April 3, 2019

Office of the Inspector General
Department of Health and Human Services (HHS)
Room 5527, Cohen Building
330 Independence Avenue SW, Washington, DC 20201

Re: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (OIG–0936–P)

To Whom It May Concern:

On behalf of the Medicare Subcommittee of the American Academy of Actuaries,[1] I appreciate the opportunity to comment on the proposed rule regarding the removal of safe harbor protection for rebates involving prescription pharmaceuticals and the creation of new safe harbor protections. Our comments focus on the Medicare Advantage (MA) and Medicare Part D bid development processes. These bids are developed, often by actuaries, at the same time, and changes to Part D bids can affect MA bids, and vice versa. We highlight what regulatory information is used when developing bids and when that information is needed to reasonably allow for the bid deadlines to be met. Understanding the bid development process can help ensure regulatory changes provide enough lead time for any new requirements to be incorporated into plan bids.

Under the proposed rule, drug manufacturers would no longer be allowed to provide drug rebates to Part D sponsors. Instead, prescription drug discounts could be offered directly to patients at the point of sale. These rule changes are far-reaching and would affect prescription drug prices, beneficiary out-of-pocket costs, and Part D premiums, although there is uncertainty regarding the magnitude of the effects. In addition, the proposed rules were released late in the current bid development process, creating uncertainty because it is unclear whether the rules will be finalized before the bid-filing deadline and whether they will be effective for the 2020 contract year.

Major changes such as those in the proposed rule typically require the full multi-year bid development period to properly incorporate the changes into insurer bids and operations. In the

[1] The American Academy of Actuaries is a 19,500-member professional association whose mission is to serve the public and the U.S. actuarial profession. For more than 50 years, the Academy has assisted public policymakers on all levels by providing leadership, objective expertise, and actuarial advice on risk and financial security issues. The Academy also sets qualification, practice, and professionalism standards for actuaries in the United States.

face of regulatory uncertainty, insurers might be developing two sets of bids before the comment period ends—one reflecting the proposed rules and one reflecting current rules, hopeful that final regulatory decisions are made before bid submission so the appropriate bid can be filed. Other insurers could be preparing bids under either one or the other rebate approaches, based on their estimation of final regulatory decisions and timing. There are risks to both strategies. The bid preparation and submission timeline is challenging even when one set of bids is prepared. Preparing a second set of bids under a very different set of assumptions would take additional time, jeopardizing the quality of the submissions. And if different plans submit bids based on organization-specific regulatory expectations for 2020, there could be many downstream implications for what plan participants see in terms of 2020 plan designs and premiums. In particular, because direct subsidy and low-income premium subsidy amounts are a function of plan bids, there needs to be consistency in bidding approaches to ensure equitable outcomes among plans. Moreover, it could be difficult to implement the necessary operational changes in such a short time period should a 2020 implementation date be finalized.

Bid Development Timeline

By the first Monday in June, MA organizations and prescription drug plan sponsors must submit their MA and Part D bids to the Centers for Medicare and Medicaid Services (CMS) for coverage the following year. But this deadline is only one of many important points in the bid development process. Bids are the culmination of more than a year's work, including actuarial analysis of prior claims and trend projections, provider and vendor negotiations, product changes, and planning for / implementation of new regulatory requirements. After bids are submitted, they are reviewed by actuaries contracted by CMS and might need to be resubmitted if issues are identified. The annual open enrollment period for MA and Part D plans runs from Oct. 15 to Dec. 7.

The following is an overview of the key dates in a typical MA and Part D bid development process, in this case assuming a 2020 contract year. This process begins more than a year prior to when the plan year begins. In this timeline, the plan year begins in 2020, with bids being due to CMS in 2019, and the bid development beginning in 2018.

Illustrative Bid Development Process Timeline
Example Assuming a 2020 Contract Year

Month	Year	Bid Development Process Steps
June-July	2018	Start of the bid planning process. Any regulations requiring insurers to implement major operational system changes would need to be finalized by this time so they can be incorporated by the beginning of the 2020 contract year.
September	2018	If new regulations offer additional plan flexibility, insurers would consider whether to incorporate such flexibility into their products. To do so, they could seek clarifications of rules and/or conduct research. By September, insurers would decide whether to pursue any newly available flexibility and incorporate it into their current or new products.

October	2018	Provider contracts and networks for new service areas are explored. Decisions are made regarding service area and product expansions. Pharmacy benefit managers (PBMs) begin negotiating with manufacturers and developing preliminary formularies.
November	2018	Notice of Intent to Apply submissions are due for insurers expanding service areas or offering new products. Any minor regulatory changes requiring vendor contracting (e.g., changes in network adequacy) would have needed to be finalized in November to allow enough time for any additional contracting.
December	2018	Insurer decisions made regarding whether to participate in new limited-scope programs (e.g., pilot programs).
Late January / Early February	2019	CMS releases the Advance Notice and Draft Call Letter, which detail proposed updates to the factors and methodologies used to pay plans. To the extent the updates are routine and in line with the early preview of ratebook growth rates, insurers will have time to implement changes. If updates are more substantial and lacking in detail, it could be more difficult for insurers to incorporate changes in time for their bid submission. The Advance Notice has been used to announce major changes not taking effect until the subsequent bidding period (i.e., for the 2021 contract year). This additional time allows insurers to analyze and consider how to accommodate the changes (if at all).
February	2019	Examine base year (i.e., 2018) experience data and create initial projections for contract year 2020. Risk score and benchmark changes (e.g., risk score normalization factors, fee-for-service (FFS) and MA growth percentages, average geographic adjustments) are needed for the revenue projections.
Early March	2019	Insurer conducts first round of internal reviews for contract year 2020 bid development, with input from various areas, including product development, mid-level management, medical management, risk adjustment teams, provider partners, network contractors, etc. Preliminary or second draft formularies are created.
Late March	2019	Insurer aims to finalize service areas and provider negotiations. Insurer incorporates any necessary changes resulting from prior-year bid audit.
April	2019	During April, insurers refine assumptions and create updated projections for 2020.
Early April	2019	CMS releases the Final Notice, finalizing the factors and methodologies used to pay plans.
Mid-April	2019	CMS releases bid pricing tool (BPT) and plan benefit package (PBP) software and instructions. Internal compliance testing (e.g.,

		meaningful difference tests, total beneficiary cost (TBC) tests) cannot begin until the PBP software and instructions and TBC models are made available. Insurer conducts second round of internal reviews.
Late April-Early May	2019	Insurer conducts final round of reviews (with senior management) and finalizes all bid assumptions, subject to changes necessitated by subsequent TBC or other compliance testing.
May	2019	Throughout May, insurers are running quality control tests for 2020 bids, including gain/loss margin tests, BPT review, and PBP review.
Early May	2019	CMS releases TBC software. Insurer conducts TBC testing.
Early May	2019	CMS releases final formulary reference file.
Mid-May	2019	PBMs provide formulary files to insurers.
Late May	2019	Final service area expansion approval/denial by CMS.
Late May	2019	Insurers revise bids to reflect results from TBC testing, gain/loss testing, Part D formulary changes, service area changes, or other changes. Insurer obtains senior management approval of changes. Insurer assembles package of documentation and other materials required to support bid.
First Monday in June	2019	Bid submission deadline for 2020.
Early June-July	2019	Bids are reviewed by actuaries contracted by CMS; insurers may be required to provide additional information or to resubmit their bids.
Late July	2019	Release of part D national average bid amount, base beneficiary premium, and regional low-income premium subsidy amounts.
Late July-Early August	2019	MA-PD rebates may need to be reallocated through changes to premiums or supplemental benefits. Bids are resubmitted to calibrate the national averages with their target premium levels.
October 15-December 7	2019	Annual enrollment period for 2020.
January 1	2020	Contract year begins.

As illustrated in the timeline example, decisions regarding any product or service area changes, formulary composition, participation in voluntary (e.g., pilot) programs or enhanced flexibility options, and assumptions/projections need to be made well in advance of the June bid deadline. Insurers aim to have final decisions, along with an understanding of the operational and financial impacts, made by April to allow time to run bid quality control tests and finalize results in May. This testing is necessary to prevent bid submission errors requiring resubmissions or errors affecting Medicare beneficiaries or payments by CMS. Key regulations or requirements released or changed by CMS late in the bid development process could lead to significant re-work and

compressed internal review. New information released late in the bidding process could leave insufficient time for insurers to be able to incorporate all of the changes.

The sample timeline identifies several key items typically released by CMS relatively late in the bidding process, potentially causing delays or reworking of bids. In general, earlier releases of these items (or the provision of early previews or drafts) could improve the ability for insurers to incorporate any changes, conduct required testing, and allow sufficient time for internal review. These key releases include:

- The Bid Pricing Tool (BPT) and Plan Benefit Package (PBP) software and instructions are released a couple of weeks after the release of the Final Notice in April. Plan sponsors are required to use these tools to prepare their actuarial bid and benefit and cost-sharing filings. (Releasing the BPT and PBP tools on the same day as the Final Notice—or at least sooner than the current timing—would improve the timing of downstream items, including Total Beneficiary Cost (TBC) testing, which is discussed further below.)

- The formulary reference file is released in early May and thereafter PBM vendors release an updated formulary file to include with the bid submission. Changes to this file can affect out-of-pocket cost values and have downstream effects on TBC.

- TBC software is released in early May, meaning TBC testing is conducted late in the bid process and may necessitate revisiting prior decisions and potential rework. TBC is a test conducted by CMS on MA and Part D bids which is designed to ensure that for a given plan, the increase in beneficiary premiums plus out-of-pocket costs do not exceed a certain threshold. Bids with TPC values that exceed the threshold published in the final bid instructions will not be approved. An earlier release of TBC software, combined with an earlier release of the formulary reference files and BPT and PBP software, could facilitate earlier completion of TBC testing and allow additional time for internal review.

- CMS does not approve/disapprove service area expansions (SAE) until May. Up until that time, insurers use considerable resources to model multiple scenarios, assuming the SAE is either approved or disapproved.

In addition, changes to regulations should be released as early as possible for insurers to be able to make the necessary operational and bidding changes to accommodate them. Ideally, major rule changes—such as changes in safe harbor protections for prescription drug rebates—would be announced no later than two years before they take effect (in other words, in 2018 for the 2020 contract year). Otherwise, there might not be enough time for insurers, and the actuaries who work on the bid process, to evaluate the financial and operational implications and incorporate those changes into their bids, especially if final rules would not be available until at or near the bid submission deadline.

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We would welcome the opportunity to speak with you in more detail and answer any questions you have regarding these comments. If you have any questions or would like to discuss further,

please contact David Linn, the Academy's senior health policy analyst, at 202-223-8196 or linn@actuary.org.

Sincerely,

Michael J. Thompson, MAAA, FSA
Chairperson, Medicare Subcommittee
American Academy of Actuaries

cc: Demetrios Kousoukas, Principal Deputy Administrator & Director of the Center for Medicare