

# Senate Finance Committee Releases Details of Drug Pricing Bill

July 24, 2019

Yesterday, the Senate Finance Committee Chairman Chuck Grassley (R-Iowa) and Ranking Member Ron Wyden (D-Oregon) released a [description](#) of The Prescription Drug Pricing Reduction Act of 2019, a bipartisan drug pricing bill that has been the subject of much anticipation. According to the accompanying [press release](#), the bill is intended “to lower the price of prescription drugs for Americans.” The next step in the legislative process is a hearing by the Senate Finance Committee [scheduled](#) for Thursday, July 25, at 9:30 am. Before becoming law, the bill would have to be passed by both the Senate and the House, before moving to the President for signature.

If enacted into law, the implications of the bill would be wide-ranging and would directly affect, among other stakeholders, drug manufacturers, insurers, and hospitals. Among other things, the bill would impose new transparency requirements on drug manufacturers, Medicare Part D plan sponsors, and pharmacy benefit managers (PBMs); impose new rules regarding manufacturer Medicaid drug rebates; re-structure the Medicare Part D benefit; set new caps on payment rates for Medicare Part B drugs, biologicals, and biosimilars; and eliminate grandfathering protection for certain provider-based hospital outpatient departments.

We have summarized key proposals below based on the information that is currently available, which does not include the text of the proposed legislation itself. The Senate Finance Committee has not released the text of the bill at this time but has posted a series of proposed amendments on the hearing website.

## Medicaid

The Senate Finance Committee proposal would make a variety of changes to the Medicaid program and, in particular, the Medicaid Drug Rebate Program (MDRP).

**First**, the proposal would make a number of changes to state Medicaid pharmacy and therapeutics (P&T) committees and drug use review (DUR) boards:

- ***Required P&T committees.*** Section 201 of the proposal would require state Medicaid programs that establish a drug formulary to create a P&T committee composed of “physicians, pharmacists, and other appropriate individuals appointed by the state governor” to “develop and review the Medicaid covered outpatient drug formularies.” States would be required to implement a publicly accessible conflict of interest policy for

P&T committees and to apply committee requirements “to formularies used by managed care organizations or other entities that dispense[] [covered outpatient drugs (CODs)] to Medicaid beneficiaries.” A state DUR board may “serve as the P&T committee as long as [it meets] the enhanced P&T committee requirements.”

- ***Conflict of interest policies for DURs.*** Section 202 would require states to implement conflict of interest policies for DUR board members. DUR boards would further be required to submit an annual report to the state Medicaid program identifying DUR board members and any conflicts of interest. Managed care plans under contract to state Medicaid programs would have to comply with such conflict of interest reporting requirements.
- ***Government Accountability Office (GAO) investigations and report.*** Section 203 would require the GAO “to investigate potential and existing state Medicaid program DUR board and P&T committee conflicts of interest,” and the GAO “would be required to submit a report to Congress within 24 months of the enactment date” detailing its findings.

**Second,** the proposal would increase manufacturer Medicaid drug rebate liability:

- ***Increase of maximum rebate amount by changing the rebate cap.*** According to the bill summary, Section 209 would “increas[e] the maximum allowable Medicaid rebate permissible in a rebate period from 100% of a covered outpatient drug’s average manufacturer price (AMP) to 125% effective for rebate periods beginning October 1, 2022.” The description is unclear, however, because it appears to also suggest that, beginning fiscal year (FY) 2022, the Medicaid rebate would not be subject to any cap where current AMP is greater than “base year AMP” adjusted for inflation using the Consumer Price Index for All Urban Consumers (CPI-U). Instead of being subject to the cap, the manufacturer would “be subject to all rebate obligations that would otherwise be due if there was no cap on rebate obligations.”
- ***State Medicaid program option to invoice rebates for CODs paid for as part of a bundled payment.*** In a departure from the current COD limiting definition, Section 210 proposes that, “at the option of a state, . . . the term ‘covered outpatient drug’ may include any drug, biological product, or insulin as part of a bundled payment if it is provided on an outpatient basis as part of, or as incident to and in the same setting as, physicians’ services or outpatient hospital services.”

**Third,** the proposal would make changes to MDRP program integrity and civil monetary penalty (CMP) requirements:

- ***Required Health and Human Services (HHS) audits of manufacturers under the MDRP and related CMPs.*** Section 204 would “require the HHS Secretary to audit the price and drug product information reported by COD manufacturers to ensure accuracy and timeliness.” HHS would further be able to “survey wholesalers and manufacturers, including direct seller manufacturers, when necessary, to verify manufacturer prices, including [wholesale acquisition cost (WAC)] and AMP.” In addition to other CMPs, HHS “would be authorized to impose [CMPs] up to \$185,000 on wholesalers, manufacturers, or direct sellers of CODs if those entities refused to provide information about audit or surveyed charges or prices or knowingly provide[d] false information.”
- ***Increased CMPs.*** Section 204 also would increase CMPs for a manufacturer’s failure to provide timely information under Social Security Act (SSA) Section 1927(b)(3)(C)(i) from \$10,000 per day to \$50,000 for the first day information is not timely reported and \$19,000 for each subsequent day, per drug. The maximum CMP for knowingly reporting false information at SSA Section 1927(b)(3)(C)(ii) would increase from \$100,000 to

\$500,000. (The CMP amounts currently set forth in the statute are subject to increases based on inflation and so in practice are greater than \$10,000 and \$100,000.)

**Fourth**, the proposal would prevent manufacturers from reflecting sales of authorized generics in the branded drug's AMP. Specifically, Section 205 would "exclude authorized generic drugs from the calculation of AMP under the Medicaid drug rebate program" and would "amend the statutory definition of wholesaler to exclude COD manufacturers." The intent is to amend statutory requirements that currently "have the effect of lowering the product's AMP [where a branded product has an associated authorized generic], thereby decreasing manufacturers' Medicaid rebate obligations for those products."

**Fifth**, Section 208 "would add an option for states . . . to pay for certain [CODs] through risk-sharing value-based agreements beginning January 1, 2022." The CODs at issue are "gene therap[ies] for a rare disease that . . . [are] expected to cure or reduce the symptoms of the disease after not more than three administrations." Agreements would have to meet certain criteria to qualify under the proposal, including providing for installment payments that meet certain requirements. It appears that HHS would have to approve these agreements, analogous to approving supplemental rebate agreements.

**Finally**, the proposal would adopt a number of additional changes related to pricing transparency and payments for PBM services:

- **Manufacturer reporting of WAC for publication.** Section 206 of the proposal would "require manufacturers to report [WAC] for covered outpatient drugs and for the Secretary to make that information available on a public website."
- **Survey of retail community pharmacy national average drug acquisition cost.** Section 206 would amend SSA Section 1927(f) to "require the HHS Secretary to conduct a survey of retail community drug prices to include the national average drug acquisition cost." Retail community pharmacies receiving payment related to dispensing CODs to Medicaid beneficiaries would be required to respond to the survey, with a failure to respond potentially resulting in penalties. Survey information would be made publicly available, and HHS would be instructed to issue a report to Congress examining specialty drug coverage and reimbursement under Medicaid.
- **Limitations on payment for PBM services.** Section 206 also would "require payment for pharmacy management services to be limited to ingredient cost and a professional dispensing fee that is not less than the professional dispensing fee that the State plan or waiver would pay, passed through in their entirety to the pharmacy that dispenses the drug . . ." Payment to PBMs would be "limited to a reasonable administrative fee," and the PBM would have to "make available to the State, and the HHS Secretary upon request, all costs and payments related to CODs and accompanying administrative services." The provision "would make any form of spread pricing unallowable for purposes of claiming Federal matching payments under Medicaid." According to the bill summary, spread pricing is the difference between what managed care organizations pay to PBMs and the amount the PBM ultimately pays to the pharmacy, a difference that can be substantial when looked at across all generic drugs.

## Medicare Part B

The Senate Finance Committee proposal would make a number of changes to Medicare Part B, creating two new rebate/refund obligations under the program and changing government price reporting requirements.

**First**, Section 107 would require certain inflation-based rebates for products covered under Medicare Part B (and Medicare Part D, discussed below). It would require a rebate for separately payable brand prescription drugs or biologicals furnished in hospital outpatient departments.

physician offices, and ambulatory surgical centers under Medicare Part B, for which the average sales price (ASP) has increased faster than inflation. The inflation rebate, which would be imposed beginning on or after January 1, 2021, would be tied to the ASP of a product on the later of July 1, 2019, or the date the product is first marketed by the manufacturer. Manufacturers failing to pay the rebate would be subject to CMPs of 125 percent of the required rebate amount, in addition to other penalties and assessments.

**Second**, Section 108 would require manufacturers to pay Medicare a refund for unused amounts of certain single-dose vial drugs payable under Medicare Part B that exceed a minimum threshold, starting on July 1, 2021. Manufacturers would have to pay a refund for these products in “the amount by which the Medicare payment attributed to the unused units exceeds 10% of the amount Medicare paid for total units.” HHS would be able to increase this threshold through notice and comment rulemaking. Manufacturers failing to pay the refund would be subject to CMPs of 125 percent of the refund amount.

**Finally**, the proposal would make the following changes to Medicare Part B reimbursement and price reporting requirements:

- **ASP reporting requirement expanded to all manufacturers.** Section 101 “would require prescription drug, biological, and biosimilar manufacturers that do not have a Medicaid drug rebate agreement to report ASP information to [HHS] that would be used to help establish Medicare payment rates . . . beginning with the first calendar quarter after the date of enactment.”
- **Excluding coupons provided to privately insured individuals from ASP.** Section 102 “would require prescription drug, biological, and biosimilar manufacturers to exclude the value of coupons provided to privately insured individuals from each drug’s ASP, as reported to the HHS Secretary” for product sales beginning on July 1, 2021. Notably, “[m]anufacturers would not have to exclude contributions to patient assistance programs or foundations, which are generally provided to patients based on need and not specific to the contributing manufacturer’s drug.”
- **Definition of “bona fide service fees” for ASP.** Section 109 would narrow the definition of “bona fide service fees” for ASP purposes to explicitly prohibit “fees based on the percentage of sales; and fees determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties.”
- **WAC add-on payment for new drugs.** Under current law, HHS is permitted to use either WAC or a payment methodology that was in effect on November 1, 2003, to determine reimbursement for new drugs, biologicals, and biosimilars for which ASP is not yet available. Section 103 would specify that the add-on payment for WAC-based reimbursement for new products would be capped at no more than 3 percent of WAC, consistent with existing regulation. The bill summary does not specify whether this provision would require HHS to use WAC instead of an alternative payment methodology in setting reimbursement rates for new products.
- **Payment rate for new biosimilars.** Section 104 would establish a payment rate for new biosimilars approved on or after July 1, 2020, “that would be the lesser of: (1) the biosimilar’s WAC plus a 3% [sic]; or (2) ASP plus 6% of the reference biological product.” Current Medicare rules specify that the payment rate for new biosimilars is WAC plus 3%.
- **Temporary increase in Part B payment for biosimilars.** Section 105 would establish a temporary add-on payment for biosimilars paid for by Medicare as of December 31, 2019, of 8 percent of the reference biological product’s ASP instead of 6 percent of the reference biological product’s ASP for a five year period starting January 1, 2020, “[t]o encourage development of lower priced biosimilar biological products.” Under the proposal, a biosimilar would be paid at 100% of its ASP plus 8 percent of the reference biological’s ASP.

- **Maximum add-on payment for drugs, biologicals, and biosimilars.** Currently, the Medicare Part B payment rate is the ASP for a product (or the WAC for a new product) plus an add-on percentage of the ASP. For example, most drugs and biologicals are currently paid at ASP plus a 6 percent add-on. Section 110 would cap the add-on amount at \$1,000 starting on January 1, 2021, through December 31, 2028 for drugs that are separately payable when furnished in a physician office, hospital outpatient department, or ambulatory surgical center. For 2029 and each subsequent year, the \$1,000 cap would be updated by an inflation factor.
- **Off-campus provider-based outpatient departments.** Section 111 would eliminate the exception for grandfathered provider-based hospital outpatient departments from the physician fee schedule payment methodology. Beginning on January 1, 2021, payment for services in all off-campus hospital outpatient departments would be made at the Medicare physician fee schedule rate. The payment reduction would be made in a non-budget neutral fashion, meaning that decreases in payments would not be offset by increases in payments for other services.

## Medicare Part D

**First**, the proposal would substantially redesign Medicare Part D starting on January 1, 2022. Among other things, Section 121 would eliminate the “donut hole” coverage gap by lowering the catastrophic coverage out-of-pocket threshold to \$3,100 in 2022 and indexed thereafter to growth in Medicare Part D spending. The proposal would sunset the existing coverage gap discount program (under which manufacturers pay 70% of drug costs in the donut hole), and instead establish a new discount program under which manufacturers that offer drugs covered under Medicare Part D would be required to provide 20 percent discounts off negotiated prices during catastrophic coverage, including for Low-Income Subsidy (LIS) beneficiaries.

Manufacturers would be required to provide these catastrophic coverage discounts for brand-name drugs, biologicals, and biosimilars and would be subject to new reporting requirements to demonstrate compliance.

CMPs would be authorized where manufacturers fail to provide required catastrophic coverage discounts. HHS would also be authorized to terminate a manufacturer catastrophic coverage agreement for a “knowing and willful” violation of program requirements.

**Second**, the proposal would also make various other changes related to the design or implementation of Medicare Part D:

- **Medicare Part D rebates for drug prices outpacing inflation.** Section 128 would require manufacturers, beginning on January 1, 2022, to enter into rebate agreements with HHS and pay rebates for certain covered Part D brand drugs and biologics whose list price increases beyond the pace of inflation, similar to the inflation-based rebate proposed with respect to Medicare Part B. The baseline for the determination would be the list price of the product on the later of July 1, 2019, or the date the product is first marketed by the manufacturer. Manufacturers failing to pay the rebate would be subject to CMPs of 125 percent of the required rebate amount, in addition to other penalties and assessments.
- **Public disclosure of drug discounts and other PBM provisions.** Section 123 would establish a new transparency requirement under which HHS would post on a public website data that have been reported by PBMs and insurers regarding prescription drug sales and prices under Medicare Part D and with respect to Qualified Health Plans (QHPs), including information on aggregate price concessions and information about the difference between what insurers pay a PBM and what the PBM pays pharmacies. Medicare Part D plan sponsors would also be subject to new financial audit requirements related to their PBM contracts.

- **HHS sharing of drug price and rebate data with MedPAC and MACPAC.** Section 122 “would allow the HHS Secretary to share Medicare Part D and Medicaid drug price and rebate data with the executive directors of [the Medicare Payment Advisory Commission (MedPAC)] and the Medicaid and CHIP Payment and Access Commission (MACPAC) for purposes of monitoring, program recommendations, and analysis of Medicare Part D and Medicaid programs and the State Children’s Health Insurance Program,” subject to certain confidentiality protections. These data sharing requirements would take effect immediately on enactment of the legislation.
- **Public disclosure of direct and indirect remuneration (DIR) review and audit results.** Section 124 would require HHS to publicly report discrepancies related to Medicare Part D plan DIR information. Starting in 2020, public reporting of the results of independent third party financial audits of Medicare Part D plans, including DIR information, would also be required.
- **Improvements to provision of Medicare Parts A and B claims data to prescription drug plans.** Currently, prescription drug plan sponsors do not have access to medical claims data collected under fee-for-service Medicare. Starting on January 1, 2021, Section 126 of the bill would allow Medicare Part D plan sponsors to use certain Medicare fee-for-service claims data for Medicare Part D coverage determinations related to approved purposes—such as to improve therapeutic outcomes.
- **Permanent authorization of retroactive Medicare Part D coverage for low-income beneficiaries pilot program.** Starting no later than 2022, Section 127 would permanently authorize the Limited Income Newly Eligible Transition (LI NET) program (which has been piloted since 2010). The LI NET benefit would provide transitional coverage to individuals who were either fully or partially LIS-eligible but had not yet enrolled in the Medicare Part D benefit (or had enrolled but did not yet have effective coverage).

### Additional Requirements

The proposal would also effect a number of other changes:

- **Drug manufacturer transparency requirements.** Section 141 would require drug manufacturers to provide, at HHS’s request, price justifications with respect to “increases for prescription drugs and biological products, as measured by the WAC or changes in the WAC” where HHS determines the price increase met or exceeded certain specified thresholds. HHS “would be required to publicly post the price justifications” unless the manufacturer instead reduces the list price for the drug for six months so that “it no longer [meets] the qualifying criteria.” Manufacturers would be subject to CMPs of \$10,000 per day for failing to submit a timely price justification and up to \$100,000 for each item of false information knowingly submitted.
- **Expanded permissive exclusion authority.** Section 142 would give HHS permissive authority to exclude certain individuals or entities (e.g., officers and directors, managing employees, owners) based on their *prior* affiliation with entities sanctioned with respect to federal healthcare program participation. (Existing law already provides permissive exclusion authority for *current* owners, officers and managing employees.)

### Congressional Budget Office (CBO) Score

The CBO score for the bill is not yet available. However, the press release issued by Senators Grassley and Wyden indicates that the score concludes that:

- Taxpayers would save \$85 billion on Medicare, largely due to the changes to the Medicare Part D benefit and the additional inflationary rebates, and \$15 billion on Medicaid as a

result of the changes to price reporting calculations and the maximum drug rebates allowed.

- Beneficiaries would save \$27 billion in out-of-pocket costs and \$5 billion in premiums under these proposals.

Consumers in the commercial market are also expected to see some benefits, though it is unclear how.

We will monitor for any changes to this bill. As always, it is important that you carefully review the proposed legislation to identify all issues relevant to your organization.

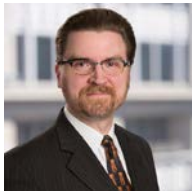
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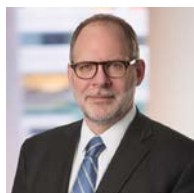
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