct a study on the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expenditures in Medicare and Medicaid.
- **MedPAC Report on Shifting Coverage of Certain Part B Drugs to Part D –** Sec. 147 directs MedPAC to conduct a study on the effects of shifting coverage of drugs from Part B to Part D, including the effects on program spending, cost-sharing and feasibility.
- **Obligations to Tribal Communities** – Sec. 148 directs GAO to conduct a study on access and cost of prescription drugs to tribal communities and includes a review of what Indian health programs pay for prescriptions drugs and recommendations to align discounts in Medicaid drug rebate program with drugs furnished by Indian Health Services.

<u>Medicaid</u>

- **P&T Committee Improvements** – Sec. 201 delineates state requirements with respect to formulary committees, or pharmacy and therapeutics committees (P&T committees), including that state-established P&T committees develop and review Medicaid covered outpatient drug formularies. It also sets forth requirements with respect to P&T committee composition; and conflict of interest policies. States may elect to use a drug use review (DUR) board to serve as the P&T committee so long as it meets the aforementioned P&T committee requirements.
- **Improving Reporting Requirements and Developing Standards for the Use of DUR Boards** – Sec. 202 delineates the membership qualifications of drug use review (DUR) boards and establishes reporting requirements. DUR boards are required to report to the any conflicts of interest with respect to members of the board. Managed Care entities will also be required to submit drug utilization review activities to the DUR. Additionally, the Secretary will establish national standards for Medicaid drug use review through CMS guidance, within 18 months of the law's enactment.
- **GAO Report on Conflicts of Interest in State Medicaid DUR Boards and P&T Committees** – Sec. 203 requires GAO to, within 24 months of the bill's enactment, report on potential and existing state Medicaid program DUR board and P&T committee conflicts of interest.

- **Drug Rebate Program Accuracy** – Sec. 204 aims to improve the oversight of information submitted by covered outpatient drug (COD) manufacturers under the Medicaid Drug Rebate Program, including through HHS audits of price and drug information; surveys of wholesalers and manufacturers to verify manufacturer prices, including wholesale acquisition cost (WAC) (list price) and average manufacturer price (AMP). The provision authorizes HHS to impose civil monetary penalties (CMPs) in certain circumstances (including the knowing provision of false information) and requires HHS to report, within 18 months of enactment, on the need for any additional regulatory or statutory changes necessary to ensure timely and accurate reporting of drug price and product information. It also delineates other reporting requirements of HHS.
- **Excluding Authorized Generics from AMP Calculation** – Sec. 205 excludes authorized generic drugs from the calculation of AMP under the Medicaid Drug Rebate Program, effective on the first day of the first quarter that begins upon the date of enactment. It also amends the statutory definition of wholesaler to exclude COD manufacturers.
- **Preventing Price Spreading** – Sec. 206 requires pass-through pricing for CODs in Medicaid, including under managed care. It stipulates that payment for pharmacy management services be limited to ingredient cost and a professional dispensing fee (paid by the state), passed through in its entirety to the pharmacy dispensing the drug. The provision limits PBM payment for administrative services to a reasonable fee, with transparency/reporting requirements from the PBM to the state and HHS delineated. It applies to contracts executed or renewed on or after 18 months of the bill's enactment and also requires surveys of retail community pharmacies, as well as a HHS report examining specialty drug coverage and Medicaid reimbursement thereof. Failure to provide to provide timely information or the reporting of false information will result in civil money penalties.
- **T-MSIS Drug Data** – Sec. 207 stipulates public reporting requirements of HHS on Medicaid provider prescribing patterns for CODs and, if possible, the territories as well (effective CY 2021). The report is to include various components, such as a state-specific comparison of prescription utilization management tools. No later than May 1 of each calendar year beginning with 2021, HHS will publish the public report on provider prescribing patterns.
- **Risk-Sharing Value-based Agreements to Expand Access to Life-Saving Drugs** – Sec. 208 permits states, at state option, to pay for certain CODs via risk-sharing value-based arrangements, effective Jan. 1, 2022. Such arrangements could be leveraged for CODs intended for one-time use potentially curative treatment, such as a form of gene therapy for rare diseases. The section also delineates the requirements states must meet to submit a request for HHS approval.
- **Maximum Rebate under Medicaid Drug Rebate Program** – Sec. 209 increases the maximum allowable Medicaid rebate in a rebate period to 125 percent of a COD's AMP (up from 100 percent of AMP), effective for rebate periods beginning Oct. 1, 2022. Also, beginning FY 2022, subjects manufacturers to all rebate obligations otherwise due if there were no cap on the obligations if a manufacturer increases their AMP for a COD beyond its base year AMP (trended forward by CPIU).
- **Application of Medicaid Drug Rebate Requirement to Drugs Provided in HOPDs** – Sec. 210 permits states, as part of a service bundle or value-based treatment, to include any drug, biological product or insulin provided on an outpatient basis as part of, or as incident to, physicians' services or outpatient hospital services. Effective one year after the date of enactment. The provision requires HHS to issue guidance no later than one year after the date of enactment to states and other relevant stakeholders regarding implementation.