January 24, 2019

Filed electronically at https://www.regulations.gov

Mr. Alex M. Azar, II
HHS Secretary
Department of Health and Human Services
Attention: CMS–4180-P
P.O. Box 8013
Baltimore, MD 21244–8013

Ms. Seema Verma
CMS Administrator
Centers for Medicare & Medicaid Services
Attention: CMS–4180-P
P.O. Box 8013
Baltimore, MD 21244–8013

Re: Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses Proposed Rule [CMS–4180–P]

Dear Secretary Azar and Administrator Verma:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to comment on the Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses (hereafter referred to as the "Proposed Rule") as published in the Federal Register (83 FR 62152) on November 30, 2018.

PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the Exchanges established by the Affordable Care Act.

PCMA appreciates several of the changes CMS proposes in the Drug Pricing Proposed Rule, which underscore the Agency's ongoing willingness to assess how to improve Part D by allowing Part D sponsors to use all tools at their disposal to address the high and rising prices of prescription drugs. PCMA asks CMS to reconsider the proposal relating to the treatment of pharmacy Direct and Indirect Remuneration (DIR), as it does not meaningfully address these problems, and otherwise diminishes the ability of Part D plan sponsors to control costs borne by taxpayers, consumers, and beneficiaries.

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Executive Summary

Our summary list of recommendations includes the following:

I. **Protected Classes:** PCMA continues to recommend eliminating the protected class requirements altogether. In the absence of eliminating protected classes, PCMA supports all three proposals offered by CMS to better align treatment of these drugs to the rest of the Part D program and the commercial market, and offers a range of suggestions to improve the effectiveness of these proposals. (p. 4)

II. **Gag Clauses:** PCMA supports CMS' proposal, which ensures that beneficiaries pay the lowest applicable cost-sharing to obtain the drugs they need. PCMA further recommends that CMS address the potential unintended consequences where Part D beneficiaries purchase drugs outside their plan. (p.14)

III. **E-prescribing and Real-time Benefit Tools (RTBT):** PCMA appreciates CMS' willingness to address the need for enhanced communication regarding drug costs among payers, prescribers, and beneficiaries, but recommends that January 1, 2020 be a date for voluntary adoption of RTBT. (p. 16)

IV. **Part D Explanation of Benefits (EOB):** PCMA recommends that CMS not proceed with its proposed approach to require that a range of new drug price information be included in the EOB, because such changes do not improve a beneficiary's ability to make the most informed decision at the point of prescribing or pharmacy counter. PCMA provides several other options to provide real-time access to pricing information. (p. 23)

V. **Medicare Advantage and Step Therapy for Part B Drugs:** PCMA strongly supports the new added flexibility to allow MA plans to structure the savings associated with a Part B drug utilization management program as either a rewards and incentive program or as savings reflected in plan bids to lower premiums and/or improve supplemental benefits. (p. 28)

VI. **Treatment of Pharmacy DIR:** PCMA recommends CMS abandon its proposal on price concessions in the negotiated price for a host of policy, technical, and legal reasons. This policy would not improve patient care, would hamper competition among plans and pharmacies, and would harm beneficiaries through higher premiums. (p. 34)

We address in our attached comments the issues in the order in which they appear in the Proposed Rule. We appreciate the opportunity to comment and we urge CMS to adopt PCMA's recommendations as set forth below. If you have any questions, or if we can provide you with any further information, please do not hesitate to contact me at wkrasner@pcmanet.org.

Sincerely,

Wendy Krasner
Vice President, Regulatory Affairs

cc: Demetrios Kouzoukas, CMS
Cheri Rice, CMS
Kristin Bass, PCMA
Tim Dube, PCMA

Enclosure

I. Revisions to the Protected Class Policy

Proposal:

CMS proposes to modify the protected class provisions of Medicare Part D in three meaningful ways. First, it would allow broader use of UM tools around these drugs' protected indications. Second, CMS would allow Part D plan sponsors to exclude a new formulation of an existing protected class drug under certain specific conditions. Third, plans would have the ability to omit protected class drugs from formularies in the event that these drugs' prices increase faster than the background rate of inflation. Specifically, CMS requests comments on the following topics:

- CMS solicits comments on the concerns it outlined with the protected class policy. CMS asks for "evidence and research indicating that [its] concerns are warranted given real world experience." (p. 62156)

- CMS asks for comment on whether the proposal for an exception to the current protected class requirements to permit prior authorization for protected class drugs should be limited to new starts only. (p. 62158)

- CMS proposes to permit Part D sponsors to exclude from their formularies any single-source drug/biologic in a protected class if it has a price increase beyond the rate of inflation, as calculated using the Consumer Price Index for all Urban Consumers (CPI-U). CMS seeks comments on whether an alternative pricing threshold to the CPI-U should be considered for this exception. (p. 62160)

- CMS asks for comments about whether the CPI specific to prescription drugs (CPI-PD) or to medical care more broadly (CPI-M) should serve as the pricing threshold for its policy. (p. 62160)

- CMS solicits comments on whether an increase in a price other than the drug's Wholesale Acquisition Cost (WAC) should be used to determine whether the protected class drug could be excluded from a Part D formulary. (p. 62160)

- CMS asks whether the policy should apply only to single-source drugs/biologics or whether a "broader mix of drugs" should be eligible for formulary exclusion. (p. 62160)

- CMS solicits comments regarding whether an increase in WAC beyond CPI-U for any National Drug Code (NDC) assigned to a particular brand drug or single-source generic drug should be grounds for allowing a sponsor to exclude all NDCs assigned to that drug from the formulary. (p. 62160)

- CMS solicits comments on whether the WAC as of some date other than September 1, 2018 should be used as the baseline for WAC for drugs that are on the market on or before September 1, 2018. (p. 62161)

- CMS solicits comments on the merits of its proposal to have Part D sponsors monitor changes in WAC and CPI-U or if a more effective approach would be for CMS to monitor the price changes and provide a list of drugs that could be excluded from Part D formularies for a given contract year. If commenters believe CMS should provide the list, CMS asks when it should be released each year. (p. 62162)

- CMS asks for input on whether a Part D sponsor should be able to exclude a protected class drug from its formulary for any future contract year once its WAC increased more rapidly than the cumulative increase in inflation. (p. 62163)

- CMS seeks input on whether the price threshold exceptions should apply to all drugs in protected classes of a given manufacturer (or just the one with the excessive price increases). (p. 62163)

- CMS solicits comments on the impact of its policy proposal on Part D enrollees. (p. 62163)

- CMS asks whether there are additional considerations that would be necessary to minimize interruptions in existing therapy for protected class drugs for protected indications during prior authorization processes and increases in overall Medicare spending from increased utilization of services related to adverse events from interruptions in therapy. If additional considerations would be necessary, CMS asks why its current requirements and protections are inadequate or could be improved. (p. 62164)

- CMS seeks comment on what specific patient populations, patient characteristics, protected class drugs or classes would require additional special transition or other protections and how they can be consistently identified. (p. 62164)

- CMS asks for comment on other tools that could be used to minimize interruptions in existing therapy of protected class drugs for protected class indications during prior authorization processes. (p. 62164)

Discussion:

PCMA supports CMS' efforts to converge plan management tools for protected class and non-protected class drugs. While CMS is not proposing to eliminate any of the classes' designations, or modify the requirements for assigning or retaining protected class status, CMS should

consider whether the protected class policy is needed at all moving forward. The protected class policy no longer serves a public policy purpose that is justified by its costs and should be eliminated. As CMS notes in the preamble to the Proposed Rule, "the circumstances that existed when this [protected class] policy was originally implemented have changed dramatically in the nearly 12 years the program has been in operation." As discussed below, PCMA believes the historic underpinnings for this policy no longer exist and thus the policy is unwarranted. Our comments begin by providing our overarching feedback on the protected class policy as it exists today. We then provide specific comments on CMS' current proposal.

- Allows drug companies to monopoly price their drugs. This Administration has made it clear that the high price of prescription drugs must be addressed.[1] It has made substantial efforts to bring greater competition into the market to lower prices, through the fastest rate of generic drug approvals on record,[2] and identifying unsavory patent-related practices.[3] Under the current protected class policy, Part D plans are greatly limited in their ability to negotiate cost-saving discounts for seniors for protected class drugs. Eliminating the protected class policy would bring immediate and significant competition to classes of drugs that offer life-saving benefits, but at prices that are simply too high for many beneficiaries.

- Historical justification is no longer warranted. As CMS notes in the preamble to the Proposed Rule, the protected classes policy was intended to protect Medicare and Medicaid dually-eligible individuals transitioning from Medicaid to Part D coverage. In the 13 years since, those individuals, their caretakers, and Part D plan sponsors have learned how to operate successfully within the Part D program and are at significantly lower risk of medication complications. Part D plans afford enrollees sufficient safeguards and share in their interest of maintaining treatment on appropriate therapies. Existing beneficiary safeguards, such as the appeals and exceptions processes, ensure enrollees do not go without medically appropriate therapy.

- Clinically outdated and unnecessary given market conditions. A working group convened by CMS in 2013 recommended eliminating three of the six current protected classes and, in 2014, CMS considered adopting a similar proposal.[4] The market changes described among those three classes (generic entry, clear clinical guidelines) have been occurring within the other three classes as well. For example, a recent Avalere study found that a vast majority of prescriptions filled in each of the six classes are now for

[1] President Donald J. Trump's Blueprint To Lower Drug Prices, May 11, 2018. Available at https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/.
[2] For example, see https://fee.org/articles/fda-approved-record-number-of-generic-drugs-in-2018/.
[3] For example , see https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm613881.htmhttps://www.fda.gov/newsevents/newsroom/pressannouncements/ucm613881.htm.
[4] See Protected Class Review Panel, 2013, available at https://www.pharmamedtechbi.com/~/media/Supporting%20Documents/The%20Pink%20Sheet/76/4/Protected%20class%20review%20panel.pdf.

generic drugs, and a growing share of products now have multiple source competition.[5] Indeed, we speculate that had CMS convened a similar workgroup prior to this rulemaking, clinical experts may have recommended the complete elimination of the protected classes given these trends.

- Increases costs to taxpayers and beneficiaries.

    - *Premiums*. Because plan sponsors must cover all or substantially all protected class drugs, they are generally limited to assigning higher cost-sharing when negotiating for lower net costs. Currently, CMS allows only limited application of prior authorization for drugs in protected classes, so utilization is not as well-checked as it is in other classes. Rebates for protected class drugs are significantly lower than for non-protected class drugs,[6] meaning net prices paid – and thus premiums for all enrollees – are higher as a direct result of the protected class policy. CMS has previously acknowledged this very point.[7]

    - *Cost-sharing*. Per an analysis by the consulting firm Avalere, plans are more likely to designate protected class drugs as specialty or non-preferred brands or non-preferred generics, such that beneficiaries pay higher cost-sharing relative to non-protected classes.[8] Eliminating the protected class policy altogether would therefore lead to lower beneficiary coinsurance payments.

In sum, the protected class policy is no longer necessary in the Part D program and should be eliminated through rulemaking, under existing CMS authority. However, we support each of CMS' three proposals as a step in the right direction. We agree with the authors of a recent *Health Affairs* blog post that these proposed changes "strike a new balance between providing broad formulary access to these protected classes of drugs while still encouraging competition among manufacturers to control growing costs."[9] We provide additional clarification or suggestions for improvement as noted.

[5] Partnership for Part D Access, "Medicare Part D's Six Protected Classes Policy." December 2018.
[6] Hoadley, J. "Understanding the Role of Rebates in Prescription Drug Pricing." Presented November 28, 2018. Available at http://www.allhealthpolicy.org/wp-content/uploads/2018/10/JackHoadleyPresentation-AHP_briefing-11282018.pptx.pdf. CMS also provided several citations validating this point in the Proposed Rule.
[7] In the preamble to CMS' Part D rule for 2010, it estimated that the protected class policy increased program costs by over $4 billion from 2010-2018. See 74 Fed. Reg. at 2881, January 16, 2009.
[8] Op Cit., Partnership for Part D Access (See Footnote 5)
[9] Kocot, SL, McCutcheon T, and White R. "Protected Class Policy Can Promote Both Patient Access And Competition." 2019: *Health Affairs* Blog. Available at https://www.healthaffairs.org/do/10.1377/hblog20190118.805215/full/.

1. Broader use of utilization management tools in the protected classes

Currently, prior authorization and step therapy may be applied to drugs in Part D protected classes only when a patient starts a new treatment regime. Under the Proposed Rule, CMS would allow prior authorization and step therapy to be applied as they are otherwise across the benefit. If finalized, prior authorization and step therapy could be applied to protected class drugs, for both patients on current therapy and new starts. This proposal also includes the extension of a policy issued by guidance in 2018 to allow protected class drugs to be included in indication based formularies.[10]

- PCMS supports this broader application of utilization management tools. The adoption of UM tools otherwise available under Part D can reduce overall net drug costs and help beneficiaries achieve both lower premiums and out-of-pocket cost relief. Because under current policy plans are required to cover "all or substantially all" drugs in each of the protected classes, manufacturers provide fewer and lower rebates for drugs in protected classes than in non-protected classes.[11] Rebates are negotiated for cost-sharing tier placement and related to the limited application of prior authorization, rather than for formulary access and broader UM authority otherwise used in non-protected classes. Under the Proposed Rule, by increasing Part D sponsor leverage with greater ability to wield proven UM tools, rebates will increase, and the program and its beneficiaries will benefit.

- PCMA supports applying these utilization management tools to prescriptions for patients on existing therapy. Limiting the use of UM tools to patients newly starting treatment regimens allows for the continued overutilization of potentially inappropriate and overpriced medications. When enrollees switch plans on existing therapies, they are guaranteed a transition supply and can participate in robust exceptions, appeals, and grievance processes if they or their prescriber disagrees with a plan sponsor's coverage determination.

- PCMA supports the adoption of indication-based formulary design within the protected classes. The use of indication-based formularies in the commercial insurance market is widely described and has generated significant savings. We applaud CMS' efforts in the August 2018 HPMS memo to expressly authorize indication-based formularies in Part D. The Proposed Rule takes the next logical step and explicitly allows plan sponsors to reject from coverage (or negotiate more forcefully) protected class drugs for non-protected class uses. Providing Part D sponsors the ability to refuse to cover or impose

[10] Centers for Medicare & Medicaid Services, HPMS Memo, "Indication-Based Formulary Design Beginning in Contract Year (CY) 2020" (August 2018). Accessible at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/Downloads/HPMS-Memos/Weekly/SysHPMS-Memo-2018-Aug-29th.pdf

[11] Op. Cit., Hoadley, J. (Footnote 6).

different prior authorization, step therapy, or cost-sharing designations based on the use of the product will help drive beneficiaries toward therapies that offer the greatest value.

- PCMA supports the existing beneficiary protections. Existing beneficiary protections, as laid out in the Proposed Rule and well-described in current subregulatory guidance, related to CMS formulary review and oversight, transitions, exceptions, and appeals are sufficient. Plan sponsors know well how to operate these programs to ensure appropriate access to treatment enrollees either starting new therapies or on existing therapies. Allowing for greater use of prior authorization and step therapy for protected class drugs, and for indication-based formulary approaches for non-protected class uses of protected class drugs, does not pose a different risk to beneficiary access that is not already accounted for and managed by these existing protections.

- PCMA requests clarification regarding Part B drugs and the protected class. While the Proposed Rule does not make this direct connection, there is a chance that Medicare Advantage Prescription Drug (MA-PD) Plan Sponsors may inadvertently be required to create protected classes that are inclusive of Part B drugs, based upon the intersection of this protected class-related policy and the step therapy policy set forth for MA plan sponsors (see section V of the comments). This is contrary to the intention of the rule and we request CMS clarify this. To explain further, we interpret these policies together to allow an MA plan, through a step therapy edit, to require the use of a Part B drug prior to the use of a protected class Part D drug starting in 2020. We also interpret these policies together to allow a MA plan to require the use of a Part D protected class drug prior to the use of a Part B drug. We support both of these options as providing maximum plan flexibility to manage these high-cost drug classes, but ask that CMS clarify that these policies taken together do not require the coverage of Part B drugs that treat conditions in the protected classes.

2. Excluding new formulations of protected class drugs under certain conditions

In the Proposed Rule, CMS offers plan sponsors the flexibility to remove from their formularies new formulations of existing drugs in protected classes that do not account for a new route of administration. CMS describes how one manufacturer launched an extended release product and withdrew its standard release formulation. This evergreening effort was intended to convert existing standard release users to the extended release product, which would have a convenience advantage over impending standard release generic competitors. Under current regulations, Part D plan sponsors could keep the extended release product off their formularies, unless the drug is in a protected class. Under the “all or substantially all” standard, until the generic competitors are available, plans would be required to cover the extended release version. CMS would allow Part D plan sponsors to exclude these new formulations of drugs, even if they are in a protected class.

- PCMA wholly supports the policy described in the Proposed Rule. PCMA agrees that such behavior by drug manufacturers should be curtailed, and appreciates CMS' efforts to limit patent-related gaming by manufacturers at the expense of beneficiaries and federal healthcare dollars.

- CMS should consider renaming this policy proposal. We are concerned that CMS' description of this policy could cause confusion to manufacturers, PBMs, and Part D sponsors. In the Proposed Rule, CMS says that such drugs can be "excluded from a Part D sponsors' formulary." However, "excluded drugs" are defined at Section 1860D-2(e) of the Social Security Act, and this proposal is not referencing that provision of law but a different authority. We recommend something such as "omitted drugs," which has a similar meaning, but doesn't create confusion with current program operations at each instance. This comment carries over to the third part of the protected classes proposal as well, on price increase-related "omissions."

- CMS should publish or otherwise identify the drugs to which this policy could be applied. While we support the proposed exclusion of protected class drugs, we are concerned that the policy could put CMS and its Part D plan sponsors in a position of punishing behavior that is currently legally permissible, even if undesirable. It would not be fair for plans that take no action to be seen as complicit in this kind of behavior, and request that rather than placing the burden upon plans to identify appropriate circumstances for its application, CMS instead should proactively inform plans when new formulations that are not new routes of administration are available and subject to this proposed policy. Since CMS does not have jurisdiction over drug manufacturer patent terms and exclusivity periods, we request that the agency ensure that it coordinate with other federal agencies to produce a valid list, updated as appropriate

- PCMA supports application to interchangeable biosimilars. PCMA also fully supports that CMS is proposing to broaden the regulatory language in § 423.120(b)(2)(vi)(A) to incorporate interchangeable biosimilars into the definition of a drug for the purposes of meeting protected class formulary criteria. While there are currently not yet standards for the approval of interchangeable biologics, or applications being reviewed by FDA for such a drug, upon their introduction, this will allow for more rapid uptake of these potentially lower cost product forms.

3. Price change-related exclusions

In the current pharmaceutical marketplace, manufacturers are free to price their products as they see fit, and the price is but one input among many in a negotiation with PBMs for formulary access and placement. In the protected classes, Part D sponsors currently do not have the option of omitting drugs whose prices do not justify their benefits, including drugs that have experienced significant price increases out of line with their demonstrated clinical value. By

contrast, outside of the protected classes in Part D, if a drug is deemed too expensive given its clinical value, and the formulary requirements can be met otherwise, a Part D sponsor is not required to cover a high cost drug or one with unjustified price increases. Beneficiaries can access such drugs under formulary exceptions, if needed. Below, PCMA offers its support and requests several clarifications to the proposed policy.

The inconsistency in CMS and HHS' discussions regarding the positive effect of rebates in the pharmaceutical marketplace notwithstanding, PCMA appreciates CMS' interest in serving as a check on list price increases for Part D drugs, and agrees that drugs in protected classes are at greater risk for unwarranted price increases. Our members would welcome the opportunity to advocate for beneficiaries and taxpayers and secure lower net prices for protected class drugs. In conjunction with the proposal to allow plan sponsors broader use of UM tools, long-term savings under this price increase-related formulary omission policy are very likely. However, we would like to raise a few concerns and suggestions.

- Policing manufacturer pricing behavior. PCMA requests that CMS consider publishing all of the drugs that have exceeded the inflationary threshold for the specified applicable period. We find it inappropriate that Part D plan sponsors should be the policing force on this issue. When a manufacturer raises the price of its drug, it telegraphs that price change to wholesalers and pharmacies through pricing compendia. That change is immediate and applicable nationwide. By instead asking the more than 200 Part D plan sponsors to monitor for price changes at the time of bid completion against a benchmark price adds complexity and administrative burden to an already complex bid process. It also increases the likelihood of inconsistent determinations. After CMS publishes the drug list, CMS could grant manufacturers a period of time to object to their drug's placement (mistakes can happen). Sponsors can then reference this list as the basis for re-opening a negotiation with a manufacturer.

- Multiple source brands. The policy should extend to multiple source brand drugs in the protected classes as well. As proposed, CMS would apply it to only single source drugs and biologicals. However, as stipulated by CMS in justifying the proposal to exclude new formulations of protected class drugs, multiple source brands continue to exert market power either through longer-term contracts or evergreening strategies. Part D transition and grandfathering requirements are generous, and Part D plans should not be subjected to unchecked price increases on drugs for which patients are stable merely because a generic of only a different dosage form may exist.

- All protected class drugs from the manufacturer. The policy should also encompass all of a manufacturer's protected class drugs. As proposed, CMS would allow a plan to omit a single source protected class drug (defined as all NDCs attributed to that single source drug name) that exceeds the inflationary threshold. However, in the preamble, CMS contemplates allowing plans to omit all drugs from a manufacturer, all protected class

drugs, or merely the offending protected class drug. By instead allowing plan sponsors to omit all protected class drugs from the manufacturer, CMS would provide sufficient leverage to Part D sponsors to obtain reasonable rebates for continued formulary access. A manufacturer markets a suite of drugs in a protected class, either for different lines of therapy or different sub-indications of a broader use. Allowing plans to hold all of these drugs in limbo if one exceeds the inflationary threshold will provide more bargaining power and provide a more concrete constraint on manufacturer behavior. These offending manufacturers' non-protected brand drugs are already subject to sufficient competition and pressures.

- Price inflation calculation and benchmark. As CMS proposes, CPI-U and WAC are the most appropriate metrics and prices to use to measure price inflation and the price of a drug. However, as CMS surely knows, under the Part D program, nearly all transactions are completed in terms of negotiated price, the definition of which is being addressed elsewhere in the Proposed Rule (see our comments in section VI of these comments). While Part D sponsors monitor WAC, their contracts with manufacturers may include price protection, and as such may be protected from any change in WAC during the contract year. Thus, plan sponsors' motivation to apply such a policy may be muted. CMS should consider other options, such as publishing the list of drugs and manufacturers that exceed the inflationary limit, so these drugs and their manufacturers can be subjected to public scrutiny, as additional pressure against these kinds of behaviors.

- Data availability. Access to WAC pricing generally requires a paid subscription to a pricing compendium. While most plan sponsors have these resources available, independent analysis and confirmation would not be possible without bearing that expense, making the use of WAC less than wholly transparent to the public. PCMA does, however, recommend that CMS publish its earlier-referenced internal analysis on price changes among protected class drugs for independent scrutiny. We also recommend that CMS regularly update it to compare price changes over time, and assess whether the policy change has had the desired effect.

- Clarification requested on the reason for protected class price increases and the role of rebates. This Administration believes pharmaceutical companies raise their prices because of rebates. However, it is well-documented that rebates are lower and price increases are more common for protected class drugs than non-protected class drugs.[12,13,14] It seems to us that if rebates drove list price increases, protected class drugs would not need a policy intervention such as the one CMS is proposing related to

[12] Ibid.
[13] Bennette CS et al. Steady Increase In Prices For Oral Anticancer Drugs After Market Launch Suggests A Lack Of Competitive Pressure. Health Aff (Millwood). 2016 May 1;35(5):805-12.
[14] Gordon N et al. Trajectories of Injectable Cancer Drug Costs After Launch in the United States. J Clin Oncol. 2018 Feb 1;36(4):319-325.

price increases. We would be interested to have CMS articulate as to why it believes prices are increasing for protected class drugs, since it clearly is not rebates.

<u>PCMA Recommendations</u>: PCMA continues to recommend eliminating the protected class requirements altogether. In the absence of eliminating protected classes, PCMA supports all three proposals offered by CMS to better align treatment of these drugs to the rest of the Part D program and the commercial market, and offers a range of suggestions to improve the effectiveness of these proposals.

II. Prohibition Against Gag clauses in Pharmacy Contracts

Proposal:

HHS proposes to implement Pub. L. 115-262 ("Know the Lowest Price Act of 2018) which prohibits Medicare Part D plan sponsors from restricting their network pharmacies from informing a patient that the same drug or a competitor could be purchased at a lower cash price off-insurance. CMS notes that these types of provisions are referred to as "gag clauses." (p. 62164)

Discussion:

PCMA and its PBM members oppose use of gag clauses in contracts with pharmacies, and support that consumers should always pay the lesser of the cost-sharing for a drug under their insurance plan or the cost of the drug. Similarly, we support pharmacists telling patients when the cash price for a drug is less than their cost-sharing amount under the Part D plan. We would note, however, that this situation should not exist in Medicare Part D given that Medicare Part D rules and guidance require Part D plan sponsors to ensure that beneficiaries are charged the lesser of a drug's negotiated price or applicable cost-share for covered drugs in all phases of the benefit. For example, if an enrollee has a $30 copayment for a medication but the plan's negotiated price of the drug is $15, the beneficiary will pay $15.

PCMA encourages CMS to consider whether and if so how to deal with the issue that beneficiaries may not always come out ahead if they pay cash instead of using their insurance or Medicare benefit. Some of these concerns are noted below.

- While we recognize the need for beneficiaries to lower their out-of-pocket costs and are committed to providing access at the lowest possible cost, we are concerned about unintended financial and clinical consequences where Part D beneficiaries purchase drugs outside of their plans. For example, out-of-network prescription claims for urgent or emergency cases can count toward the beneficiary's deductible and True Out-of-Pocket (TrOOP) calculated expenses if the beneficiary submits the claim for reimbursement, but absent an urgent or emergency situation, beneficiaries are expected to use network pharmacies in their Part D plans for the prescription to count toward the beneficiary's deductible or TrOOP calculated expenses.

- Additionally, if a plan is not aware of a medication purchased by a beneficiary outside the benefit, it cannot effectively provide care coordination, or medication management and monitoring of high risk medications. In particular, accessing drugs outside of one's prescription drug benefit could limit Part D plan sponsors' ability to effectively monitor at-risk beneficiaries' use of opioids.

- PCMA has concerns that purchasing drugs outside of Medicare may leave beneficiaries out of programs like medication therapy management, as the drugs not covered through Medicare may not be visible to the Part D plan.

- As well, potential drug-drug interactions may be missed if the beneficiary fills prescriptions at more than one pharmacy.

- Finally, we urge CMS to consider implications for opioid abuse. If beneficiaries realize that they may be able to get opioid prescriptions filled by just paying cash, it may provide an incentive to use this as a mechanism to avoid having these prescriptions show up to their Part D plan, thus undercutting the wide range of initiatives underway to allow Part D plan sponsors to best provide oversight and management of potential opioid abuse.

Thus, PCMA recommends that pharmacists alerting patients of a potential lower cash price also inform them of potential financial and clinical ramifications if they decide to pay cash instead of using their prescription drug benefit.

Finally, as HHS considers the pharmacy gag clause issue, it should take into account unintended downstream consequences such as whether (a) pharmacies will now be encouraged to tell patients about the availability of coupons, or other manufacturers-paid assistance, and (b) dual eligibles will be both confused and dissatisfied as they will be told that they can pay cash for their prescriptions covered under Medicare but not under Medicaid.

***PCMA Recommendation*: PCMA supports beneficiaries paying the lowest applicable cost-sharing to obtain the drugs they need and opposes any policy or contract terms that would prevent pharmacists from informing beneficiaries when their prescribed drug may be available to them at a lower cost. We believe that pharmacists should have the right to provide a beneficiary with information regarding the amount of the cost-share for a prescription drug. However, we urge CMS to address the potential unintended financial and clinical consequences where Part D beneficiaries purchase drugs outside of their plan and specifically to address these concerns regarding prescriptions for opioids.**

III. Proposed Adoption of a Real-Time Benefit Tool

Proposal:

- CMS solicits comments on assessments from knowledgeable parties about whether any of the standards for a real-time benefit tool (RTBT) that currently are under development may be suitable to meet CMS' intended purposes of presenting prescribers with formulary options that are all clinically appropriate and accurately reflect the costs of their patient's specific formulary and benefit options under their drug benefit plan and are integrated into the electronic prescribing (e-prescribing) workflow and electronic medical record system. (p. 62167)

- CMS solicits comments on the proposal to require that all Part D plan sponsors implement one or more RTBT, including the feasibility for plans to meet the proposed January 1, 2020 deadline. (p. 62167)

- CMS welcomes comments on how the proposal may or may not expedite its goal of giving each Part D enrollee and clinicians access to meaningful decision support through RTBT. CMS seeks feedback about RTBT standardization efforts, including planned fulfillment of any milestones that standardization bodies have already or are likely to meet in advance of the proposed January 1, 2020 deadline. (p. 62167)

- CMS asks for comments regarding the impact of the proposal on plans and providers, including overall interoperability and the impact on medical record systems. (p. 62167)

- CMS asks for comments regarding the impact of the proposed effective date on the industry and other interested stakeholders. (p. 62167)

Discussion:

PCMA appreciates CMS' willingness to address the need for enhanced communication regarding drug costs among payers, prescribers and beneficiaries. In general, the proposed rule appears to be an appropriate first step in achieving the Administrations' goals around price transparency, which is expected to lead to better health outcomes. Providing real-time prescription benefit information that includes the beneficiary's financial responsibility allows beneficiaries and their providers to make more fully informed decisions about their treatment options. If a beneficiary is prescribed a drug therapy she cannot afford and she forgoes treatment as a result, she is likely to experience complications that will cost her, Medicare, and taxpayers more. Providing the beneficiary accurate information on her cost-sharing at the point of prescribing will facilitate discussions between beneficiaries and their prescribers about the most effective treatment that is affordable for the beneficiary.

1. Use 2020 to phase-in RTBT, but do not mandate adoption

CMS' approach to implementing tools that will facilitate the provision of real-time pharmacy benefit information is one that recognizes the pace of change in the industry, and reflects the need for near-term action. Many PCMA members have already taken steps to use proprietary real-time benefit verification tools that are currently available on the marketplace. While having one tool in place that at least one EHR or e-Prescribing system supports by January 1, 2020 is not an unreasonable expectation for many PCMA members, this apparent readiness is largely dependent upon both the final rule related to RTBT (timing and content) and the content of the 2020 Call Letter. Importantly, implementation of RTBT tools also depends on an additional factor outside of the control of PBMs: the readiness of Electronic Medical Record or e-Prescribing vendors to support any RTBT.

Given these concerns, we would recommend that January 1, 2020 be a date for voluntary adoption of RTBT, with its required use by January 1, 2021 with respect to the implementation of a single RTBT that is interoperable with one e-prescribing system and one EMR system. We point CMS to its flexible adoption of the Appropriate Use Criteria as described in the CY2019 Medicare Physician Fee Schedule (see 82 FR 59688), for which CMS implemented voluntary participation from July 2018 through the end of 2019, and mandatory participation beginning in 2020. The first 18 months are intended to provide feedback to providers, vendors, and CMS about how the program can operate more efficiently. A similar "learning system" may be warranted here given the number of unknown variables at this point in time.

The potential burden on EMR/e-Prescribing vendors is not one to be taken lightly and very well may determine when RTBT integration and adoption can occur. Vendors will be focused in 2019 on ensuring compliance with the requirement to use NCPDP SCRIPT Standard v2017071 beginning January 1, 2020. We understand that in most cases, their workload has already been allocated for 2019. There is also the challenge of potentially supporting more than one RTBT to accommodate a payer's RTBT choices.

We also encourage CMS to consider the cost associated with implementation as it prepares for the final rule and selects a mandatory implementation deadline. These implementation costs place a burden on providers and if they don't participate, then the RTBT has no effect, let alone its desired or anticipated effects. If an EMR vendor were to implement a RTBT in 2019, that functionality still needs to be implemented by each of their care system clients, which may require the clients to implement a software upgrade. Scheduling all care system clients to implement a software upgrade in less than a year may not be realistic for a vendor to support due to resource availability and training needs for providers.

The proposed baseline of one tool/one Electronic Health Record (EHR) being implemented on a *voluntary* baseline in 2020 will allow the industry to evaluate the efficacy of the tools, and their impact on clinical and financial outcomes, while allowing for the concurrent development of a

national standard. PCMA believes that a national standard will ease implementation for EHRs and e-Prescribing systems, which is a crucial step for widespread adoption. However, we do not believe that progress should be delayed by waiting for the publication of a standard (which is currently expected in late 2019). Adoption time frames are generally driven by industry interest or regulatory requirement and historical experience would indicate that a minimum of 12 months is needed. Given that many proprietary RTBTs are available in the marketplace and have been implemented, and most RTBT vendors are participating in the development of the standard, the transition to the standard may not present significant burden to the industry.

At the same time, it is important that the differences between the existing proprietary tools and the potential standard are well understood and adequate time is allowed for testing and implementation of the standard, including for existing multiple users of RTBTs to adapt to the standard. As an example, most proprietary tools support the communication of three to five alternative products whereas the standard is expected to enable the exchange of up to ten alternative products. The standard is also being designed to support communication of restricted recipient program information as well as other provider network constraints. It is unclear if the current tools include this functionality or if it is information that providers would use if included as part of a pricing tool. Input from those voluntarily using a RTBT will inform the development of the standard and ensure the final version is robust enough to meet industry needs and CMS' requirements while still providing value and a timely response.

2. Greater clarity required regarding the type of information to be communicated to prescribers

As CMS further develops this proposal, PCMA also seeks additional clarity regarding the expectation of exactly what information must be communicated, beyond the beneficiary's anticipated cost share, by the RTBT. The preamble to the proposed rule states as follows:

> "Therefore, we are proposing that each Part D sponsor be required to implement a RTBT capable of integrating with prescribers' e-prescribing and EMR systems to provide ***complete, accurate, timely, clinically appropriate and patient-specific real-time formulary and benefit information*** to the prescriber." (p. 62165; Emphasis added.)

It is unclear from the preamble if complete formulary and benefit information includes all elements that are part of the NCPDP Formulary and Benefit Standard. Clarification of "clinically appropriate and patient-specific formulary and benefit information" is needed. Each RTBT and payer may interpret this differently, resulting in different information being presented to providers and patients. This will frustrate both providers and patients, and lead to skepticism about the value of the information being provided by the RTBT.

3. Importance of costs as "estimated"

We also would reinforce the point that the RTBT response is taken at a moment-in-time and reflects the conditions in place at that moment. The RTBT response provides the beneficiary's estimated financial responsibility based on those conditions. This response could change based on any number of factors (e.g., change in pharmacy, when the prescription claim is processed, other claims that may have been processed). The plan cannot be responsible for the difference between the estimated financial responsibility included in the RTBT response and the actual financial responsibility at the time of dispensing. In the final rule, CMS should clearly provide that the benefit information provided in the RTBT at the point-of-service (POS) is "estimated" and relieve plans of any liability for inaccurate or out-of-date cost-sharing information.

4. Timing impact when standard is issued

PCMA acknowledges that when a real-time prescription benefit standard is published, the content of a real-time benefit transaction may change, according to the requirements of the standard. PCMA suggests that there be a period of time (e.g., 12-18 months) where the standard is used, and enhancements made based on user experience, before the use of the standard is mandated, in order to ensure that the standard will robustly support the needs of patients and prescribers as well as the industry.

5. CMS should explore alternatives to the inclusion of negotiated price in RTBT

CMS has indicated its interest in the inclusion of "each drug's full negotiated price." In general, PCMA believes:

- To our knowledge, this is not an element that is currently supported by the proprietary tools, nor is it included in the standard under development.

- The current definition itself would appear to be far too vague to be worth creating a standard as contingent amounts that cannot be "reasonably determined" at POS are not included in the negotiated price, and are constantly changing depending on pharmacy performance.

- Given that, as discussed in several sections of these comments, CMS is considering proposing to change the definition of "negotiated price" for some future year, and the fact that the negotiated price may be subject to changes, due to contract provisions, we would request that this language not be included in the final rule.

More work is needed to determine how to best communicate with the provider the plan's cost for the medication. Given the current uncertainty regarding the definition of "negotiated price" as noted above, as well as the lack of utility associated with any possible field based on this amount, we believe a more appropriate pricing field would be an existing cost field in the PDE.

To our knowledge, neither current RTBTs, nor the standard under development, include any information on the drug's cost, or the amount the plan is paying the pharmacy. This is an enhancement that would need to be brought forward by industry participants to the vendors and NCPDP to ensure it is incorporated into future versions of software and the standard. Even if this amount is added, it would not reflect the final negotiated price net of any rebates or other DIR amounts so its value is questionable. It is also possible that including this information would delay the response time. Providers expect transactions to occur in seconds, or sub-seconds. Complex calculations to determine plan cost could increase the response time to levels that providers find unacceptable, likely precluding the use of RTBT. For example, plan cost for Part D drugs may vary across network pharmacies even if beneficiary cost-sharing is the same. It is not clear to PCMA that plan cost variances such as these would impact utilization choices since prescribers do not recommend pharmacies to patients. Rather, sharing approximate plan cost with the prescriber is worth considering, especially in situations where the provider is part of a risk-based arrangement with the payer. Sharing this information must take into account the need to protect proprietary contractual information and is a goal worth striving towards but may be premature at this point.

6. CMS should reassess its position on patient consent concerns

PCMA has significant concerns regarding the provision in the proposed rule that states: "Patients must specifically consent to use of their protected health information for RTBT." This provision appears to place an undue burden on providers to gather explicit consent, which almost certainly will hinder or, indeed, preclude the use of RTBT. Providers would have to modify their workflow and systems to capture such explicit consent and those systemic changes are not likely to be completed before January 1, 2020. Indeed, under current law, providers must simply provide HIPAA privacy notices, and not specifically track patient consent for every use of personally identifiable health information. PCMA is puzzled why CMS would adopt such a standard, given the significant debate and consideration that went into crafting the HIPAA privacy rule, and believes that the language in HIPAA and/or state statute regarding the use of protected health information for treatment, payment and health care operations that essentially presumes patient consent upon presenting for care is sufficient to allow the use of RTBT.

7. Concerns regarding Medical Loss Ratio (MLR)

Finally, we are concerned with the possible disincentive for plans to spend large amounts of funds in these administrative services if the amounts will be counted on the administrative side of the MLR calculation. We would suggest that CMS provide one of two alternatives to this conundrum.

- CMS could specify that amounts spent to develop, purchase, test, and administer the RTBT tool be excluded from the MLR calculation at least for a number of years until these systems are fully up and running, or

- CMS could provide that amounts expended on the RTBT are considered related to quality for purposes of the MLR calculation.

8. Regulatory Impact Analysis

In the regulatory impact section on Part D E-prescribing, CMS notes that due to a lack of data, it cannot score this provision. It provides a list of data items needed and asks for comments on any of the factors. The list of items for which CMS does not have adequate data is: current usage of RTBT, use of intermediaries for software, software costs, lower tier cost-sharing substitution, cost after implementation, cost to providers, and number of impacted beneficiaries.

Below we provide a few insights on the issues identified for feedback. Please note that several of the questions are related to provider implementation, which is outside PCMA's purview.

- CMS solicits comments on whether there will be additional RTBT savings from generic substitutions. (p. 62185) We believe that possible additional savings might include:
    - Additional savings due to generic substitution and biosimilar utilization are possible, based upon how the RTBT accounts for plan costs (approximate or specific).
    - Providers who hold some risk to prescribe lower cost generics either based on dosage form or based on differences in retail pharmacy pricing.
    - Regarding biosimilars, if net costs are the same or lower, and beneficiary cost-sharing is as well (as we would expect), there could be significant savings available.

- CMS believes the primary source of savings of RTBT would be the prescribing of lower tier cost-sharing drugs and asks for stakeholder comment on this perspective. (p. 62186)
    - We concur. Savings will likely come from selection of lower tier products, assuming those are lower cost products for the plans.

- CMS asks for feedback on whether the potential benefits or cost savings associated with RTBT proposal outweigh the potential costs of the proposal. (p. 62187)
    - We note that potential costs need to consider all stakeholders; if the providers don't participate, then the savings won't be realized by the plans.

<u>PCMA Recommendation</u>: PCMA appreciates CMS' willingness to address the need for enhanced communication regarding drug costs among payers, prescribers, and beneficiaries and believes that in general, the proposed rule appears to be an appropriate first step in achieving the Administration's goals around price transparency, which is expected to lead to better health outcomes. However, in light of a range of issues that remain to be resolved, PCMA recommends that January 1, 2020 be a date for voluntary adoption of RTBT, (e.g., a single RTBT that is interoperable with one e-prescribing system and one EMR system).

IV. Part D Explanation of Benefits (EOB)

Proposal:

CMS seeks to further transparency efforts through improvements in beneficiary education materials, such as the Part D EOB. CMS believes that requiring Part D sponsors to include additional information about negotiated drug price changes and lower cost therapeutic alternatives in the EOB would help improve the cost transparency of Part D prescriptions and mitigate drug price increases. CMS proposes two specific new requirements to the EOB to accomplish this goal. (p. 62168) Specifically, Part D sponsors would be required to:

- Include the cumulative percentage change in the negotiated price in the EOB, and
- Provide information about drugs that are therapeutic alternatives with lower cost-sharing, when available.

Discussion:

Our recommendations on these specific proposals are set forth below. Initially, however, we note our overall concerns that the EOB is not the most appropriate vehicle for increased price transparency through beneficiary education. While information added to the EOB could provide price increase data that would be viewed when the EOB is received in the enrollee's mail, CMS must recognize that this is not real-time information and would not change real-time decisions about the most cost-effective options available to the enrollee. Instead, we continue to believe that CMS should authorize Part D plan sponsors to add additional information to the EOB statement that educates beneficiaries as to where to find out if prices for their drugs have changed on a real-time basis. In our recommendation section below, we reiterate the range of steps that we encourage the agency to take to achieve meaningful real-time pricing options.[15]

1. **CMS requests specific feedback on operationalizing drug price information for beneficiaries in the EOB including the percent change in negotiated price since the close of open enrollment and the percent change in prices since the beginning of the benefit year.**

We have several concerns with the percent change pricing information displaying on the Part D EOB.

- First, resources available to enrollees regarding pricing are volatile. Some are "point in time" while others are "projected". The consequences of this confusion include that the beneficiary may be unknowingly steered toward a drug that ultimately costs them more.

[15] These options were also discussed in PCMA's comments on the Blueprint. To view the full text of PCMA's Blueprint RFI comments on this topic, please go to https://www.regulations.gov/document?D=CMS-2018-0075-2579. See pages 120-124.

Likewise, if an enrollee receives the same drug but with a different NDC (as may become more common as manufacturers consider that option), drug pricing could potentially be different and thus inaccurate for that enrollee.

- The Usual & Customary (U&C) amount might not change even if the negotiated price increases. This could lead to enrollee confusion and potential inaccuracy. Similarly, if the price changed retroactively due to pricing issues, the Part D sponsors would not have a mechanism to account for that in the EOB.

- As CMS is aware, EOBs are sent at the end of the month. The enrollee typically already would have received the drug by the time the EOB arrives. It would not help the enrollee to receive this information 30 days or more after the fact. Moreover, as noted above, the price may have changed.

- Likewise, we have concerns about CMS' concept of including the percent change since open enrollment. This could be misleading, as enrollees might not know at what date they priced the drug. The price could change from the date they priced it to the end of open enrollment. There is no time stamp available. If CMS proceeds, it will need to provide a specific date associated with what is considered "the end of open enrollment" as the proposed rule does not address this issue. For example, is that 10/15 of the previous year? Or December 7? Or the date the beneficiary enrolled? What if open enrollment is extended due to emergency scenarios?

- Finally, we have concerns regarding the complexity of an additional repository to house the information needed to support the historical change in price from one month to the next. CMS' estimation of $0.2 million is on the low end of the cost scale for this system to be developed, tested, and implemented.

2. CMS solicits comments on the proposed changes to Part D to require EOB sponsors to include information about negotiated price changes and lower-cost therapeutic alternatives in the Part D EOBs

We also have several concerns regarding displaying lower cost therapeutic alternatives as well as negotiated price changes. In an already long and complicated document, having to display this amount of information will certainly increase the length of the document and thus decrease the chances that the enrollee will even read it. Additionally, lower cost alternatives might change over time.

As noted in our prior comments, it is much more effective to make enrollees aware of these types of options at the time of prescribing rather than trying to do this on the backend well after the prescription has been filled.

We are further concerned about the vagueness of the language proposed.

- In the Proposed Rule, CMS is considering for a future plan year proposing a significant redefinition of the term "negotiated price." Yet, in its proposal to amend the Part D EOB, it neither addresses which definition of negotiated price will be required to be disclosed nor does it discuss the relative merits of disclosing the negotiated price, as currently defined. For example, given that Part D sponsors currently have the flexibility to reflect certain rebate and price concessions after the POS, it is unclear whether or not the negotiated price is a meaningful measure for purposes of consumer education. In addition, CMS also fails to address how this proposal would interface with the coverage gap discount program, which currently defines the term negotiated price as it was defined at the time of the enactment of the ACA. We strongly urge CMS to not include any new obligations vis-à-vis negotiated price until it determines what changes it seeks to that term and then conducts the required notice and comment rulemaking for any such change.

- We also are confused by CMS' comment that lower cost therapeutic alternatives could include a different drug, not within the same category or class, but that has a Medically-Accepted Indication (MAI) to treat the same condition. Frankly, we do not understand how Part D plans could include MAIs in the EOB since the plans may not know the condition being treated. Specifically, the ability to include the MAI assumes that the plan can access Medicare Parts A and B claims data on a timely basis, which, as CMS knows, is often not the case. Indeed, in the comments we filed on the first proposed Part D rule for 2020,[16] we noted our concerns that the proposed rule would not allow plans to use the claims data for a broad range of necessary purposes. At a minimum, regardless of the final EOB requirements, we suggest that CMS clearly provide that use of claims data for determination of whether lower cost therapeutic alternatives are available is a permissible use.

- CMS acknowledges that "alternatives may not always be available" (p. 62168) but then notes that plans would have the option to include relevant beneficiary-specific information. It is not clear whether CMS' acknowledgement that alternatives may not always be available is meant to reference the specific beneficiary or the general population. We again believe this could be very confusing to a beneficiary to try to understand the difference between what might generally be an alternative as compared to what might be available that is appropriate specifically for them. We reiterate that it

[16] See PCMA's comments on the proposed rule "Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021." Filed December 21, 2018, but not yet posted on regulations.gov.

would be much more preferable to refer enrollees to resources that address possible alternatives.

Instead, we would recommend that, instead of displaying the actual alternatives, Part D sponsors could include an asterisk with a disclaimer. Options might include language such as either off the following:

- A lower cost therapeutic alternative may exist for this drug. Log on to the web or talk to your Pharmacist.

- You did not take the generic form of this drug, consider talking to your doctor to get the generic form of this drug.

***PCMA Recommendation*: PCMA recommends that CMS not proceed with its proposed approach regarding the Part D EOBs. Rather, CMS should consider the range of alternatives we suggest below including content in the EOB which directs beneficiaries as to where they can find additional information on drug prices and alternatives.**

PCMA encourages HHS to take all of the following steps:

- ***Authorize Part D plan sponsors to add additional information to the EOB statement that educates beneficiaries as to where to find out if prices for their drugs have changed.***

- ***Make updating the HIPAA regulations to implement the NCPDP ePA standard a priority as part of its drug pricing efforts.***

- ***Examine current RTBT technology and consider how it can be better integrated into the normal flow of a prescriber's work, how prescribers may be encouraged to adopt such technology, and how HHS might encourage or require competing RTBT technologies to be seamlessly interoperable with one another.***

- ***Help facilitate the development of systems that provide pharmacists with all information available about lower cost options, primarily through development of an NCPDP standard, recognizing that the information is most useful at the point of prescribing.***

- ***Improve the Medicare Plan Finder (MPF) tool and the timeliness of the information to reduce inconsistencies between the pricing data submitted by Part D plan sponsors for the MPF listing and the price at the time a prescription is filled.***

- ***Make a drug pricing comparison tool available to beneficiaries via either the medicare.gov website or MPF to provide pricing for multiple formulary alternatives, rather just the price in response to a one drug query as is currently available.***

V. Medicare Advantage and Step Therapy for Part B Drugs

Proposal:

- CMS asks for comments regarding the impact that allowing step therapy for Part B drugs would have on MA plans and enrollees. (p. 62169)

- CMS solicits comments about whether its proposal imposing education and information responsibilities, in combination with existing regulations on care coordination, are sufficient to ensure that MA plans specifically address step therapy programs for Part B drugs as part of their care coordination responsibilities. (p. 62169)

- CMS solicits comments on its proposal that MA plans with step therapy programs would be required to have P&T Committees and whether the requirement should be expanded to all MA plans that have any UM policy applicable to Part B drugs. CMS also asks whether there are any other options that would meet the policy goal of ensuring that step therapy programs are medically appropriate. (p. 62170)

- CMS solicits comments on its proposal to permit MA plans to use off-label drugs in a step therapy program only when such drugs are supported by widely used treatment guidelines or clinical literature that CMS considers to be best practices. (p. 62170)

- CMS expressly solicits comments on the following details of its proposal and whether there are additional considerations that would further the goals of balancing cost savings and efficiencies with enrollee access, enhanced quality and due process (p. 62173):
    - the restriction to new starts;
    - the new requirement for establishment and use of a P&T Committee for MA plans that use step therapy;
    - the prohibition on using non-covered drugs, and off-label drugs in certain circumstances, in step therapy programs; and
    - the organization determination and appeals timelines and processes for Part B dugs, especially the proposal to not permit MA organizations to extend the proposed time frames for requests for Part B drugs.

Discussion:

PCMA has long supported the use of evidence based UM techniques for Part B drugs to lower out-of-pocket costs for beneficiaries and stimulate increased price competition in the Part B drug market. The historic barrier to more efficient management of Part B drug utilization is that existing Medicare policies made it impossible for MA plans to leverage market-based tools of competition to lower costs.[17] Without such tools, manufacturers had nearly unlimited pricing power, as evidenced by the ever-increasing costs of Part B drugs. Since 2009, Medicare Part B drug spending has grown at an average rate of 9 percent per year.[18] About half of the growth in

[17] HPMS Memo, Prohibition on Imposing Mandatory Step Therapy for Part B Drugs and Services (September 2012).
[18] MedPAC Report to the Congress: Medicare and the Health Care Delivery System, June 2017.

Part B drug spending from 2009 to 2013 was accounted for by price growth, which reflects increased prices for existing products and shifts in the mix of drugs, including the adoption of new drugs.

With the release of the August 2018 HPMS memo in which CMS appropriately reinterpreted MA plan statutory authority in this regard, Part B drugs can now be exposed to increased competitive forces to reduce out-of-pocket costs for beneficiaries. We agree with CMS' preamble affirmation of the statutory authority of MA plans to implement UM tools for Part B drugs.[19] We applaud CMS for revising the previous interpretation of this policy as we have long held that it was not supportable and served as an impediment to utilizing best practice UM tools to bring market-based competition to Part B. Further, we strongly support this regulatory proposal that would memorialize the use of these tools in the MA program with appropriate beneficiary safeguards and protections.

Below we review a range of specific issues for CMS to consider as it finalizes this proposal.

1. Use of Part D Pharmacy and Therapeutics (P&T) Committee

We support CMS' proposal that UM of any Part B drugs be approved through the plans' existing P&T Committee process, as required in 42 CFR Part 423. These P&T Committees have been very successful in reviewing UM in Part D. As with the coverage and appeals process discussed below, it is both reasonable and efficient to have these duly constituted entities handle the UM not only for step therapy but also for other UM policies (e.g. prior authorization or dosage limits) that may be applicable to Part B drugs.

In the preamble, CMS notes that it may release subregulatory guidance concerning the application of the P&T Committee requirements in the context of Part B drugs. To the extent that such guidance is necessary, we would urge CMS to build on current Part D P&T Committee protocols to the greatest extent possible and to avoid the creation of additional burdens on the operations of the committees that could undermine their effectiveness or lead to inconsistent protocols for Part D vs Part B drugs.

2. Use of Part D coverage determinations and appeals time frames

We likewise support CMS' proposal to align the organizational determinations and appeals time frames for Part B covered drugs with the existing time frames for coverage determinations and appeals in the Part D program. These are important beneficiary protections that are patterned on the current appeals process in Part D. As CMS acknowledges, these provisions have been shown to provide appropriate beneficiary safeguards and protections.

[19] Social Security Act Sections 1851 (c)(1)(G) and (c)(2)(B); CFR 422.4(a)(1)(ii)

Our only note of caution in this regard is that the Part D organizational determinations and appeals time frames are currently being revised both through the subregulatory effort to release a new appeals chapter and through the proposed changes in the pending Part C and D Policy & Technical proposed rule for 2020. As we have urged in our comments on both of these issuances, we believe it is critical for there to be clear, consistent standards and that all of the changes being considered be implemented timely and in a way that can meaningfully be adopted by Part D plan sponsors (and now by MA plan sponsors). Thus we reiterate the need to make sure that all of the comments on both the pending chapter and the rule are considered and adopted to assure meaningful and consistent adoption. To the extent CMS finalizes proposed changes in the appeals chapter or underlying appeals regulations, we encourage CMS to ensure that those changes are consistent across both Parts B and D.

3. Off-label drug use in the context of Part B drug utilization management

PCMA supports the use of prior authorization and step therapy for off-label drugs to determine whether such drugs are supported by widely used treatment guidelines or clinical literature that CMS considers to be based on best practices. Off-Label or non-FDA approved drug use refers to the prescribing of an FDA-approved medication for a use that is not included in the product indications or labeling. This term specifically refers to drugs or dosages used for diagnoses that are not approved by the FDA and may or may not have adequate medical evidence supporting safety and efficacy. Off-label prescribing of drugs is common in clinical practice and many off-label uses are effective, well documented in peer reviewed literature and the compendia, and are widely employed as 'standard of care' treatments.

However, support of this proposed policy must be distinguished from a position that supports off-evidence drug use. Off-evidence drug use further distinguishes the concept of off-label use and refers to indications for which there is a lack of sufficient evidence for safety and/or efficacy for a particular medication. An off-evidence use of a medication is considered experimental and investigational should not be utilized as part of a Part B drug UM program.

It is also critical that CMS is very clear about what CMS considers to be "best practices" in this regard. We do not think CMS should define "best practices," as we would fear that anything that CMS sought to produce in this regard would be subject to rebuttal by a range of interests. Rather, we recommend that CMS finalize this proposal such that off-label drug use is permitted in the UM policies of MAIs for Part B drugs provided that such use is supported in one of the compendia identified for use by Part D plan sponsors[20] or for Part B coverage[21], or in best practice clinical guidelines as recognized by a plan's P&T Committee. We believe that such an

[20] See SSA Sec. 1860D-2(e)(4), which references the Medicaid covered outpatient drug definition at SSA 1927(g)(1)(B)(i).

[21] See SSA Sec. 1861(t)(2)(B)(ii)(I) and subsequent regulations and guidance. We note that in the CY 2008 Physician Fee Schedule rule CMS established a subregulatory process for recognizing new compendia. We believe this process, as well as the internal processes of each plan's P&T Committee, we be sufficient to ensure plans are equipped to make reasonable determinations as to clinically appropriate, medically accepted indications.

approach is consistent with the market-based principles applied to Part D that CMS engenders to duplicate for Part B drugs and ensures that beneficiaries are only prescribed drugs which are well-documented and supported by evidence.

Another important consideration for plan sponsors is the role of Independent Review Entities (IRE). Specifically, with regard to "best practices," CMS should instruct and train IREs that the plan's choice of compendia, P&T Committees, or clinical practice guidelines to determine MAIs is not subject to the IRE's judgment. These plan choices are made within the scope of the flexibility granted them under the law, and are approved by CMS as part of its approval of the Part D plan's formulary for the given plan year. We urge CMS to be very clear that IRE redeterminations against a plan must be made using the "best practices" documents that the plan itself is using. Further, we request again that the IRE be required to provide plan sponsors the rationale for each redetermination it makes regarding the plan's enrollees, for plan process improvement.

4. Part B utilization management should not be limited to new starts

PCMA understands from its members that they estimate that only a small percentage of their 2019 calendar year Part B drugs will be managed through the new Part B Drug Step Therapy policy authorized in the August 2018 HPMS memo. This is largely driven by the 2019 policy that limits the applicability of step therapy to new starts only and significantly limits the cost saving opportunities for enrollees and for Medicare.

We support the CMS policy decision in this regard for 2019 given the unique timing and circumstances that did not allow for transparent and clear communication and marketing to potential enrollees of the Part B drugs that would be subject to UM in 2019. However, for plan year 2020 and future years, we recommend that CMS permit Part B drug UM for both new and existing prescriptions subject to sufficient enrollee education and disclosure.

As discussed below, we recommend that MA plans market and display Part B preferred drug lists, similar to Part D formularies, in a way that clearly communicates which drugs are subject to UM. This effort will educate potential enrollees in their purchasing decisions during annual open enrollment, while allowing for the broader expansion of UM tools in Part B. Combined with the CMS proposal, which we support, to align organizational determinations and appeals time frames for Part B covered drugs with the existing time frames for coverage determinations and appeals in the Part D program, we believe that such efforts would provide robust beneficiary protections to ensure appropriate access to Part B drugs.

We also note that allowing UM on Part B drugs for all enrollees and not just for new starts would be consistent with the proposal under protected classes to allow UM for those already taking a protected class drug. (See our comments in Section I above.) We are concerned it would be

confusing to beneficiaries and inconsistent policy to allow UM for new starts only in some cases, but in others allow UM for all enrollees and not just new starts.

5. Flexibility on how savings are returned to enrollees

In a welcome change from how the option operates in 2019, CMS proposes for 2020 and beyond that MA plans now have the option of either coupling drug management coordination with rewards and incentives to pass back savings to beneficiaries, or else to reflect such savings in the plan's bid. We believe this flexibility is an important option in the next section and below we suggest some specific parameters for inclusion in the bids.

6. Part B drug management savings included in plan bids

Applying UM techniques permitted in Medicare Part D to the management of Part B covered drug utilization is a logical step to improved management of drug costs in Part B. There is sufficient competition in several Part B drug categories and classes that can now be leveraged by MA plans using evidence based UM and private market based price negotiation tools including rebates to reduce costs for beneficiaries. Prior to the August 2018 HPMS memo, MA plans generally lacked the ability to use many of the essential Part D tools, namely prior authorization and step therapy, to negotiate with the manufacturers of Part B drug therapies. According to our members, as much as half of Part B drug spending on behalf of MA enrollees is attributable to drug classes where robust competition exists, and safety and efficacy elements are not clinically different, including those listed by CMS in the Proposed Rule. Implementation of this proposal therefore could result in savings in excess of CMS' estimates.

We note that appropriate management of these drugs by plan sponsors, including the negotiation and collection of rebates for preferred status, will have effects on fee-for-service (FFS) Part B drug spending as well. These rebates will be included in the calculation of Part B drugs' Average Sales Price, which is the basis for reimbursement under FFS. Since beneficiaries are assessed 20% coinsurance on Part B services, in time, reductions in ASP due to this policy will provide savings to non-MA enrollees and the Trust Fund as well.

We support the proposed MA plan flexibility to structure savings associated with a Part B drug UM program as either a rewards and incentive program or as savings reflected in plan bids to lower premiums and/or improve supplemental benefits. Typically most MA plans assess the same cost-sharing for all Part B covered drugs. As part of the construct of applying savings from Part B drug UM to the plan bid, CMS should affirm plan flexibility and extend its description in this regulation and in subregulatory guidance such as the Medicare Managed Care Manual to allow plans to implement at least a two-tiered Part B drug preferred drug list with differential cost-sharing for preferred and non-preferred drugs. For example, a preferred drug could have enrollee cost-sharing of 10 percent and a non-preferred drug could have standard 20 percent cost-sharing. Or, the use of the generic drug when available could have $0 cost-sharing.

Differentiated cost-sharing can produce both enrollee and prescriber behavior changes regarding medication selection that aligns incentives with evidence based utilization as well as reduce out-of-pocket costs for members.[22]

In conjunction with a tiered Part B preferred drug list with differential cost-sharing, we recommend that MA plans that implement Part B drug UM and incorporate such savings into their bid publish and market the Part B preferred drug list and provide an online link to ensure enrollees have access to preferred Part B drug coverage information to make informed purchasing decisions during annual open enrollment. Part B preferred drug policies should be publically accessible.

PCMA Recommendation: PCMA supports the new added flexibility to allow MA plans to structure the savings associated with a Part B drug UM program as either a rewards and incentive program or as savings reflected in plan bids to lower premiums and/or improve supplemental benefits. In the final rule, we encourage CMS to clarify that MA plans have the flexibility to implement tiered preferred drug lists with differential cost-sharing in order to further extract the value of UM tools and market-based competition in Part B.

[22] See for example Hoadley JM. "In Medicare Part D Plans, Low Or Zero Copays And Other Features To Encourage The Use Of Generic Statins Work, Could Save Billions. Health Affairs (Millwood); 2012: 31(10).

VI. Pharmacy Price Concessions in the Negotiated Price (§ 423.100)

Proposal:

In the preamble, CMS notes that Part D plans, PBMs, and pharmacies have entered into an increasing number of performance-based arrangements where the price that a Part D plan ultimately pays for a drug may change over time depending on certain performance metrics (for example, generic dispensing rates or medication adherence rates). Recent trends show that pharmacy price concessions (negative adjustments for poor performance) are the predominant form of pharmacy performance-based arrangements today. In the proposed rule, CMS notes that pharmacy price concessions, net of all pharmacy incentive payments, grew more than 45,000 percent between 2010 and 2017.

The current regulatory definition of "negotiated price," as most recently amended in the agency's May 2014 final rule for CY 2015 (79 Fed. Red 29,844), excludes from this amount "contingent price concessions that cannot reasonably be determined at the point-of-sale." Because performance-based arrangements can only be determined after the POS, the negotiated price of a drug (on which enrollee cost-sharing is based) is often higher than the price a pharmacy ultimately receives (net of all price concessions) for a drug dispensed to an enrollee.

CMS notes it is considering deleting the current regulatory definition of negotiated price at 42 C.F.R. 423.100 and replacing it with "the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or the sponsor's intermediary." In other words, if CMS were to formally propose amending the regulatory definition, the negotiated price would now be the lowest price a pharmacy could receive from a Part D plan if it were to receive the maximum negative payment adjustment as a result of any contingent performance-based arrangement. CMS is also soliciting comments on alternatives to this lowest possible reimbursement approach, including an approach that would require Part D plans to pass on something less than 100% of pharmacy price concessions in order to temper premium impact.

CMS is proposing two additional modifications to the definition of "negotiated price." First, it is proposing that negotiated price must include all pharmacy price concessions and dispensing fees, but must exclude pharmacy incentive payments (those contingent fees that serve to *increase*, rather than decrease, the price ultimately paid to the pharmacy). Second, CMS is considering whether to continue to allow Part D plans to pass through to the enrollee at the POS non-pharmacy price concessions, such as manufacturer rebates.

CMS further notes that under current law, manufacturer liability for the coverage gap is based on the negotiated price of a drug. For purposes of determining manufacturer coverage gap liability, however, the ACA specifically referenced the definition of "negotiated price" at the time that the ACA was enacted. In light of this restriction, CMS notes that it believes it would be

inappropriate to “require” Part D plans to include all price concessions in the negotiated price for purposes of the coverage gap discount program. However, in the preamble, CMS states that it believes it has the authority to require Part D plans to include all pharmacy price concessions in the negotiated price in the coverage gap phase of the Part D benefit. As an alternative, CMS notes it would need to operationalize different definitions of “negotiated price” for the coverage gap versus the non-coverage gap phases of the Part D benefit. CMS is soliciting comments on these approaches, as well as alternatives.

Finally, CMS also reiterates its guidance from the final 2015 Part D rule that pharmacy administrative service fees that take the form of a negative deduction to the payment from the Part D plan to the pharmacy are properly treated as pharmacy price concessions and not as administrative service fees.

Discussion:

As discussed below, PCMA has numerous policy and legal concerns with the proposed change to the definition of negotiated price, including:

- If CMS were to proceed with its proposed approach, it would devalue pay-for-performance standards, which aim to improve patient care. We are concerned that this would be counterproductive to a value-based Part D program and contrary to the direction of all other components of the Medicare program which are seeking to be more value-based.

- The price concession policy discussion in the Proposed Rule relies on a number of inaccurate and unsupported assumptions and anecdotes, including that higher DIR drives Part D plan profits. In addition, the policy would have a near-universal adverse impact on enrollee premiums, while benefitting a small minority of enrollees in terms of lower cost-sharing. By and large, the proposal amounts to a giveaway to pharmacies and manufacturers, harming a majority of enrollees as well as taxpayer resources.

- The proposed redefinition of negotiated price raises numerous legal objections, including: (1) it violates the non-interference clause (42 U.S.C. § 1395w-111(i)) and impermissibly establishes a price structure for the reimbursement of Part D drugs; (2) it could eviscerate preferred pharmacy networks in violation of the pharmacy access provisions of the Part D statute; and (3) by failing to actually propose the policy for FY 2020, the proposal violates the Administrative Procedures Act notice requirement.

A. Policy Implications of the Price Concession Proposal

1. The proposal might serve to eliminate most post-POS pharmacy price concessions tied to performance targets that lower program costs and enhance quality, making it more difficult for Part D plans to encourage utilization of higher quality, cost-efficient pharmacies

PCMA strongly believes that Part D plans should retain the flexibility to use pharmacy price concessions to lower negotiated prices or to report them as DIR. However, we are concerned that the proposal, by redefining negotiated price as "the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug," effectively eliminates the use of post-POS price concessions. In particular, because the proposal requires that the price paid to a pharmacy for a covered Part D drug be net of all possible downward adjustments, it eliminates the ability of Part D plans to employ performance-based negative pharmacy payment adjustments. These price adjustments, which typically include both upside and downside incentives, are often based on performance targets such as generic dispensing rates or other value-based performance measures. These types of post-POS price concessions reduce costs to the government, reduce premiums for beneficiaries, and enhance quality. If CMS were to formally propose to redefine negotiated price in a way which effectively eliminates post-POS price concessions, Part D plans would lose a vital tool to encourage utilization of higher quality, cost-efficient pharmacies. Further, although Part D plans would not be prohibited from replacing these post-POS price concessions with pharmacy incentive payments (positive DIR), given that such arrangements have the effect of *increasing* premiums, we do not expect wide adoption of such payment arrangements. As a result, Part D plans and PBMs are left handicapped in their ability to effectively manage pharmacy performance.

As CMS correctly notes in the preamble: "Part D sponsors and their contracted PBMs have been increasingly successful in recent years at negotiating price concessions from network pharmacies."[23] As a result of this and other market-based tools, Part D plans and their contracted PBMs have successfully put downward pressure on plan premiums, as well as the government's subsidies of those premiums. Indeed, as CMS notes: "the average premium has declined each year since 2017 due in part to sponsors' projecting in their bids that DIR growth would outpace the growth in projected gross drug costs each year."[24] In addition, the average Medicare direct subsidy paid by the government to cover a share of the cost of coverage under a Part D plan has also declined, by an average of 9.4 percent per year between 2010 and 2017.

[23] 83 Fed. Reg. 62,174, 62,152 (November 30, 2018).
[24] 83 Fed. Reg. at 61,175.

Post-POS price concessions enable plans and pharmacies to align incentives toward improving practice patterns at the pharmacy that is not only analogous to the pay-for-performance incentives that Medicare uses with a wide range of providers, but also integral to ongoing efforts to incorporate Part D tools into Medicare Part B. Eliminating this tool will decrease pharmacy performance and accountability.

We are also concerned by CMS' position that incentive fees that only increase prices to pharmacies can be excluded from the negotiated price, whereas those that result, or could result, in a decrease, cannot be excluded. CMS does not articulate any rational basis for preferable treatment for pharmacy incentive payments over pharmacy price concessions. This special treatment for higher payments to pharmacies serves to underscore the arbitrary and capricious nature of the whole CMS effort to redefine negotiated price.

As a final matter, we note that the elimination or restriction of performance-based pharmacy arrangements is entirely out-of-line with current CMS payment policy. The Administration's drug pricing blueprint, "American Patients First," emphasized both the need to expand and incentivize value-based arrangements, as well as the critical need to remove government impediments to these types of performance-based activities.[25] So, too, CMS has recently prioritized similar initiatives including its recently announced policy to permit indication-based formulary design in Part D beginning in CY 2020.[26] Restricting or eliminating payment arrangements which incentivize pharmacy performance is counterintuitive to these ongoing efforts to bring increased value to the Part D program as well as the rest of Medicare.

***PCMA Recommendation*: Pharmacy price concessions serve a critical role in driving pharmacy quality, medication adherence, and other key quality measures that provide a net benefit to the Part D program. As CMS readily acknowledges in the proposed rule, pharmacy price concessions negotiated by Part D sponsors and PBMs bear a direct correlation to the recent decline in beneficiary premiums, as well as the average Medicare direct subsidy paid by the federal government.**

2. Underlying assumptions regarding Part D plan bid projections are flawed and based in anecdote, not reality

As partial basis for its proposal to address pharmacy price concessions, CMS cites anecdotal evidence that Part D plans deliberately underproject DIR in order to increase plan profits. In particular, CMS posits that plans may be incentivized to underproject the pharmacy price concessions it anticipates reporting as DIR as a way to increase plan profits. Not only is this assertion not grounded in any evidence, but as the agency is well aware, the Part D risk corridor

[25] "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs," (May 2018).
[26] Op. Cit., Centers for Medicare & Medicaid Services, HPMS Memo (August 2018)

program incentivizes plan sponsors to accurately project DIR in their bids by penalizing plans for under-projecting DIR. As such, there is no incentive for a Part D plan to under-project pharmacy price concessions.

From a pricing perspective, underwriting is a rolling wave, and it is not valid to look only at one year. A plan may get more DIR or fewer claims than projected in one-year, and then its premium can be lower the next year. While CMS seems to be looking at this as a one year period for calculating profits, the wave of constant underwriting balances out over time. There is just no "runaway" profit opportunity in Part D. There are multiple mechanisms in place to prevent abuse of the system, and it is unreasonable for CMS to argue that POS price concessions are needed to prevent such abuse. Some of the many other programmatic features that limit Part D plan sponsor profits include the MLR provisions and bid review. Further, the CMS Office of the Actuary will not approve a bid if the plan sponsor is consistently off with its projections. Likewise, CMS performs audits to ensure proper bid protocols are followed.

It is worth reviewing in detail how the Part D risk corridor program penalizes plans if they under-project DIR in their bids. Under the program, plan sponsors may share a portion of savings or losses with the federal government. Total savings or losses are calculated as the difference between a plan's "target amount" (what the plan was actually paid through the direct subsidy plus enrollee premium related to the standardized bid amount) and its actual allowable costs. The target amount reflects the plan sponsor's expected costs as projected in the bid. Both the target amount and actual allowable costs exclude administrative expenses and margin and are net of DIR.

- Plans retain 100% of savings or losses within 5% of the target amount. Plans share 50% of the savings or losses that are 5%-10% different from the target amount, and share 80% (retain 20%) of the savings or losses that are more than 10% different from the target amount.

- The Part D risk corridor program incentivizes plan sponsors to project DIR accurately in their bids. Consider the following example (amounts per enrollee per month):

Projected DIR in Bid	$10.00
Target Amount (Gross of DIR)	$100
Target Amount (Net of DIR)	$100 - $10 = $90
Actual DIR	$20.00
Actual Allowable Costs (Gross of DIR)	$100 (assumes same as projected target)
Actual Allowable Costs (Gross of DIR)	$100 - $20 = $80

Since the plan's actual allowable costs ($80) are more than 5% lower than the target amount ($90), the plan must share a portion of the savings with the federal government. Had the plan accurately projected $20 of DIR in the bid, it would not have to share any savings with the government, and could have instead used that savings to reduce the enrollee premium.

- The above example highlights how the risk corridor program penalizes plans for under-projecting DIR in bids. Such under-projection results in (1) sharing a portion of DIR with the federal government through risk corridors, and (2) having a higher (and therefore less competitive) premium. Plans may increase their profits when they accurately project DIR in the bid, as the lower resulting premium typically increases enrollment. Competitive premiums are especially important in the basic stand-alone Part D market, where plan sponsors have strong incentives to reduce their bids to gain auto-assigned LIS enrollees.

- This risk corridor dynamic is not specific to DIR. Differences between actual and projected amounts for most cost-related bid assumptions have the same effect. For example, if a plan sponsor under-projects discounts, its target amount would be greater than its actual allowable costs, and it may end up sharing a portion of the discount "savings" with the government.

***PCMA Recommendation*: CMS should consider the many inaccurate and missing assumptions that appear to underlie – and drive – its assessment of the impact of price concessions on plan profit. We urge CMS to go back to the drawing board and reassess the underpinnings of its price concessions proposals.**

3. CMS' proposed redefinition of "negotiated price" will result in increased premiums for most beneficiaries, while benefitting only a small minority of beneficiaries by way of lower cost-sharing

CMS' incomplete impact Tables 9 and 10 reflect only money transfers between limited parties. Simply put, the impact analysis is static and needs to show additional program impacts that incorporate plan, manufacturer and beneficiary behavioral responses to the proposals discussed in the preamble. Moreover, on a per-beneficiary basis, CMS significantly overstates the positive impact this will have on beneficiary cost-sharing, while downplaying the very real premium increases that will result from this policy. In particular, while a limited number of beneficiaries will realize positive benefits through slightly lower cost-sharing, the vast majority of beneficiaries will experience only increased premiums.

First, the percent of beneficiaries that achieve net savings with POS price concessions as outlined in the preamble, taking into account both the impact on cost-sharing AND premiums, is overstated. It would not produce meaningful savings for the vast majority of beneficiaries. Overall, reflecting pharmacy price concessions at POS increases beneficiary premiums (or

premium subsidies) for all beneficiaries and reduces beneficiary cost-sharing when beneficiaries pay coinsurance (see Table 10). However, approximately 35% of beneficiaries in the Part D market are low-income individuals who receive government subsidies for both premium and cost-sharing. Therefore, we assume low-income beneficiaries are affected minimally, if at all, by the premium and cost-sharing impacts that result from reflecting pharmacy price concessions at the POS.

For the 65% of beneficiaries who are non-low-income and do not receive government subsidies, the majority end the year in the deductible or initial coverage limit Part D benefit phases. Approximately 15% of non-low-income beneficiaries have higher claims and end the year in the coverage gap or catastrophic phases. These non-low-income beneficiaries that end the year in the coverage gap or catastrophic phases make up approximately 10% of the total Part D. In general, it is only these non-low-income beneficiaries with higher claims whose cost-sharing savings would outweigh the premium increase (i.e. would achieve net savings) if pharmacy price concessions were reflected at the POS. Accordingly, PCMA urges CMS to reassess the underpinnings of its policy.

PCMA Recommendation: PCMA is concerned that CMS overstates the impact of its proposed price concession policy on beneficiary cost-sharing, and downplays the impact on premiums. In particular, while the price concession policy if proposed and finalized would benefit a minority of higher-income Part D enrollees with coinsurance, it would impact nearly all beneficiaries by way of higher premiums.

4. The proposal adversely impacts beneficiary choice

In the preamble, CMS concedes that post-POS concessions can result in comparatively lower premiums.[27] Many Part D plan enrollees have a preference for experiencing savings through lower premiums rather than through lower negotiated prices at the counter, as has been demonstrated by the enrollment growth in lower-premium Part D plans with preferred pharmacy networks. By obtaining some concessions in the form of post-POS adjustments and reporting them as DIR, a Part D sponsor can make these pharmacy savings available to all plan members. DIR allows sponsors to align this beneficiary preference with efficient, low-cost pharmacy channels, and give beneficiaries an option to choose between products with lower premiums and products with lower negotiated prices.

Moreover, pharmacies aggressively compete for preferred status in low premium plans. Since beneficiaries prefer these plans, pharmacies (and, in particular, large retail-based pharmacies) are willing to make substantial concessions, some based on proven volume, to ensure they have access to a large and fast growing membership base. Since beneficiaries are not nearly as sensitive to (or aware of) POS negotiated prices in comparison to premiums, elimination of

[27] 83. Fed. Reg. at 62,175 ("The main benefit to a Part D beneficiary of price concessions applied as DIR at the end of the coverage year (and not to the negotiated price at the point of sale) is a lower plan premium.")

pharmacy price concessions will result in less effective competition between pharmacies for network placement. Pharmacies are much more willing to offer discounts if they believe those discounts will bring them additional volume. Thus, the use of post-POS price concessions can give sponsors further leverage with pharmacies to negotiate prices, which decreases costs for the entire program.

***PCMA Recommendation*: Based on PCMA's PBM member experience, many beneficiaries prefer to shop based on premium, rather than negotiated price or cost-sharing. If CMS insists on adopting a policy that modifies current DIR policy, it should factor in enrollee desire for lower premiums.**

5. Requiring a standard set of metrics from which plans and pharmacies would base their contractual agreements will hamper plans' ability to develop innovative contracting strategies

One of the primary justifications that CMS puts forward is that the proposal would increase price transparency, and price transparency reduces prices.[28] However, this is not accurate when it comes to public disclosure of post-POS pharmacy pricing adjustments. Staff at the Federal Trade Commission (FTC) have extensive experience analyzing the economic impacts of proposed legal restrictions and mandates that would affect pharmaceutical pricing practices, including legislation aimed directly at PBM/pharmacy price transparency. FTC staff has repeatedly concluded that regulatory interference with contractual terms likely will result in increased prices and public disclosure of proprietary pricing information leads to "knowledge of rivals' prices (that) can dilute incentives to bid aggressively and facilitate tacit collusion, which increases prices."[29] Given this evidence on pricing from the FTC that apparently contradicts CMS' assertion that its proposed policy would increase price competition, we believe CMS should consult evidence or further explain why its interpretation is correct.

***PCMA Recommendation*: As basis for its proposed price concession policy, CMS cites the benefit to the program provided by increased price transparency. However, as numerous FTC reports have noted, increased price transparency can ultimately result in increased program expenses. PCMA recommends that CMS reassess the evidence in this regard.**

[28] 83 Fed. Reg. at 62,176.
[29] Letter from the Federal Trade Commissions to Terry G. Kilgore, Member, Commonwealth of Virginia House of Delegates (October 2, 2006).

6. Additional Considerations

a. Pharmacy cash flow

Many pharmacy DIR arrangements are currently structured such that the plan pays the full POS drug price when a drug is dispensed, and the pharmacy potentially reimburses the plan for a portion of the drug cost after the POS. From a cash flow perspective, this is advantageous to the pharmacy, since they benefit from collecting revenue earlier and get the float on the funds. However, under the proposed "lowest possible reimbursement" arrangement discussed in the preamble, pharmacies would lose this cash flow advantage.

The following simplified scenario illustrates this dynamic using investment income to quantify the different cash flow timing.

Assume an initial drug price of $100 on January 1st, with a provision that the pharmacy pays the plan 0% to 5% of the drug cost at the end of the year based on quality metrics. Assume the pharmacy expenses for the drug are $90, and the pharmacy ends the year paying 4% of drug costs to the plan, having missed most, but not all, of its metrics on quality.

	[A]	[B]	[C] = [A]-[B]	[D] = 3%*([A]-$90)	[E] = [C]-$90+[D]
	POS drug price (plan to pharmacy)	Post-POS DIR (pharmacy to plan)	Final reimbursement to pharmacy	Assumed 3% investment income	Pharmacy profit
Current	$100	$4	$96	$0.30	$6.30
Proposed	$95	-$1	$96	$0.15	$6.15

In the above example, the "Proposed" POS drug price of $95 is the lowest possible reimbursement for the drug. The pharmacy collects investment income on the full spread ($100 POS price less $90 drug expense) in the current environment, but would collect only on the spread at the lowest possible price ($95 POS price less $90 drug expense) in the proposed scenario, reducing the pharmacy's ultimate revenue. In addition, the lower upfront pharmacy reimbursement under the approach discussed in the Proposed Rule may pose challenges for small, independent pharmacies that do not have a lot of capital.

b. Preferred network disruption

As proposed, the "lowest possible reimbursement" pharmacy price concession policy would eliminate DIR payments from pharmacies to plan sponsors. One, perhaps unintended, consequence of this proposal would be the negative impact to preferred pharmacy networks. In

particular, by eliminating pharmacy price concessions, plan sponsors and pharmacies would be forced to negotiate in preferred network arrangements based on discount differentials alone.

As CMS is well aware, the innovation of preferred networks has significantly reduced Part D program costs, including government costs and enrollee premiums. Perhaps most importantly for purposes of this proposal, the growth of preferred pharmacy arrangements has provided enrollees access to reduced cost-sharing when choose to pick up their prescription at preferred pharmacies. A direct effect of this proposal could be a loss of these savings for beneficiaries. Post-POS DIR is a key driver of preferred network savings for many plan sponsors. The elimination of pharmacy DIR may deteriorate the value of preferred networks, which may result in reduced cost-sharing differentials between preferred and non-preferred pharmacies (i.e. reduced enrollee access to lower preferred cost-sharing). In addition, some plan sponsors may realistically no longer be able to offer robust preferred network arrangements. As CMS further considers the impact of its price concession policy, we urge the agency to consider the unintended and negative impact on preferred pharmacy networks.

c. Determination of drug-level "lowest possible reimbursement" amount

Many pharmacy DIR arrangements are based on aggregate, rather than drug-level, metrics. For example, payments may be based on an overall percentage of ingredient cost or per script amount. These aggregate metrics may not be appropriate to apply at the drug level. This could result in yet another set of contracting and operational challenges as plan sponsors and pharmacies work to implement a new drug-level approach.

PCMA Recommendation: There are significant unintended consequences of the proposal, including for pharmacies, which CMS should consider as it revisits how to proceed on pharmacy price concessions.

B. Legal Assessment

In addition to the numerous policy concerns as articulated above that PCMA has with the proposed redefinition of "negotiated price," there are also a number of significant legal impediments to the proposed policy. As we note below, the proposed definition of "negotiated price" conflicts with existing statutory authority in the Part D program (including non-interference and the statutory definition of "negotiated price"), and also raises several procedural concerns under the Administrative Procedures Act. As CMS considers the best path forward and weighs various and competing policy goals, it must ensure that any finalized policy complies with applicable legal authorities.

1. The proposed redefinition of "negotiated price" violates the noninterference clause of the MMA

Under the Part D statute, CMS is explicitly prohibited from "interfer[ing] with the negotiations between drug manufacturers and pharmacies and Part D plan sponsors."[30] Preventing such interference was very clearly the intent of Congress when it created the Part D program, as evidenced by multiple Conference report statements. This provision has long been understood as prohibiting CMS from interfering in payment negotiations between both Part D plan sponsors and pharmacies, and Part D plan sponsors and manufacturers.[31] Indeed, CMS has long taken an appropriate view of the noninterference clause's applicability to negotiations between Part D plan sponsors and pharmacies and manufacturers, reflecting the understanding that the Part D program's success is built upon free market competition. In the 2005 final Part D rule, for example, CMS interpreted the non-interference clause as prohibiting CMS from "interfer[ing] with negotiations between drug manufacturers and pharmacies and PDP sponsors, and requir[ing] a particular formulary or a price structure for the reimbursement of covered Part D drugs."[32] This free market approach (and CMS' past willingness to abide by the statute and not to step in between negotiations) is generally credited for the overwhelming success of the program.[33]

CMS is now contemplating significant limits on the degree with which Part D plans can negotiate pharmacy price concessions outside of those applied at the POS. As explained above, under a proposal that would require that all or a certain percentage price concessions be passed through at POS, Part D plan sponsors and their PBMs will lose the ability to negotiate downside incentives with pharmacies tied to performance or quality targets as well as suffer significant impairment in their ability to negotiate rates with pharmacies. By requiring all pharmacy price concessions to be passed through at POS, Part D plans would lose nearly all significant

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[30] 42 U.S.C. § 1395w-111(i)(1).

[31] See House Conference Report No. 108-391 at 461 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 1840 ("In order to promote competition, the Secretary is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and Part D plans.") See also *id*. at 748-9 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 2105 ("[t]hese negotiations would be carried out by private plans, eager to capture market share through lower premiums, and manufacturers, willing to negotiate discounts for volume assurance. Such private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.")

[32] 70 Fed. Reg. 4,194, 4,396 (January 28, 2005). See also 69 Fed. Reg. 46,632, 46,681 (August 3, 2004) (where CMS stated that the MMA "envisions that most price negotiation including discounts, rebates, or other direct or indirect subsidies or remunerations would take place between PDP sponsors or MA organizations (or their subcontractors) and pharmacies and pharmaceutical manufacturers" and that "price negotiation would be conducted by the private drug benefit managers and plans that are already familiar with negotiating prices of prescription drugs on a local, regional or national basis.")

[33] "In beginning with the words 'In order to promote competition under this part and in carrying out this part. . .' we believe that the Congress intended that the activities addressed in the rest of the provision should take place through private market competition." 79 Fed. Reg. 29,874 (May 23, 2014).

negotiating leverage in pharmacy negotiations, resulting in billions in excess costs to the Part D program, and to beneficiaries, as CMS has explicitly acknowledges in the proposed rule.[34]

Thus, to the extent the proposed rule would mandate that certain kinds of concessions be passed through at POS, as opposed to being reflected as DIR, it would clearly constitute interference in Part D plan sponsor negotiations. Such allocation price concessions are appropriately the subject of business negotiations between Part D sponsors and pharmacies. CMS' previous statements have correctly recognized that mandating particular pricing features—as opposed to a requirement about how payments must be reported—would constitute interference in pharmacy-Part D sponsor negotiations.[35] Under the statute, CMS may not interfere in those negotiations.

***PCMA Recommendation*: Simply put, by proposing to prevent Part D sponsors from negotiating price concessions outside of those applied at POS, CMS obviously is directly interfering with negotiations between pharmacies and Part D sponsors in violation of §1860D-11(i)(1).**

2. The negotiated price proposal also impermissibly institutes a price structure (42 U.S.C. § 1395w111(i))

The Part D statute also states that CMS may not require "a particular formulary or institute a price structure for the reimbursement of covered part D drugs."[36] Yet, by suggesting potential policies which would, if adopted, create a structure around pharmacy prices– with some or all price concessions required to be included at POS – CMS would also clearly be violating the prohibition against instituting a price structure for the reimbursement of covered Part D drugs if it were to adopt the proposals suggested in the Proposed Rule.[37]

As with its interpretation of the non-interference clause, with respect to the prohibition against instituting a price structure, CMS has previously carefully balanced the competing goals of pharmacy access and Part D plan flexibility, ensuring neither of these requirements is read out of the statute. While neither Congress nor the agency has ever formally adopted a definition of "price structure," the meaning of the clause is clear: CMS is prohibited from not only specifying a "standard" (e.g., what is paid or how payments are calculated), but also imposing any "structure" (e.g., any rules around the elements of that pricing). This meaning is evident both from the plain language of the statute (i.e., the term "structure" is commonly defined as an arrangement or organization of elements or parts[38]), as well as other language in the Part D statute. For

[34] 83 Fed. Reg. 62,152, 62,192 (November 30, 2018).
[35] See 79 Fed. Reg. at 29,873 ("In practice we have generally invoked the spirit of this provision in declining to intervene in negotiations or disputes involving payment-related contractual terms between participants in the drug distribution channel.")
[36] 42 U.S.C. § 1395w-111(i)(2)
[37] See 70 Fed. Reg. 4,194, 4300 (January 28, 2005).
[38] Merriam-Webster Dictionary (online); available at http://www.merriam-webster.com/dictionary/structure.

example, the significance of the clause is evident when one compares it to how Congress phrased the limitation on CMS activity involving formularies. In particular, section 1860D-11(i)(2) prohibits CMS from requiring a "particular" formulary. The statute does not use the same modifier "particular" in front of the price structure language.

Thus, CMS' proposal very clearly implicates, and would, if adopted, violate, the prohibition on establishment of a price structure. In particular – and by way of example – by requiring that all pharmacy price concessions be passed through at POS, CMS is effectively instituting a price structure for pharmacy payment whereby plans are forced to negotiate only on the lowest possible price/rates with each and every pharmacy with which they contract. Inevitably, such a single variable negotiating system will result in standard rates across all pharmacy lines of business.

***PCMA Recommendation*: CMS is proposing to create a structure around pharmacy prices, with all price concessions required to be included at POS except for certain additional payments that may be made to pharmacies. This structure violates the plain meaning of §1860D-11(i)(2).**

3. The redefinition of negotiated price is incompatible with the Coverage Gap Discount Program – and requires a statutory change by Congress

In the preamble, CMS notes a major legal hurdle in adoption of its proposal: for purposes of calculation of manufacturer liability under the coverage gap discount program, the statute references the term "negotiated price" as it was defined in regulations at the time of the passage of the Affordable Care Act.[39] Notably this regulatory definition enacted in 2010 references only the price concessions that the Part D sponsor had elected to pass-through at POS. As such, if CMS were to adopt the policies in the proposal, it would be de facto adopting two different definitions of "negotiated price" for purpose of the Part D program. CMS is therefore (rightly) concerned that it does not have the legal authority to require Part D plan sponsors to include pharmacy price concessions in the negotiated price that is used by manufacturers for purposes of determining their coverage gap discounts.

However, rather than grappling with this conflict in law, CMS believes it can ignore the plain statutory language of the ACA which very clearly grants Part D plans with the discretion to reduce the amount used to calculate the negotiated price by those price concession it has "elected to pass through" at the POS, and require Part D plans to include all pharmacy price concessions in the negotiated price in the coverage gap phase of the Part D benefit. As a basis for this policy, CMS argues: (1) such concessions necessarily affect the amount that the pharmacy received in total for a particular drug; and (2) pharmacy price concessions account for

[39] 83 Fed. Reg. 62,152, 62,179 (November 30, 2018) ("Because the statutory definition of negotiated price for purposes of the coverage gap discount program references price concessions that the Part D sponsor has elected to pass through at the point of sale, we do not believe it would appropriate to require sponsors to include all price concessions in the negotiated price for purposes of the coverage gap discount program.")

only a share of all price concessions a sponsor might receive. Neither of these justifications address the very obvious conflict with the regulation definition of negotiated price at the time the ACA was enacted. In particular, that regulatory definition very clearly affords Part D plans the authority to reduce the negotiated price by "those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale."[40] CMS has failed to indicate how this very clear flexibility can be read out of that regulatory definition.

If, in fact, CMS is constrained in changing the definition of negotiated price for purposes of the Coverage Gap Discount Program – which we believe it is – the agency must address the innumerable operational and legal issues that would arise as a result. For example, from an operational standpoint, it is entirely unclear how Part D plans, PBMs, and pharmacies could operationalize two difference definitions of negotiated price depending on where an enrollee is in the benefit phase. Two separate definitions of "negotiated price" would be operationally challenging, require time to implement, and would increase administrative costs for pharmacies, plan sponsors, PBMs, and other stakeholders.

***PCMA Recommendation*: Congress very clearly intended that, for purposes of the coverage gap discount program, the term "negotiated price" have the definition in place at the time of the enactment of the ACA. This definition plainly affords Part D plans the authority and flexibility to reflect pharmacy price concessions in the negotiated price. As a result, CMS' proposed redefinition of negotiated price is largely unworkable until Congress acts to amend the statute to align the multiple definitions. CMS cannot simply ignore the very plain statutory language.**

4. The proposed redefinition of "negotiated price" violates the statutory definition of negotiated price

The Part D statute clearly requires that negotiated prices "shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations." PCMA is concerned that the policy changes discussed in the proposed rule would be substantively flawed under the Administrative Procedures Act (APA) as arbitrary and capricious and not otherwise in accordance with law. In particular, the underlying statutory language ("take into account") unambiguously indicates Congress did not intend that Part D sponsors be *required* to pass on pharmacy price concessions at the POS as CMS now proposes.

Indeed, as CMS readily admits in the preamble, the agency has previously interpreted the statute to mean that "some, but not all, price concessions must be applied to the negotiated price."[41] Moreover, even if the statutory language were found to be ambiguous, CMS' policy

[40] 42 C.F.R. § 423.2305.
[41] 83 Fed. Reg. 62,152, 62,177 (November 30, 2018).

changes would be inconsistent with Congress' intent to provide Part D sponsors with flexibility in administering the Part D prescription drug benefit as a private market model. As such, a reviewing court is likely to find such policy changes as substantively invalid because they would be promulgated *ultra vires* and/or would be "arbitrary, capricious, or manifestly contrary to the statute."[42]

As explained in more detail below, because the policy changes discussed in the proposal would constitute legislative rules, they would be entitled to *Chevron* deference.[43] Under *Chevron*, a court reviewing an agency's construction of a statute which it administers must examine two questions. The first is whether "Congress has directly spoken to the precise question at issue" ("*Chevron* Step One").[44] If the statute is unambiguous, then that is the end of the inquiry and the unambiguous text of the statute must be followed.[45] If, however, "the court determines Congress has not directly addressed the precise question at issue…the question for the court is whether the agency's [interpretation] is based on a permissible construction of the statute" ("*Chevron* Step Two").[46]

Here, a reviewing court is likely to find that CMS' finalization of the price concessions policy discussed in the proposed would fail *Chevron* Step One as being promulgated beyond the agency's delegated authority, given the narrow definition of "negotiated prices," and therefore not be entitled to deference. As the D.C. Circuit observed in *Arent v. Shalala*,[47]

> Chevron is principally concerned with whether an agency has authority to act under a statute. Thus, a reviewing court's inquiry under Chevron is rooted in statutory analysis and is focused on discerning the boundaries of Congress' delegation of authority to the agency; and as long as the agency stays within that delegation, it is free to make policy choices in interpreting the statute, and such interpretations are entitled to deference…In such a case, the question for the reviewing court is whether the agency's construction of the statute is faithful to its plain meaning, or, if the statute has no plain meaning, whether the agency's interpretation "is based on a permissible construction of the statute." (internal citations and quotations omitted) (alterations made).

In this instance, CMS does not have the statutory authority to require that negotiated prices reflect all pharmacy price concessions. Congress has spoken to the issue of negotiated price concessions in the Medicare Part D program. More specifically, Congress has stated that negotiated prices "shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations…."[48] If Congress

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[42] See *Chevron, U.S.A., Inc. v. NRDC, Inc*., 467 U.S. 837, 844 (1984)
[43] See *Nat'l Mining Ass'n*, 758 F.3d at 251 ("Legislative rules generally receive Chevron deference….").
[44] *Chevron U.S.A., Inc*., 467 U.S. at 842.
[45] Id.
[46] Id. at 843.
[47] 70 F.3d 610, 615 (D.C. Cir. 1995).
[48] 42 U.S.C. § 1395w-102(d)(1)(B).

intended to dictate that negotiated price concessions must be passed through to beneficiaries at the POS, it would have surely foreclosed the possibility that Part D sponsors could report negotiated price concessions used to reduce costs under the plan in other ways. As CMS previously noted, "had the Congress intended that all negotiated price concessions be passed through to beneficiaries, they would have used a phrase other than "take into account" in the definition of term 'negotiated prices.'"[49] However, Congress clearly did not do this.[50] Therefore, it is entirely unclear under what statutory authority CMS would justify its interference with Part D sponsors' management of plan costs. Congress unambiguously gave Part D sponsors, not CMS, the prerogative of determining how much negotiated price concessions are appropriate to pass through at the POS. In short, CMS cannot, sua sponte, create statutory authority out of thin air by juxtaposing itself with Part D sponsors in the management of negotiated price concessions.[51]

Even assuming *arguendo* that CMS' suggested policies could advance to *Chevron* Step Two, a reviewing court would likely find them to be arbitrary, capricious, or manifestly contrary to the statute. The appropriate inquiry under *Chevron* Step Two is whether CMS' suggested redefinition of negotiated price is a "reasonable" interpretation of the statute.[52]

First, it is difficult to see how CMS can read out of the plain statutory language a key phrase defining – and limiting – how a negotiated price is calculated. In particular, had Congress intended that Part D plans include all price concessions in the calculation of a negotiated price, certainly they would not have suggests plans "take into account" such amounts. Indeed, and as noted above, the agency has previously recognized on multiple occasions that it was Congress' intent to be "permissive – that Part D sponsors are permitted to choose how much of their negotiated price concessions to pass through to Part D beneficiaries at the point-of-sale."[53] Moreover, as we have noted earlier in these comments, Congress fundamentally intended the Medicare prescription drug benefit to be a private market model.[54] For example, Congress gives Part D sponsors significant flexibility in designing their prescription drug plans, as long as they can show it is actuarially equivalent to standard prescription drug coverage.[55] As discussed

[49] 70 Fed. Reg. at 4194, 4244 (Jan. 28, 2005) (supra n. 3)
[50] See id. at § 1395w-102(d)(2).
[51] See *Railway Labor Executives' Ass'n v. National Medication Bd*., 29 F.3d 655, 671 (D.C. Cir. 1994) (finding that the agency was not entitled to deference because "Congress has directly spoken to the precise question at issue in this case, so there is no gap for the agency to fill.")
[52] See generally *Chevron U.S.A. Inc.,* 467 at 844; *Texas v. United States*, 497 F.3d 491, 506 (5th Cir. 2007) ("[C]hevron step two compels a judicial evaluation of congressional intent.")
[53] 74 Fed. Reg. 1,494, 1,511 (January 12, 2009).
[54] See *United States ex. rel. Spay v. CVS Caremark Group*, 913 F. Supp. 2d 125, 132 ("[M]edicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D "sponsors" to administer prescription drug plans.").
[55] See 42 U.S.C. §1395w-102(a)(1)(B); see also 42 U.S.C. 1395w-104(b)(3) (providing PDP sponsors wide flexibility to develop formularies within certain parameters).

above, Congress also prohibits the Secretary from interfering in "negotiations between drug manufacturers, and pharmacies and PDP sponsors," reinforcing once again the private market focus of the Part D program.[56]

Yet it is against this statutory scheme and legislative history that CMS suggests that its interpretation, which involves dictating how Part D sponsors must manage their negotiated price concessions, is reasonable. CMS' argument here is similar to HHS' unsuccessful argument in *Cent. United Life Ins. Co. v. Burwell*.[57] In that case, the court invalidated an amendment to the regulatory criteria for fixed indemnity plans to be considered an "excepted benefit" under the Public Health Services Act ("PHSA").[58] According to the court, that Congress explicitly listed the criteria for fixed indemnity plans in statute foreclosed HHS' addition of another criterion through regulations.[59] Although HHS couched its amendment as a reasonable interpretation of the PHSA's second criterion,[60] the court rejected this characterization by noting that "ambiguity is a creature not of definitional possibilities but of statutory context."[61] The court asserted that, viewed in its proper context, HHS misread the PHSA and therefore was not entitled to Chevron deference.[62] Similarly here, CMS takes a perceived ambiguity regarding whether Part D sponsors are required to pass through negotiated price concessions at the POS, and then hurls forward to the conclusion that it must dictate how Part D sponsors must pass through these price concessions. Simply put, this interpretation is inconsistent with Congress' intent to leave such decisions to the discretion of Part D sponsors.[63]

***PCMA Recommendation*: CMS has on multiple previous occasions recognized that the term "negotiated price", as defined by Congress, grants Part D plans the discretion in how it will treat pharmacy price concessions. CMS cannot now purport to interpret the statute in a way that eliminates post-point-of-sale pharmacy discounts, given that the agency previously found that the plain language of the statute permitted such discounts. In the preamble to the Proposed Rule, CMS acknowledges that it is "reinterpreting" §1860D-2(d)(1)(B) (see 83 Fed. Reg. 62,177), but otherwise fails to address how its new definition departs from its past interpretation and practice.**

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[56] 42 U.S.C. § 1395w-111(h)(i)(1).
[57] *Cent. United Life Ins. Co. v. Burwell*, 827 F.3d 70 (D.C. Cir. 2016).
[58] Id. at 72-73.
[59] Id. at 74.
[60] That a fixed indemnity plan must offer "independent, noncoordinated benefits." See 42 U.S.C. 300gg-63(b). HHS argued that this implied "there's something the benefits must be independent from or not coordinated with, and Congress's silence left room for HHS to read that unspoken 'something' as though it meant 'minimum essential coverage.'")
[61] Id. at 74 (quoting *Brown v. Gardner*, 513 U.S. 115, 118 (1994)).
[62] Id. ("[The] agency's rule was an act of amendment, not interpretation").
[63] See *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 229 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear."); see also *Jordan v. Sec'y of Educ.*, 194 F.3d 169, 171-72 (D.C. Cir. 1999) (concluding, under similar circumstances, an agency's decision to "add an obligation that is not in the statute . . . changed the nature of the statute" and that the "Secretary may not rewrite the statute")

5. The Administrative Procedures Act (APA) requires CMS to engage in notice-and-comment rulemaking prior to finalizing any substantive change to the treatment of pharmacy price concessions

In the preamble to the proposed rule, CMS states, in part:

> We would consider implementing, *for 2020 or another future year*, a provision that defines price concession in a broad manner, to include all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce the costs incurred under Part D plans by Part D sponsors. (p. 62,152)

PCMA is very concerned by what appears to be a flagrant disregard for notice-and-comment rulemaking procedures and – in particular – the requirement that the agency put *on actual notice* the public prior to finalizing any new policies. Rather than developing a researched and vetted policy and formally proposing it for comment, CMS has taken the unusual and frankly disturbing step of reserving its right to finalize a proposal for FY 2020, without actually formally proposing the policy. Interested stakeholders are thus left in the dark as to whether or not the agency actually considers the policy proposed, and if so, when it intends to finalize such policy. Given the clear violation of the APA's notice requirement in this instant case, we believe the APA would require CMS to issue new notice-and-comment rulemaking prior to finalizing any changes to its price concessions policy.

a. The price concession policy is subject to notice-and-comment rulemaking procedures

As a threshold matter, even assuming arguendo that CMS can change its negotiated prices policy to require that negotiated price concessions be passed on at the POS (as discussed above, we believe the agency lacks the authority to do so), doing so would require that the agency undergo notice-and-comment rulemaking because such a change constitutes a legislative rule.

At the outset, CMS has already engaged in rulemaking to implement section 1860D-2(d)(1)(B) of the SSA, which requires that Part D sponsors provide beneficiaries with access to negotiated prices for covered Part D drugs.[64] Although CMS defines the terms "negotiated prices" and establishes a requirement that qualified prescription drug coverage include access to negotiated prices in its implementing regulations, the agency has never required that negotiated price concessions be passed to beneficiaries at the POS.[65] Indeed, from the earliest days of Medicare Part D, CMS has explicitly acknowledged that under the Part D statute, Part D plans

[64] 42 C.F.R. 423.100 (defining the term "negotiated prices"); 42 C.F.R. 423.104 (requiring that Part D sponsors provide Part D enrollees with access to negotiated prices for qualified prescription drug coverage)
[65] CMS itself acknowledges this much in the proposed rule. See 83 Fed. Reg. at 62,177.

are permitted, but not required, to pass through rebates and price concessions at POS.[66] As a result, even assuming solely for purposes of these comments on the proposed rule, that the statute permitted CMS to adopt such a change, imposing it would be effectively introducing a new condition that Part D sponsors must satisfy in order to offer qualified prescription drug coverage.

The APA distinguishes between "rules" that must be issued pursuant to notice-and-comment, (also referred to as "legislative rules") from those that do not require notice-and-comment, (known as "interpretive rules").[67] The APA does not further define "interpretive rules," but the Supreme Court has stated that a "critical feature" of an interpretive rule is that it is "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers."[68] Importantly, however, interpretive rules "do not have the force and effect of law…."[69] By contrast, "an agency action that sets forth legally binding obligations or prohibitions on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements—is a legislative rule."[70] Notably, courts have applied the same standard for determining rules subject to the SSA's procedural requirements.[71] Requiring Part D sponsors to pass through or pharmacy price concessions at POS would clearly, under this definition, constitute a legislative rule and fall subject to the APA's and SSA's notice-and-comment rulemaking procedures. This type of requirement would effectively impose a "legally binding obligation" on Part D sponsors to pass through at least a certain portion of negotiated price concessions at the POS in order to participate in the Medicare Part D program. Stated differently, a Part D sponsor that chose not to comply with this requirement would be prohibited from offering any type of Part D plan to beneficiaries. Because such a requirement would have the "force and effect of law," CMS would need to adhere to the APA's and SSA's procedural strictures before finalizing it.

b. CMS has failed to provide published notice of its price concessions proposal

The APA requires an agency to provide published notice of its proposed rulemaking. In doing so, the agency's notice must include "either the terms or substance of the proposed rule or a description of the subjects and issues involved."[72] That is, the agency must describe "the range

[66] See, e.g., 70 Fed. Reg. 4,194, 4,244 (Jan. 28, 2005) (noting that "[h]ad Congress intended that all negotiated price concessions be passed through to beneficiaries, they would have used a phrase other than 'take into account' in the definition of the term 'negotiated price.'")
[67] See 5 U.S.C. § 553(b)(A) (stating that the notice-and-comment process "does not apply" to "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice.")
[68] See *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (internal citations omitted).
[69] Id.
[70] See *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251-52 (D.C. Cir. 2014).
[71] See *Clarian Health West, LLC v. Burwell,* 206 F. Supp. 3d 393, 408 (D.D.C. 2016) ("As a general matter, courts use the APA's standards for determining whether or not a particular Medicare rule is a "substantive" one for notice-and-comment purposes").
[72] See 5 U.S.C. § 553(b)(3).

of alternatives being considered with reasonable specificity."[73] "Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed agency decisionmaking."[74]

This requirement is satisfied where an agency's final rule is a "logical outgrowth" of its rulemaking proposal.[75] A final rule is a "logical outgrowth" when stakeholders, "ex ante, should have anticipated that such a requirement might be imposed."[76] When analyzing whether a final rule is a logical outgrowth of the proposed rule, courts apply the "standard functionally by asking whether the purposes of notice and comment have been adequately served…that is, whether a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule."[77] In other words, "[t]he essential inquiry focuses on whether interested parties reasonably could have anticipated the final rulemaking from the draft [rule]."[78]

In this instance, CMS cannot support finalizing policies discussed in the Proposed Rule as a "logical outgrowth" of a proposed rule. At the outset, CMS explicitly preceded its discussion regarding pharmacy price concessions at the POS with the clear statement that "feedback received will be used for consideration in future rulemaking on this topic."[79] Indeed, and as addressed elsewhere in these comments, CMS' discussion of negotiated price concessions reflects only a preliminary understanding of the issues as evidenced by CMS' vague proposals, admitted legal barriers, and open-ended solicitations for "ideas." Given CMS' own indecisiveness on the topic and its representation that it would consider proposing the policy for a "future plan year,"[80] stakeholders have not been apprised as to whether or not CMS is truly proposing the price concessions policy in a way that substantive comments are being solicited. Therefore, a reviewing court would likely find that it not reasonable to anticipate that the agency could then turn around and summarily finalize policies on this topic for FY 2020.[81]

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[73] See *Small Refiner Lead Phase-Down Task Force v. United States Environmental Protection Agency*, 705 F.2d 506, 549 (D.C. Cir. 1983).
[74] See *Home Box Office v. Federal Communications Commission*, 567 F.2d 9, 36 (D.C. Cir. 1977).
[75] See *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1221 (D.C. Cir. 1980).
[76] See *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 549.
[77] See *American Water Works Ass'n v. EPA*, 40 F.3d 1266 (D.C. Cir. 1994) (emphasis added) (internal quotations and citations omitted).
[78] See *Anne Arundel County v. EPA*, 963 F.2d 412, 418 (D.C. Cir. 1992) (internal quotations and citations omitted).
[79] See "Press Release: CMS Takes Action to Lower Prescription Drug Costs by Modernizing Medicare," (November 26, 2018) ("… the agency is also *considering a policy* that would require pharmacy rebates to be passed on to seniors to lower their drug costs at the pharmacy counter.") (Emphasis added.)
[80] 83 Fed. Reg. 61,152, 62,154 (November 30, 2018).
[81] See id. at 418; see also 5 U.S.C. § 553(b) (requiring that "rule making" start with a general notice of proposed rulemaking).

CMS also cannot rely on an argument that "general" discussions of policy considerations, such as the ones in the preamble in question, constitute notice that the agency is in fact proposing policy changes.[82] Furthermore, it would also be inappropriate for CMS to argue that stakeholders responding to the proposed rule should have "actual notice" of proposed changes simply because other commenters may have anticipated a change in policy.[83]

In addition to the APA, the Social Security Act (SSA) also imposes separate procedural requirements on HHS before it "prescribes regulations as may be necessary to carry out the administration of the insurance programs under this title."[84] The SSA provides that "no rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the…eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation…"[85] Moreover, final rules published by the agency that are not the logical outgrowth of a previously published rule "are treated as a proposed regulation" and may not take effect until the public is given an opportunity to comment and the rule is republished.[86]

Here, CMS' suggested policies in the proposed rule clearly implicate the SSA's procedural requirements. First, CMS' suggested policies requiring negotiated price concessions be passed through at the POS constitute a "requirement" imposed on Part D sponsors because they do not have a choice regarding compliance with these policies. Second, this requirement represents a change in longstanding policy, as CMS itself acknowledges. Finally, the requirement governs the "substantive legal standard" for plan eligibility to furnish services to Part D beneficiaries. Accordingly, CMS must issue a proposed rule and engage in notice-and-comment before finalizing any of the policies described in the RFI.[87]

6. CMS' proposed implementation timeframe of 2020 is not feasible

As CMS is well aware, Part D plan sponsors are already well into the process of developing their 2020 bids, and bids must be finalized well in advance of their due date in June 2019. Anticipating CMS will require several months to review what we expect will be lengthy and

[82] See *AFL-CIO v. Donavan*, 757 F.2d 330, 340 (1985) (rejecting the Department of Labor's contention that the final rule "grew out of competing suggestions during the comment period" because there was "no indication [] to be found" that the regulation in question was subject to change).
[83] See id. at 340-41 (dismissing the agency's proposition that commenters may anticipate changes in policy based on the comments of other stakeholders, stating that "As a general rule, [an agency] must itself provide notice of a regulatory proposal."); see also *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 549 (stating that an agency "cannot bootstrap notice from a comment.").
[84] 42 U.S.C. § 1395hh(a)(1).
[85] Id. at §1395hh(a)(2); see also *Clarian Health West, LLC v. Burwell*, 206 F. Supp. 3d 393, 408 (D.D.C. 2016) ("As a general matter, courts use the APA's standards for determining whether or not a particular Medicare rule is a "substantive" one for notice-and-comment purposes")
[86] Id. at §1395hh(a)(4).
[87] See *Allina Health Servs. v. Price*, 863 F.3d 937, 943-44 (D.C. Cir. 2017) (holding that HHS violated the procedural requirements of the SSA in including Part C days in 2012 Medicare DSH fraction).

numerous comments on this proposed rule, and in light of the need to release any final rules for 2020 as well as the final 2020 Call Letter on or around April 1st, we believe it will be impossible for CMS to finalize any proposed rule in time for plans to factor in major changes to bid variable for CY 2020. Indeed, one of the biggest challenges will be the need to revise virtually every pharmacy contract – and renegotiate entire pharmacy networks – to reflect the new rules. Therefore, notwithstanding our strong belief that CMS lacks the legal authority adopt such a policy, in the final rule CMS should provide that any changes affecting pharmacy price concessions will not be effective for CY 2020.

***PCMA Recommendation*: CMS has not complied with the APA's notice-and-comment rulemaking requirements by failing to propose a new definition of negotiated price and related revisions to its pharmacy price concession policy for 2020. As such, should the agency wish to adopt a new definition of negotiated price and the related terms, it must first formally propose such a policy in a new round of notice-and-comment rulemaking.**