IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:21-cv-00095-JDB

Oral Hearing Requested

PLAINTIFF'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT

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GLOSSARY

Term	Definition
CMS	Centers for Medicare & Medicaid Services
HHS	U.S. Department of Health and Human Services
HHS-OIG	U.S. Department of Health and Human Services – Office of Inspector General
OMB	Office of Management and Budget
PBM	Pharmacy benefit manager
PCMA	Pharmaceutical Care Management Association
Proposed Rule	84 Fed. Reg. 2340 (Feb. 6, 2019)
Rebate Rule	85 Fed. Reg. 76666 (Nov. 30, 2020)

INTRODUCTION

In the waning days of the Trump administration, the Department of Health and Human Services Office of Inspector General ("HHS-OIG") rushed out a new rule—the "Rebate Rule"—that radically transforms how prescription drugs are priced and paid for in the Medicare Part D program. *See* 85 Fed. Reg. 76666 (Nov. 30, 2020). The Rebate Rule is the product of an erratic and highly irregular administrative process that has left scores of market participants now hurtling towards imminent disaster. This motion addresses the most immediate problem created by the Rule: the arbitrary and unworkable effective date that is already having a devastating impact on preparations for the 2022 contract year, sowing confusion and chaos.

HHS-OIG first proposed the Rebate Rule in 2019, and it provoked a tsunami of concern about increased premiums for beneficiaries, skyrocketing federal spending, and a need for a delayed effective date so Part D plan sponsors would not be forced to adjust to the new rule in the middle of their annual cycle of submitting bids to the government to provide Part D plans. The Department of Health and Human Services ("HHS")'s own actuaries estimated that the proposed rule would cost up to $196 billion over ten years—making it one of the most expensive regulations in history—and would increase seniors' prescription drug plan premiums by as much as 25%.

HHS-OIG swiftly withdrew the proposal, and the matter seemed to be over. Or so everyone thought. More than a year later, President Trump abruptly revived the proposal, ordering Secretary Azar to "complete the rulemaking process." Azar got the message, directing HHS-OIG to issue the final rule just four months later.

Not surprisingly, given this tumultuous procedural history, the Rebate Rule suffers from numerous fatal legal flaws. But for purposes of this motion, there is one critical flaw of immediate importance: The Rule is set to take effect on January 1, 2022, but it was issued smackdab in the middle of the bidding process for Medicare Part D contract year 2022, leaving participants without

enough time to start over and formulate new bids that account for the massive changes wrought by the Rule under program deadlines. Preparing a Part D plan for market is a complex, ongoing, year-round process, involving many different parties, that begins more than a year before the "contract year" in which the plan takes effect, with Part D bid submissions due in the first week of June of the preceding contract year. Here, because the process for contract year 2022 was already well underway when HHS-OIG issued the Rule in late November 2020, the entire process was derailed, and months of work negotiating coverage and drug pricing for thousands of drugs based on the prior regulatory regime necessary to submit bids this June went down the drain. As a result, market participants have been forced to try to redo those negotiations in the event the Rule takes effect as scheduled—all to try to restructure their affairs in line with HHS-OIG's new rule, and to have it done by the first week of June. In just six months, all this work—and re-work—needs to be done.

HHS-OIG's herky-jerky, last-minute approach in this rulemaking has made preparing bids virtually impossible. The Rebate Rule has unleashed an avalanche of unanswered questions about the Part D bidding process, formulary designs, benefit structure, and beneficiary-facing materials, that can be resolved only by the Centers for Medicare & Medicaid Services ("CMS")—the agency within HHS that administers the Medicare program and issues important implementing guidance to participants. In its haste to meet the President's demand, however, HHS-OIG set the effective date of the Rule so soon that CMS couldn't act in time even if it tried, and HHS-OIG said that any problems with the effective date were simply not its concern. This is not the reasoned decisionmaking the Administrative Procedure Act ("APA") requires. And the natural reaction to this regulatory chaos and uncertainty will be increased premiums and federal spending—the opposite of HHS-OIG's central premise for moving forward with the Rebate Rule.

Despite scores of commenters warning HHS-OIG about these very problems, HHS-OIG

failed to meaningfully consider an alternative effective date, offer any meaningful justification for interfering with the 2022 bid cycle, or explain why it departed from its customary practice of working cooperatively with CMS to ensure the smooth operation of the Medicare Part D program. Instead, the agency forged ahead apparently without even any internal coordination with CMS on critical questions of implementation and timing, and adopted an effective date that utterly failed to account for the fact that the effective date suggested by commenters during the *April 2019* comment cycle no longer made sense in *November 2020* when the proposal arose from the dead.

For these reasons, Pharmaceutical Care Management Association ("PCMA") respectfully moves for partial summary judgment on its APA claim against HHS-OIG. Given the rapidly approaching June deadline and the need for immediate relief, PCMA limits this motion to the timing issue. As explained below, the agency failed to consider the impact of the Rebate Rule's timing or justify its implementation schedule; overlooked reasonable, less-burdensome implementation timelines; and parted from prior agency practices. The Rule's effective date therefore cannot stand.

BACKGROUND

I. Medicare Part D Plan Sponsors Design Competing, Federally Subsidized Drug Plans And PBMs Negotiate Manufacturer Rebates To Control Drug Costs

Medicare Part D, enacted in 2003 and effective in 2006, is a federal program that assists seniors and disabled Americans with paying for prescription drugs.[1] CMS, an agency within HHS, administers the Medicare program. In 2019, Medicare Part D covered 47.2 million Americans.[2]

Congress designed Part D as a private-sector solution that uses market competition to

[1] *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[2] *See* Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2020 Annual Report* at 10 (Apr. 22, 2020), go.cms.gov/3rVB7YC.

ensure affordable and efficient access to drug coverage.[3] Private drug plan sponsors contract with CMS to offer subsidized coverage on an annual basis. Sponsors set the price, scope, and terms of coverage and compete for enrollees, allowing enrollees to choose the plan that works best for them.

Part D gives plan sponsors flexibility to determine the list of drugs they will cover—called a "formulary"—and to divide those drugs into "tiers" subject to different levels of coverage.[4] Plans can also set utilization management rules to prevent drug misuse or control costs—*e.g.*, by limiting how much of a particular medication an enrollee can receive at once, or by requiring enrollees to get plan approval before filling a prescription or try lower-cost options before using a more expensive drug.[5] Enrollees typically contribute to the cost of providing coverage by paying subsidized monthly premiums plus a share of the cost of each drug. Cost sharing may include some combination of a deductible that must be satisfied each year before the plan makes any payments, a flat copayment for each drug, or coinsurance—a percentage of the drug's pharmacy price. Plan sponsors must offer "standard" coverage—with four phases of cost sharing set by statute[6]—and then they may also offer up to two types of "alternative" coverage, meaning deductibles, copayments, and coinsurance are set by the plan.[7]

Part D plan sponsors typically employ pharmacy benefit managers ("PBMs") to administer their plans and control the cost of providing coverage. One way PBMs do this is by negotiating price concessions from drug manufacturers' nominal "list" prices. Since the start of the Part D program, these concessions have typically taken the form of retrospective rebates paid to PBMs

[3] *See* Conference Report, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 108 Cong. Rec. S15670, S15671-72 (Nov. 24, 2003) (Statement of Sen. Bill Frist).

[4] *See* CMS, *What Medicare Part D drug plans cover*, bit.ly/3hC1FJm.

[5] CMS, 7 Prescription Drug Benefit Manual § 60.1 (Feb. 19, 2010), go.cms.gov/3oLN54T.

[6] 42 C.F.R. §§ 423.104(d), .315(c), .329(c).

[7] *Id.* §§ 423.100, .104(e), .265(d)(2).

by manufacturers after the point of sale—rather than, *e.g.*, at the pharmacy counter. Under Part D, PBMs pass on average 99.6% of those rebates on to plan sponsors.[8] PBMs' ability to secure rebates factors into the mix of benefits plans can offer and the premiums enrollees pay for the plan.

II. PBMs And Plan Sponsors Begin Negotiating Rebates, Designing Plans, And Preparing Bids For Each Contract Year More Than A Year Before Plans Take Effect

Preparing a Part D plan for market is a complex, ongoing, year-round process, involving many different parties, that begins more than a year before the "contract year" in which the plan takes effect. Each year, PBMs and plan sponsors for each plan must negotiate with manufacturers, set plan formularies and utilization management rules, design the plan, and submit "bids" to CMS reflecting a uniform benefit package, including enrollee premiums and cost-sharing requirements, and an estimate of the average monthly revenue requirements to provide drug coverage. 42 C.F.R. § 423.265(c)-(d). The timeline for a typical contract year, using 2019 as an example, is as follows:

Example: Timeline of Bid Process for Contract Year 2019[9]	
Date	**Action**
June-October 2017	Plan sponsors start planning to submit bids for the following June.
October-December 2017	Plan sponsors begin to develop formulary strategies. PBMs and plan sponsors begin discussing contracts with manufacturers and soliciting and receiving requests for rebate proposals.
December 2017-March 2018	PBMs and plan sponsors negotiate rebate terms offered by manufacturers.
March 2018	Plan sponsors finalize the formulary structures for upcoming bids.
March-May 2018	Plan sponsors design their plans.

[8] Government Accountability Office, *MEDICARE PART D Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization* at 16 (July 2019), bit.ly/2XQ8Apx.

[9] *See* American Academy of Actuaries Comment Letter at 2-3 (Apr. 3, 2019), bit.ly/3ifIx4z; ("American Academy of Actuaries Commenter Letter"); Kaiser Permanente Comment Letter at 33 (Apr. 8, 2019), bit.ly/3oM0Xw8; BlueCross BlueShield Association Comment Letter at 16 (Apr. 8, 2019) ("BCBS Comment Letter"), bit.ly/2XIBEz2.

Example: Timeline of Bid Process for Contract Year 2019[9]	
Date	**Action**
First week of May 2018	Plan actuaries lock down plan assumptions and certify bids.
May-June 2018	Plan sponsors finalize bids and all accompanying documentation.
First Monday of June 2018	Plan sponsors submit bids for the upcoming 2019 contract year.[10]
June-August 2018	CMS reviews and approves bids and negotiates with plan sponsors.
Early September 2018	Plan sponsors enter into contracts with CMS.
September-October 2018	Plan sponsors complete plan materials for potential enrollees and take all steps necessary to implement required system changes.
October 2018	Plan enrollment opens.
October 2018-January 2019	Plan sponsors, PBMs, and other contractors take any remaining steps needed to ensure full compliance with all Part D requirements.
January 1, 2019	Plan coverage begins.

Plans need a host of information from CMS in order to complete their negotiations, finalize plan design, submit bids, and meet the Part D requirements for providing coverage under accepted bids. In a typical year, that information may include Part D benefit parameters for deductibles, initial coverage limits, cost-sharing payments, and formulary tier thresholds; formulary guidance (e.g., allowing for coverage by specific indications); changes in Part D payment methodologies; updates to CMS's Bid Pricing Tool (the approved data-entry format through which plan sponsors submit information for their bids); congressionally mandated updates to opioid use disorder programs; and updates to tools that enrollees use to select plans, such as CMS's Star Ratings system and the Medicare Plan Finder Tool.[11] Just as important, CMS also must advise PBMs and plan

[10] *See* 42 C.F.R. § 423.265 (setting bid deadline).

[11] *See* PCMA Comment Letter at 65-71 (Apr. 8, 2019), bit.ly/2NbENpj.

sponsors of any policy or technical changes that could influence bid submission, including any changes that may be necessary in response to legislative changes or applicable HHS regulations.

CMS has historically provided the information that plan sponsors need through a combination of notice-and-comment rulemaking and subregulatory guidance:

- No later than April or May, CMS typically completes notice-and-comment rulemaking addressing **Policy and Technical Changes** for the upcoming contract year, ranging from major changes in policy (*e.g.*, changing the "protected classes" of drugs that plans are generally required to cover) to minor "technical" issues such as contract termination notification requirements and requirements related to the release of Part D data.[12]

- CMS historically prepares a two-part **Advance Notice**. **Part I** of the Advance Notice primarily concerns Medicare Part C (which is not at issue here), and is historically issued in December or January.[13] **Part II** covers CMS payment and policy updates for both Parts C and D, and is historically issued in January or February.[14] CMS is required by law to provide a 60-day comment period for Part I, 42 U.S.C. § 1395w-23(a)(1)(I), and it historically provides a 30-day comment period for Part II.[15]

- CMS historically considers comments on the Advance Notices and finalizes its payment and policy updates in a final **Rate Announcement** issued in early April.[16] CMS is required by law to finalize the part of this Rate Announcement corresponding to Part I of the Advance Notice 60 days before bids are due. 42 U.S.C. § 1395w-23(b)(1)(B); 42 C.F.R. § 422.312(a)(1). CMS historically issues the entire Rate Announcement at this time.

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[12] *See, e.g.*, *Medicare Program; Contract Year 2015 Policy and Technical Changes*, 79 Fed. Reg. 1918, 1936 (Jan. 10, 2014) (proposed rule); *Medicare Program; Contract Year 2015 Policy and Technical Changes*, 79 Fed. Reg. 29844 (May 23, 2014) (final rule); *see also Medicare Program; Contract Year 2019 Policy and Technical Changes*, 83 Fed. Reg. 16440 (Apr. 16, 2018).

[13] CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 – Part I* at 1 (Dec. 27, 2017), go.cms.gov/3s9KrrZ; CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2020 – Part I* at 1 (Dec. 20, 2018), go.cms.gov/3ooBHf8.

[14] CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2020 – Part II* (Jan. 30, 2019), go.cms.gov/2MG08H2 ("CY 2020 Advance Notice Part II"); CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 – Part II* (Feb. 1, 2018), go.cms.gov/3nucf6A ("CY 2019 Advance Notice Part II").

[15] *See* CY 2019 Advance Notice Part II, *supra*, at 1 (calling for comments by March 5, 2018).

[16] *See* CMS, *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* (Apr. 2, 2018), go.cms.gov/3q2hegz; *Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* (Apr. 1, 2019), go.cms.gov/3q4a7V6.

Example: Timeline of CMS Guidance for Contract Year 2019[17]	
Date	**Action**
November 28, 2017	CMS issues Policy and Technical Changes proposed rule.
December 27, 2017	CMS issues Part I of the Advance Notice for comment.
February 1, 2018	CMS issues Part II of the Advance Notice for comment.
April 2, 2018	After considering comments on the Advance Notices, CMS issues Rate Announcement finalizing payment and policy updates.
April 16, 2018	CMS publishes Policy and Technical Changes final rule.
June 3, 2018	Plan sponsors submit bids for the upcoming 2019 contract year.

Until the most recently completed bid cycle (for the 2021 contract year), Part II of the Advance Notice included a **Call Letter** containing information "useful" to plan sponsors "as they prepare their bids for the new contract year" and "draft bid and operational guidance for plans."[18] For example, the Call Letter included "changes in the Part D payment methodology," "annual adjustments" to "benefit parameters" for "standard" Part D plans, and information on "formulary submissions," "tier composition," and "utilization review controls."[19] Following the Supreme Court's decision in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), however, CMS shifted any substantive information that would be "typically included in the annual Call Letter" into the

[17] *See Medicare Program; Contract Year 2019 Policy and Technical Changes*, 82 Fed. Reg. 56336 (Nov. 28, 2017) (proposed rule); CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 – Part I*, *supra*; CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 – Part II*, *supra*; CMS, *Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter*, *supra*; *Medicare Program; Contract Year 2019 Policy and Technical Changes*, 83 Fed. Reg. 16440 (Apr. 16, 2018) (final rule).

[18] CY 2019 Advance Notice Part II, *supra*, at 2.

[19] *Id*. at 1-2, 193-220.

Policy and Technical Changes rule promulgated through notice-and-comment rulemaking.[20] That decision reflects *Allina*'s holding that the Medicare Act's notice-and-comment requirement, 42 U.S.C. § 1395hh(a)(2), applies more broadly than the APA's requirement, and can apply even to general policy statements if they establish or change a substantive legal standard, 139 S. Ct. at 1811-14. Under the new procedure, CMS is now required to begin the process of providing critical information to PBMs and plan sponsors even earlier in the bid cycle to allow for notice-and-comment rulemaking and ensure that the necessary determinations and information can be finalized with sufficient time for PBMs and plan sponsors to negotiate with manufacturers, design plans, finalize bids by the deadline, and bring their plans into compliance before the contract year starts.

III. In February 2019, HHS-OIG Initiates A New Rulemaking Seeking To Fundamentally Alter How Manufacturer Rebates Are Paid Under Medicare Part D

In February 2019, HHS initiated a new rulemaking seeking to fundamentally alter the dynamics of Medicare Part D by subjecting the longstanding practice of retrospective rebates to significant criminal and civil liability under the federal anti-kickback statute, 42 U.S.C. § 1320a-7b.[21]

The anti-kickback statute makes it unlawful—subject to harsh civil and criminal penalties—for any person to "knowingly and willfully" pay or receive "remuneration" in exchange for, among other things, recommending items or services reimbursed by federal health care programs. 42 U.S.C. § 1320a-7b(b)(1)-(2). Since the start of the Part D program, however, retrospective rebates have been protected from federal anti-kickback liability by a regulatory safe harbor promulgated by HHS-OIG—the agency within HHS that is tasked with interpreting the federal anti-

[20] CMS, *2021 Medicare Advantage and Part D Advance Notice Part II Fact Sheet* (Feb. 5, 2020) ("CMS will not be publishing a Call Letter for 2021"), go.cms.gov/39uibrB; *see also Medicare and Medicaid Programs; Contract Year 2021 Policy and Technical Changes*, 85 Fed. Reg. 9002, 9003 (Feb. 18, 2020) (noting that CMS was "codify[ing] in regulation several CMS interpretive policies previously adopted through the annual Call Letter").

[21] *See Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals*, 84 Fed. Reg. 2340, 2340 (Feb. 6, 2019) ("Proposed Rule").

kickback statute. This safe harbor—known as the "discount safe harbor"—protects any "discount" that a drug seller offers a buyer, including a "rebate," if its "terms" are "disclosed in writing to the buyer at the time of the initial sale" and the buyer discloses certain information to the Secretary upon request. 42 C.F.R. § 1001.952(h)(1)(iii), (h)(4).

The Proposed Rule would have amended this safe harbor—effective January 1, 2020—"so that it would no longer protect price reductions from manufacturers to plan sponsors under Medicare Part D," "either directly or through PBMs acting under contract with plan sponsors under Medicare Part D." 84 Fed. Reg. at 2347-48. HHS-OIG also proposed a new "point-of-sale" safe harbor that would protect discounts applied at the point of sale—*e.g.*, the pharmacy counter. *Id.* at 2348. HHS-OIG's goal was to channel price concessions through the new point-of-sale safe harbor—"replacing rebates with discounts"—so that the price concessions "would be passed on to beneficiaries at the point of sale" instead of reducing premiums. *Id.* at 2352, 2355.

IV. Commenters Criticize The Proposed Rule And Urge HHS-OIG To Delay Its Effective Date To Allow Time For PBMs, Plan Sponsors, And CMS To Account For The Rule

HHS-OIG received more than 25,000 comment letters on the Proposed Rule. While the pharmaceutical industry broadly praised the rule,[22] others warned that it would increase overall drug prices, leading to higher premiums and greater federal spending.[23] Commenters also sounded several alarm bells about HHS-OIG's proposed timeline for implementing a final rule:

[22] *See, e.g.*, PhRMA Comment Letter at 2-3 (Apr. 8, 2019), bit.ly/39z5USx; Biotechnology Innovation Organization Comment Letter at 1-2 (Apr. 8, 2019), bit.ly/3bOgkRb; GlaxoSmithKline Comment Letter at 1 (Apr. 8, 2019), bit.ly/3oRbKoW; Novartis Comment Letter at 2-3, 5 (Apr. 8, 2019), bit.ly/2XFczoG; Bayer Comment Letter at 8 (Apr. 8, 2019), bit.ly/35EAysD.

[23] *See, e.g.*, PCMA Comment Letter, *supra*, at 9-13, 37-42, 58; America's Health Insurance Plans Comment Letter at 2 (Apr. 8, 2019), bit.ly/3svU2cw ("AHIP Comment Letter"); Anthem Comment Letter at 1 (Apr. 8, 2019), bit.ly/3nHaovq; CVS Health Comment Letter at 2 (Apr. 8, 2019), bit.ly/39zuDX1 ("CVS Comment Letter"); Magellan Health Comment Letter at 6-7 (Apr. 8, 2019), bit.ly/3ssuo8x ("Magellan Comment Letter"); Garthwaite Comment Letter at 1 (Apr. 8, 2019), bit.ly/3ihBbxk; MedPAC Comment Letter at 1-2 (Apr. 5, 2019), bit.ly/3sorH8h.

First, commenters observed that if the Proposed Rule were finalized, CMS would need to initiate "additional rulemaking and guidance on a host of Medicare . . . issues" to resolve ambiguities arising from the Rebate Rule about the bidding process, formulary designs, benefit structure, and enrollee-facing materials.[24] PCMA provided six pages of questions—covering several separate categories—that CMS would need to resolve through rulemaking or guidance. For example:

- **True Out-of-Pocket costs**: "Standard" Part D benefit plans have four distinct phases: deductible, initial coverage, coverage gap, and catastrophic. "True out-of-pocket costs" is a term of art used in Medicare regulations to determine the kinds of expenditures that count towards triggering different phases of coverage under a "standard" Part D plan.[25] For example, when an enrollee in a standard plan has incurred a threshold amount of true out-of-pocket costs—currently $6,550—the enrollee enters the catastrophic phase, in which the enrollee pays approximately 5% coinsurance on the cost of each drug, CMS reimburses plans for 80% in the form of reinsurance, and the plan covers the remaining approximately 15%.[26] Under the Rebate Rule, however, it is not clear whether a point-of-sale price concession will count toward an enrollee's true out-of-pocket costs.[27] Sponsors of standard plans need to know whether price concessions count toward true out-of-pocket costs to calculate the cost of providing coverage under the plan, and thus to calculate premiums and bids.[28] Sponsors of alternative plans need this information to determine if their plans are actuarially equivalent to the standard plan, as they must be for CMS to approve them.[29]

- **RxHCC model**. CMS adjusts Part D plan direct subsidy payments with a risk score, paying more for sicker enrollees and less for healthy enrollees, so that plans have equal incentive to target sicker and healthier enrollees.[30] CMS makes these risk adjustments using

[24] Magellan Comment Letter, *supra*, at 5; *see also, e.g.*, CVS Comment Letter, *supra*, at 13 ("A final rule released without sufficient lead time to provide definitive direction for plan bids before they are due cannot impact the [upcoming] plan year."); BCBS Comment Letter, *supra*, at 16-17 (identifying the need for CMS guidance on numerous issues, such as calculating "patients' true out-of-pocket costs," "plan sponsor reporting," "beneficiary-facing communications," and "risk adjustment model[s]"); Prime Therapeutics Comment Letter at 12 (Apr. 8, 2019), bit.ly/3iiemcT ("Additional CMS guidance will be necessary for plan actuaries to properly incorporate changes into prescription coverage benefits.").

[25] 42 C.F.R. §§ 423.104(d)(5), .315(c), .329(c).

[26] *See* CMS, *Catastrophic Coverage*, bit.ly/2XPt95s.

[27] *See* PCMA Comment Letter, *supra*, at 66; *see also* BCBS Comment Letter, *supra*, at 16-17.

[28] 42 C.F.R. §§ 423.104(d)(5), .315(c), .329(c).

[29] *Id.* §§ 423.100, .104(e), .265(d)(2).

[30] MedPac, *Report to the Congress: Medicare and the Health Care Delivery System* at 145 (June 2015), bit.ly/39Z7Tjt.

what is known as the "RxHCC model" (the prescription drug hierarchical condition category model), which predicts drug benefit spending based on certain characteristics of an enrollee. The RxHCC model thus directly affects how plan sponsors are compensated by CMS. It is also important to plan sponsors' bidding process, because plan sponsors calculate cost projections for their bids based upon the average enrollee, which is mathematically determined by leveraging the Part D risk adjustment model.[31] Accordingly, plan sponsors and PBMs need to know how CMS will recalibrate the RxHCC model "to reflect the new applicable costs associated with high-rebate and low-rebate classes" and to "protect plans against the expectation of adverse selection caused by the visibility of the discounts."[32]

- **Bid Pricing Tool**. The Bid Pricing Tool is the CMS-approved Excel workbook format for plan sponsors to provide information to CMS in its bid submissions.[33] The Bid Pricing Tool changes each year and provides a variety of formulas, baselines, and numerical adjustments for plan sponsors to use.[34] Plan sponsors need this information to accurately build and submit their bids—yet "each component part" of the tool will "require a re-assessment" in light of the Rebate Rule.[35] For example, the Bid Pricing Tool historically has treated manufacturer rebates as part of a larger categorical group of direct and indirect remuneration collected retrospectively, such as discounts collected from pharmacies.[36] Because the Rebate Rule does not impact other forms of direct and indirect remuneration, CMS will need to segregate these amounts in the Bid Pricing Tool and provide technical guidance on how the new point-of-sale discount category would impact the overall bid.

- **Low-income subsidies**. Under Part D, more than one-fourth of enrollees qualify for a low-income subsidy for both cost-sharing and premiums.[37] In 2019, those subsidies accounted for $27 billion of the $85 billion mandatory federal outlay on Part D.[38] Each year, CMS releases regional "benchmark" figures, which is the monthly Part D plan premium that CMS will pay for enrollees qualifying for the low-income subsidy.[39] If a qualifying individual enrolls in a Part D plan that has a premium higher than their state's benchmark, then

[31] *See* PCMA Comment Letter, *supra,* at 108.

[32] *Id.*; *see id.* at 67.

[33] CMS, *Attachment E-2: Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2022* at 4, go.cms.gov/3nVVPEB.

[34] *See id.* at 4, 28-30.

[35] PCMA Comment Letter, *supra*, at 50, 68.

[36] *See, e.g.*, CMS, *Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2019* at 14-15 (Apr. 6, 2018), go.cms.gov/3iF5nT2.

[37] *See* Kaiser Family Foundation, *Medicare Part D in 2016 and Trends over Time* (Sept. 16, 2016), bit.ly/3sLqtnL.

[38] Congressional Budget Office, *Medicare—CBO's Baseline as of March 6, 2020* at 2 (Mar. 6, 2020), bit.ly/39iv4G9

[39] *See* CMS, *Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information* at 3-4 (July 29, 2020) (announcing "Part D Regional Low-Income Premium Subsidy Amounts"), go.cms.gov/2Y8qGmM.

the enrollee is responsible for paying the difference.[40] If the enrollee does not choose a plan, CMS may auto-enroll them or facilitate their enrollment in a prescription drug plan that is at or below the applicable benchmark.[41] Under the Rebate Rule, it is unclear if low-income subsidies will be applied net of point-of-sale discounts.[42] Plan sponsors and PBMs need this information because the bidding strategy for enrollees qualifying for low-income subsidies is a significant component of the overall Part D strategy—for example, some plan sponsors prefer auto-enrollment, and some do not—and deciding whether to set premiums above or below benchmarks is a critical strategic decision.

- **Data reporting**. Every time an enrollee fills a prescription under Medicare Part D, plan sponsors must submit "prescription drug event" data to CMS.[43] The prescription drug event record contains information about the prescription drug cost and payment data, which enables CMS to pay plans and administer the Part D benefit. Under the Rebate Rule, it is unclear whether the prescription drug event record or procedures for reporting that record will change when a point-of-sale discount is provided.[44] Plan sponsors need this information in time to make changes to IT systems, and test and audit them, so they can accurately report event data to CMS and avoid duplicate, disputed, or erroneous discounts.

- **Medicare Plan Finder**. The Medicare Plan Finder is a tool that allows potential enrollees to compare plans based on their coverage options—including coverage of specific drugs enrollees need—as well as premiums and out-of-pocket costs, before making a selection when the enrollment period opens in October each year.[45] It is critical that the Medicare Plan Finder is not only accurate and comprehensive, but also understandable to the senior and disabled populations selecting among plans. Changing the Plan Finder often takes years, as CMS run the changes through beneficiary focus groups, programming checks, and user-testing procedures.[46] CMS will need to update the Medicare Plan Finder to account for the Rebate Rule, and to make sure that enrollees understand the information provided to them with respect to point-of-sale discounts so that Americans can choose the plan that is best for them.[47] And plan sponsors need "technical guidance" on whether, and how, they should incorporate point-of-sale price concessions into their Plan Finder pricing file submissions that are due along with their bids.[48] This information is important because

[40] *See id.*

[41] *See* Medicare Rights Ctr., *Part D when you have Medicare and Extra Help*, bit.ly/3pfYkTt.

[42] *See* PCMA Comment Letter, *supra*, at 67; *see also id.* at 40-41, 52.

[43] *See* CMS, *Questions and Answers on Obtaining PDE Data* at 1, go.cms.gov/3nUsFFx.

[44] PCMA Comment Letter, *supra*, at 68-69.

[45] *See* Medicare.gov, *Shop & compare 2021 plans with the Medicare Plan Finder*, bit.ly/3bNE2wN.

[46] *See, e.g.*, CMS, *Draft Medicare 2018 Part C & D Star Ratings Technical Notes* at i (Sept. 6, 2017) (noting that CMS "added focus group tested language" to the Medicare Plan Finder), go.cms.gov/3c8m6gq.

[47] PCMA Comment Letter, *supra*, at 69.

[48] *Id.* at 107.

CMS compares the drug prices that plan sponsors provide for the Medicare Plan Finder with the prices that enrollees actually pay, and incorporate that comparison into CMS's Star Ratings—a 1-5 ranking system of plans that are displayed to enrollees.[49] Without receiving technical guidance from CMS, plan sponsors will be incapable of providing accurate prices for the Medicare Plan Finder.

- **Formulary structure**. Each year, plan sponsors determine the list of drugs they will cover and divide those drugs into "tiers" subject to different levels of coverage.[50] CMS reviews these formularies to ensure they comply with numerous regulatory requirements regarding the formulary's composition, structure, and general alignment with other formularies. The Rebate Rule contemplates point-of-sale discounts for certain drug purchases, but it is not clear whether Medicare regulations would allow plan sponsors to place rebated or discounted drugs on their own formulary tier, or how the formulary review process may change.[51] PBMs and plan sponsors need this information early in the bid cycle to make decisions about how to structure their formularies—including where to place particular drugs on the formulary—and to negotiate with manufacturers accordingly.[52] PBMs and plan sponsors also need to ensure they do not submit plans with outlier formularies, such as plans that cover significantly fewer drugs with a price concession at the point of sale. Knowing where to place a drug on a formulary is important because enrollees, particularly those with a specific condition, "shop generally based upon premium and formulary position for their prescribed medicine."[53]

- **Benefit Design**. Plan sponsors can base formulary tiers on either copayments or coinsurance, and plans offering alternative coverage set levels of copayments or coinsurance that must be actuarially equivalent to plans offering standard coverage.[54] Most plan sponsors prefer to use copayments because enrollees prefer predictable flat costs. Under the Rebate Rule, plan sponsors will need to adjust copayment amounts to reflect the new point-of-sale discounts.[55] But plan sponsors do not know how they may permissibly adjust copayments in their benefit designs.[56] For example, plan sponsors might be able to conduct actuarial equivalent testing and reduce copays for *all* drugs in a given formulary tier based on average price concession; or, plan sponsors might be able to reduce the actual copay for a *specific* drug by the amount of that drug's specific price concession. Plan sponsors need a single, clear answer in order to offer copayment-based plan designs.

These examples merely scratch the surface. ***A list of outstanding questions is attached as Exhibit***

[49] *See* CMS, *MPF Price Accuracy* (June 22, 2020), bit.ly/3c1ToO8.

[50] *See* CMS, *What Medicare Part D drug plans cover*, bit.ly/3hC1FJm.

[51] *See* PCMA Comment Letter, *supra*, at 70, 107.

[52] *See id.* at 85.

[53] *See id.* at 35.

[54] *See supra*, at 4.

[55] *See* Rebate Rule, 85 Fed. Reg. at 76673.

[56] *See* PCMA Comment Letter, *supra*, at 66-67.

A hereto. "Importantly," PCMA cautioned, "these CMS programmatic issues must be addressed and resolved prior to the effective date of any safe harbor changes in order to provide the Part D program some level of certainty as to how the program will operate."[57] Commenters thus urged HHS-OIG to coordinate with CMS for a smooth transition to the Rebate Rule.[58]

Second, stakeholders highlighted the extensive administrative hurdles to implementation that HHS-OIG ignored or overlooked, given the numerous "program and legal requirements that Part D sponsors . . . must comply with."[59] For example, the National Council for Prescription Drug Programs, a non-profit standards development organization for information exchanges related to healthcare, outlined potential methods that it could implement to administer point-of-sale transactions and chargeback amounts.[60] It estimated that, if the outlined approaches conformed with the Rebate Rule, the process would take about 10 to 12 months from publication of any final rule, plus additional time for industry to modify its operations accordingly.[61]

Third, commenters urged HHS-OIG not to issue a final rule in the middle of a bidding cycle. Given the "complex development process" for bid submissions, releasing a final rule midstream would be "unworkable and likely to cause significant disruption to [Medicare plan] beneficiaries."[62] If a rule were released after plan sponsors and PBMs had already invested significant

[57] *Id.* at 65.

[58] *See id.* at 9 ("[T]he issuance of this Proposed Rule solely by OIG and without coordination with CMS is inappropriate.").

[59] National Council for Prescription Drug Programs Comment Letter at 2 (Apr. 8, 2019), bit.ly/2NagmIH ("NCPDP Comment Letter"); *see also* AHIP Comment Letter, *supra*, at 2 (detailing "concerns about the likelihood of significant operational challenges associated with moving to a new system with little time to rigorously test the system").

[60] NCPDP Comment Letter, *supra*, at 3-4.

[61] *Id.* at 6, 10. NCPDP also outlined one approach that, if authorized by HHS-OIG, would not require NCPDP to modify its current standard, *id.* at 7, but HHS-OIG has yet to confirm whether this approach would comply with the Rebate Rule. Rebate Rule, 85 Fed. Reg. at 76669-700.

[62] BCBS Comment Letter, *supra*, at 16.

resources to negotiate contracts with manufacturers for the contract year in which the rule took effect—negotiations that take months of work and careful planning—"plan sponsors would need to essentially begin the process again, . . . renegotiat[ing] contracts" covering thousands of medicines.[63] Further delay could force plan sponsors to scrap ongoing bid development and "re-pric[e] . . . bids,"[64] or wastefully develop two sets of alternative bids, one reflecting the proposed rule and one reflecting the current regulatory regime.[65]

Based on these three concerns, commenters in 2019 asked HHS-OIG to "provide stakeholders sufficient time to comply" with a final rule by "delay[ing] the [rule's] effective date to at least" the contract year *after* the one for which plan sponsors were preparing when HHS-OIG issued the rule.[66] At the time, plan sponsors were anticipating a final rule issued in mid- to late 2019, at the start of the planning process for the 2021 contract year. Accordingly, commenters proposed an effective date of ***2022***. The commenters were not simply pushing off compliance to another day. As a group of actuaries summarized, "[b]ids are the culmination of more than a year's work," and "[m]ajor changes such as those in the proposed rule typically require the full multi-year bid development period to properly incorporate the changes," so any regulatory changes needed to "provide enough lead time for any new requirements to be incorporated into plan bids."[67]

Even CMS recognized, in an April 2019 guidance document, that changes to the regulatory safe harbors could create substantial uncertainty. That is why the agency noted that, "[i]f there is a change in the safe harbor rules effective in 2020," it would "conduct a [two-year] demonstration that would test an efficient transition for beneficiaries and plans to such a change in the Part D

[63] *Id.*

[64] *Id.*

[65] American Academy of Actuaries Comment Letter, *supra*, at 1-2.

[66] CVS Comment Letter, *supra*, at 13.

[67] American Academy of Actuaries Comment Letter, *supra*, at 1-2.

program."[68] Commenters supported the proposed two-year demonstration, which would have delayed much of the financial impact of the rule on Part D plans until 2022.[69]

V. In July 2019, HHS-OIG Withdraws The Proposed Rule Over Widespread Concerns That It Would Raise Premiums And Increase Federal Spending

The Proposed Rule was not well received within the Trump administration. Public reports pointed to a "pretty wide consensus" among Executive Branch officials that the Proposed Rule "was a terrible idea" because the "cost was exorbitant and it was perceived as a bailout to Big Pharma."[70] These concerns reflected actuarial studies predicting that the Proposed Rule, if finalized, would lead to increased premiums and increased federal spending.[71] HHS-OIG accordingly withdrew the Proposed Rule on July 10, 2019. The withdrawal was reflected in multiple government publications[72] and confirmed by the White House.[73] Secretary Azar explained that the Rule was withdrawn to avoid "any risk that [the Rule] could cause seniors' premiums to increase."[74]

VI. In November 2020, HHS-OIG Revives The Rebate Rule—Effective January 1, 2022—In The Middle Of The 2022 Bid Cycle

More than a year later, in July 2020, President Trump suddenly reversed course and signed

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[68] Memorandum from Seema Verma, Administrator, CMS, to Part D Plan Sponsors (Apr. 5, 2019), go.cms.gov/38KQAmC.

[69] *See* CVS Comment Letter, *supra*, at 14.

[70] Yasmeen Abutaleb, *et al.*, *Trump kills key drug price proposal he once embraced*, Wash. Post (July 11, 2019), wapo.st/3rKLWMO (quoting a "senior administration official").

[71] *See, e.g.*, Congressional Budget Office, *Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projects—Supplemental Material for Updated Budget Projections: 2019 to 2019* (May 2019), bit.ly/2LUF1QI.

[72] *See, e.g.*, Office of Information & Regulatory Affairs, *OIRA Conclusion of EO 12866 Regulatory Review*, bit.ly/3bHLIAt; Office of Management and Budget, *Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection*, RIN 0936-AA08 (Fall 2019), bit.ly/39yAmw4.

[73] Shira Stein, *Trump Kills Drug Rebate 'Safe Harbor' Rule That Favored Pharma*, Bloomberg Law (July 11, 2019), bit.ly/3o1CsdX.

[74] Peter Sullivan, *White House withdraws controversial rule to eliminate drug rebates*, The Hill (July 11, 2019), bit.ly/3bIQLkc.

an Executive Order providing that Secretary Azar "shall complete the rulemaking process" so long as the "action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs."[75] By that time, industry attention had shifted to contract year 2022, and PBMs and plan sponsors were preparing for the June 8, 2021 deadline to submit bids for 2022.

In response to the Executive Order, HHS-OIG threw a wrench into those preparations by releasing the Rule in the middle of the 2022 bid cycle. After rushing the Rule through Office of Management and Budget ("OMB") review in just five days[76]—far short of the 90 days ordinarily available for OMB review of significant regulations[77]—HHS-OIG published the Rebate Rule on November 30, 2020.[78]

Like the Proposed Rule, the Rebate Rule eliminates the regulatory safe harbor for discounts in the Medicare Part D context and replaces it with the new point-of-sale safe harbor. As demanded by the Executive Order, Secretary Azar supported the Rule with a public statement purporting to "confirm that in [his] view the [Rebate] Rule . . . is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs."[79] HHS-OIG relied on this statement in support of its decision to issue the Rule.[80]

HHS-OIG set a January 1, 2022 effective date for the revisions to the discount safe

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[75] Exec. Order 13939, *Lowering Prices for Patients by Eliminating Kickbacks to Middlemen*, 85 Fed. Reg. 45759, 45759 (July 29, 2020).

[76] OMB, *OIRA Economically Significant Executive Order Reviews*, bit.ly/35S7w92 (search of 2020 HHS rules).

[77] Exec. Order 12866 § 6(b)(2), 58 Fed. Reg. 51735, 51742 (Oct. 4, 1993).

[78] Rebate Rule, 85 Fed. Reg. at 76666.

[79] HHS Press Office, *Secretary Azar Confirmation In Response to Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen* (Nov. 20, 2020), bit.ly/3sv32yQ ("Azar Statement").

[80] Rebate Rule, 85 Fed. Reg. at 76666.

harbor.[81] That date means that plan sponsors' bids for contract year 2022, which are due to be submitted in June 2021—barely six months after the Rebate Rule's publication—would need to account for the vastly different, new regulatory regime. As a result, as soon as HHS-OIG published the Rule, PBMs—who had already been negotiating with manufacturers and developing bids, as they do every year—were set back months behind schedule with no realistic chance to catch up.

HHS-OIG claimed that it was honoring commenters' request for a 2022 effective date.[82] But 2022 was the earliest date that commenters suggested, back in the comment cycle in 2019, would have been appropriate ***had the Rebate Rule been promulgated in 2019***. HHS-OIG never accounted for the fact that it was issuing the Rebate Rule ***in November 2020***—more than a year after the issuance date contemplated by the Proposed Rule—or the comments urging HHS-OIG to set the Rebate Rule's effective date for the year *after* the contract year at issue in whatever bid cycle was underway when the Rebate Rule was published, which would have been contract year ***2023***. While HHS-OIG curtly acknowledged "concern[s] about the impact of the Proposed Rule on the Part D bid process"—including that "rulemaking or guidance by CMS will be necessary to implement" the Rule—it disclaimed any responsibility for ensuring the resolution of these issues before the start of the bidding cycle corresponding to the Rule's effective date.[83] HHS-OIG simply slammed the door on the issue, repeating at least 25 times that "[c]omments related to CMS's administration of the Part D program are outside the scope of this rulemaking."[84] Although HHS-OIG claimed that it had "consulted with CMS in the promulgation of this final rule," it provided no details regarding how it consulted with CMS, what CMS's views were, or what CMS may

[81] *Id.* at 76666.

[82] *Id.* at 76691.

[83] *Id.* at 76673.

[84] *Id.* (five times); *see also*, *e.g.*, *id.* at 76672 (four times), 76674 (three times), 76675, 76683, 76684 (twice), 76685 (twice), 76689, 76690, 76692, 76696, 76698, 76709, 76714.

anticipate doing to alleviate the commenters' concerns.[85]

VII. PBMs And Plan Sponsors Are Still Waiting For Necessary Information From CMS

Although HHS-OIG asserted that the January 2022 effective date "should provide adequate time for parties to come into compliance and to minimize any disruption,"[86] the facts on the ground reveal a far different reality. Although President Trump ordered Secretary Azar to restart the rule-making process in July 2020, CMS proceeded with its Advance Notice process without accounting for a potentially forthcoming Rebate Rule in any way. In fact, CMS released Advance Notices for contract year 2022 "earlier than in past practice," issuing Part I in September 2020 and Part II in October 2020.[87] The comment period on these Advance Notices thus ended on November 30, 2020—the *same* day the Rebate Rule was published in the Federal Register.[88] As a result, neither the CMS notices issued as part of the 2022 Advance Notice process nor any of the comments submitted in that process had an opportunity to address the Rebate Rule—even though that rule will have profound impacts on bidding, benefits, and payments for plans and enrollees.[89] And when CMS completed the process by issuing its Rate Announcement on January 15, 2021, CMS conceded it lacked sufficient time to react to the Rebate Rule, and would have to "take it into consideration for the future."[90] In response to commenters "express[ing] concern" that CMS's

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[85] *Id*. at 76673.

[86] *Id*. at 76691.

[87] CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2022 – Part I* at 3 (Sept. 14, 2020), go.cms.gov/3bI4QON ("2022 Advance Notice Part I"); CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2022 – Part II* at 5 (Oct. 30, 2020), go.cms.gov/3ifnn6x ("2022 Advance Notice Part II").

[88] 2022 Advance Notice Part II, *supra*, at 1.

[89] *See* PCMA Comment on Advance Notice of Methodological Changes for Calendar Year (CY) 2022, at 1 (Nov. 30, 2020) ("The Notice does not address [the Rebate Rule] in any way."), bit.ly/2XHXXFh.

[90] *See* CMS, *Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies* at 66 (Jan. 15, 2021), go.cms.gov/3qma3jA.

RxHCC risk adjustment model "does not account for the impact of the" Rebate Rule, for example, CMS stated that, "[g]iven" the Rebate Rule's "recen[t]" issuance, "there was neither sufficient time nor information available to analyze the potential impact of the [Rebate R]ule on Part D expenditures and, in particular, plan liability, used to calibrate the RxHCC model."[91]

Even after the Rebate Rule was published, CMS has proceeded as if the Rule did not exist. On December 23, 2020, for example, CMS released its instructions for completing the Bid Pricing Tool—the CMS-approved format for plan sponsors to provide information to CMS in bid submissions—and provided instructions that made sense only in the pre-Rebate Rule world. When instructing plan sponsors how to enter "the total amount of rebates [they] received," for example, CMS noted that "[t]otal rebates include all direct and indirect remuneration received after the point-of-sale transaction."[92] That is, CMS's instructions contemplate bids *including* the kind of after-sale rebates that HHS-OIG has now removed from regulatory protections—underscoring the lack of appropriate (or apparently any) coordination between HHS-OIG and CMS when HHS-OIG finalized the Rebate Rule. Similarly, CMS issued "Final Part D bidding instructions" on January 19 informing plan sponsors of the window of time for plan sponsors to submit formularies to CMS and certain benefit parameters for alternative plans, but never mentioned the Rebate Rule.[93]

Moreover, CMS has yet to issue a notice of proposed rulemaking for Policy and Technical Changes addressing the implications of the Rebate Rule. Instead, on January 19, 2021—without even mentioning the Rebate Rule—CMS finalized a *separate rulemaking* on Policy and Technical

[91] *Id.* at 70.

[92] CMS, *Attachment E-2: Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2022* at 36 (Dec. 23, 2020), go.cms.gov/3nVVPEB; *see also id.* at 37 (same, for supplemental drugs), 46 (same).

[93] CMS, *Contract Year (CY) 2022 Final Part D Bidding Instructions* at 1-4 (Jan. 19, 2021), attached as Ex. B hereto.

Changes first proposed on *February 18, 2020*, after the Rebate Rule was initially withdrawn and before President Trump directed Secretary Azar to revive it.[94] On a similar timeline, even if CMS proposed a new Policy and Technical Changes rule on the day of this filing, it would not finalize the rule until long past the June 7, 2021 bid deadline for the 2022 contract year, and with no time for PBMs and plan sponsors to come into compliance with the Rebate Rule.

LEGAL STANDARD

Summary judgment is required if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In the administrative-law context, summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Itserve All., Inc. v. Cissna*, 443 F. Supp. 3d 14, 30 (D.D.C. 2020) (quoting *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006)). Under the APA, courts "shall . . . hold unlawful and set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2).

ARGUMENT

The APA required HHS-OIG to "consider [all] important aspect[s] of the problem" and "articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). In rushing the Rebate Rule out the door in the middle of the bidding process for coverage year 2022, while applying the changes to that very same contract year despite numerous commenters having raised the timing problem, HHS-OIG failed to meet its obligations under the APA.

[94] *See* 85 Fed. Reg. 9002 (Feb. 18, 2020) (proposed rule); 86 Fed. Reg. 5864 (Jan. 19, 2021) (final rule).

As detailed above, HHS-OIG's rollout of the Rule was, with all due respect, a mess. The agency originally proposed the Rebate Rule nearly two years ago—in February 2019—but soon withdrew it as "a terrible idea" whose costs would have been "exorbitant."[95] That is how matters stood—with the Rule entirely withdrawn—for more than a year, until President Trump abruptly revived it in July 2020, with his term winding down, by ordering Secretary Azar to "complete the rulemaking process."[96] Secretary Azar promptly complied. Despite having received more than 25,000 comments in the original proceeding—many warning HHS-OIG of the devastating consequences of eliminating the decades-old retrospective rebate system that has been prevalent in Medicare Part D since its origin—HHS-OIG produced and issued a final rule in just a few months after the executive order, plowing ahead with its preordained conclusion with little consideration for the implementation difficulties that would arise and apparently failing to coordinate *even within HHS* by taking account of the interrelated CMS process.

That is how we got to the impossible timing situation PCMA's members now face: an agency issuing a rule applicable to contract year 2022 in late November 2020—well into the bidding process for the 2022 contract year, with less than six months left until the bidding deadline. The stop-go, rushed nature of the Rebate Rule is a textbook example of unreasoned—and unreasonable—decisionmaking. Plaintiff has alleged several unlawful aspects of the Rule and will raise those in a subsequent motion. The immediate concern, however, is the January 1, 2022 effective date for the Rule that is already having a devastating impact on preparations for the Part D 2022 contract year, sowing confusion and chaos. Because that date is arbitrary and capricious, PCMA

[95] Abutaleb et al., *supra*.

[96] Exec. Order 13939, 85 Fed. Reg. at 45759.

respectfully requests that this Court set it aside.[97]

I. The Effective Date Of The Rebate Rule Is Arbitrary And Capricious

Dozens of commenters warned HHS-OIG that proceeding with the Rule without waiting for critical input from CMS would have disastrous consequences for contract year 2022. Commenters warned that PBMs and plan sponsors must have this input before they can negotiate with manufacturers, set formularies and plan terms, submit bids to CMS, and implement the new point-of-sale discounts system imposed by the Rule. But in its haste to promulgate the Rule before the end of the Trump administration, HHS-OIG ignored these warnings and broke with its settled practice of coordinating major rules with CMS to ensure consistency and clarity in policy and to address implementation questions in federal programs. HHS-OIG never squarely addressed the Rule's impact on 2022, nor did it meaningfully consider a reasonable, less-burdensome implementation timeline or offer any countervailing reason for putting the Rule into effect so abruptly. These failures are hallmarks of arbitrary and capricious agency decisionmaking.

A. HHS-OIG Failed To Account For The Effective Date's Impact On The 2022 Contract Year

The Rebate Rule's effective date threatens the 2022 contract year in three ways. *First*, there is not enough time to implement the Rule for that contract year. There is simply no way

[97] PCMA has associational standing to bring these claims on behalf of its members because: (1) "at least one of its members would have standing to sue in [its] own right"; (2) "the interest [PCMA] seeks to protect is germane to its purpose"; and (3) "neither the claim asserted nor the relief requested requires [its] member to participate in the lawsuit." *Chesapeake Climate Action Network v. EPA*, 952 F.3d 310, 318 (D.C. Cir. 2020). PCMA's members would have standing because they rely on the regulatory safe harbor eliminated by the Rebate Rule, and they now face the cost and burden of having to modify their price concessions practices and restructure existing business models in the middle of the 2022 bid cycle. *See* Decl. of Adam W. Kautzner ¶¶ 13-21, Decl. of Kent D. Rogers ¶¶ 8-16, Decl. of Joseph Anderson ¶¶ 7-17, Exs. 1-3 to Decl. of Juan Carlos Scott ("PCMA Decl."), filed as Ex. C herewith. Preventing these injuries is germane to PCMA's purpose to promote PBMs and the proven tools they utilize, and to preserve the ability of PBMs to lower costs and better health outcomes. PCMA Decl. ¶¶ 5-8, 11-18. There is no need for PCMA's members to participate because this suit raises pure questions of law under the APA and Declaratory Judgment Act. *See* Compl. ¶¶ 262-75.

CMS can issue the necessary regulations and guidance in time for PBMs and plan sponsors to complete negotiations with manufacturers, design their plans, prepare bids to CMS, and implement the Rule. *Second*, the resulting chaos will weaken plan offerings. At best, plan sponsors will increase premiums—driving up enrollees' out-of-pocket costs and federal spending—to account for the risks they face in an uncertain regulatory environment. *Third*, by the time the Rule was issued in November 2020, PBMs and plan sponsors had *already* spent significant resources, in reliance on the safe harbor eliminated by the Rule, negotiating retrospective rebates with manufacturers—resources that will go to waste if the Rule takes effect in 2022. In failing to address these serious concerns, despite the fact that numerous commenters flagged the need for a workable transition period, HHS-OIG violated the APA's requirements for reasoned decisionmaking.

1. The Effective Date Does Not Allow Enough Time For CMS To Provide Necessary Guidance

Plan sponsors and PBMs currently have less than five months remaining to complete negotiations with manufacturers, finalize their plans, and submit their bids by the June 7, 2021 bid deadline. But PBMs and plan sponsors still lack critical information from CMS about the bidding process, formularies, enrollee materials, and benefit structure necessary to complete negotiations by March, design plans and finalize actuarial assumptions by the first week of May, finalize and submit bids by the first Monday of June, and implement any changes to retail and specialty pharmacy transaction standards. *See supra*, at , 5-6, 11-15, 20-22. The Rebate Rule simply does not provide sufficient time for CMS to address these issues in time for PBMs, plan sponsors, pharmacies, and other stakeholders to take CMS's answers into account.

Many if not most of the determinations left for CMS to make require notice-and-comment rulemaking. The Medicare Act requires CMS to provide public notice and a 60-day comment period for any "rule, requirement, or other statement of policy . . . that establishes or changes a

substantive legal standard governing . . . the payment for services." 42 U.S.C. § 1395hh(a)(2). Given that requirement, CMS has historically promulgated both major policy changes and minor technical changes through notice-and-comment rulemaking in its roughly annual Policy and Technical Changes rule. *See supra*, at 7-9. Until the bid cycle for the 2021 contract year, CMS also provided subregulatory guidance to PBMs and plan sponsors through an annual Call Letter. But even if this form of subregulatory guidance previously would have been an option for some of the issues that stakeholders need CMS to resolve, CMS has now—following the Supreme Court's 2019 decision in *Allina*—determined that even information historically included in its Call Letter, if substantive, must be shifted to its Policy and Technical Changes rule and promulgated through notice-and-comment rulemaking. *See supra*, at 8-9.

It will take months for CMS to provide this information through its Policy and Technical Changes rule. CMS will need to work internally to resolve the myriad issues that HHS-OIG left open, make decisions about how to address each issue, and draft a Notice of Proposed Rulemaking. After that, CMS must solicit public comments for 60 days as well as OMB review. *See* 42 U.S.C. § 1395hh(b)(1). Then it will take CMS time to review, analyze, discuss, and answer comments as part of any final rule. Even after CMS's job is done, CMS must send the final rule to OMB for review, and OMB has at least 90 days to review the rule (a review period that the OMB Director may extend to 120 days). Exec. Order 12866 § 6(b)(2), 58 Fed. Reg. 51735, 51742 (Oct. 4, 1993).

The timeline simply does not work. There is no indication that CMS has even started on the necessary rulemaking. And even if CMS issued the proposed rule the day of this filing, solicited public comments for 60 days, took 30 days to respond to comments, and received approval from OMB in 90 days, the final rule would not be published until July 23, 2021—more than a month *after* the bid deadline.

Nothing that CMS has done recently indicates the determinations that plan sponsors need can, or will, be completed in time. Last year, it took CMS four months to finish part of the Policy and Technical Changes rulemaking that it started in February 2020, and seven months to finish the remainder.[98] And the Policy and Technical Changes rulemaking process is now more complicated because of the Rebate Rule's major changes to the Part D program. Addressing these additional, complex issues will only extend the period necessary to complete rulemaking. CMS has acknowledged as much, informing stakeholders two weeks before this filing that the agency needed more time to study the Rebate Rule and will have to address it in "the future."[99]

CMS's recent conduct suggests, moreover, that it has not even started preparing a new notice of proposed rulemaking that accounts for the Rebate Rule: In recent weeks, CMS has published a Bid Pricing Tool that still contemplates the very retrospective rebates that HHS-OIG sought to outlaw in the Rule,[100] issued a Policy and Technical Changes final rule wrapping up *last year's* proposals that did not mention the Rule at all,[101] issued final Part D bidding instructions that likewise did not mention the Rule at all,[102] and already issued the final Rate Announcement that customarily ends the Advance Notice process.[103] With less than five months remaining before the bidding deadline, there is no realistic expectation that CMS, already behind schedule, will provide the necessary answers to plan sponsors through any forthcoming rulemaking.

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[98] 85 Fed. Reg. 9002 (Feb. 18, 2020) (proposed rule); 85 Fed. Reg. 33796 (June 2, 2020) (final rule); 86 Fed. Reg. 5864 (Jan. 19, 2021) (final rule).

[99] CMS, *Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies*, *supra*, at 66, 70.

[100] CMS, *Attachment E-2: Instructions for Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2022*, *supra*, at 36, 37, 46.

[101] 86 Fed. Reg. 5864.

[102] CMS, *Contract Year (CY) 2022 Final Part D Bidding Instructions*, *supra*, at 1-4.

[103] CMS, *Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies*, *supra*.

In analogous situations, courts have readily rejected agencies' attempts to change the rules of the game midstream without giving parties time to adapt to the new rule, and this Court should do the same here. *See, e.g., Nat'l Ass'n of Independent Television Producers & Distributors v. FCC*, 502 F.2d 249, 254 (2d Cir. 1974); *AFL-CIO v. Chao*, 298 F. Supp. 2d 104, 128 (D.D.C. 2004), *aff'd in part, rev'd and vacated in part on other grounds*, 409 F.3d 377 (D.C. Cir. 2005).

Independent Television Producers is illustrative. There, the FCC had amended certain regulations governing prime time television, and it set "the effective date" of those amendments "only eight months" in the future. 502 F.2d at 254. The court held that this was arbitrary because (among other things) the networks had testified that, at that time, program planning was already well underway. *Id.* (such planning "begins twelve to eighteen months before the start of the season"). That testimony, the court recognized, "directly contradict[ed] the Commission's claim that a shorter time [was] in the public interest." *Id.* Thus, "any effective date earlier than" eighteen months following the FCC's issuance of the amendments "would be unreasonable because" it would give networks "inadequate time" to adjust to the amendments. *Id.* at 255.

AFL-CIO reached a similar result. In that case, the Secretary of Labor had adopted a final rule with only a few months' lead time. 298 F. Supp. 2d at 126. There, based on the effective date of the rule, certain labor unions would have had "less than two months" to develop a new accounting system. *Id.* "For a number of reasons," all readily applicable here, the court held that the agency's timeline could not withstand arbitrary-and-capricious review. *Id.* *First*, a "majority of the comment[ers]" opposed the "effective date," explaining that unions would not have had sufficient time to reorganize their affairs. *Id.* *Second*, software with which the unions wanted to test their revamped accounting systems was not yet available. *Id.* at 127. And *third*, the "Secretary [had] claimed no particular need for [such] urgency." *Id.* For all these reasons, the "effective

date" set by the Secretary was "arbitrary and capricious and in violation of the APA." *Id.* at 128.

The Rebate Rule suffers from the same infirmities. Numerous commenters urged HHS-OIG to provide stakeholders more lead time to comply, taking care to note the many specific issues that CMS and others would need to resolve. *See supra*, at 11-16. Like the networks in *Independent Television Producers*, market participants warned the agency that the rule would impact a process that had already begun, and that they would have inadequate time to adjust to the rule before submitting their bids. *See* 502 F.2d at 254. While television program planning is surely complicated, the planning process for Medicare Part D, a large and highly regulated government program, is *exceptionally* complex. It also involves especially long lead times given the various parties and moving parts involved, the size of the program, and the need to explain any changes to the 47 million seniors and disabled Americans that enroll each year. *See supra*, at 5-9. And like the unions in *AFL-CIO*, commenters made clear that market participants needed more time to comply. *See* 298 F. Supp. 2d at 127. Moreover, commenters informed the agency that a relevant "electronic reporting" tool was not yet available to assist commenters in restructuring their affairs, as the rule required. *Id.*[104] In these circumstances, HHS-OIG cannot credibly claim that the January 2022 effective date is reasonable.

Unsurprisingly, in setting such an unreasonable timeline, HHS-OIG failed to "consider [all] important aspect[s] of the problem." *State Farm Mut.*, 463 U.S. at 43. HHS-OIG overlooked the extensive administrative hurdles to implementing the Rebate Rule before the June bid submission deadline. *Supra*, at 15. The agency, to be sure, briefly acknowledged some of those hurdles—that PBMs and other stakeholders would need "new . . . electronic health care transaction codes

[104] NCPDP Comment Letter, *supra*, at 3-4 (describing technical changes that would need to be made to programs for healthcare information exchange); AHIP Comment Letter, *supra*, at 2 (detailing "concerns about the likelihood of significant operational challenges associated with moving to a new system with little time to rigorously test the system").

for pharmacy claims," 85 Fed. Reg. at 76692—but, yet again, it offered no meaningful response. The agency simply declared that it set the effective date after "further consideration." *Id.* "Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a hallmark of reasoned decisionmaking." *Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020).

The timing of the Rebate Rule leaves PBMs and other stakeholders hurtling toward the June 2021 bid submission deadline, without enough time for CMS to give PBMs the determinations they need to submit actuarially sound bids. *Supra*, at 25-27. But HHS-OIG refused to consider the matter altogether. At least 25 times, the agency responded to comments raising concerns about the bidding process by punting: "Comments related to CMS's administration of the Part D program are outside the scope of this rulemaking." 85 Fed. Reg. at 76673; *supra*, at 19.

HHS-OIG's refusal to consider and respond to these comments by simply asserting they were beyond the scope of its rulemaking was arbitrary and capricious. As the D.C. Circuit has held, an agency "cannot get away so easily from obligations under the APA to respond to 'relevant and significant comments.'" *Del. Dep't of Nat. Res. & Envtl. Control v. EPA*, 785 F.3d 1, 15 (D.C. Cir. 2015) (quoting *Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 225 (D.C. Cir. 2007)). In *Delaware Department of Natural Resources*, commenters objected to a final rule on the grounds that it threatened the reliability of energy markets by creating incentives for backup generators to replace more efficient, traditional power generators. *Id.* at 14. As HHS-OIG did here, the EPA there "essentially said that it was not its job to worry about those concerns: 'The issues related'" to "'management of energy markets and competition between various forms of electric generation are,'" the agency claimed, "'far afield from EPA's responsibilities for setting standards under the [Clean Air Act].'" *Id.* at 15. According to the EPA, therefore, such concerns "should be left to the entities that are responsible for maintaining the reliability of the electric grid." *Id.*

The D.C. Circuit disagreed. It explained that "an agency must respond sufficiently to 'enable [the court] to see what major issues of policy were ventilated . . . and why the agency reacted to them as it did.'" *Del. Dep't of Nat. Res.*, 785 F.3d at 15 (quoting *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993)). And in no event can the agency "excuse its inadequate responses by passing the entire issue off onto a different agency," as the EPA tried there, and as HHS-OIG tried here. *Id.* at 16. "Administrative law does not permit such a dodge." *Id.* (citing *Gen. Chem. Corp. v. United States*, 817 F.2d 844, 846 (D.C. Cir. 1987) (per curiam)).

Here, HHS-OIG had an obligation to address the commenters' concerns head on. The agency, of course, had no obligation to issue guidance on behalf of CMS. But HHS-OIG *did* have an obligation to at least *assess* whether, as a direct result of its *own* rule, the stakeholders that it regulates would necessarily have needed additional CMS guidance in order to run their businesses, as multiple commenters explained was the case, and to address that concern in some substantive way. *Supra*, at 11-15. That is a real, concrete concern that HHS-OIG should have factored into its analysis. By not doing so—and not even *considering* whether PBMs and other stakeholders needed guidance from CMS—HHS-OIG acted arbitrarily and capriciously.

2. HHS-OIG's Rushed Implementation Schedule Will Significantly Impact Premiums For The 2022 Contract Year

Even if PBMs and plan sponsors were able to complete the bidding process without timely regulations from CMS, regulatory uncertainty on its own increases business risk and is likely to increase costs in the form of premium increases—undermining the Rebate Rule's very foundation.

The Rebate Rule's central premise is that, consistent with the Executive Order's explicit demand, "there will not be an increase in federal spending, patient out-of-pocket costs, or premiums for Part D beneficiaries."[105] Concerns about increased premiums and federal spending are the

[105] Rebate Rule, 85 Fed. Reg. at 76721.

reason the Proposed Rule was withdrawn the first time around: Executive officials were concerned that the Rule's "cost was exorbitant,"[106] and the President did "not want any risk that [HHS-OIG's] actions could cause seniors' premiums to increase."[107] President Trump's Executive Order thus directed Secretary Azar to restart the rulemaking only if he concluded that the Rebate Rule "is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs."[108] Secretary Azar purported to make that finding—albeit without any support, *see* Compl. ¶ 149—and HHS-OIG cited it prominently in the Rule.[109]

But the timing problems injected by HHS-OIG's rushed implementation schedule will cause the very thing HHS-OIG said it must avoid. By forcing a 2022 effective date on plan sponsors and PBMs who were already working on bids for contract year 2022, HHS-OIG created significant regulatory uncertainty that has yet to be addressed and cannot be addressed with sufficient lead time before the June 2021 bids. *See supra*, at 25-27. And as the Supreme Court has recognized in the Affordable Care Act context, "uncertainty" in creating a health plan "affect[s] the rates [plan sponsors] set." *Maine Cmty. Health Options v. United States*, 140 S. Ct. 1308, 1316 (2020). As PCMA explained, "higher uncertainty means higher risk, which translates into higher costs."[110] Commenters thus warned that "[w]ith the uncertainty created by the Proposed Rule, . . . plans [might] increase premiums by more than projected by HHS."[111] In addition, the infusion of regulatory uncertainty forces the industry to "incur substantial compliance costs in

[106] Abutaleb, et al., *supra*.

[107] Sullivan, *supra*.

[108] Exec. Order 13939, 85 Fed. Reg. at 45759.

[109] *See* Azar Statement, *supra*; Rebate Rule, 85 Fed. Reg. at 76666.

[110] PCMA Comment Letter, *supra*, at 38.

[111] *Id.*; *see also* Cigna Comment Letter at 13 (Apr. 8, 2019), bit.ly/2Y638z2 (noting "dramatic changes to premiums" that would result if Rule's effective date impacted a bid cycle that was "already well underway").

creating and aligning new payment systems," which would be "transferred to consumers through higher drug prices and premiums."[112]

One need not look far for an illustration of the perils of such regulatory changes. When the Affordable Care Act ("ACA") was enacted in 2010, it required insurance carriers offering health plans on an exchange to comply with its new requirements by 2014—meaning that individuals with non-compliant health plans had to buy compliant health plans by that date.[113] By November 2013, insurance carriers had designed health plans to be compliant with the ACA, and had "se[t] rates" for the upcoming year.[114] But HHS made a last-minute change, unilaterally announcing in November 2013 a new "transitional policy" that allowed individuals to remain on their existing health plans, even if those plans did not comply with the ACA.[115] As a result, fewer people enrolled on the exchanges than the insurance carriers anticipated when setting their rates. The consequences were dire: Insurance companies lost "billions of dollars" in the next two years.[116] Predictably, these losses led to significant increases in premiums.[117] Anticipating similar risks in the wake of the Rebate Rule, plan sponsors will likely need to increase 2022 premiums.

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[112] Anthem Comment Letter, *supra*, at 17-19 (explaining that Proposed Rule "fail[ed] to adequately explain operational and administrative details" of the change to point-of-sale discounts).

[113] Pub. L. No. 111-148, 124 Stat. 119 § 1253 (2010).

[114] Letter from Gary Cohen, CMS, to State Insurance Commissioners at 3 (Nov. 14, 2013), go.cms.gov/32QFMP5.

[115] *Id.* at 1.

[116] Bruce Japsen, *Insurer Obamacare Losses Reach Billions of Dollars after Two Years*, Forbes (Feb. 7, 2016), bit.ly/35UN3R3; *see Maine Cmty. Health*, 140 S. Ct. at 1317 (discussing losses).

[117] *See* CMS, *Premiums on the Federally-facilitated Exchanges drop in 2019* (Oct. 11, 2018) (noting that after Affordable Care Act "regulations took effect in 2014, average individual market premiums more than doubled" from 2013 to 2017), go.cms.gov/35UslQZ; HHS, *Individual Market Premium Changes: 2013-2017* at 1 (May 23, 2017) ("Premiums for individual market coverage have increased significantly" from 2014 to 2017), bit.ly/2XWReal.

Agencies must "consider . . . the relevant factors" and "important aspect[s] of the problem" when promulgating a rule, *State Farm Mut.*, 463 U.S. at 42-43, but HHS-OIG never contemplated how plan sponsors, PBMs, and other stakeholders would react if the Rebate Rule left them adrift at sea without necessary regulatory guidance for their upcoming bids. For that reason alone, the Rebate Rule's effective date is arbitrary and capricious. And if HHS-OIG had analyzed the problem, it would have seen that its rush to implement the Rebate Rule was counterproductively creating the precise conditions that the President said must *not* happen. Because the Rebate Rule is "based significantly on the flawed presumption" and "underlying premise" that premiums would not increase, and because HHS-OIG failed to account for the increase in premiums needed to counteract the uncertainty that HHS-OIG created by rushing a rulemaking out the door with inadequate lead time for the industry to adjust, the Rebate Rule's effective date is arbitrary and capricious. *Am. Equity Inv. Life Ins. Co. v. SEC*, 613 F.3d 166, 179 (D.C. Cir. 2010); *see also Sorenson Commc'ns v. FCC*, 765 F.3d 37, 50 (D.C. Cir. 2014) (vacating new speed-of-answer requirement that agency adopted "based in part upon the explicit premise that it would not increase labor costs over the historical costs . . . contrary to the general relationship suggested by [the petitioner]").

3. The Effective Date Undercuts The Investment PBMs And Plan Sponsors Had Already Made In Negotiations With Manufacturers In Reliance On Preexisting Regulations Before HHS-OIG Changed The Regulatory Regime For Contract Year 2022

Even if CMS could complete the necessary rulemaking in time for PBMs and plan sponsors to adapt to the Rebate Rule, HHS-OIG would need to account for the significant investments that PBMs and other stakeholders had *already* sunk into their June 2021 bidding submissions. Its failure to do so is an independent "defect" that is fatal to the Rebate Rule. *Dep't of Homeland of Sec. v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020).

When a "prior policy has engendered serious reliance interests," those interests "must be

taken into account." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (citing *Smiley v. Citibank (S.D.), N.A.*, 517 U.S. 735, 742 (1996)). "It would be arbitrary or capricious to ignore such matters." *Regents of Univ. of Cal.*, 140 S. Ct. at 1913 (quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016)). Yet that is exactly what HHS-OIG did here. When HHS-OIG issued the Rebate Rule in November 2020, after it had laid dormant for more than a year, with an effective date of January 1, 2022, the bidding process for contract year 2022 was already well underway. PBMs and plan sponsors had already spent months hammering out the terms of contracts with manufacturers for the coverage year.[118] And they were already deep into the process of crafting the bids that would need to be submitted just six months later. Those investments in time, money, and energy created significant value: Through thousands of hours of effort, hundreds of employees at dozens of companies had advanced the ball toward making available for another year the prescription drug coverage relied on by millions of Americans.[119]

HHS-OIG undid that work with the stroke of a pen. By revising the regulatory discount safe harbor so that it would no longer protect the very rebates that PBMs had spent months negotiating—and by setting the effective date so that the Rebate Rule would apply to the coming contract year—the agency forced PBMs back to the beginning of the entire process. HHS-OIG ensured that plan sponsors and PBMs "would need to essentially begin the process again, including renegotiation of contracts and re-pricing of bids" covering thousands of medicines.[120]

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[118] *See supra*, at 5-6, 15-16; PCMA Decl. Ex. 1 ¶ 14, Ex. 2 ¶¶ 7, 9, 12-13, 15, Ex. 3 ¶¶ 11-12.

[119] *See, e.g.*, PCMA Decl. Ex. 1 ¶¶ 8, 14 (noting that one PBM devotes 17 employees to facilitate manufacturer negotiation and contract processes, and had "already invested substantial time and effort to commence negotiations with manufacturers for the 2022 contract year" by the time HHS-OIG published the Rebate Rule); PCMA Decl. Ex. 2 ¶ 7 (similar); Nat'l Ass'n of Ins. Comm'rs, *Pharmacy Benefit Managers* (Jan. 28, 2020) (noting there are "66 PBM companies" as of 2020), bit.ly/3pcGgtu.

[120] BCBS Comment Letter, *supra*, at 16; *supra*, at 15-16.

HHS-OIG never accounted for these substantial "reliance costs." *Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 54 (D.D.C. 2019). It acknowledged that PBMs and plan sponsors would need to "renegotiate contracts,"[121] but ignored the "investments" PBMs and other stakeholders had *already* "sunk" into developing the bids that HHS-OIG upended, *Council of Parent Attorneys*, 365 F. Supp. 3d at 54. Those investments were substantial. And the "costs" PBMs "incurred" making those investments—in full reliance on then-existing regulatory requirements—should have been factored into the agency's consideration of costs and benefits—but it was not. *Id.*; *see Regents of Univ. of Cal.*, 140 S. Ct. at 1915 ("[B]ecause [the agency] was 'not writing on a blank slate,'" it "*was* required to assess whether there were reliance interests").

Had HHS-OIG properly "considered [such] reliance interests," it may very well have "considered more accommodating [compliance] dates . . . to allow" PBMs to retain the value of the work they had previously done. *Regents of Univ. of Cal.*, 140 S. Ct. at 1914. Indeed, HHS-OIG's failure to consider reliance interests is particularly problematic here, where the agency had publicly withdrawn the proposed rule over a year before the action at issue now. Unlike in a typical rulemaking, therefore, where the final rule is immediately preceded by the proposal, here, PBMs would have "had no reason to anticipate" an imminent change; *Anne Arundel Cty. v. EPA*, 963 F.2d 412, 418 (D.C. Cir. 1992); the withdrawal would have "lulled [them] into concluding that they did not need to" prepare for a final rule, *Nat'l Lifeline Ass'n v. FCC*, 921 F.3d 1102, 1118 (D.C. Cir. 2019). Given this "uncertain[ty]" surrounding the "status" of any rule change, then, PBMs were particularly justified in relying on the regulatory status quo. *Nat'l Ass'n of Independent Television Producers*, 502 F.2d at 254. And "[h]aving justifiably" done so, they should have been "entitled to more opportunity to adjust to the new rule." *Id.* at 255.

[121] Rebate Rule, 85 Fed. Reg. at 76692.

B. HHS-OIG Failed To Justify The Implementation Schedule It Set

Given the serious and documented problems with applying the Rebate Rule to the 2022 contract year, HHS-OIG had every reason to adopt a more workable plan. Yet HHS-OIG forged ahead with a January 2022 effective date, without any meaningful consideration of a later date or any countervailing justification for interfering with the 2022 bid cycle. HHS-OIG's failure to consider alternatives or identify any need for a 2022 effective date further illustrates the arbitrary and capricious nature of the effective date.

1. HHS-OIG Ignored Commenters' Requests To Delay The Effective Date

"An agency is required to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives." *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 242 (D.C. Cir. 2008) (internal quotation marks omitted). While this standard does not "broadly require an agency to consider all policy alternatives in reaching [a] decision," *State Farm Mut.*, 463 U.S. at 51, an agency must at least consider those alternatives that are "significant and viable," *Farmers Union Cent. Exch., Inc. v. FERC*, 734 F.2d 1486, 1511 n.54 (D.C. Cir. 1984); *see also Chamber of Commerce v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005) (an agency must consider an alternative that is "neither frivolous nor out of bounds"). Thus, "where a party raises facially reasonable alternatives . . . , the agency must *either* consider those alternatives *or* give some reason . . . for declining to do so." *Laclede Gas Co. v. FERC*, 873 F.2d 1494, 1498 (D.C. Cir. 1989).

Here, HHS-OIG failed adequately to consider "significant and viable" alternatives to a January 2022 effective date. Indeed, in the context of the tumultuous rulemaking process that led to the Rebate Rule, HHS-OIG's discussion of commenters' proposed alternatives bordered on the irresponsible.

As HHS-OIG tells it, commenters asked for a January 2022 effective date, and they got a January 2022 effective date—problem solved. Referencing "[v]arious commenters" who "stated that the effective date should be delayed . . . until 2022,"[122] HHS-OIG insisted repeatedly that the 2022 effective date was "[b]ased on the comments received,"[123] as if the agency had simply accepted commenters' proposal. HHS-OIG then suggested multiple times that this 2022 effective date effectively mooted commenters' concerns about a 2020 or 2021 effective date.[124]

What HHS-OIG ignored is that ***commenters made these comments in early 2019***, in response to the notice of proposed rulemaking issued in February 2019 that proposed an effective date of January 1, 2020.[125] The comment period for the 2019 Proposed Rule ran from February 6, 2019 to April 8, 2019.[126] At the time, PBMs and plan sponsors were in the middle of the 2020 bid cycle and anticipating that a final rule could be issued in mid- to late 2019 at the start of the 2021 bid cycle. Given the Proposed Rule's January 1, 2020 effective date, it was clear that HHS-OIG intended to complete the rulemaking well before the 2022 bid cycle—as it was on track to do before the Rule was withdrawn. *See supra*, at 17. Accordingly, when commenters urged HHS-OIG to delay the Rule's effective date until at least 2022, *see supra*, at 16, they plainly meant that the Rule should not take effect until ***the contract year after the one for which plan sponsors were preparing*** when HHS-OIG issued the rule. After all, the comments made clear *why* a 2022

[122] Rebate Rule, 85 Fed. Reg. at 76692; *see also id.* at 76691 ("Another commenter urged OIG to delay the effective date of the final rule until 2022.").

[123] *Id.* at 76691-92 (three times); *see also id.* at 76692 ("[b]ased on the feedback we have received").

[124] *Id.* at 76692 ("[W]e are now finalizing an effective date of January 1, 2022 . . . which should avoid the disruptions and potential harm described by the commenters."), 76673 ("[B]y finalizing this rule with a January 1, 2022 implementation date . . . we have addressed concerns related to the 2020 bid submission.").

[125] Proposed Rule, 84 Fed. Reg. at 2348.

[126] *Id*. at 2340.

effective date was warranted at the time: "Major changes such as those in the proposed rule typically require the *full multi-year bid development period* to properly incorporate the changes."[127]

Ultimately, though, the Rebate Rule was not issued in 2019. Instead, HHS-OIG ***withdrew the Proposed Rule***—and left it withdrawn for ***more than a year***—before reversing course again and finalizing the Rule without any further call for public comment. By November 30, 2020, when HHS-OIG issued the Rebate Rule—21 months after it was proposed—commenters' proposals to delay the Rule pointed to an effective date of at least 2023—the next contract year that would allow a "full multi-year bid development period to properly incorporate the changes." The original Proposed Rule's January 1, 2020 effective date had passed, and January 1, 2021 was barely a month away, so January 1, 2022 was no longer a concession; it was the earliest HHS-OIG could have made the rule effective without undercutting existing bids.

Treating the January 1, 2022 effective date as essentially adopting commenters' proposals "mischaracterizes commenters' suggestions," and is "not reasoned decisionmaking." *Cigar Ass'n of Am. v. U.S. Food & Drug Admin.*, 2020 WL 4816459, at *15 (D.D.C. Aug. 19, 2020). It ignores the basic problem that this date was suggested before the Proposed Rule was withdrawn and lay dormant for more than a year; after that passage of time, it was not reasonable for HHS-OIG to simply act as if the commenters' original proposed effective date still made sense. But HHS-OIG gave no "reasoned explanation for its rejection of [the] alternatives" that pointed to a 2023 effective date. *Am. Radio Relay League, Inc.*, 524 F.3d at 242 (quoting *City of Brookings Mun. Tel. Co. v. FCC*, 822 F.2d 1153, 1169 (D.C. Cir. 1987)). Instead, it simply stated without explanation that making the "changes to . . . the discount safe harbor . . . effective January 1, 2022 . . . should

[127] American Academy of Actuaries Comment Letter, *supra*, at 1-2 (emphasis added).

provide adequate time for parties to come into compliance and to minimize any disruption."[128] But merely stating that position in "conclusory manner"—without engaging with the reasons commenters gave for urging HHS-OIG to delay the rule—is insufficient under the APA. *Gresham*, 950 F.3d at 103. The Rule's effective date is therefore arbitrary and capricious.

2. HHS-OIG Offered No Reason For Urgency And Never Weighed The Costs And Benefits Of The Date It Chose

HHS-OIG's decision to apply the Rebate Rule to the contract year corresponding to an *ongoing* bid cycle is particularly troubling in light of the agency's failure to offer any reason why a January 1, 2022 effective date was necessary.

In *AFL-CIO*, the court held that a widely criticized effective date giving regulated parties only a few months to develop and adapt accounting systems was arbitrary and capricious, in part because the agency "claimed no particular need for extraordinary urgency." 298 F. Supp. 2d at 127. So too here. HHS-OIG repeatedly claimed that its January 2022 effective date "provide[d] adequate time for parties to come into compliance."[129] But HHS-OIG never claimed a "particular need" to set such an imminent deadline; there is simply no need for "urgency." *AFL-CIO*, 298 F. Supp. 2d at 127. And HHS-OIG did not "explain how" plan sponsors and PBMs "could possibly make [the] far-reaching changes" that they need to make in less than six months, "especially when" the discount safe harbor has been in place for decades. *Id.* at 128.

Nor did HHS-OIG balance any purported benefits of having the Rebate Rule immediately impact the ongoing bidding cycle against the drawbacks of doing so.[130] Weighing both the good

[128] Rebate Rule, 85 Fed. Reg. at 76691.

[129] *Id.*; *see also, e.g.*, *id.* at 76693 (similar).

[130] *See id.* at 76691-93 (discussing comments on effective date without mentioning any costs to immediate implementation).

and the bad consequences of a rule, including its effective date, is a basic administrative responsibility. *AFL-CIO*, 298 F. Supp. 2d at 127-28. HHS-OIG failed it. By failing to provide any reason for its urgency and failing to balance the costs and benefits of such urgency, HHS-OIG has provided "no reasonable justification for setting a January 1, [2022] effective date." *Id.* at 128.

HHS-OIG's own actions undercut any argument for urgency. If there were an urgent need for the Rebate Rule to take effect, the agency could have moved forward with its rulemaking in 2019. Instead, the agency withdrew the Rebate Rule, and it remained withdrawn for an entire year before the President's Executive Order abruptly revived it. *See supra*, at 17-18. Courts may not "sanction agency action when the agency . . . fails to justify seeming inconsistencies in its approach," *Jubilant Draximage Inc. v. Int'l Trade Comm'n*, 396 F. Supp. 3d 113, 121 (D.D.C. 2019) (quoting *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 884 (D.C. Cir. 2004)), and here, HHS-OIG's actions do not comport with its words. PBMs, plan sponsors, and enrollees should not pay the price for the administration's indecisiveness.

C. HHS-OIG Departed Without Reason Or Explanation From Prior Agency Practice Of Coordinating Internally With CMS

The Rebate Rule's rollout is also arbitrary and capricious because of multiple "unexplained inconsistenc[ies]" with prior agency practice. *Encino Motorcars*, 136 S. Ct. at 2126 (an "'[u]nexplained inconsistency' in agency policy is 'a reason for holding an interpretation to be an arbitrary and capricious change from agency practice'" (alteration in original) (quoting *Nat'l Cable & Telecommc'ns Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005))); *see also Lone Mountain Processing, Inc. v. Sec'y of Labor*, 709 F.3d 1161, 1164 (D.C. Cir. 2013) ("'[A]n agency changing its course must supply a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored.' Failing to supply such analysis renders the agency's action arbitrary and capricious." (quoting *Greater Boston Television Corp. v. FCC*, 444 F.2d 841,

852 (D.C. Cir. 1970))); *United Mun. Distribs. Grp. v. FERC*, 732 F.2d 202, 210 (D.C. Cir. 1984) ("[A]gencies must give a reasoned analysis for departures from prior agency practice.").

Before (and after) the Rebate Rule, HHS-OIG has consistently attempted to reconcile its regulations with relevant CMS standards and guidance—which makes sense given the interrelated role of the CMS information and the fact that CMS is, after all, *part of HHS*. In 2014, for example, Congress had added a new statutory safe harbor that exempted from the definition of "remuneration" under the anti-kickback statute a plan sponsor's waiver of certain beneficiary copayments for generic drugs.[131] In proposing regulations to implement that provision, HHS-OIG made clear that it intended to act "consistently with current CMS guidance."[132] HHS-OIG knew exactly what that guidance entailed. Thus, plan sponsors seeking to offer exempted waivers would need to disclose those waivers "in their benefit plan package submissions to CMS."[133] And while HHS-OIG's new regulations would not be effective "until a future date," the agency committed to "not exercise [its] enforcement authority against [any] plans complying with CMS requirements for these waivers in the interim."[134]

Likewise, in 2019, HHS-OIG proposed new regulatory safe harbors for certain value-based arrangements and other services.[135] Again, HHS-OIG emphasized that it "would examine [its] rules in combination with any rules CMS may choose to finalize with the goal of creating an overall

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[131] *Medicare and State Health Care Programs*, 79 Fed. Reg. 59717, 59728 (Oct. 3, 2014).

[132] *Id.*

[133] *Id.*

[134] *Id.*; *see also* HHS-OIG, *Federal Agencies Address Legal Issues Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (discussing HHS-OIG and CMS using "coordinated effort[s]" to address "legal issues" under the Affordable Care Act), bit.ly/3sQnwSM.

[135] *Medicare and State Healthcare Programs*, 84 Fed. Reg. 55694, 55696 (Oct. 17, 2019).

regulatory landscape that is well-coordinated."[136] HHS-OIG did exactly that. In the final rule, issued days after the Rebate Rule, the agency made clear that it was "mindful of reducing burden on providers and other industry stakeholders," and for that reason, it had "sought to align" its "terminology and safe harbor conditions with those being adopted by CMS" in related regulations.[137] Thus, the "OIG and CMS rules" could be expected to "operat[e] together."[138]

Just two days earlier, however, HHS-OIG took an entirely different tack with respect to the Rebate Rule. Although numerous commenters "expressed concern about the impact of the Proposed Rule on the Part D bid process," including that "rulemaking or guidance by CMS [would] be necessary to implement" the rule, HHS-OIG steadfastly maintained that "[c]omments related to CMS's administration of the Part D program [were] outside the scope of this rulemaking."[139] Gone were the days of "creating an overall regulatory landscape that is well-coordinated" between HHS-OIG and CMS.[140] Instead, HHS-OIG repeatedly disclaimed any meaningful knowledge of CMS's activity, repeating on at least 25 occasions that worries about the Rebate Rule's effect on the Part D bidding process were entirely outside of HHS-OIG's concern. *See supra*, at 19.

This ostrich-like approach to the concerns raised by commenters about the interplay between HHS-OIG and CMS regulations and the failure to even coordinate internally with CMS cannot reasonably be squared with the cooperative, CMS-aware approach displayed in other rule-

[136] *Id.*; *see also id.* ("We note that OIG's proposed new safe harbor for cybersecurity items and services and modifications to the existing safe harbor for electronic health record items and services are closely aligned with CMS' proposals.").

[137] *Medicare and State Healthcare Programs*, 85 Fed. Reg. 77684, 77689 (Dec. 2, 2020).

[138] *Id.*

[139] Rebate Rule, 85 Fed. Reg. at 76673.

[140] *Medicare and State Healthcare Programs*, 84 Fed. Reg. at 55696.

makings—both before and after the Rebate Rule. HHS-OIG's failure to recognize, let alone provide a "reasoned" explanation for, this inconsistency "renders the agency's action arbitrary and capricious." *Lone Mountain Processing*, 709 F.3d at 1164.

II. The Rule's Deficiencies Require Vacatur Of The Effective Date.

In light of all the foregoing, the Rebate Rule's effective date must be set aside to avoid an impending train wreck for contract year 2022. The D.C. Circuit has made clear that "vacatur is the normal remedy" for an APA violation. *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014). And the APA "itself contemplates vacatur as the usual remedy when an agency fails to provide a reasoned explanation for its regulations." *AARP v. EEOC*, 292 F. Supp. 3d 238, 242 (D.D.C. 2017); *see Am. Petro. Inst. v. SEC*, 953 F. Supp. 2d 5, 25 (D.D.C. 2013) (explaining that "arbitrary and capricious reasoning" is a "serious error" that favors vacatur); 5 U.S.C. § 706(2) ("The reviewing court shall . . . hold unlawful and set aside . . . ."); *id.* § 551(4) ("'rule' means the whole or a part of an agency statement . . . .").

Although the presumption of vacatur "is not absolute," *Council of Parent Attorneys*, 365 F. Supp. 3d at 55, the factors that have caused courts to remand without vacatur in certain cases, assuming that practice is permissible, *see Milk Train Inc v. Veneman*, 310 F.3d 747, 757-58 (D.C. Cir. 2002) (Sentelle, J., dissenting), are absent here. Public health and safety, for example, are not threatened by vacatur of the Rebate Rule's effective date. *NRDC v. EPA*, 489 F.3d 1250, 1265 (D.C. Cir. 2007) (Rogers, J., concurring in part and dissenting in part). Manufacturers have offered retrospective rebates to PBMs for more than three decades, and HHS-OIG has never claimed that these rebates endanger anyone. Nor could it. Moreover, this is not a case where the regulatory "egg has been scrambled"; in fact, vacatur will merely maintain "the status quo ante" as plan sponsors and PBMs prepare their 2022 bids for submission in June 2021. *Milk Train*, 310 F.3d at 756 (internal quotation marks omitted).

Conversely, if the Rebate Rule is allowed to take effect prematurely on January 1, 2022, PBMs and other stakeholders will be subjected to a radical new regulatory regime that will wreak havoc on the Part D bidding process for contract year 2022, notwithstanding HHS-OIG's failure to adequately consider important aspects of the problem. "[P]arties should not normally be forced to comply with a rule that has been found to violate the APA." *AFL-CIO v. Chao*, 496 F. Supp. 2d 76, 92 (D.D.C. 2007) (vacating rule). Moreover, plan beneficiaries will be injured, given the confusion about Medicare Plan Finder changes, covered drugs, and increased premiums. The Rebate Rule's effective date must be vacated to avoid these unnecessary results.

PCMA plans to file a further motion for summary judgment detailing the additional aspects of the Rebate Rule that violated the APA, once the immediate crisis of the effective date is resolved. Thus, as a practical matter, "the Court has not addressed [PCMA's] other challenges," so "questions remain about other aspects of the [Rebate] Rule"; it would make no sense to leave the Rebate Rule in place and make plan sponsors' forthcoming bids conform to the Rule despite an unlawful effective date and other fatal flaws. *Am. Petro. Inst.*, 953 F. Supp. 2d at 25 (citing *Cement Kiln Recycling v. EPA*, 255 F.3d 855, 872 (D.C. Cir. 2001)); *see* Compl. ¶¶ 156-72, 197-261. If HHS-OIG still wants to pursue the Rebate Rule, it can then come up with a new effective date based on reasoned decisionmaking that takes the various timing issues into proper account.

CONCLUSION

For the foregoing reasons, PMCA's motion for summary judgment should be granted.

Dated: January 25, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of January, 2021, I caused a copy of the foregoing document to be served on all parties pursuant to Federal Rule of Civil Procedure 5(b)(2) by mailing the document via FedEx for next-day delivery to the following addresses.

United States Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

United States Department of Health and Human Services - Office of Inspector General
330 Independence Avenue, S.W.
Washington, D.C. 20201

United States Department of Health and Human Services - Office of Counsel to the Inspector General
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:21-cv-00095-JDB

PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT

EXHIBIT A

Table 4. Medicare Part D Details Needed for Implementation of Proposed Rebate Rule.

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Benefit design	Does the price concession count toward a patient's TrOOP?	42 CFR §. 423.104		
Benefit design	Does the price concession count toward total drug cost?	42 CFR §. 423.104		
Benefit design	Does the price concession count toward negotiated price for purposes of the Coverage Gap Discount Program?	42 CFR §. 423.104		
Benefit design	If price concessions are negotiated at the plan sponsor level, across all plan benefit packages and benefit phases and populations, how would CMS require them to be apportioned to enrollee cost-sharing?	42 CFR §. 423.104		
Benefit design	Can a manufacturer offer different price concessions for the same drug to the same plan sponsor depending on the plan benefit package?	42 CFR §. 423.104		
Benefit design	If a price concession is granted in one benefit phase, must it apply to all benefit phases?	42 CFR §. 423.104		
Benefit design	In the Coverage Gap, what happens to plan payments and enrollee cost-sharing if the price concession exceeds 30%?	42 CFR §. 423.104; 42 CFR § 423.2320		
Benefit design	If price concessions aren't applied uniformly across benefit phases, how will CMS handle straddle claims?	42 CFR § 423.104; 42 CFR § 423.329		
Benefit design	How will pricing be handled for drugs that can be covered under Part B or Part D and are adjudicated using CMS systems (e.g. immunosuppressants for prevention of transplant rejection) or "white bagged"? When covered as Part B, what if Part D cost-sharing would be lower due to price concessions? Could a beneficiary appeal?	42 CFR § 423.104; 42 CFR § 423.566		
Benefit design	How does the price concession reduce cost-sharing if the enrollee has a copay for preferred brand drugs?	42 CFR § 423.104		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Benefit design	What cost-sharing should a plan assess for drugs where the total price concessions bring the net cost of a drug to or below $0.00? For example, if the rebate passed through at the point of sale is larger than beneficiary coinsurance, because of the manufacturer discount that is also provided in the Coverage Gap?	42 CFR § 423.104		
Benefit design	Many vaccines are covered by Part D plans. Does the change in safe harbors apply to vaccines? Many plans include them on $0 tiers (especially the USPSTF endorsed preventive services vaccines). How could a price concession be “passed through” when the cost-sharing is already $0?	42 CFR § 423.104		
Benefit design	Since risk adjustments are used to calculate the bid amounts, will CMS recalibrate the RxHCC model to reflect the new applicable costs associated with high-rebate versus low-rebate classes?	42 CFR § 423.265		
Benefit design/LIS	What if LIS enrollee is in the copay phase of benefit?	42 CFR § 423.782		
Benefit design/LIS	What if tier is $0 for an LIS enrollee? (e.g. a biosimilar on the preferred drug tier)	42 CFR § 423.782		
Benefit design/LIS	What if LIS enrollee is in the $0 cost-sharing benefit phase?	42 CFR § 423.782		
Benefit design/LIS	Will the de minimis premium policy for LIS be increased for 2020? This may be critical to avoid massive plan disruption for LIS enrollees.	42 CFR § 423.782		
Beneficiary design – different types of pharmacies	The rule discusses pharmacies only in general terms but the application of the rule to various kinds of pharmacies is complicated – LTC, mail order, specialty will have different applications and expectations.	42 CFR § 423.120 42 CFR § 423.124		
Beneficiary rights	How would CMS expect plans to apply tiering exceptions policies? Would the percentage price concession applied to the lower-tier drug be applied to the higher-tier drug’s price?	42 CFR § 423.578		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Beneficiary rights	How would CMS expect plans to apply formulary exceptions when approving a no price concession drug?	42 CFR § 423.578		
Beneficiary rights	What are beneficiary appeal rights, if any, regarding the amount of rebate they receive?	42 CFR § 423.566		
Beneficiary rights	How will CMS handle transition fills given the likelihood of significant formulary changes and enrollment changes for the first year this is in effect?	42 CFR § 423.120(b)(3)		
Bid process	If price concessions are negotiated at the plan sponsor level, rather than the plan benefit package level, how would CMS require them to be allocated in the bid?	42 CFR § 423.265		
Bid process	What is the timing for updating the Bid Pricing Tool to accommodate these changes to price concessions?	42 CFR § 423.265		
Bid process	How would CMS handle OOPC tool and Total Beneficiary Cost revisions?	42 CFR § 423.265		
Bid process	How will changes in Part D bid amounts be incorporated into MA-PD submissions?	42 CFR § 423.265 42 CFR § 422.254		
Bid process	Would CMS require other plan types (e.g. EGWPs) to follow its lead on the above topics?	42 CFR § 423.265		
Data reporting	Will there be changes to the PDE record? How will claims be reported where a rebate was provided?	Medicare Part D Reporting Requirements		
Data reporting	What is the effect on PDE data reporting procedures? Would the price concession be reported on the estimated rebate field?	Medicare Part D Reporting Requirements		
Data reporting	Since only plan sponsors have all the data to submit PDEs (and PDEs are the basis for the Coverage Gap Discount Program), how will PDEs be reported when wholesalers are involved?	Medicare Part D Reporting Requirements		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Data reporting	How are claims to be reported where a rebate was provided but the script was later determined not to be eligible for a rebate (e.g., due to 340B, denial, patient recoupment, duplicate claims)?	Medicare Part D Reporting Requirements		
Data reporting	How will these price concessions be reflected in DIR reports and how will CMS revise DIR reporting procedures to account for these price concessions? And, how will the reporting requirements be revised to account for the new requirements for PBM service fees?	42 CFR § 423.352; 42 CFR § 423.360		
Data reporting	Would existing NCPDP reporting mechanisms be able to accommodate these changes?	NCPDP Reporting Standards		
Data reporting	Would CMS need to create a manufacturer agreement since confidential data is being collected and reported?	42 CFR § 423.322		
Definitions	Will CMS adopt the same definitions as OIG? What is the definition of a rebated or discounted drug? How will the definition of 100% rebate at POS accommodate those drugs that are rebatable but are then subject to retroactive denial due to a range of reasons (e.g., due to 340B, patient recoupment, duplicative claims)? What is the definition of negotiated price for rebated drugs or discounted drugs? What is the definition of a chargeback?	42 CFR § 423.100; 42 CFR § 423.308		
Enrollee communications	What price is to be reported on Medicare Plan Finder (MPF)? How often will prices be required to be updated?	TBD		
Enrollee communications	What price is reported on the Explanation of Benefits (EOB)?	42 CFR § 423.128		
Enrollee communications	What price is to be reported on the forthcoming Real Time Benefit Tool (RTBT)?	TBD		
Enrollee communications	What changes will be required by CMS in terms of the language in the Evidence of Coverage (EOC) and model marketing materials?	42 CFR § 423.128		
Enrollee communications	Will enrollees be told the price concession amount at POS? What if a plan uses both rebates passed through at POS and discounts?	42 CFR § 423.128; 42 CFR § 423.132		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Enrollee communications	Would the plan Advanced Notice of Changes (ANOC) have to be revised for 2020 (and annually thereafter) to reflect changes in the rebate status?	42 CFR § 423.128		
Formulary structure	Will the CMS formulary review process change? If a plan has both rebated drugs and discounted drugs (in lieu of rebates) is that to be reflected in the formulary?	42 CFR § 423.272		
Formulary structure	Can rebated drugs be placed on their own tier? Will additional tiers be allowed to accommodate the new arrangements?	42 CFR § 423.104; 42 CFR § 423.272		
Formulary structure	If a manufacturer's price concession takes the form of alternative NDCs for existing products, how will CMS adopt formulary flexibility to allow for this?	TBD		
Formulary structure	If instead of rebates or discounts, a manufacturer provides the same drug but gives it a new NDC, or offers it as an authorized generic, or an authorized biosimilar, or some other alternative category, how is such option treated under the formulary? E.g., can a plan meet the two drugs per category/class by offering a rebated drug with POS pass-through and the same drug with a different NDC?	TBD		
Other Part D requirements – MLR	How will the significant new costs (e.g., to update systems, update contracts, staff call centers) be included for purposes of administrative costs for purposes of MLR compliance? In order to meet the targets, plans will have to collect significantly higher premiums and make larger than expected claims payments, driving up enrollee and taxpayer costs if there isn't an exception for these new costs.	42 CFR § 423.2420		
Other Part D requirements – MTM	How would the price concession or reduction be accounted for in the cost component of MTM? Might previously-qualified enrollees no longer qualify as they no longer meet the cost-threshold?	42 CFR § 423.153		

Category	Rulemaking or guidance needed	Citation	Is there a different approach if…	
			Rebates are passed through at POS	Discounts replace rebates
Other Part D requirements – prompt pay	Will payments to pharmacies still be subject to prompt pay? How will that work with regard to chargeback payments where CMS has no regulatory authority over wholesalers?	42 CFR § 423.520		
Other Part D requirements – star ratings	For appeals and exceptions, will CMS handle beneficiary complaints in such a way that plan quality ratings are not affected? (E.g., enrollee thinks rebate should be higher, but it isn't)	42 CFR § 423.186		
Other Part D requirements – transition fill	How will the price concessions or reductions be applied to transition fills?	42 CFR § 423.120		
Reconciliation	Use of projected price concessions on market share – what if not achieved?	42 CFR § 423.343		
Reconciliation	How will the price concessions be reported for purposes of reconciliation?	42 CFR § 423.343		
Reconciliation	Will CMS create a process to reconcile over- or under-payments of price concessions to enrollees?	42 CFR § 423.343		
Risk score model	When and how will CMS recalibrate the RxHCC model to reflect these changes? If there is meaningful selection bias (e.g., all Hep C beneficiaries enroll in the same plan), how will the model compensate for that?	42 CFR § 423.265		
Administrative burden	What of the above needs to go through PRA processes, notice-and-comment rulemaking versus guidance, or other formal mechanisms?	TBD		
Attestation	Plan sponsors are required to certify the accuracy, completeness and truthfulness of all data. Without complete, detailed and workable guidance on every facet of this undertaking, plan sponsors will not be able to make these certifications. CMS must provide an alternative good faith compliance approach as the standard one is not viable for the foreseeable future.	42 CFR § 423.265		

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Defendants.

Case No. 1:21-cv-00095-JDB

PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 00-00-00
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: January 19, 2021

TO: All Prescription Drug Plans, Medicare Advantage- Prescription Drug Plans, Section 1876 Cost Plans, Medicare-Medicaid Plans, and PACE plans

FROM: Amy Larrick Chavez-Valdez, Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Contract Year (CY) 2022 Final Part D Bidding Instructions

This guidance document contains information on the Part D program, and provides helpful instructions and reminders as Part D sponsors prepare to submit bids for CY 2022.

Formulary Submissions

CY 2022 Formulary Submission Windows

The CY 2022 HPMS formulary submission window will open this year on May 17, 2021 and close at 11:59 p.m. PDT on June 7, 2021. Consistent with 42 C.F.R. § 423.265(b), CMS must be in receipt of a successfully submitted and validated formulary submission by the deadline of June 7, 2021 in order for the formulary to be considered for review. The Part D formulary is part of the plan's complete bid and therefore a failure to submit and link a formulary to each plan that uses a formulary by the statutory deadline of the first Monday in June as required by section 1860D-11(b) of the Social Security Act (the Act), may result in denial of that bid submission (please refer to the section *Incomplete and Inaccurate Bid Submissions* in the CY 2020 Final Call Letter at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf). As a reminder, Program of All-Inclusive Care for the Elderly (PACE) organizations that intend to implement a formulary drug list or utilization management requirements for Part D drugs must also submit a formulary to CMS as outlined above. Following the review and approval of initial CY 2022 formulary submissions, a subsequent limited update window will be provided in August 2021. We do not expect sponsors to make significant enhancements or significant negative changes to existing formulary drugs during this window, since the formulary version that was initially submitted to CMS for review was considered in the bid and Part D benefits review. Details

regarding subsequent CY 2022 formulary submission windows will be contained in future HPMS memorandums.

CY 2022 Formulary Reference File

CMS will release the first CY 2022 FRF in March 2021. The March FRF release will be used in the production of the Bid Review Out-of-Pocket Cost (OOPC) model tool, scheduled to be released in April 2021, in order to assist plan sponsors in satisfying PDP meaningful difference requirements prior to bid submission. Sponsors should note that the Bid Review OOPC model released in April will not be modified to incorporate any subsequent FRF updates, as described below. CMS will update the CY 2022 FRF prior to the June 7 formulary submission deadline. Since the OOPC model incorporates Medicare Current Beneficiary Survey (MCBS) data from 2016 and 2017, new Part D drugs cannot be included in the Bid Review OOPC model since they would not have appeared in the survey. Further, given the limited timeframe between the May release of the CY 2022 FRF and the June 7 deadline, CMS is unable to accommodate an updated version of the 2022 OOPC model to incorporate the new generics that may be added to the May FRF. Therefore, CMS advises plan sponsors that any newly added drugs on the May release of the CY 2022 FRF will not be included in the 2022 Bid Review OOPC model.

Medication Therapy Management (MTM)

In the January 19, 2021, Federal Register, CMS published a final rule titled "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS-4190-F2)" (https://www.federalregister.gov/public-inspection/2021-00538/medicare-and-medicaid-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare) that implements changes to MTM programs for CY 2022 (January 2021 final rule). This rule changes the definition of "targeted beneficiaries" for the purposes of MTM programs to include at-risk beneficiaries in a drug management program (42 C.F.R. § 423.153(d)(2)(ii)), and requires sponsors to provide MTM enrollees with information on the safe disposal of controlled substances (42 C.F.R. § 423.153(d)(1)(vii)(E)).

A memo containing MTM program guidance and submission instructions for CY 2022 will be released in early April. The memo will be available on the CMS.gov MTM page at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html.

CY 2022 MTM Submissions and Attestations

Annually, sponsors submit an MTM program description to CMS through the HPMS for review and approval. CMS evaluates each program description to verify that it meets the current minimum requirements for the program year. These requirements do not apply to MA Private Fee for Service (MA-PFFS) organizations (see 42 C.F.R. § 423.153(e)) or PACE organizations. The requirements do apply to Employer Group Waiver Plans (EGWPs).

The CY 2022 HPMS MTM submission window will open this year on April 26, 2021 and close at 11:59 p.m. PDT on May 10, 2021. As such, the CY 2022 MTM program attestation deadline is May 24, 2021 at 11:59 p.m. PDT.

Annual Cost Threshold

Pursuant to 42 C.F.R. § 423.153(d), for 2012 and subsequent years, the annual cost threshold for targeting beneficiaries under 42 C.F.R. § 423.153(d)(2)(iii)(B) is specified as costs for covered Part D drugs in an amount greater than or equal to $3,000 increased by the annual percentage specified in 42 C.F.R. § 423.104(d)(5)(iv). The 2021 MTM program annual cost threshold is $4,376. The 2022 MTM program annual cost threshold will be the 2021 annual cost threshold adjusted based on the annual percentage increase of 7.31%, as specified in the CY 2022 Announcement of Medicare Advantage Capitation Rates and Part C and Part D Payment Policies. Therefore, the MTM Eligibility Threshold for CY 2022 is $4,696.

Part D Benefit Parameters for Non-Defined Standard Plans

Part D sponsors have the ability to offer Non-Defined Standard Plans under which they can modify certain benefit parameters, including tiered cost sharing. The CY 2022 Part D benefit parameters for Non-Defined Standard Plans are set forth in the table below, addressing three key areas: PDP meaningful difference, tiered cost sharing, and the specialty tier threshold. Pursuant to 42 C.F.R. § 423.272(b)(3)(i), CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package or plan cost structure is substantially different from those of other plan offerings by the sponsor in the service area, as defined under § 423.265(b)(2), with respect to key characteristics such as beneficiary out-of-pocket costs and formulary structures. Pursuant to § 423.104(d)(2)(iii), tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS to be discriminatory. CMS will use the values included in the chart below as part of our benefit and formulary review and negotiation of CY 2022 bids. CMS will scrutinize plan benefits that do not meet these parameters pursuant to our negotiation authority under 42 C.F.R. § 423.272(a).

Specialty Tiers

Part D sponsors may exempt formulary tiers in which it places very high-cost Part D drugs from its tiering exceptions process, consistent with 42 C.F.R. § 423.578(a)(6)(iii). In the January 2021 final rule CMS finalized allowing a second, preferred specialty tier beginning January 1, 2022 and several changes to the methodology and calculation of the specialty-tier cost threshold (see 42 C.F.R. § 423.104(d)(2)(iv)). Under the new policy, in order for a Part D sponsor to place a Part D drug on a specialty tier, a Part D drug's 30-day equivalent ingredient cost must exceed a dollar-per-month threshold established by CMS as set forth in the regulation. For CY 2022, the specialty-tier cost threshold is set at $830, as a 30-day equivalent ingredient cost. Consistent with § 423.104(d)(2)(iv)(D), CMS sets the maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing specialty tier, at 25% if the plan requires the standard deductible, 33% cost-sharing if no deductible is required, or some percentage in-between dependent on a decreased deductible. Therefore, for plans that offer two

specialty tiers, the cost sharing for the lower cost-sharing, preferred, specialty tier must be anything less than that of the higher cost-sharing, specialty tier.

Benefit Parameters for CY 2022 Threshold Values

Benefit Parameter	CY 2022 Threshold Values
Minimum Meaningful Differences (PDP Cost-Sharing OOPC)[1]	
Enhanced Alternative Plan vs. Basic Plan	$22
Maximum Copay: Pre-ICL and Additional Cost-Sharing Reductions in the Gap (3 or more tiers)	S [2,3]
Preferred Generic Tier	<$20 [4]
Generic Tier	$20
Preferred Brand/Brand Tier	$47
Non-Preferred Drug Tier	$100
Non-Preferred Brand Tier	$100
Injectable Tier	$100
Select Care/Diabetic Tiers[5]	$11
Vaccine Tier	$0
Maximum Coinsurance: Pre-ICL (3 or more tiers)	S [2,3]
Preferred Generic Tier	25%
Generic Tier	25%
Preferred Brand/Brand Tier	25%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable Tier	33%
Select Care/Diabetic Tiers[5]	15%
Vaccine Tier	0%
Maximum Coinsurance: Additional Cost-Sharing Reductions in the Gap for Applicable Beneficiaries (all tier designs)	S [6]
Preferred Generic Tier	15%
Generic Tier	15%
Preferred Brand/Brand Tier	50%
Non-Preferred Drug Tier	50%
Non-Preferred Brand Tier	50%
Injectable Tier	50%
Select Care/Diabetic Tiers[5]	50%
Vaccine Tier	0%
Minimum Specialty Tier Eligibility	
1-month supply at in-network retail pharmacy	$830

[1] CMS is currently working on technical enhancements to the OOPC model, but is mindful of a common stakeholder request for stability in the meaningful difference threshold. As such, the Enhanced Alternative Plan to Basic Plan meaningful difference minimum threshold will be maintained at the level from CY 2019.

[2] These thresholds are based on the 95th percentile of the CY 2020 Bid Data. As in previous years, we will also set similar thresholds for plans with atypical tiering structures, such as a two tier formulary.

[3] "S" in the above chart refers to "standard retail cost sharing" at a network pharmacy. Standard retail cost sharing (S) is cost sharing other than preferred retail cost sharing offered at a network pharmacy.
[4] There is no separate maximum cost-share threshold for the Preferred Generic tier. Cost sharing for the Preferred Generic tier that is lower than that for the cost sharing of the Generic tier will not be subject to additional scrutiny. Equivalent cost sharing for the Preferred Generic and Generic tiers will be accepted in the case when a sponsor buys down the cost sharing to $0 for both generic tiers.
5 The Select Care Drug and Select Diabetic Drug Tiers provide a meaningful benefit offering when they have low or $0 beneficiary cost sharing for drugs targeting specific conditions (e.g., $0 tier for drugs related to diabetes and/or smoking cessation). We continue to expect cost sharing for the Vaccine tier, or Select Care/Select Diabetes tiers that contain vaccines, to be $0.
[6] Additional gap cost-sharing reductions for applicable beneficiaries are communicated in the PBP at the tier level and sponsors may elect to provide this benefit for all drugs on a tier (full tier coverage) or a subset of drugs on a tier (partial tier coverage). If the additional gap cost-sharing reduction benefit for a brand labeled tier applies to only non-applicable (i.e., generic) drugs or both generic and applicable drugs on that tier, then the generic drug beneficiary coinsurance maximum of 15% applies. Injectable, Specialty, Select Care and Select Diabetic Drug labeled tiers for which additional gap coverage is offered, if any, will be analyzed in the same manner as brand labeled tiers with respect to beneficiary coinsurance maximums. Note, the beneficiary coinsurance maximums for the coverage gap reflect the plan liability, but exclude the 70% manufacturer discount for applicable drugs.

Improving Drug Utilization Review Controls in Medicare Part D

Opioid Safety Edits

For the most recent information regarding Part D opioid point-of-sale (POS) safety edit(s), see the HPMS memo, "*Contract Year (CY) 2021 Opioid Safety Edit Reminders and Recommendations*" released on November 4, 2020. Comprehensive guidance for sponsors and educational materials for providers, beneficiaries, and other partners (pharmacies, professional organizations, advocacy groups, etc.) is available on the Improving Drug Utilization Review Controls in Part D webpage: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html. CMS will continue to update this page, including the FAQs, to provide additional guidance as needed for CY 2022 and future years.

Drug Management Programs

The January 2021 final rule implements changes to Part D drug management programs (DMPs) for 2022. This rule requires all Part D plan sponsors to have a DMP by January 1, 2022 (consistent with section 1860D-4(c)(1)(F)), revises the criteria used to identify potential at-risk beneficiaries (42 C.F.R. § 423.153(f)(16)), and makes other technical changes to these programs (42 C.F.R. § 423.153(f)(15)(ii)(D); 42 C.F.R. § 423.100). Policy and technical guidance and FAQs for DMPs are available on the Improving Drug Utilization Review Controls in Part D webpage: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html. CMS will continue to update this page to provide additional guidance as needed for CY 2022 and future years.

Coordination of Benefits (COB) User Fee

Pursuant to Section 1860D-24(a)(3) of the Act and 42 C.F.R. § 423.464(c), CMS is authorized to impose user fees on Part D sponsors for the transmittal of information necessary for benefit coordination between sponsors and other entities providing prescription drug coverage. We review and update this user fee annually to reflect the costs associated with COB activities for the specific year. The 2022 COB user fee will be collected at a monthly rate of $ 0.1166 for the first 9 months of the coverage year for a total user fee of $1.05 per enrollee per year. Part D sponsors should account for this COB user fee when developing their 2022 bids.

Administrative Information

The policies described in this memo will be used in the evaluation of CY 2022 bids submitted by Part D sponsors in accordance with our negotiation authority under section1860D-11(d)(2) of the Act. Unless otherwise noted in this document or adopted in the January 2021 final rule, the guidance issued in the Final CY 2020 Call Letter applies for CY 2022 (see https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf). The following is a non-exhaustive list of CY 2020 Call Letter policies that apply for CY2022:

- Incomplete and Inaccurate Bid Submissions
- Plan Corrections
- Improving Access to Opioid-Reversal Agents
- Access to Medication-Assisted Treatment
- Part D PBP MRx Enhancements
- Benefit Review
- Tier Composition
- Improving Access to Part D Vaccines
- Improving Access to Generic and Biosimilar Medicines
- PDP Crosswalk Policy
- Low Enrollment Plans (Standalone PDPs only)
- PDP Non-Renewal Policy Clarifications
- Part D Mail Order Auto-Ship Modifications

We are applying the policies mentioned in this memo in the same manner for CY 2022 as they were applied in CY 2020. We therefore are not soliciting comments on these policies. Should CMS make any changes to the Benefit Parameters or Tier Thresholds for CY 2023 or beyond, such changes would be made in future rulemaking as necessary.

For questions related to Part D Benefits, please email PartDBenefits@cms.hhs.gov.
For questions related to Part D Policy, please email PartDPolicy@cms.hhs.gov.
For questions related to Part D Formularies, please email PartDFormularies@cms.hhs.gov.
For questions related to Part D MTM Programs, please email PartD_MTM@cms.hhs.gov.
For questions related to Part D opioid safety edits or drug management programs, please email PartD_OM@cms.hhs.gov.

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,

Defendants.

Case No. 1:21-cv-00095-JDB

PLAINTIFF'S MOTION FOR EXPEDITED DECISION

Plaintiff Pharmaceutical Care Management Association ("PCMA") moves for an expedited decision of its motion for partial summary judgment, filed contemporaneously herewith. *See* ECF No. 11. The motion for partial summary judgment challenges as arbitrary and capricious the effective date of the "Rebate Rule," a final rule issued by the Department of Health and Human Services Office of Inspector General ("HHS-OIG"). *See Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals*, 85 Fed. Reg. 76666 (Nov. 30, 2020). In light of the exigencies of the situation created by the effective date, as set forth below, PCMA respectfully requests a decision no later than March 1, 2021. *See* 28 U.S.C. § 1657(a) (a federal court "shall expedite the consideration of any action . . . if good cause therefore is shown").[1]

[1] Pursuant to Local Rule 7(m), PCMA attempted to confer with opposing counsel to discuss this motion; because no attorney for Defendants has entered an appearance, PCMA's counsel emailed the Acting General Counsel of HHS (Daniel J. Barry), three Deputy General Counsel of HHS (Lisa Barclay, Paul Rodriguez, and Sean Keveney), Senior Advisor to the General Counsel at HHS (Elizabeth Gianturco), U.S. Attorney's Office for the District of Columbia (Michael R. Sherwin), and Deputy Director of the Federal Programs Branch (Elizabeth Shapiro). PCMA did not receive a response as of this filing.

PCMA filed a Complaint on January 12, 2021, alleging that the Rebate Rule violates the Administrative Procedure Act because it exceeds HHS-OIG's statutory authority, was promulgated without observance of the APA's notice-and-comment-rulemaking requirement, and unreasonably departs from settled principles of agency decisionmaking. *See* ECF No. 1. The Rebate Rule transforms the way prescription drugs are priced and paid for in the Medicare Part D program. In the Part D program, private drug plan sponsors contract with the Centers for Medicare & Medicaid Services ("CMS"), an agency within HHS, to offer subsidized drug coverage on an annual basis. Part D plan sponsors typically employ pharmacy benefit managers ("PBMs")—whom PCMA represents as a national trade association—to administer their drug plans, including negotiate price concessions from drug manufacturers' list prices. These concessions are typically retrospective rebates paid by manufacturers to PBMs after the point of sale—rather than at the pharmacy counter—and have long been protected from liability by regulatory safe harbors. The Rebate Rule, however, removes the existing regulatory safe harbor and channels price concessions through a new point-of-sale safe harbor.

One particular aspect of the Rebate Rule presents an urgent timing problem for PBMs, and PCMA's motion for partial summary judgment and this motion for expedited decision focus on that issue: The effective date of January 1, 2022 for the revisions to the safe harbor with respect to Part D. *See* Rebate Rule, 85 Fed. Reg. at 76666. Although 2022 generally may not sound imminent, it *is* in the context of the lengthy and complex Part D planning process with respect to a coverage year for plan sponsors, PBMs, and enrollees. Plan sponsors must submit bids for a contract year by the first Monday in June of the *preceding* year to CMS in order to obtain approval to offer Part D plans for that contract year—here, that means that bids for contract year 2022, when the Rebate Rule will take effect, are due on June 7, 2021. 42 C.F.R. § 423.265. And the work

required to ready a bid for submission is a year-round cycle for plan sponsors, involving negotiations with manufacturers, plan designing, and subjecting bids to actuarial analyses—meaning that, here, plan sponsors and PBMs began this process for contract year 2022 last summer, before HHS-OIG even published the Rebate Rule, and are in the midst of that process now. *See* ECF No. 11-1 at 5-9, 29-30, 35-37. In addition, plan sponsors and PBMs formulate their bids based on regulations issued and guidance provided by CMS, which is still not available, because HHS-OIG apparently failed to coordinate with CMS on the practical implications of the Rebate Rule. *See id.* at 11-15, 20-22, 25-31. As explained in PCMA's motion, HHS-OIG's choice of effective date is arbitrary and capricious because HHS-OIG: (1) failed to account for the effective date's impact on the 2022 contract year; (2) failed to justify the implementation schedule it set; and (3) departed from prior agency practice without reason or explanation. *Id.* at 22-44.

PCMA limited its motion for partial summary judgment to the issue of the Rebate Rule's effective date, because of the chaos and confusion surrounding the Part D bid process for contract year 2022 caused by the effective date. *See* Fed. R. Civ. P. 56(b) ("[A] party may file a motion for summary judgment at any time until 30 days after the close of discovery."). Plan sponsors and PBMs need to know whether their forthcoming bids must comply with the unlawful Rebate Rule. Those bids have a looming June 7 deadline that cannot be moved, so plan sponsors and PBMs cannot wait for a resolution of the effective date issue in the ordinary course of litigation. Nor can plan sponsors and PBMs wait for an answer on the eve of their bid submissions. Plan sponsors and PBMs are working on their bids right now and, as explained in the partial motion for summary judgment filed contemporaneously herewith, there are concrete steps that plan sponsors need to take in March or earlier if they want to submit their bids by the June deadline and do so with any measure of accuracy. *See* ECF No. 11-1 at 5-9, 29-30, 35-37. Making matters worse, HHS-OIG

intentionally left unresolved a host of questions regarding the Rebate Rule's impact on the Part D bidding process, plan designs, benefit structure, and enrollee-facing materials. *Id.* at 11-15, 20-22. Only CMS can resolve those questions, and until plan sponsors and PBMs receive these determinations from CMS, they are adrift at sea as they try to develop their plan offerings for contract year 2022. But CMS cannot issue the necessary notice-and-comment regulations and guidance in time for PBMs and plan sponsors to account for them in June 2021 bids. *See id.* at 20-22, 25-27.

Because PBMs and plan sponsors need prompt resolution of the validity of the Rebate Rule's effective date, PCMA respectfully requests a decision no later than March 1, 2021. PCMA's proposed timing would allow briefing on the partial motion for summary judgment to proceed along the ordinary briefing schedule for motions. Under this Court's Local Rule 7(b), Defendants' response to PCMA's partial motion for summary judgment is due 14 days after filing of the motion, or **February 8, 2021**. And under this Court's Local Rule 7(d), PCMA's reply is due 7 days after Defendants serve their response, or **February 15, 2021**. PCMA stands ready to expedite this schedule, however, if the Court so desires, to accommodate the requested resolution date. PCMA has requested a hearing on its motion for partial summary judgment, *see* ECF No. 11, at 1, if it is possible and convenient for the Court to hold a hearing and preserve a March 1, 2021 decision date, but preserving the requested decision date is of paramount interest to PCMA.

For the foregoing reasons, PMCA's motion for expedited decision of its partial motion for summary judgment should be granted.

Dated: January 25, 2021

Respectfully submitted,

/s/ Helgi C. Walker

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of January, 2021, I caused a copy of the foregoing document to be served on all parties pursuant to Federal Rule of Civil Procedure 5(b)(2) by mailing the document via FedEx for next-day delivery to the following addresses.

United States Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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330 Independence Avenue, S.W.
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