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January 25, 2019

Submitted electronically via Regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4180-P
P.O. Box 8013
Baltimore, MD 21244–8013

Re: CMS–4180-P; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma:

The Pew Charitable Trusts (Pew) is pleased to offer comments on the Proposed Rule titled Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses ("the proposed rule"). Pew is an independent, nonpartisan research and public policy organization dedicated to serving the American public. Our drug spending research initiative is focused on identifying policies that would allow public programs to better manage spending on pharmaceuticals while ensuring that patients have access to the drugs that they need.

Pew commends the Department of Health and Human Services (HHS) Centers for Medicare & Medicaid Services (CMS) for its commitment to addressing drug spending in the Medicare Part D and Medicare Advantage programs. In our comments, we express support for the CMS goal of reducing drug spending through increasing plan sponsors' ability to negotiate price concessions with pharmaceutical manufacturers; we express concern, however, that pharmaceutical manufacturers would significantly benefit from the proposal to base beneficiary cost-sharing on the lowest possible reimbursement a pharmacy may receive.

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**CMS Concerns With the Protected Class Policy and Proposals**

Pew concurs with the Administration's desire to reduce drug spending in the Medicare Part D program, including spending on protected classes drugs, which include numerous high-cost, yet highly-important, drugs that face little competition to reduce prices. We believe that the Centers for Medicare & Medicaid Services' (CMS') regulatory impact analysis in the proposed rule is consistent with our analysis showing

that revising the protected classes policy may only generate limited savings.[1] Reforming the protected classes as proposed may be both good policy and may yield additional savings, but these savings appear to be limited.

While Pew did not have access to actual rebates provided by manufacturers to Part D sponsors, our analysis suggested that rebates on certain high-spend drugs within the protected classes appear to be in line with aggregate rebate amounts for other high-spend drugs, consistent with CMS' findings in the regulatory impact analysis. Rebates on brand drugs are generally dependent on whether there is competition between branded manufacturers within a therapeutic class, and certain classes, like antiretrovirals to treat HIV, do not have significant branded competition and therefore would not be expected to see significant rebating, even absent the protected classes policy. As CMS notes, for "antineoplastics, antiretrovirals, and immunosuppressants, the narrower indications and complicating clinical criteria would limit Part D sponsors' ability to do significant management"[2] of these drugs, ultimately limiting rebate potential. This is consistent with Pew's analysis that "Medicare's other formulary protections may limit PDPs' ability to exclude a drug, even absent a protected class designation."[3]

For the anticonvulsant, antidepressant, and antipsychotic classes where CMS believes plans could find additional savings from implementing step therapy, CMS estimates that total savings from additional rebates would only total $11M in 2020.[4] CMS attributes these limited savings to the fact that "current rebates concentrate on a handful of drugs for which manufacturers already pay relatively high rebates," defined as rebates of 25% or more of a drug's costs.[5] This is consistent with Pew's analysis that rebates for competitive therapies within the protected classes appear to be similar to rebates for competitive therapies outside of the protected classes.

CMS estimates that an additional $104M in 2020 savings will be generated through generic substitution for patients using brand drugs for which a generic is available,[6] savings nearly 10 times greater than those projected for increased rebates on brand drugs. Pew supports CMS' goal of transitioning patients to clinically-appropriate generic drugs when available; however, MedPAC has concluded that "protected status does not appear to affect plan sponsors' ability to encourage the use of generics,"[7] and it is unclear how the proposal will significantly expand plans' ability to transition patients to generics.

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[1] Pew Charitable Trusts. Policy Proposal: Revising Medicare's Protected Classes Policy. March 7, 2018. Available at: https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicares-protected-classes-policy. Accessed Jan. 16, 2019.
[2] 83 Federal Register 62152-62201, 62184. CMS–4180-P; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (RIN 0938-AT92). Nov. 30, 2018.
[3] *Supra* note 1.
[4] 83 Fed. Reg. 62184.
[5] *Id*.
[6] *Id*.
[7] Medicare Payment Advisory Commission. Status Report on the Medicare Prescription Drug Program (Part D). March 2017, p. 412. Available at: http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf. Accessed Jan. 16, 2019.

Therefore, while Pew supports the Administration's efforts to reduce drug prices in the protected classes, we believe that other policies that attempt to limit drug price growth or the high launch prices of new drugs, discussed below, may generate greater savings with positive spillover effects to non-Medicare drug purchasers.

**Broader Use of Prior Authorization for Protected Class Drugs**

Pew supports the Administration's proposal to broaden utilization management techniques within the protected classes, subject to clinical criteria and beneficiary protections. In particular, we share the concern that manufacturers of drugs that are primarily used for a non-protected class therapeutic application may pursue an indication that falls within a protected class in order to reduce plan sponsors' ability to engage in clinically appropriate utilization management for the primary, non-protected class application.[8] The limited prior authorization discussed – a determination that a protected class drug with more than one indication is being used for the indication that falls within a protected class – is a common-sense utilization management strategy that should not unduly burden beneficiaries and will allow plan sponsors to appropriately manage non-protected classes utilization. In the proposed regulatory text, CMS outlines a broader use of prior authorization and step therapy beyond identifying whether the drug is prescribed for to treat a protected class condition.[9] We encourage CMS to publish clear standards for how CMS will complete the review and approval specified in the proposed regulatory text. Clear standards will better allow plan sponsors to negotiate price concessions from manufacturers, as plans will have better certainty that their proposed utilization management criteria will be accepted by CMS. Developing clear standards through rulemaking will also benefit patients, as it will allow beneficiary advocates to comment on the appropriate protections for specific implementation of additional utilization management within the protected classes rather than simply allowing comment on whether or not additional utilization management should be allowed.

**New Formulations**

Pew supports the proposal to discourage drug evergreening by allowing Part D plan sponsors to exclude a new formulation of an active moiety that does not provide a unique route of administration.[10] This builds on the long-standing ability of sponsors to exclude extended-release formulations when the immediate-release formulation is available – a tool that manufacturers have attempted to circumvent by withdrawing the immediate-release formulation from the market.[11] Such a strategy has broader repercussions in that removing the immediate-release formulation from the market may also inhibit the development of generic immediate-release formulations by making it impossible for generic manufacturers to access the product samples needed for their applications. Therefore, the CMS proposal may also hasten availability of generic immediate-release formulations for all purchasers,

[8] 83 Fed. Reg. 62158.
[9] 83 Fed. Reg. 62200. ("Prior authorization and step therapy requirements that are implemented to confirm use is intended for a protected class indication, ensure clinically appropriate use, promote utilization of preferred formulary alternatives, or a combination thereof, subject to CMS review and approval.")
[10] 83 Fed. Reg. 62519.
[11] *Id*.

reducing drug spending beyond the Medicare program. This proposal would harmonize plans' ability to manage evergreen reformulations both within and outside the protected classes, subject to the same general formulary adequacy beneficiary protections.

Pew also supports the CMS clarification that the existing active moiety definition does not require plan sponsors to offer formulary coverage of two mirrored chemical structures provided they produce the same pharmacological response, even when one may have greater milligram-potency than the other.[12] In the examples provided – citalopram vs. escitalopram and omeprazole vs. esomeprazole – manufacturers introduced the reformulated product shortly before generic versions of the initial product became available,[13] an evergreening strategy that can significantly increase drug spending. Allowing plan sponsors to meet the protected class "substantially all" requirement by only including the initial formulation may discourage this manufacturer practice, generating savings for both Medicare beneficiaries and non-Medicare purchasers.

**Pricing Threshold for Protected Class Drug Formulary Exclusions**

Pew concurs with the proposal to allow sponsors to exclude protected class drugs with price increases above the rate of inflation; however, this would not limit growth in the launch prices of new drugs, which have been found to drive spending increases among specialty drugs.[14] CMS states that "allowed cost per days' supply" increased more for protected-class brand drugs than non-protected-class brand drugs from 2015 to 2017; however, the lack of detail in the published analysis makes it impossible to determine whether this difference reflects (1) the average of same-drug price increases over the period, or (2) the increase in the average allowed-cost of all drugs in each category, including new market entrants during this period. If the latter, the launch of higher-priced new antineoplastic drugs may disproportionately affect the trend. To that end, we note that in its regulatory impact assessment, CMS finds that many drugs in the protected classes already have high levels of rebating (over 25 percent) and that three of the protected classes (antineoplastics, antiretrovirals, and immunosuppressants) are unlikely to see additional savings from increased plan utilization management.[15] This denotes significant heterogeneity across the different protected classes, signaling that cost trends within the protected

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[12] *Id*.

[13] Esomeprazole was approved in February 2001; the first generic formulation of omeprazole was approved in November 2002. (Food and Drug Administration. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Product-specific approval details available at: https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=021153 and https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=075410). Escitalopram was approved in August 2002; the first generic formulation of citalopram was approved in October 2004. (Food and Drug Administration. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Product-specific approval details available at: https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=021323 and https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=077038).

[14] Hernandez I, Good CB, Cutler DM, Gellad WF, Parekh N, Shrank WH. The Contribution Of New Product Entry Versus Existing Product Inflation In The Rising Costs Of Drugs. *Health Affairs*. Jan. 1, 2019;38(1):76-83.

[15] 83 Fed. Reg. 62184.

classes should not be aggregated into a single figure and that it may be inappropriate to directly compare price trends in the aggregated protected classes to aggregated non-protected classes.

Allowing sponsors to exclude drugs with price increases above the rate of inflation may offer additional negotiating leverage. In implementing this policy, we concur with the CMS proposal to use the Consumer Price Index-Urban (CPI-U) rather than inflation factors tied to health care, medical spending, or drug costs themselves, as these alternate factors would allow for greater price increases and themselves reflect excessive drug price increases.[16] While CPI-U is appropriate for single-source brand drugs and biologics, for which prices do not reflect the marginal cost of production,[17] it may be inappropriate for generic drugs with limited margins that may be responsive to changes in cost inputs. When inflation is low or negative, this could have a severe impact on generic drugs (though the low cost of generic drugs and the fact that they generally do not negotiate rebates with plan sponsors mitigates this concern). However, some generic drugs have taken significant price increases in recent years that do not appear to correspond to increases in production costs;[18] to discourage this behavior, CMS could establish a threshold for generic price increases (such as CPI-U plus 10 percent) that would trigger the exclusion criteria, which manufacturers could rebut upon a demonstration that the price increase was driven by a material increase in the cost of production. The ability to rebut the trigger based on a demonstration of material cost increases would protect generic manufacturers that face cost increases in times of economic downturn when CPI-U may be stagnant or negative while still targeting generic manufacturers who increase costs unnecessarily.

When implementing an inflation-based exclusion trigger for new drugs, CMS should mitigate any potential gaming by manufacturers by resetting the baseline price for a drug if the drug's price falls below the initial baseline. For example, a manufacturer could artificially inflate a drug's Wholesale Acquisition Cost (WAC) in the first quarter by introducing the drug late in the quarter and only selling a few units at an inflated price, then lower the price in the following quarter to the intended WAC. This artificially-inflated baseline may allow the manufacturer to continue to take price increases above inflation from the second-quarter WAC without triggering exclusion. Resetting the baseline any time WAC falls below the initial baseline would discourage any potential gaming of the baseline.

For new drugs, CMS should consider establishing a reference baseline price consistent with the inflation-adjusted launch prices of leading therapeutic alternatives in the class rather than allowing the manufacturer to establish its own baseline price. Rising specialty drug costs are mostly driven by new product entry rather than price increases for existing drugs,[19] and developing a reference baseline for these drugs based on the inflation-adjusted launch price of therapeutic alternatives could discourage high launch prices. For example, to establish a baseline reference price, CMS could create a volume-weighted average of the inflation-adjusted launch prices of the three top-selling existing therapies within the therapeutic class. This baseline reference price would be increased by a multiplier for

[16] 83 Fed. Reg. 62160.
[17] Suh DC, Manning Jr WG, Schondelmeyer S, Hadsall RS. Effect of multiple-source entry on price competition after patent expiration in the pharmaceutical industry. *Health Services Research*. Jun. 2000;35(2):529.
[18] Rowland C. Investigation of generic 'cartel' expands to 300 drugs. *Washington Post*. Dec. 9, 2018.
[19] *Supra* note 14.

presumed clinical improvement based on the average age of the three top-selling existing therapies: if the volume-weighted average age of reference drugs is over 10 years, the baseline reference price would be 200 percent of the average inflation-adjusted launch price; if the average age is 5-10 years, 150 percent of the average price; and less than 5 years would be 125 percent of the average price. If the launch price of the drug exceeds this baseline reference price, it would trigger the exclusion policy. Manufacturers could rebut the baseline reference price by demonstrating incremental clinical benefit above the baseline reference price using recognized comparative effectiveness standards or standards determined by CMS. This approach would effectively extend the inflation trigger on existing drugs to new drugs, lowering price growth for new drugs.

CMS has solicited comments on particular aspects of the pricing threshold calculation and alternative proposals, which we address here. We support the proposal that if the price of any National Drug Code (NDC) associated with a drug reaches the exclusion trigger, the plan sponsor may exclude all NDCs associated with that drug.[20] This would prevent manufacturers from attempting to raise prices on a formulation designed for the non-Medicare market while maintaining lower price growth for a Medicare-focused formulation, potentially reducing cost growth for other payers. We also support the proposal that if a manufacturer triggers the exclusion criteria in any one year, plan sponsors could exclude the drug in all subsequent years.[21] This would discourage manufacturers taking higher price increases when there is no competition from therapeutic alternatives (when plans may need to keep the drug on formulary because it is the only treatment available) but not taking price increases once competition emerges. This may also slow price growth for new therapies, as prices for existing therapies may not rise as quickly to serve as reference price floors for new products. However, CMS should consider an exception to this rule when a drug triggers the exclusion criteria by maintaining the same price while CPI-U is negative, as manufacturers may not be able to quickly respond to economic downturns. Manufacturers that take any price increases when CPI-U is negative, however, should continue to trigger this ongoing exclusion penalty. Similarly, we also support the CMS proposal to allow sponsors to exclude all drugs by a manufacturer if any drug by the manufacturer triggers the exclusion criteria.[22] Applying the penalty across the manufacturer's portfolio is consistent with inclusion criteria in other federal purchasing programs,[23] prohibiting manufacturers from picking and choosing which products will be available to federal program beneficiaries. Further, this will discourage manufacturers from taking price increases on older products that will soon face generic competition to encourage sponsors to switch patients to newer products that will not. For example, in 2016 Gilead Sciences increased the prices of two protected classes drugs, Complera and Stribild, by seven percent while maintaining the same price for two newer drugs in the same class, Odefsey and Genvoya.[24] Odefsey and Genvoya differ only slightly from Complera and Stribild, replacing tenofivir disoproxil fumarate (TDF)

[20] 83 Fed. Reg. 62160.
[21] 83 Fed. Reg. 62163.
[22] *Id*.
[23] 42 U.S.C. § 1396r–8 - Payment for covered outpatient drugs.
[24] Sullivan, E. Gilead's new price hikes on HIV drugs anger AIDS activists. *STAT News*. July 5, 2016. Available at: https://www.statnews.com/pharmalot/2016/07/05/gilead-hiv-aids-drug-prices/. Accessed Jan. 14, 2019.

with tenofivir alafenamide fumarate (TAF), a pro-drug formulation of TDF. Investors greeted the news favorably, noting that the price hikes would "ensure (the) durability of the HIV franchise" as patients transitioned from the soon-to-be-generic Complera and Stribild to Odefsey and Genvoya.[25] CMS should allow plan sponsors to exclude all protected class products of a manufacturer if the manufacturer triggers the exclusion threshold on any protected class product, discouraging manufacturers from using price hikes to improperly shift utilization in ways that could increase drug spending over the long-term.

**Prohibition Against Gag Clauses in Pharmacy Contracts**

Pew supports CMS' conforming regulations to eliminate gag clauses in Part D plans,[26] consistent with the requirements of the "Know the Lowest Price Act of 2018."[27] We further encourage CMS to require plan sponsors to count all cash payments for drugs toward beneficiaries' deductibles and other cost-sharing accumulating metrics, including those cash payments made when a pharmacist informs a beneficiary that the cash purchase price for a drug is lower than the cost-sharing payment under the beneficiary's Medicare plan. Including these payments in the cost-sharing accumulation would discourage plans from setting cost-sharing payments artificially high to shift spending outside of the Medicare Part D program and would reduce beneficiary overall out-of-pocket spending.

**Proposed Adoption of a Real-Time Benefit Tool (RTBT)**

Pew supports the CMS proposal to develop a real-time benefit tool (RTBT) that will allow clinicians to determine drug coverage and cost-sharing information at the time of prescribing.[28] We concur that this tool may better help clinicians choose the most appropriate medication for clients and encourage adherence. Further, we believe that the development and standardization of a RTBT will hasten uptake outside of the Medicare market, reducing costs for other payers. Outside of the Medicare program, RTBT may also discourage the use of manufacturer co-pay assistance programs that may increase overall health spending,[29] as clinicians will be able to determine whether lower-cost options are available at the time of prescribing. This may provide plan sponsors with additional leverage in negotiating rebates with pharmaceutical manufacturers, establishing new lower rebate standards that may also be applied to negotiations by Part D sponsors, which could lower Part D spending.

[25] *Id.*
[26] 83 Fed. Reg. 62164.
[27] Public Law 115-262.
[28] 83 Fed. Reg. 62165.
[29] Ubel PA, Bach PB. Copay Assistance for Expensive Drugs: A Helping Hand that Raises Costs. *Annals of Internal Medicine*. Dec. 20, 2016;165(12):878-9.

**Medicare Advantage and Step Therapy for Part B Drugs**

As Pew has previously commented,[30] we support CMS' efforts to introduce competition and negotiation for Medicare Part B drugs, including the use of step therapy within Medicare Advantage plans.[31] Not only does this proposal have the ability to reduce spending within the Medicare program, but it will also provide a model for other payers to negotiate discounted prices for physician-administered drugs. This in turn may lower spending in the traditional Medicare Part B program if pricing metrics reflect these commercial discounts, though modifications may need to be made to price reporting programs to ensure that Medicare is not paying more than commercial insurers.

Pew supports the CMS proposal to require Medicare Advantage plans developing step therapy programs for physician-administered drugs to use the same pharmacy and therapeutics (P&T) committee requirements that govern the Medicare Part D program.[32] These standards are well-understood by plan sponsors and beneficiary advocates, allowing for easier development of new step therapy programs. We also commend CMS for specifically identifying specific drugs for treatment of macular degeneration as clinically comparable candidates that would be well-suited to the introduction of step therapy.[33] In 2011, the HHS Office of Inspector General (OIG) found potential savings to Medicare Part B of $1.1B in 2008 and 2009, with beneficiary savings of $275M in cost-sharing payments, if prices of drugs in this category were indexed to the lowest-cost agent.[34] We commend CMS for implementing this recommendation.

CMS has proposed that any step therapy requirements would not be permitted to disrupt enrollees' ongoing Part B drug therapies.[35] We agree with the intent behind this proposal to protect beneficiaries, but we encourage CMS to develop safeguards that would allow plans to transition beneficiaries to a lower-cost biosimilar in clinically appropriate circumstances. Numerous studies have demonstrated that patients can be safely switched from a reference biologic product to a biosimilar product without any significant impact on clinical outcomes.[36] Patients may even benefit from such switching if lower cost-sharing improves adherence or increases beneficiaries' financial security. Allowing Medicare Advantage plans to engage in this kind of switching, subject to clinical appropriateness, could encourage a more robust biosimilar market, as manufacturers would have more incentive to compete with each other for market share. As CMS has noted, current incentives in the Medicare Part B program may lead clinicians

[30] Pew Charitable Trusts. Pew Responds to White House's Drug Pricing Blueprint Information Request. July 16, 2018. Available at: https://www.pewtrusts.org/en/research-and-analysis/speeches-and-testimony/2018/07/16/pew-responds-to-white-houses-drug-pricing-blueprint-information-request. Accessed Jan. 16, 2019.
[31] 83 Fed. Reg. 62618.
[32] 83 Fed. Reg. 62170.
[33] 83 Fed. Reg. 62188.
[34] Department of Health and Human Serviced Office of Inspector General. Review of Medicare Part B Avastin and Lucentis Treatments for Age-Related Macular Degeneration. A-01-10-00514, Sept. 2011. Available at: https://oig.hhs.gov/oas/reports/region10/11000514.pdf. Accessed Jan. 16, 2019.
[35] 83 Fed. Reg. 62170.
[36] Cohen HP, Blauvelt A, Rifkin RM, Danese S, Gokhale SB, Woollett G. Switching Reference Medicines to Biosimilars: A Systematic Literature Review of Clinical Outcomes. *Drugs*. 2018;78(4):463-478.

to prefer the more expensive, reference biologic product,[37] reducing the incentive for biosimilar manufacturers to enter the market and compete on price. If Medicare Advantage plans are able to drive utilization to a particular biosimilar, though, this promise of a more-guaranteed share of the marketplace may encourage additional biosimilar manufacturers to enter the market, creating competition that yields savings for both Medicare and other payers.

As an alternative to step therapy for beneficiaries with ongoing Part B therapies, CMS could require plans and clinicians to notify beneficiaries if a lower-cost therapeutic alternative is available. This would allow the beneficiaries to self-select a lower-cost therapy; plans could even waive or sharply reduce cost-sharing for the lower-cost therapeutic alternative. This strategy may counteract any incentives clinicians face to prescribe more expensive therapies, a truly market-driven solution to encourage the development of therapeutic competition, including biosimilar therapies.

The use of step therapy by Medicare Advantage plans may encourage non-Medicare plans to adopt similar techniques, likely resulting in rebate payments for physician-administered drugs. These rebates could, in turn, lower spending in the traditional Medicare Part B program if they are reflected in Part B price reporting metrics. Under current practice, the Average Sales Price (ASP) calculation used to set Part B reimbursement is replaced with the Medicaid Average Manufacturer Price (AMP) calculation when ASP exceeds AMP by more than 5 percent in the two previous quarters or three of the previous four quarters.[38] Because Part B drugs are inhaled, infused, instilled, implanted, or injected ("5i drugs"), AMP for these drugs generally includes discounts and rebates to insurers and Pharmacy Benefit Managers (PBMs),[39] which are excluded from ASP.[40] These discounts are reflected in lower AMPs for Part B drugs, which can in some cases trigger AMP substitution of ASP for Medicare reimbursement. However, the AMP calculation also includes all sales under the Medicare Part B program, as the manufacturer performing the calculation does not know whether a unit sold to a physician will ultimately be used for a Medicare or non-Medicare patient. If Medicare Part B sales comprise a significant portion of total sales, then any PBM rebates that are included in the AMP calculation will only moderately reduce AMP, leaving Medicare Part B to pay higher prices than commercial payers. To ensure that AMP truly reflects commercial market sales and discounts for Part B drugs, CMS could instruct manufacturers to remove all units billed under the Medicare Part B program from AMP; CMS billing records could be used to identify sales to be excluded from the AMP calculation. This would also

[37] 83 Fed. Reg.37046, 37213. CMS–1695–P; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model. ("because the 6-percent add-on results in an increased Medicare payment for a higher-cost drug relative to a lower-cost drug, the use of more expensive drugs may generate more revenue for a health care provider … Meanwhile, the ASP-based methodology creates no direct incentives for furnishing high-value drug therapies.")
[38] 42 CFR § 414.904(d)(3).
[39] 42 U.S.C. § 1396r–8(k)(1)(B)(i)(IV).
[40] 42 U.S.C. § 1395w–3a(c)(2)(A); 42 U.S.C. § 1396r–8(c)(1)(C)(i).

harmonize treatment of Medicare Part B sales with Medicare Part D sales, as all sales and discounts provided under the Medicare Part D program for 5i drugs are exempted from the AMP calculation.[41]

**Pharmacy Price Concessions in the Negotiated Prices**

Pew supports the goal of reducing beneficiary out-of-pocket costs and re-distributing these drug costs to premiums. However, as noted in the draft rule, the proposed mechanism to achieve this goal will increase total Medicare drug spending and increase manufacturer revenues. CMS should consider alternate approaches.

As proposed, CMS would require plans to calculate beneficiary co-payments not on the initial payment realized by the pharmacy (as in current practice),[42] but based on the lowest possible net pharmacy payment after the plan adjusts direct or indirect remuneration (DIR) payments to reflect pharmacy performance metrics. This proposal would reduce beneficiary cost-sharing by $14.8B, but would result in increased beneficiary costs through higher premiums ($5.6B from 2020-2029), for a net savings to beneficiaries of $9.2B. In addition, the change would result in fewer beneficiaries reaching the Coverage Gap phase of the Part D benefit, where costs are largely borne by drug manufacturers. Therefore, the net effect would be to increase manufacturer revenues by $5.8B from 2020-2029 and increase Medicare premium contributions by $16.6B.[43]

We therefore recommend that CMS explore additional policy options that would redistribute beneficiary cost-sharing to premiums without reducing manufacturers' contributions to the Part D program. One approach to achieving this goal would be for CMS to reduce beneficiary cost-sharing as outlined in the proposed rule, but to maintain the existing system for calculating progression through benefit phases. Specifically, CMS could require plans to use the existing standard of undiscounted pharmacy reimbursement for the purpose of accumulating spending to determine progression through the benefit phases. In the Coverage Gap, the manufacturer contribution would similarly be calculated under the current model, using undiscounted pharmacy reimbursement. This would continue to move beneficiaries through the coverage phases under current practice, preserving manufacturers' contributions to the program, but would reduce the amount beneficiaries actually pay at the counter. Plan sponsors already have sophisticated out-of-pocket spending tracking mechanisms that could be adapted for this type of tracking.[44]

[41] 42 CFR 447.504(e)(8).
[42] 83 Fed. Reg. 62174.
[43] 83 Fed. Reg. 62192.
[44] Pew Charitable Trusts. Medicare Part D Coverage Gap Proposal Would Not Reduce Drug Spending. Dec. 4, 2018 Available at: https://www.pewtrusts.org/en/research-and-analysis/articles/2018/12/04/medicare-part-d-coverage-gap-proposal-would-not-reduce-drug-spending. Accessed Jan. 16, 2019.

**Pharmacy Administrative Services Fees**

Pew supports the CMS proposal to require any administrative fees realized through payment deductions as price concessions.[45] This would result in more accurate bids that reduce excess revenue that may be retained by sponsors in subsequent risk sharing payments, ultimately reducing costs to beneficiaries and the Medicare program through lower premiums. Bona fide administrative fees should be recorded as administrative costs and not payment deductions.

**Defining Price Concession**

Pew support the CMS proposal to define price concession, a term frequently used in the Part D program without a formal definition.[46] We further support the proposal to broadly define price concession to include a panoply of transactions that may reduce prices, and we encourage CMS to continue updating this definition through guidance and regulation to respond to any attempts by manufacturers, sponsors, or other intermediaries to avoid properly reporting price concessions.

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We appreciate the opportunity to respond to this proposal and commend the Administration for its attention to drug spending. Should you have any further questions, please contact us by phone at 202-540-6939 or via email at sdickson@pewtrusts.org.

Sincerely,

Allan Coukell, BscPharm
Senior Director, Health Programs

Sean Dickson, JD MPH
Officer, Drug Spending Research Initiative

[45] 83 Fed. Reg. 62179.
[46] 83 Fed. Reg. 62180.