

January 16, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

VIA ELECTRONIC FILING TO:
<http://www.regulations.gov>

Re: [CMS-4182-P] Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

Dear Ms. Verma:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to comment on proposed Contract Year 2019 Policy and Technical Changes to the Medicare Advantage Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (the proposed rule).¹ PhRMA is a voluntary association of research-based pharmaceutical and biotechnology companies devoted to inventing medicines to allow patients to lead longer, healthier, more productive lives. Consistent with that mission, PhRMA companies are committed to the continued success of the Medicare Prescription Drug Benefit Program (Part D).

Nearly 15 years following the enactment of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), Part D has succeeded beyond expectations, delivering affordable prescription drug coverage for more than 40 million seniors and disabled individuals at a lower cost to taxpayers than was originally anticipated. PhRMA has long supported Part D as the gold standard for government-sponsored health care programs.

Strong competition among private plans has fueled the Part D program's success. Multiple, competing plans work to keep costs low by negotiating rebates with biopharmaceutical companies to reduce the cost of Part D covered drugs—by as much as 30 percent to 70 percent for branded products.² While these savings are significant, PhRMA is increasingly concerned that the discounts offered on branded products are not extended to Part D beneficiaries, who are increasingly subject to coinsurance tied to an undiscounted price with no maximum out-of-pocket protection. For some beneficiaries, Part D coverage is

¹ 82 Fed. Reg. 56336, November 28, 2017

² QuintilesIMS Institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates, October 2016; Gronholt-Pederson J, Skydsgaard N, Neely J, Novo Nordisk Defends U.S. Diabetes Drug Pricing. *Reuters* November 4, 2016; Silverman E, What the "Shocking" Gilead Discounts on its Hepatitis C Drugs Will Mean, *Wall Street Journal*, February 4, 2015; Barrett P, Langreth R, The Crazy Math Behind Drug Prices: Intermediaries that Negotiate to Lower Prices May Cause Them To Increase Too, *Bloomberg Businessweek*, June 29, 2017.

no longer affordable notwithstanding the low and stable premiums. In the absence of change, the value of Part D coverage could continue to erode over time; as health plans negotiate more and larger rebates that are not shared with patients at the point-of-sale, those patients effectively bear a higher and higher percentage of the cost of their medicines. In other words, their coverage is worth less.

PhRMA strongly supports CMS's inclusion of a Request for Information (RFI) on approaches to re-balance the program by passing through some level of negotiated rebates to patients. We believe this single policy change could yield lower out-of-pocket costs immediately (upon taking effect) for millions of beneficiaries while also generating multi-billion dollar savings to the federal government over a ten year window.

We also support CMS' steps in this rule to enhance competition and improve patient choice by removing unnecessary barriers to plan innovation, like the meaningful differences policy for Medicare Advantage (MA) plans. Of course, plan flexibility needs to be counter-balanced by strong patient protections like non-discrimination requirements and related policies that ensure *all* beneficiaries can get access to a Medicare plan that covers the care they need, regardless of health status. As CMS moves forward on proposals to grant formulary flexibility to Part D and MA-Part D plans, we urge retention of the six protected classes policy, the transition fill policy, and notification requirements tied to formulary changes. We also encourage the agency to closely reexamine the current specialty tier policy, which may be complicating the benefit and yielding little—if any—protection for Part D beneficiaries at this time.

We look forward to engagement with CMS on a thoughtful evolution of the Medicare Part D program to ensure it meets the needs of beneficiaries, makes prudent use of federal dollars, continues to be an engine for innovation in health benefits design, care management, consumer engagement, and biopharmaceutical discovery.

Our detailed comments follow below.

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A.17: Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point-of-Sale [p. 56419]

Description: CMS is soliciting feedback on a potential future proposal to require Part D plan sponsors to pass through a minimum portion of manufacturer negotiated rebates and all pharmacy price concessions to beneficiaries at the point-of-sale. Currently, plan sponsors are allowed, but generally do not apply rebates and price concessions to lower the negotiated price of a drug at the point-of-sale. Rebates and price concessions not applied in this manner are instead reported to CMS at the end of the coverage year as direct and indirect remuneration (DIR). In describing its rationale for issuing this Request for Information, CMS notes the following:

- Plan sponsors and their pharmacy benefit managers (PBMs) are increasingly negotiating large price concessions from pharmaceutical manufacturers and network pharmacies. Between 2010

and 2015, price concessions—the majority of which are manufacturer rebates—received by plan sponsors and PBMs increased by nearly 24 percent per year, about twice as fast as total Part D gross drug costs.³

- At the time Part D was established, CMS believed plans would pass through a large portion of negotiated rebates and other price concessions directly to beneficiaries, and that setting a minimum threshold was unnecessary and might serve to undercut competitive market forces. Over time, however, CMS has observed that plan sponsors seldom pass through rebates or price concessions at the point-of-sale, preferring instead to apply them as DIR at the end of the coverage year.⁴
- When Part D plans fail to reflect manufacturer rebates and pharmacy price concessions in the price of a drug at the point-of-sale, beneficiaries end up paying a larger share of the drug’s cost. For many beneficiaries, this means higher overall out-of-pocket spending, even accounting for premium savings resulting from the growth in DIR. For millions of low income beneficiaries whose cost-sharing is subsidized by Medicare, these higher costs are borne by the government.⁵
- Analysis conducted by CMS indicates that the actual amount of DIR received in recent years by Part D plan sponsors and their PBMs has consistently exceeded the estimated amount of DIR plan sponsors include in their annual bids. CMS notes that when a plan sponsor receives more price concessions than originally estimated, “any DIR received that is above the projected amount factored into a plan’s bid contributes primarily to plan profits, not lower premiums.”⁶
- CMS has observed that plan sponsors have begun negotiating more high-rebate arrangements, which puts upward pressure on Part D program costs as plan sponsors shift costs to the government through higher low-income cost-sharing subsidies and higher reinsurance costs.⁷
- Variation in the treatment of rebates and pharmacy price concessions by plan sponsors may have a negative effect on the competitive balance of the Part D program. For example, a sponsor who applies price concessions as DIR at the end of the coverage year may be able to submit a lower bid than a competitor who applies price concessions at the point-of-sale, resulting in a competitive advantage for the former.⁸

³ 82 Fed. Reg. at 56419.

⁴ Id.

⁵ 82 Fed. Reg. at 56420.

⁶ Id.

⁷ 82 Fed. Reg. at 56420-56421.

⁸ 82 Fed. Reg. at 56421.

Comments:

PhRMA strongly believes that beneficiaries should directly benefit from the significant price negotiations taking place in the Part D market today and we commend the agency for issuing this Request for Information (RFI) on sharing savings from negotiated rebates directly with patients at the point-of-sale. Echoing many of the themes CMS raises in the RFI, PhRMA believes that requiring a minimum portion of manufacturer rebates to be passed through at the point-of-sale would improve affordability for patients, better align stakeholder incentives, and make the successful Part D program work even better for millions of seniors and disabled beneficiaries.

1. Part D Plan Sponsors Often Negotiate Substantial Rebates, but the Savings Aren't Always Used to Lower Beneficiary and Government Costs

The Medicare Part D program has succeeded beyond expectations in providing affordable prescription drug coverage for more than 42 million seniors and disabled individuals, at a far lower cost than anticipated.⁹ The program's success is due to strong competition among private health plans that work to keep costs low and negotiate with pharmaceutical manufacturers for savings. The Medicare Trustees report that rebates for many brand medicines are "substantial"¹⁰ and that average rebate levels have increased in each year of the program.¹¹ According to a study by QuintilesIMS, Part D plans negotiate an average 35.3 percent rebate for brand medicines across 12 widely-used therapeutic classes,¹² with other sources noting that rebates can be as high as 70 percent.¹³

Current guidance allows Part D plan sponsors to reflect the savings from negotiated rebates in one of two ways: either by directly reducing the cost of the medicine that generated the rebate at the time a prescription is dispensed, or by applying aggregate rebate savings as DIR at the end of the year to reduce overall plan liability and lower premiums for all enrollees. At the time Part D was implemented, CMS believed plan sponsors would pass through a large portion of negotiated rebates directly at the point-of-sale, thereby lowering costs for beneficiaries filling prescriptions for the medicines that generated those rebates; however, the agency has observed that plans seldom pass through rebates in this manner.¹⁴ Instead, plan sponsors typically apply rebates in aggregate as DIR at the end of the year to lower premiums

⁹ 2017 Medicare Trustees Report, p. 141.

¹⁰ 2017 Medicare Trustees Report, p. 147, footnote 66.

¹¹ 2017 Medicare Trustees Report, p. 147, Table IV. B8; and Medicare Trustees Reports for 2007 through 2016.

¹² QuintilesIMS Institute, "Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates," October 2016.

¹³ *Id.*; Gronholt-Pedersen J, Skydsgaard N, Neely J. Novo Nordisk Defends U.S. Diabetes Drug Pricing. *Reuters*. November 4, 2016. <http://www.reuters.com/article/us-novo-nordisk-prices-idUSKBN12Z184>; Silverman E. What the 'Shocking' Gilead Discounts on its Hepatitis C Drugs Will Mean. *Wall Street Journal*. February 4, 2015.

<https://blogs.wsj.com/pharmalot/2015/02/04/what-the-shocking-gilead-discounts-on-its-hepatitis-c-drugs-will-mean/>

Barrett P, Langreth R. The Crazy Math Behind Drug Prices: Intermediaries that Negotiate to Lower Prices May Cause Them To Increase Too. *Bloomberg Businessweek*, June 29, 2017. <https://www.bloomberg.com/news/articles/2017-06-29/the-crazy-math-behind-drug-prices/>

¹⁴ 82 Fed. Reg. at 56419.

and reduce the government's subsidies of those premiums, rather than using rebate savings to directly lower costs for patients facing high cost-sharing at the pharmacy.

Millions of beneficiaries face higher out-of-pocket costs when plan sponsors do not pass on rebates at the point-of-sale, even when savings from lower premiums are factored in. This is especially true for beneficiaries with deductibles or coinsurance, whose prescription drug cost-sharing is based on an undiscounted price that does not take rebate savings for their medicine into account. According to one actuarial firm, the failure of plan sponsors to pass along a portion of the rebate at the point-of-sale has led to a system of "reverse insurance," whereby plan sponsors require patients with high drug expenditures to pay more out-of-pocket, while rebate savings are spread out among all beneficiaries in the form of lower premiums.¹⁵ In effect, chronically ill Medicare patients with high drug costs end up subsidizing premiums for healthier enrollees, which is contrary to how health insurance is supposed to work.

While applying aggregate rebate savings at the end of the year allows a plan sponsor to lower premiums, both CMS and the Medicare Payment Advisory Commission (MedPAC) have raised questions about the incentives created by this practice. For example, CMS has observed that Part D plan sponsor bids do not always reflect accurate DIR estimates and the actual amount of DIR collected by Part D plan sponsors and PBMs has consistently exceeded the amount of projected DIR submitted during the bid process. The agency also expresses concern that Part D rules provide plan sponsors with incentives to steer utilization toward medicines with high rebates and "weak incentives, and in some cases even, no incentive, to lower prices at the point-of-sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available."¹⁶

These observations suggest that the current Part D rules regarding the treatment of DIR may not always provide plan sponsors with strong incentives to negotiate the lowest cost treatment options for beneficiaries or the Medicare program. CMS should require Part D plans to pass through a portion of negotiated rebates at the point-of-sale to reduce out-of-pocket costs at the pharmacy for millions of beneficiaries, lower government cost-sharing subsidies and reinsurance payments, and strengthen the program's competitive incentives.

2. Applying Negotiated Rebates at the Point-of-Sale Could Generate Up to \$73B in Federal Government Savings Over 10 Years

As discussed in more detail below, the financial impact of potentially applying a portion of negotiated rebates directly at the point-of-sale involves several offsetting components. In the proposed rule, CMS projects this policy change (absent behavioral impacts) could result in a 10-year overall net increase in federal government costs, primarily resulting from increased direct subsidies and increased low-income premium subsidies.¹⁷ Analysis by the actuarial firm Milliman suggests that taking into account behavioral

¹⁵ Girod CS, Hart SK, Weltz S. 2017 Milliman Medical Index. May 2017.

<http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf>

¹⁶ *Id.*

¹⁷ 82 Fed. Reg. at 56425.

changes, although government costs would likely increase in the first year of implementation, over a 10-year period, a rebate pass through policy could generate net savings for the federal government of up to \$73B.¹⁸

Estimated Cost Impacts During the First Year of Implementation

Table 1 shows the expected impacts of a rebate pass through policy on beneficiary and government costs in the first year of implementation (the analysis assumes an implementation date of 2017). In year one, Milliman estimates that passing through 50 percent of manufacturer rebates and 100 percent of pharmacy price concessions at the point-of-sale¹⁹ would increase government costs by 1 percent and decrease total beneficiary out-of-pocket costs by 2 percent. The policy change results in a redistribution of government spending, with higher direct subsidy payments to cover all beneficiaries and lower reinsurance costs for the smaller portion of high-cost beneficiaries.

Table 1: Estimated 2017 Per Member Per Month Impact of Moving 50% of Rebates and 100% of Pharmacy Price Concessions to Point-of-Sale (POS)

Scenario	Beneficiary Costs			Government Costs				Total Costs
	Cost-Sharing ¹	Premium ¹	Total Costs	Federal Reinsurance	NADS ²	LICS ³	LIPS ⁴	
2017 National Average Bid (Baseline)	\$40.95	\$23.63	\$64.58	\$78.65	\$25.45	\$49.28	\$12.00	\$165.38
Rebates / Price Concessions at POS	\$38.79	\$24.70	\$63.49	\$70.97	\$37.85	\$45.84	\$12.55	\$167.21
Percent Change	-5.3%	4.5%	-1.7%	-9.8%	48.7%	-7.0%	4.5%	1.1%

¹ Excludes government subsidies for low-income beneficiaries. Beneficiary cost-sharing also excludes Coverage Gap Discount Program payments.

² National Average Direct Subsidy

³ Low-Income Cost-Sharing Subsidy

⁴ Low-Income Premium Subsidy

Assuming no immediate behavioral impact or any other changes to the Part D program, Milliman expects that a rebate pass through policy would affect beneficiary and government costs as follows:

- **Beneficiaries:** Average total out-of-pocket spending (including cost-sharing and premium payments) for non-low-income beneficiaries would decrease due to a reduction in cost-sharing, partially offset by a small increase in the national average member premium. In particular, non-low-income beneficiaries with spending at or above the initial coverage limit would benefit the most, while members with low utilization could see their overall costs rise slightly due to a premium increase. Reductions in patients' out-of-pocket costs would vary depending on benefit design and the mix of medications taken, but savings from negotiated rebates would more closely align with beneficiaries taking rebated medications.

¹⁸ Milliman. Reducing Part D Beneficiary Costs Through Point-of-Sale Rebates. January 2018, available at <http://www.phrma.org/report/reducing-part-d-beneficiary-costs-through-point-of-sale-rebates>

¹⁹ These pass through percentages are consistent with the proposal in the RFI, which discussed passing through a portion of manufacturer rebates and all pharmacy price concessions.

- Federal government: There are several components of government cost, each with varying impacts:
 - Federal reinsurance is expected to decrease, as fewer beneficiaries will reach catastrophic coverage due to lower spending
 - The direct subsidy is expected to increase as plan sponsors cover a greater proportion of claims costs for members, resulting in an increase in Part D plan bids
 - Low-income cost sharing subsidies (LICS) are expected to decline, correlating to reductions in overall beneficiary cost-sharing
 - Low-income premium subsidies (LIPS) are expected to increase proportionally with the increase in member premiums

Estimated 10-Year Cost Impacts

Table 1 shows the expected first-year impact of moving rebates and pharmacy price concessions to the point-of-sale. However, when considered over a longer period of time, this policy change is likely to impact stakeholder costs differently. The cost estimates in Table 1, as well as the 10-year cost estimates CMS presents in the RFI, assume no behavioral changes by Part D stakeholders in response to passing through rebates at the point-of-sale. As CMS notes, “[w]hile we did not account for behavioral changes when modeling these impacts, requiring rebates to be applied at the point-of-sale might induce changes in sponsor behavior related to drug pricing that would further reduce the cost of the Part D program for beneficiaries and taxpayers.”²⁰ According to Milliman, these potential behavioral changes, discussed in more detail below, would likely generate net savings for both beneficiaries and the federal government over a 10-year period. While several of these changes would likely lower costs for plan sponsors, PhRMA notes that they could also prevent beneficiaries from accessing the medicines they need. Accordingly, we would urge CMS to maintain rigorous oversight of appropriate coverage and formulary standards.

Behavioral changes by plan sponsors

- *Adopt lowest cost medication strategies*. If a portion of rebates were shifted to the point-of-sale, plan sponsors would likely focus on targeting medications with the lowest net costs. Formularies would shift to target increased utilization of generic and lower-cost brand medications. This change in formulary strategy could result in overall lower spending for all stakeholders and offset some of the increase in government costs expected to occur absent behavioral changes. To achieve lower net costs, plan sponsors may also place even further pressure on manufacturers and pharmacies to negotiate higher rebates and price concessions.

²⁰ 82 Fed. Reg. at 56425.

- *Increased formulary and utilization management techniques.* Beyond the strategy of favoring medications with the lowest net costs, plan sponsors may also react by narrowing their formularies or implementing more stringent utilization management criteria, such as prior authorization and step therapy.
- *Changes to benefit design.* If rebates were moved to the point-of-sale, beneficiaries would move through the Part D benefit more slowly, and more people would spend most of the year in the initial coverage limit (ICL), where plan liability is highest. This could cause plan sponsors to implement more rigorous benefit design strategies, such as increasing the cost-sharing differential between preferred and non-preferred medications, and covering more Tier 1 products at \$0 cost-sharing.

Behavioral changes by beneficiaries

- *Increased medication adherence.* Beneficiaries may become more adherent to medications due to lower cost-sharing. For example, a beneficiary who might have otherwise stopped taking a medication upon reaching the coverage gap may no longer reach the gap, making it easier for her to continue paying for the medication at a lower cost-sharing level.
- *Reduced utilization of physician and hospital care.* Increases in medication adherence are likely to generate offsetting decreases in Medicare Part A and Part B spending, due to better management of chronic disease. According to CBO, every 1 percent increase in the utilization of prescription medicines decreases Medicare spending in Parts A and B by 0.20 percent.²¹ Savings from medical offsets are not built-in to Milliman's projections, but would likely further decrease government costs over the 10-year period.

Behavioral changes by pharmaceutical manufacturers

- Pharmaceutical manufacturers may see increased pressure from plan sponsors during contracting negotiations due to a shift in plans' formulary strategies and increased emphasis on covering medicines with the lowest point-of-sale costs. Milliman expects that manufacturers may need to negotiate deeper rebates when negotiating with Part D plan sponsors.²² Other potential changes noted by Milliman—including narrower formularies, increased use of utilization management, and stronger plan sponsor incentives to pursue lower-cost medicines, among others—are likely to increase costs to the pharmaceutical industry, offsetting any potential reductions in manufacturer coverage gap liability.

The long-term impacts of a pass through policy are sensitive to assumptions about how costs and rebates are expected to grow over time and how stakeholder behaviors are altered in reaction to the

²¹ Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012. Available at: <https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>

²² Milliman. Reducing Part D Beneficiary Costs Through Point-of-Sale Rebates. January 2018, available at <http://www.phrma.org/report/reducing-part-d-beneficiary-costs-through-point-of-sale-rebates>

change. To account for behavioral changes resulting from passing through a portion of rebates at the point-of-sale, Milliman estimated the 10-year impact to beneficiary and government costs using three different sets of assumptions:

- **No behavior change:** Manufacturer rebates and plan formulary strategies do not change in response to a pass through policy.
- **Modest market response:** In response to plan contracting changes, rebates grow gradually over time and become a greater proportion of total drug costs as pharmaceutical manufacturers compete to maintain formulary access.
- **Strong market response:** In addition to assuming rebates grow modestly over time, this scenario also assumes that plan sponsors more strongly focus on formulary management, resulting in a gradual increase in the generic dispensing rate of 0.5 percent every year for four years, beginning in 2019.

As shown in Table 2, accounting for behavioral changes, passing through 50 percent of rebates and 100 percent of pharmacy price concessions at the point-of-sale could save beneficiaries an estimated \$8B to \$28B and could save the federal government an estimated \$8B to \$73B over a 10-year period.²³ Although government costs and beneficiary premiums are expected to increase in the absence of any behavioral shift, if plan sponsors are able to make even modest contracting and formulary changes, both government costs and premiums are projected to decrease.

Table 2: Estimated 2017-2026 Impact of Moving 50% of Rebates and 100% of Pharmacy Price Concession to the Point-of-Sale (POS), Including Additional Behavioral Impacts

	Total Costs (\$B)			% Change ¹		
	No Behavior Change	Modest Market Response	Strong Market Response	No Behavior Change	Modest Market Response	Strong Market Response
Beneficiary Costs	-\$4.1	-\$7.7	-\$27.7	-0.9%	-1.8%	-6.4%
Cost-Sharing	-\$12.5	-\$13.9	-\$24.8	-4.8%	-5.3%	-9.6%
Premium	\$8.4	\$6.1	-\$2.9	4.8%	3.5%	-1.6%
Government Costs	\$5.8	-\$8.4	-\$72.8	0.5%	-0.7%	-6.0%
NADS ²	\$81.6	\$80.4	\$58.5	58.0%	57.1%	41.6%
Federal Reinsurance	-\$44.4	-\$53.3	-\$71.1	-7.0%	-8.4%	-11.2%
LICS ³	-\$35.6	-\$38.6	-\$58.7	-10.0%	-10.8%	-16.5%
LIPS ⁴	\$4.3	\$3.1	-\$1.5	4.8%	3.5%	-1.6%

¹ Percent change relative to baseline projections without rebates or price concessions passed through at POS

² National average direct subsidy

³ Low-income cost-sharing subsidy

⁴ Low-income premium subsidy

²³ Id.

Absent any market response, Milliman projects that total government costs would increase by \$5.8B, or about \$1.00 per member per month, over a 10-year period. However, when anticipated behavioral changes are accounted for, a rebate pass through policy is likely to generate net savings for the federal government. Under both of Milliman's behavioral change assumptions, government costs are expected to increase in the years immediately following implementation, but the cumulative government impact quickly turns to net savings. Assuming plan sponsors more strongly focus on formulary management, the turn to savings occurs in year three; assuming only modest rebate growth, the turn to savings occurs in year five.

Milliman's estimates of the federal government savings that could result from potential behavior changes do not account for additional savings likely to accrue to Medicare Parts A and B due to improved medication adherence. Reducing cost-sharing for medications plays an important role in improving adherence and there is clear evidence that improved use of prescription medication can reduce Medicare spending on non-prescription drug services and promote better patient outcomes, particularly for patients with chronic conditions.²⁴ For example, adherence to diabetes medicines is associated with per beneficiary savings of nearly \$5000 in medical spending and \$4000 in total Medicare spending for certain therapeutic areas over two years, yet only around half of Part D beneficiaries with diabetes currently exhibit good medication adherence.²⁵ Other research shows that among the half of Part D beneficiaries adherent to their therapy for the treatment of the symptoms of Parkinson's Disease, beneficiaries experienced 14 percent lower risk of hospitalization, 33 percent lower risk of skilled nursing facility episodes, 17 percent lower risk of home health agency episodes, and over \$2200 in reduced health care expenditures over 19 months.²⁶ As beneficiaries become more adherent to medicines due to lower cost-sharing at the point-of-sale, savings from medical offsets would likely result in additional savings for the federal government over the 10-year period.

3. The Methodology to Implement Rebate Pass Through Must Be Designed to Protect Commercially-Sensitive Data and Preserve Incentives for Competition

To sustain market incentives and avoid undermining the competitive structure of Medicare Part D, it is critically important that any potential methodology for rebate pass through considered by CMS achieve the intended goals in a manner that promotes vigorous competition by avoiding the disclosure of commercially-sensitive data and preventing the cross-subsidization of competing products in a therapeutic class. To the extent possible, the methodology should also promote predictability in beneficiary cost sharing and minimize the burden of reporting, compliance and oversight for plan sponsors, manufacturers, and CMS.

²⁴ Congressional Budget Office. Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. November 2012. Available at: <https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf>

²⁵ Stuart, BC, Dai, M, Xu, J, Loh, FH, Dougherty, SJ. Does Good Medication Adherence Really Save Payers Money? *Medical Care*. 2015;53(6):517-523.

²⁶ Wei, YJ, Palumbo, FB, Simoni-Wastila, L, et al. Antiparkinson Drug Adherence and Its Association With Health Care Utilization and Economic Outcomes in a Medicare Part D Population. *Value in Health*. 2014;17(2):196-204.

Protect Confidentiality of Commercially-Sensitive Data

It is essential that CMS continue protecting commercially sensitive drug cost data (including “data on bids, rebates and other price concessions”),²⁷ as provided for in the Trade Secrets Act (18 U.S.C. § 1905) and SSA § 1860D-15. In fact, the Part D statute explicitly restricts the use and disclosure of any information that Part D plans furnish to CMS for payment purposes, which includes data on manufacturer rebates to plans. This protection extends not only to the amount of manufacturer rebates, but also to competitive strategies such as the extent to which manufacturers and PBMs and plans do or do not negotiate certain rebates. CMS recently went through a full notice-and-comment rulemaking process in which it finalized a proposal to release certain Part C bidding data and specifically excluded any Part D data elements contained in the Part C data, explaining that: “[S]ection 1860D-15(f) of the Act contains protections for data submitted by Part D sponsors in accordance with Section 1860D-15; these protections would generally prohibit public release of such data.”²⁸

Both the Federal Trade Commission (FTC) and CBO have concluded that disclosure of commercially-sensitive drug pricing data would undermine the competitive negotiations between plan sponsors and manufacturers, which could result in higher costs for prescription medicines. According to the FTC, requiring disclosure of negotiated price information can “undercut vigorous competition on drug pricing”²⁹ and “undermine competition ... between pharmaceutical manufacturers to offer discounts,” which could “raise prescription drug prices for consumers.”³⁰ CBO has stated that “the revelation of [manufacturers’] rebates to PDPs would create pressure to reduce those rebates, which would tend to increase costs for both the Medicare program and, on average, for enrollees.”³¹

Avoid Cross-Subsidization of Competing Medicines to Preserve Incentives for Market-Based Competition

CMS proposes requiring plans to pass through a portion of the cost-weighted average rebate amount calculated at the therapeutic class or category-level.³² PhRMA believes the proposed rebate pass through methodology described in the RFI will not achieve the objective of realigning market incentives, and strongly urges CMS to consider an alternative approach to implement pass through of rebates at the point-of-sale. PhRMA supports approaches to pass through rebates for specific products (structured to preserve confidentiality), and opposes use of a method that would rely on class or category-level averages.

While we appreciate that CMS has put forth this approach in an effort to preserve the confidentiality of commercially-sensitive data, we are concerned that passing through average rebates at the level of the

²⁷ 79 Fed. Reg. 1918, at 1989.

²⁸ 81 Fed. Reg. 46162, 46400.

²⁹ FTC Letter to Terry G. Kilgore, Member, Virginia House of Delegates, re: H.B. 945 (Oct. 2, 2006); FTC Letter to Representative Patrick McHenry, re: North Carolina Bill 1374 (July 15, 2005); FTC Letter to California Assembly Member Greg Aghazarian, re: AB 1960 (Sept. 7, 2004).

³⁰ FTC Letter to The Honorable Mark Formby, Mississippi House of Representatives, re: SB 2445 (March 22, 2011). See also J. Shepherd, “Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market,” *Cornell Law Review Online*. 2013; 99(1):1-22:

³¹ Letter from CBO to Congressman Barton and Congressman McCrery (Mar. 12, 2007).

³² 82 Fed. Reg. at 56421.

therapeutic class could result in the cross-subsidization of competing medicines, potentially undermining the incentives for manufacturers to continue negotiating competitive rebates and reducing the total rebate dollars received by Part D plan sponsors.

Actuaries at Milliman have concluded that a therapeutic class-level rebate that spreads rebates across multiple products would likely inhibit competition among pharmaceutical manufacturers. Milliman notes that allowing one manufacturer's rebates to be used to partially "buy down" the negotiated prices of competing products may reduce manufacturers' incentives to provide large rebates, knowing that the value is being shared with competitors in such a way as to potentially reduce their own market share.³³ Such action could reduce competition for rebates in Part D and could lead to fewer total rebate dollars received by Part D plan sponsors and PBMs.

CMS already recognizes that the cross-subsidization of competing products has the potential to harm Part D's existing competitive incentives, as evidenced by its proposal that the average rebate amount across a therapeutic class should be calculated using only drugs for which the plan sponsor has negotiated a rebate. Indeed, CMS notes that "including non-rebated drugs in this calculation would serve only to drive down the average manufacturer rebates."³⁴ CMS also observes that if one manufacturer does not offer a rebate for a medicine in a particular therapeutic class, but other manufacturers of competing medicines in that class do, requiring pass through of the average rebate amount across the entire therapeutic class would allow the first manufacturer to unfairly benefit from the rebates negotiated by its direct competitors. Actuaries have concluded that this same logic applies when competing products in a therapeutic class have differential rebate levels, since pass through of an average rebate would still allow the manufacturer of a lower rebated product to unfairly benefit from the rebates offered by its direct competitors.³⁵

Alternative Methodologies Based on Product-Level Rebates May Protect Confidentiality While Minimizing Administrative Burden

Rather than passing through rebates at the level of the therapeutic class, PhRMA urges CMS to consider alternative methodologies that would allow rebates to be passed through at the product-level, while still preserving the confidentiality of commercially-sensitive data. One alternative approach would be to allow the point-of-sale negotiated price to reflect the minimum of two or more different pass through calculations. Structuring the amount of the rebate to be passed through as a function of two or more mathematical scenarios diminishes the likelihood of a competitor or other stakeholder being able to reverse engineer the net price of a medicine. The rebate amount is not transparent to external parties because neither the calculation used to determine the negotiated price nor the actual pass through percentage would be known. To illustrate, consider the following two formulas for determining the amount of the rebate to be passed through:

³³ Milliman analysis for PhRMA. Point of Sale Rebates: Policy Scenario Analysis in the Medicare Part D Market. January 2018.

³⁴ 82 Fed. Reg. at 56422.

³⁵ Milliman analysis for PhRMA. Point of Sale Rebates: Policy Scenario Analysis in the Medicare Part D Market. January 2018.

1. A minimum percentage of the rebate is applied to reduce the negotiated price at the point-of-sale (with the plan sponsor able to pass through a higher percentage)
2. The negotiated price is no more than 25 percent above the net price paid by the plan sponsor

Using this multi-formula approach, the calculation resulting in the lowest net price would dictate the amount of the rebate passed through to the beneficiary at the point-of-sale. To illustrate continued protection of proprietary data associated with this approach, assume a medicine has a list price of \$500 and the negotiated price available to beneficiaries at the point-of-sale is \$375. In this instance:

- The rebate could be 25 percent, with the plan sponsor passing through the entire \$125 rebate under formula one or two³⁶
- OR the rebate could be 29.5 percent, with the plan sponsor passing through 85 percent of the rebate. In this case, formula one is triggered because it results in a lower negotiated price than formula two (\$375 vs. \$441)
- OR the rebate could be 33.3 percent, with the plan sponsor passing through 75 percent of the rebate. In this case, formula one is triggered because it results in a lower negotiated price than formula two (\$375 vs. \$417)
- OR the rebate could be 40 percent, with the plan sponsor passing through 51 percent of the rebate. In this case formula two is triggered because it results in a lower negotiated price than formula one (\$375 vs. \$398)

A multi-formula approach to determining the amount of the rebate passed through at the point-of-sale could be an effective way to protect the confidentiality of commercially-sensitive data, while avoiding the cross-subsidization inherent in a therapeutic class-level approach. In the hypothetical example above, using the minimum of two different pass through calculations makes it unlikely that competitors or others would be able to determine the actual amount of the rebate, even though the list price and the point-of-sale

³⁶ In these examples, we are making a simplifying assumption that before a percentage of rebates are subtracted the “negotiated price” of a drug approximates its list price. The current negotiated price definition is actually more complicated than that, as it starts with the total payment for the drug agreed upon between the plan (or its PBM) and the dispensing pharmacy (taking into account certain pharmacy price concessions) and then adds the dispensing fee. Specifically, 42 C.F.R. § 423.100 currently provides that negotiated prices are prices that:

- (1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug.
- (2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale; and
- (3) Include any dispensing fees; but
- (4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale [and].
- (5) Must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.

negotiated price are publicly known. The addition of a third or fourth calculation to this multi-formula approach would be preferable, as it would further reduce the likelihood that commercially-sensitive data could be accurately reversed engineered.

Negotiating pass through amounts in excess of the minimum-required percentage also helps to protect confidentiality, although this protection becomes less effective as the minimum required pass through percentage increases. To preserve confidentiality and allow room for negotiation, PhRMA suggests that CMS consider setting the minimum pass through requirement at a level meaningfully less than 100 percent.

A product-level multi-formula approach would also be less burdensome for CMS and plan sponsors to administer than the cost-weighted therapeutic-class average approach described in the proposed rule. Because it just requires the determination of the lesser of two or more mathematically straightforward calculations, the product-level multi-formula approach avoids many of the complexities inherent in a therapeutic class approach, such as identifying the appropriate drug classification system and developing a complex cost-weighting scheme that would require continual updating as often as quarterly or monthly. In contrast, a product-level multi-formula approach would allow point-of-sale rebate amounts to be determined by plan sponsors annually following contract negotiations with manufacturers, based on the expected rebate for each medicine with a unique 11-digit national drug code (NDC), and submitted along with the plan sponsor's submission to CMS.

With respect to the frequency of a reporting process to determine the amount of rebate to be passed through, CMS should consider the potential not only to create more administrative burden for all stakeholders, but also to create confusion for beneficiaries. Beneficiaries use the cost-sharing amounts shown in plan sponsor materials or posted on the Medicare Plan Finder to help them select and compare plans. To avoid undermining the usefulness of cost-sharing information posted on Medicare Plan Finder, we recommend that the methodology chosen minimize changes to cost-sharing amounts over the course of year to the extent possible.

To the extent that rebate agreements are structured with contingencies that would be unclear at the point-of-sale, plan sponsors could base the point-of-sale rebate amount on a good faith estimate of the rebate expected to be received, similar to how plan sponsors currently factor estimated rebates into their Part D bids.³⁷ As suggested in the proposed rule, if CMS were to move forward with a point-of-sale rebate policy, Part D plan sponsors would be best positioned to calculate the appropriate point-of-sale rebate amount, with CMS leveraging existing prescription drug event (PDE) and DIR report data to review and selectively audit sponsors' calculations. We support CMS's proposal to add a new requirement for the plan sponsor's CEO, CFO, or COO to attest to the accuracy, completeness, and truthfulness of pass through rebate data, which will encourage additional oversight and compliance.

Methodology Must Clearly Define Rebates to be Passed Through at Point-of-Sale

³⁷ Centers for Medicare & Medicaid Services. Final Medicare Part D DIR Reporting Requirements for 2016. June 23, 2016.

Because rebates commonly have multiple components, another important issue for CMS to consider in developing a pass through requirement is the type(s) of rebates to which the requirement would apply. Rebates commonly consist of a base rebate (typically associated with preferred formulary placement or with reaching a certain percentage of market share), as well as a price protection rebate (which requires manufacturers to pay additional rebates if list prices increase by more than a pre-determined threshold).³⁸ Manufacturers may also pay bona fide service fees, which are not considered by Part D guidance to be price concessions and are not reported as DIR.³⁹ In the commercial market, some plan sponsors have reported that their PBMs do not always pass through price protection rebates, or do not pass them through in full.⁴⁰ One benefits consultant has also observed that in contracts with plan sponsors, PBMs are increasingly changing the contractual definition of rebates to exclude certain administrative fees, allowing the PBM to retain these payments rather than passing them back to the plan sponsor.⁴¹ If CMS's intent is for a portion of all manufacturer-negotiated rebates to be passed through to patients at the point-of-sale, the agency should implement safeguards to prevent PBMs and plan sponsors from reclassifying, redefining, or carving out rebates to avoid the pass through requirement. We recommend that CMS review its DIR reporting requirements and associated guidance to make sure that the delineation between DIR and fees is as clear as possible, so there is no ambiguity as to how to calculate point-of-sale prices or inconsistency of application across PBMs and plan sponsors.

4. CMS Has the Authority to Implement a Policy Requiring a Minimum Pass Through

We note also that CMS has clear statutory authority to establish a point-of-sale rebate policy with a minimum pass through requirement. The statute provides that Part D plans “shall provide enrollees with access to negotiated prices used for payment for covered part D drugs” and “negotiated prices shall take into account negotiated price concessions such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs.”⁴² The statute's use of “shall” makes clear that these price concessions must be taken into account in determining negotiated prices, and the mandatory

³⁸ Milliman analysis for PhRMA. Point of Sale Rebates: Policy Scenario Analysis in the Medicare Part D Market. January 2018.

³⁹ Bona fide service fees are payments for services that do not exceed the fair market value of the services (and meet additional criteria CMS has established for a bona fide service fee). CMS' DIR guidance does not specifically define “rebate administration” or “administrative fees,” but CMS requires plans to report fees for rebate administration services that qualify as “bona fide service fees” as BFSF, and to report fees for rebate administration services that do not qualify as BFSF as DIR # 4, “Administrative fees reported as DIR.” CMS states that “in the event that an administrative fee from a manufacturer exceeds fair market value but otherwise meets the definition of a bona fide service fee, only the portion that exceeds fair market value is considered DIR and must be reported in the DIR # 4 column of the Summary DIR Report. The remaining portion must instead be reported in this [Bona Fide Service Fee] column and is not considered DIR.” CMS, June 23, 2017 Memo from Cheri Rice to All Part D Plan Sponsors, “Final Medicare Part D DIR Reporting Requirements for 2016,” at 29. There are four criteria to qualify as a BFSF, one of which is that the fee must represent fair market value. *Id.* at 28.

⁴⁰ Pharmacy Benefit Management Institute. 2017 Trends in Benefit Design Report. December 2017. Available at: https://www.pbmi.com/PBMI/Research/PBMI_Reports/Drug_Benefit_Reports/PBMI/Research/Store/BDR.aspx?hkey=bfcca9f8-610e-4eca-a908-8ff451bb2f87

⁴¹ Dross D. Will Point-of-Sale Rebates Disrupt the PBM Business? Mercer. July 31, 2017. <https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html>

⁴² Social Security Act (SSA) § 1860D-2(d)(1)(A), (B) (emphasis added).

nature of this language is emphasized by Congress' use of "may" elsewhere in this section.⁴³ Thus, the statute requires that plans reflect rebates and other price concessions in the "negotiated prices" they establish, which are used for calculating patient coinsurance and other Part D purposes. But the statute does not specify what percentage of these price concessions must be used to lower negotiated prices and thus passed through to patients at the point-of-sale or otherwise provide details about implementing the pass through requirement—thus leaving it to CMS to fill in those details, and granting CMS the authority to do so.⁴⁴

As the agency charged with administering Medicare Part D, CMS has broad authority to make rules and regulations "as may be necessary to the efficient administration" of the program,⁴⁵ as well as specific authority to interpret and administer SSA § 1860D-2(d)(1) by specifying how plans should take rebates and other price concessions into account in determining negotiated prices. Moreover, CMS has learned from its 12 years of experience administering the Part D program and collecting and analyzing data on program performance that plans seldom pass through rebates at the point-of-sale (even though CMS issued guidance on reporting point-of-sale rebates early in the program).⁴⁶ The proposed rule noted that Part D plans have shown little inclination to follow the statutory directive to "take into account" rebates in determining negotiated prices, stating that "[t]o date, sponsors have elected to include rebates and other price concessions in the negotiated price at the point-of-sale only very rarely."⁴⁷ CMS' proposal to specify a minimum percentage of rebates that must be accounted for in negotiated prices is thus the most effective way to achieve the purpose of the negotiated price provision,⁴⁸ since without a CMS-specified minimum there is no assurance that plans will take any rebates into account in negotiated prices.

CMS' proposal is also consistent with its prior interpretation of SSA § 1860D-2(d)(1). In defining "negotiated price" in its first Part D final rule in 2005, CMS chose not to set a minimum pass through

⁴³ See e.g., Kingdomware Technologies Inc. v. United States, 136 S.Ct. 1969, 1977 (2016) (holding that "[u]nlike the word 'may,' which implies discretion, the word 'shall' usually connotes a requirement" and that "when a statute distinguishes between 'may' and 'shall', it is generally clear that 'shall' imposes a mandatory duty").

⁴⁴ As the case law holds, "the power of an administrative agency to administer a congressionally created . . . program necessarily requires the formulation of policy and the making of rules to fill any gap left, implicitly or explicitly, by Congress." Morton v. Ruiz, 415 U.S. 199, 231 (1974). See also, e.g., Chevron USA, Inc. v. Natural Resources Defense Council, 467 U.S. 837, 843-44 (1984) ("if Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. . . . Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit") (citations omitted); EPA v. EME Homer City Generation, L.P., 134 S. Ct. 1584, 1604 (2014) (the statutory provision in question did not answer certain questions for EPA, and "[u]nder Chevron, we read Congress' silence as a delegation of authority to EPA to select from among reasonable options").

⁴⁵ SSA § 1102.

⁴⁶ See November 27, 2007 CMS Memo to All Part D Plan Sponsors, "Reporting Estimated Rebates Applied to the Point-of-Sale Price: Operational Guidance"; June 1, 2007 CMS Memo to All Part D Plan Sponsors, "Reporting Estimated Rebates Applied to Point-of-Sale Price."

⁴⁷ 82 Fed. Reg. at 56420 (emphasis added). And CMS knows the precise extent to which rebates are being passed through by plans, because "estimated POS rebates" have been a PDE data element (number 39) since 2008. See Prescription Drug Event Record Data Layout.

⁴⁸ The courts hold that agencies deserve particularly broad deference in circumstances such as those here, involving "a complex and highly technical regulatory on program, such as Medicare, which requires significant expertise and entail[s] the exercise of judgment grounded in policy concerns." Albert Einstein Medical Center v. Shalala, 566 F.3d 368, 373 (3d Cir. 2009) (citations and internal quotations omitted).

percentage for price concessions, expecting that “market competition [would] encourage Part D plan sponsors to pass through to enrollees a high percentage of the negotiated price concessions they obtain in the form of negotiated prices at the point-of-sale.”⁴⁹ But CMS was clear that § 1860D-2(d)(1) requires that a portion of the price concessions plans receive must be passed through to their enrollees at the point-of-sale through lower negotiated prices, stating that “we interpret the definition of the term negotiated prices in section 1860D-2(d)(1)(B) of the [Social Security] Act as requiring Part D plans to pass on to enrollees some, but not necessarily all, of these price concessions and have clarified this interpretation in our definition of the term ‘negotiated prices.’”⁵⁰

Because CMS’ expectation that plans would pass rebates through to patients largely proved mistaken, a minimum pass through requirement is a good option to share rebate savings with patients. A policy requiring that a minimum percentage of rebates be passed through to patients by reducing the negotiated prices that determine coinsurance payments follows the statute’s mandate (“negotiated prices shall take into account [rebates and other price concessions]”⁵¹ and is consistent with Congress’ intent that price concessions be reflected in negotiated prices to a meaningful degree that appreciably reduces patients’ out-of-pocket costs.

Finally, it is important to note that CMS’ authority to define negotiated price so that it “takes into account” a minimum percentage of manufacturer rebates is consistent with the noninterference clause. Under the noninterference clause—a cornerstone of Part D and a key reason for the program’s success—CMS cannot interfere with negotiations between drug manufacturers and pharmacies and Part D plans, require a particular formulary, or institute a price structure for the reimbursement of Part D drugs.⁵² But simply requiring that plans pass through to beneficiaries a minimum percentage of whatever rebates a plan has independently negotiated with a manufacturer, without any CMS involvement in those plan-manufacturer negotiations, does not interfere with those negotiations, nor does it require a particular formulary or price structure.

5. CMS Has Legal Authority to Incorporate Passed Through Rebates in Negotiated Price for Calculating Manufacturer Coverage Gap Discounts

The “negotiated price” is the basis for determining manufacturer coverage gap discounts under the Coverage Gap Discount Program established under SSA § 1860D-14A. Under section 1860D–14A(g)(6), the negotiated price used for calculating coverage gap discounts is based on the negotiated price definition in the version of 42 C.F.R. § 423.100 that was in effect when the Patient Protection and Affordable Care Act (ACA) was enacted in 2010. Under this definition, the negotiated price is “reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point-of-sale.”

⁴⁹ 70 Fed. Reg. 4194, 4244.

⁵⁰ 70 Fed. Reg. at 4244 (emphasis added).

⁵¹ SSA § 1860D-2(d)(1).

⁵² SSA §1860D-11(i).

CMS raised a question in the RFI about whether this 2010 definition provides the authority to require that the negotiated price used in calculating coverage gap discounts include rebate amounts that would be required to be passed through under a point-of-sale rebate policy.⁵³ PhRMA believes that all rebates passed through at the point-of-sale (including but not limited to those needed to reach the CMS-specified minimum) would have to be reflected in negotiated prices calculated under the 2010 regulatory definition, as all would represent rebates “that the Part D sponsor has elected to pass through.”

Under CMS’ point-of-sale rebate proposal, plans could pass through any amount of rebates greater than or equal to the CMS-specified floor. The approaches being considered by CMS envision that a plan would have a choice of passing through the CMS-specified minimum or any higher level and would thus be making an election from within a certain range of options, consistent with most choices that individuals and entities make; rarely are elections made from an unlimited set of options. Therefore, whatever amount of rebates a plan passed through would be the elected amount that must be used in calculating negotiated price under the 2010 definition referenced in SSA § 1860D-14A(g)(6).

Moreover, no viable alternatives exist to this approach. CMS might allow plans to calculate negotiated prices based on some sort of counter-factual rebate amount they decide they “would have passed through” without a CMS-specified minimum, but that hypothetical amount might not reflect the actual rebates a plan passed through to beneficiaries and would be unverifiable and subject to gaming and inconsistency, thus raising serious program integrity concerns. This hypothetical approach and the program integrity concerns it raises would be especially problematic because it would have repercussions beyond coverage gap discounts. This is because the 2010 negotiated price definition referenced in SSA § 1860D-14A(g)(6) is used in calculating both coverage gap discounts and beneficiary coinsurance payments in the coverage gap.⁵⁴ Consequently, using an interpretation of the “elected” rebate pass-through amount that was questionable and unverifiable could encourage manipulation of enrollees’ coinsurance payments as well as causing problems in the calculation of manufacturers’ coverage gap discounts.

Importantly, ensuring that the same negotiated price applies to determine costs borne by manufacturers under the coverage gap discount program and the beneficiary at point-of-sale would functionally align the definitions of negotiated prices and ensure that manufacturer payments account for 50 percent of the amount that beneficiaries would otherwise be required to pay for brand drugs in the coverage gap—the intended effect of the coverage gap discount program.⁵⁵ Note that although this clarification to negotiated price may reallocate spending in the program, and may reduce aggregate manufacturer coverage gap discount liability, the net impact of realigning incentives and spending to better reflect net prices is anticipated by actuaries to significantly increase manufacturer discounts needed to secure formulary

⁵³ 82 Fed. Reg. at 56424.

⁵⁴ See SSA § 1860D-2(b)(2)(D)(i)(the coverage for brand name drugs for an applicable beneficiary in the gap “has coinsurance ... for the negotiated price (as defined in section 1860D-14A(g)(6) of the [SSA]) that is [a specified percentage varying by year]”).

⁵⁵ See H.R. Rep. No. 111-299, at 376 (2009) (explaining the purpose of the coverage gap discount program in H.R. 3200, a predecessor to the Affordable Care Act).

placement⁵⁶—and thus lead to large government savings. Reductions in manufacturer coverage gap discount payments would be the outgrowth of a more stable Part D benefit design, lower patient cost-sharing, and relief for the federal government and taxpayers via lower reinsurance costs.

6. Timeline for Implementation

If a point-of-sale rebate policy is ultimately implemented, millions of beneficiaries would begin paying lower cost-sharing at the pharmacy immediately in the year the policy takes effect. For low-income beneficiaries, cost-sharing savings resulting from lower point-of-sale prices would instantly accrue to the government. Recognizing that the time needed to implement a pass through requirement through the rulemaking process may make it impossible to consider such a policy for plan year 2019, PhRMA believes the Secretary of HHS could exercise its existing administrative authority to negotiate the terms and conditions of the proposed bids submitted by Part D plan sponsors and encourage sponsors to begin immediately passing through a portion of negotiated rebates at the point-of-sale. Encouraging immediate pass through would accord with CMS’s authority to “regulate many aspects of how drug costs are made available and displayed to beneficiaries and treated in Part D bidding and payment processes” and to “establish rules concerning how drug costs . . . are disclosed in the marketplace, projected in Part D bids, made available to beneficiaries at the point-of-sale, reported in Explanation of Benefits (EOBs), submitted to CMS, and treated in CMS payments to Part D sponsors.”⁵⁷

PhRMA appreciates that there are many complexities inherent in crafting a policy to share a portion of negotiated rebates directly with beneficiaries at the point-of-sale. The approach we have proposed in our comments reflects our thinking to date on this important issue, but we recognize that there may be other alternative methodologies for passing through rebates that would also protect against the disclosure of commercially-sensitive data, preserve incentives for market competition, allow for innovative contracting arrangements, and maintain good beneficiary coverage. We look forward to continued engagement with CMS on how to design a rebate pass through policy that strengthens the successful Part D program by improving affordability for beneficiaries and better aligning stakeholder incentives and would welcome future opportunities to discuss additional efforts CMS could pursue to alleviate the burden of high cost-sharing.

A.1: Implementation of the Comprehensive Addiction and Recovery Act of 2016 (CARA) Provisions [p. 56340]

Description: The proposed rule would implement the CARA Part D drug management program provisions (i.e. “lock-in”) by integrating them with the current Part D Opioid Drug Utilization Review (DUR) and Overutilization Monitoring System (OMS) policy. These programs would require beneficiaries identified as

⁵⁶ Milliman. Reducing Part D Beneficiary Costs Through Point-of-Sale Rebates. January 2018, available at <http://www.phrma.org/report/reducing-part-d-beneficiary-costs-through-point-of-sale-rebates>.

⁵⁷ 79 Fed. Reg. 29844, 29875.

“at-risk” to obtain “frequently abused drugs” from specified pharmacies or providers. CMS is proposing a framework which layers sponsor lock-in programs on top of Part D’s existing opioid overutilization policies. These drug utilization management policies require that plan sponsors conduct drug utilization review to identify “at-risk” beneficiaries based on “clinical guidelines” and perform case management involving clinical contact with prescribers and verification that a beneficiary is at-risk. Through these communications with prescribers and upon reaching consensus on the appropriate level of use, plan sponsors can implement a beneficiary-specific point-of-sale claim edit to prevent coverage of unsafe levels of opioids. If prescribers are non-responsive to case management, the plan sponsor can also implement a claim edit to prevent further coverage of unsafe levels of opioids. For the 2019 plan year, plan sponsors may also limit access to frequently abused drugs through a pharmacy lock-in and/or prescriber lock-in.

The “clinical guidelines,” or criteria, for identifying at-risk beneficiaries will be published in annual guidance and will take the following approach:

- Be developed with stakeholder consultation;
- Be based on the acquisition of frequently abused drugs from multiple prescribers or pharmacies, the level of frequently abused drugs, or a combination of those factors;
- Incorporate expert opinion and analysis of Medicare data; and
- Include a program size estimate.

For the 2019 plan year, the “clinical guidelines” for identifying at-risk beneficiaries are defined as follows:

- Use of opioids greater than or equal to 90 Morphine Milligram Equivalents for any duration during the most recent 6 months (aligns with CDC opioid prescribing guidelines for the treatment of chronic pain for primary care providers); AND
- 4+ opioid prescribers AND 4+ opioid dispensing pharmacies; OR
- 6+ opioid prescribers.

The proposed rule seeks comment on the regulatory framework for implementing lock-in programs in Part D as a new feature of current opioid overutilization policies. To date, the existing policy has played a key role in reducing high risk opioid overutilization in the Part D program by 61 percent from 2011 through 2016.

Comments:

PhRMA supports the use of appropriate means to address misuse, abuse and potentially problematic utilization of prescription drugs, which can endanger patients’ safety and health, and also increase costs to the health care system through increased utilization of other health care services such as through avoidable emergency room visits and hospitalizations. We also appreciate CMS’ work to assure that efforts aimed at curbing overutilization of controlled substances do not become unduly restrictive or impede patient access to medically necessary drugs, particularly for patients with chronic pain (defined by the CDC as 3 months or more of persistent pain or pain persisting past the time of normal healing in an outpatient

setting), patients in hospice or patients with cancer diagnosis. Inappropriately restricting access, particularly for vulnerable populations would work against the goals of the Part D program and we trust that CMS is cognizant of the need to guard against these risks. Our comments seek to provide input on the overall approach to implementing Part D lock-in while also highlighting key areas where we are concerned there may be unintended consequences for patients.

PhRMA appreciates the proposed approach to implementing the CARA lock-in provisions by integrating them with current Part D Opioid DUR and OMS policy. Such an approach builds upon a framework that requires plans to perform appropriate case management with prescribers and ensure patient safety prior to limiting coverage to medicines and enrolling beneficiaries in a lock-in program. Over the years, PhRMA has expressed support for the incremental steps taken by the agency to help ensure Part D plans monitor and seek to prevent inappropriate prescribing and use through DUR and quality assurance programs. We've also expressed appreciation for the additional analyses that CMS has conducted to assess the impact and validity of the OMS opioid overutilization criteria for identifying beneficiaries whose opioid use may require focused case management. Likewise, we continue to support efforts to refine criteria for identifying potentially inappropriate levels of opioid utilization while also minimizing the identification of false positives. These efforts will remain of particular importance with the addition of more stringent drug utilization controls such as lock-in. Moving forward, a thoughtful and clinical evidence-based approach will be critical to preventing misuse and abuse in the program while also ensuring that chronic pain patients are not stigmatized or unnecessarily limited in their ability to access needed care.

A holistic view of this crisis must also consider that prescribers need appropriate training and tools to meet their patients' legitimate medical needs. While case management and clinical contact may resolve potentially inappropriate levels of opioid utilization, these efforts do not resolve the need for prescribers to have better tools to help inform their prescribing practices. Physicians and other prescribers need mandatory, ongoing training on pain management, including on the risks and benefits of prescription opioids and the use of non-opioid analgesics and other modalities of care (e.g. physical therapy, chiropractic care, and acupuncture). Increased prescriber education and training is critical to help ensure appropriate screening of patients for mental health disorders, including substance abuse. An estimated 8.2 million adults in the US have both a substance use disorder and another mental illness.⁵⁸ Yet, among those with co-occurring disorders more than half received neither mental health care nor substance use treatment in the previous year.⁵⁹ Prescribers also should be required to undertake training in and use state prescription drug monitoring programs (PDMPs) to help identify potential doctor shoppers and inform appropriate prescribing. Among primary care physicians aware of PDMPs, more than half viewed their use of these databases as having contributed to reduced abuse and diversion of prescription medicines, which

⁵⁸ Key Substance Use and Mental Health Indicators in the United States: Results from the 2016 National Health Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration.

⁵⁹ Han B, Compton WM, Blanco C, and Colpe LJ. Prevalence, Treatment, and Unmet Treatment Needs of US Adults with Mental Health and Substance Use Disorders, *Health Affairs*.2017;36(10):1739-1747.

reinforces the need to increase awareness, training, and use of these important tools.⁶⁰ Ultimately, if these tools were adequately and effectively incorporated into clinical practice they would reduce the need for plan sponsors to perform case management by informing appropriate prescribing and helping to prospectively identify at-risk patients.

As efforts to curb inappropriate levels of opioid utilization move forward, we urge CMS to consider the potential consequences of poor coverage and access policies for beneficiaries struggling with addiction. Likewise, it is important for CMS to consider the potential impact of challenges for patients in accessing non-opioid alternatives for long-term pain management, including other non-pharmacological modalities of care. While policies seeking to reduce inappropriate levels of opioid utilization in the program are critical, they cannot be considered in a vacuum. These efforts are just one component to addressing a very complex public health challenge that is devastating families and communities across our country. In order to have a meaningful impact on this crisis, we need a comprehensive and multifaceted approach which addresses not only fraud and abuse, but prescribing practices, coverage and access challenges, and other factors which play an important role in driving the current crisis.

The comments we've provided below address the proposed regulatory framework for implementing lock-in in the Part D program.

1. Frequently Abused Drugs

For the 2019 plan year, CMS has chosen to identify prescription opioids as frequently abused drugs for the purposes of implementing these provisions. We appreciate this focus and believe it is based on the appropriate level of clinical and scientific evidence to support such a designation. As CMS notes, the majority of prescription opioids are schedule II controlled substances, which have been determined by the Drug Enforcement Agency (DEA) in coordination with the Food and Drug Administration (FDA) to be associated with greater potential for abuse, through a robust scientifically verified process. Similarly, government, professional guidelines and analysis of Medicare and other drug utilization and scientific data also confirm that schedule II opioids are frequently abused drugs.

To the extent that CMS considers expanding designations of frequently abused drugs beyond opioids in subsequent plan years, we strongly urge that a similar level of evidence generation is considered before proposing drug utilization controls for other controlled substances in Part D. It is critical that consideration of expanded designations is based on objective criteria and robust evidence in order to ensure that legitimate access to medically necessary drugs is not impeded. As the proposed rule notes, there is "difficulty in establishing overuse guidelines for non-opioid controlled substances," which underscores not only the need for a robust evidence base to support potential future policy changes, but also the demand for broad stakeholder input to help inform implementation. Likewise, subsequent expansions to the definition of

⁶⁰ Rutkow L et al. Most primary care physicians are aware of prescription drug monitoring programs, but many find the data difficult to access. *Health Affairs*.2015;34(3):484-92.

frequently abused drugs should be proposed through formal notice and comment rulemaking rather than as currently proposed through the annual Parts C and D Call Letter or similar guidance.

2. Clinical Guidelines for the Purposes of Identifying At-Risk Beneficiaries

Again, we appreciate CMS' efforts to integrate CARA's lock-in provisions with existing Part D opioid DUR and OMS policies to ensure sponsors perform appropriate case management prior to implementing drug utilization controls. However, we urge caution in use of policies determining access to medications based upon thresholds such as Morphine Milligram Equivalents (MME) as this type of one-size-fits all approach may prove inappropriate in identifying potentially problematic levels of utilization for some patients, particularly given there are legitimate medical conditions where high thresholds may be appropriate. The FDA and medical professional societies acknowledge that scientific literature does not support the establishment of a recommended dose ceiling.⁶¹ Moreover, the use of such thresholds may result in a false impression of a superior safety profile and may discourage appropriate case management in consultation with a beneficiary's physician(s).

As we have noted in previous comments, we urge caution in CMS' efforts to broadly align the definition of "at-risk" beneficiaries with the *Center for Disease Control's (CDC) Guideline for Prescribing Opioids for Chronic Pain*.⁶² While we believe the guidelines are an important tool for prescribers to help inform appropriate decision-making, we express concern to the extent that the use of the 90 MME measure referenced in the guideline to define at-risk beneficiaries will serve as a maximum threshold for prescribing of opioids and may lead to undertreatment of pain in some instances. It is important to note that the guidelines were developed for the purposes of providing primary care clinicians with guidance on managing chronic pain with opioid pain relievers and may not be appropriately applied to other specialties. The CDC acknowledges that individual patient needs may vary, particularly the needs of complex patients with long-term and persistent pain management issues.

Additionally, we urge caution in the use of MME conversions based on the CDC's opioid calculator due to safety concerns. Different opioids have unique pharmacological characteristics and properties which need to be accounted for when a therapeutic opioid conversion is contemplated (e.g., methadone and tapentadol). The mathematical formula embedded in the CDC's MME calculator does not account for these differences and may result in inappropriate and dangerous conversions.⁶³ Taken together, these difficulties highlight the challenges in using a one-size-fits all approach in determining potentially inappropriate levels of opioid utilization and in guiding coverage decisions.

⁶¹ Food and Drug Administration. "CDER Response to Physicians for Responsible Opioid Prescribing Partial Petition Approval and Denial." September 10, 2013, available at <http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0818-07930>.

⁶² Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. *MMWR Recomm Rep* 2016;65(No. RR-1):1–49. <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

⁶³ Fudin J, et al. Safety Concerns with the Centers for Disease Control Opioid Calculator. *Journal of Pain Research*. 2018; 11:1-4: <https://www.dovepress.com/safety-concerns-with-the-centers-for-disease-control-opioid-calculator-peer-reviewed-article-JPR>

We encourage CMS to continue to work with various stakeholders including NIH and NIDA to develop objective measures of pain and in the interim to ensure ongoing assessment of implementation of the various drug management approaches proposed to ensure that legitimate access to pain treatments is not negatively impacted. Additionally, we encourage HHS agencies, particularly CMS, to continue to support the development and dissemination of evidence based clinical guidelines by medical sub-specialties to inform appropriate prescribing and help serve as a tool for the treatment of chronic pain. We also applaud the efforts of the HHS' Pain Management Best Practices Inter-Agency Task Force and encourage CMS to explore dissemination of these best practices moving forward.

3. Exempted Beneficiaries

In addition to exempting individuals who have elected to receive hospice care and those who are residents of long-term care facilities from being considered for a Part D lock-in program, we appreciate that CMS has taken steps to also exempt beneficiaries with cancer diagnoses. While we understand there are administrative challenges in using CMS data to determine certain categories of individuals who should be excluded from a lock-in program, we encourage CMS to require that sponsors not only perform robust case management to determine individuals who should be exempted from a Part D lock-in program (including but not limited to: palliative care patients, end-of-life care, and those with complex chronic health conditions which may cause long-term pain), but also require exclusion of these individuals upon determination of specific diagnosis or health conditions.

4. Requirements for Limiting Access to Coverage for Frequently Abuse Drugs

As noted previously, we support CMS' efforts to ensure appropriate case management is conducted, including clinical contact to determine whether prescribed medications are appropriate for the potential at-risk beneficiary's medical conditions and prescriber verification to confirm that the beneficiary is, in fact, an at-risk beneficiary. In particular, in cases where prescribers are responsive to case management and agree that a beneficiary is at-risk, we support CMS' proposal to require the additional step of requiring prescriber agreement that enrolling an at-risk beneficiary into a lock-in program is appropriate prior to limiting beneficiary access to coverage of any drugs CMS has deemed to be frequently abused. It is critical that provider discretion and clinical judgment is maintained in such situations to prevent inappropriate limitations on legitimate patient access while also ensuring providers have the flexibility to transition the care of patients who may be at-risk.

5. Limitation on the Special Enrollment Period for LIS Beneficiaries with an At-Risk Status

CMS is proposing to adjust the rules for the Special Enrollment Period (SEP)—which currently applies continuously for LIS and dually-eligible beneficiaries—to disallow beneficiaries who have been identified as potentially at-risk or designated as at-risk from using the SEP. CMS notes that 76 percent of those who would have been identified as potentially at-risk beneficiaries in 2015 receive the LIS and, thus, would otherwise be able to continuously change plans to avoid being subject to a lock-in program.

PhRMA is supportive of efforts that CMS is taking to address fraud, misuse and abuse within the Part D program. However, we do not support the proposed limitation on SEP. CMS notes that the current OMS program in Part D typically resolves cases of potential misuse without resorting to any beneficiary-specific tactic. Thus, it is likely that new designations of potential at-risk or at-risk status for beneficiaries would similarly be resolved prior to determining the appropriateness of enrolling a beneficiary in a lock-in program for frequently abused drugs. Likewise, limiting SEP for LIS and dually-eligible individuals would be premature and would result in beneficiaries losing access to an important patient protection.

Further, we are concerned that LIS and dually-eligible individuals inappropriately identified as potentially at-risk are a particularly vulnerable population who may struggle to understand the process for correcting a determination that was made in error or may otherwise be inappropriate. Therefore, due to these challenges, these beneficiaries may not only be subject to controls limiting access to needed medicines, but they may also unnecessarily face limitations in accessing the SEP regardless of the appropriateness of the determination.

CMS notes that the aim of this limitation on the SEP is to limit the possibility that those identified as potentially at-risk change plans to another plan without an established lock-in program. Thus, PhRMA proposes that CMS, instead, limit this SEP to avoid that particular outcome. In other words, beneficiaries who have been identified as potentially at-risk or designated as at-risk may only use the SEP to change Part D enrollment to another plan that has an established lock-in program.

6. Beneficiary Notices

With regard to the regulatory framework proposed for providing initial and secondary notices to beneficiaries outlining sponsor intent to implement limitations on access to coverage for frequently abused drugs, we urge CMS to take additional steps to ensure potentially at-risk beneficiaries receive these notices in a timely fashion and are able to read and understand the implications of an at-risk determination as well as the potential impact such a determination will have on access to needed medications. Again, we note our concern that the majority of individuals likely to be identified as potentially at-risk beneficiaries receive the LIS and may be constrained in their ability to understand the implications of such a limitation. Further, there currently is no stipulation that notices be sent in envelopes marked with specific guidance to beneficiaries to help differentiate these notifications for beneficiaries who may receive a considerable amount of mail from Medicare and/or Part D plans. CMS should consider additional backup processes, including phone calls or email communication to ensure patients are appropriately notified in advance of a coverage limitation. Additionally, CMS could consider requirements for prescribers to reach out to at-risk patients regarding notification and/or additional protocols to confirm receipt of notices. We urge CMS to take steps to address these risks and ensure legitimate access to needed medicines is not impeded.

7. Drug Management Program Appeals

CMS is proposing to expand the current Part D benefit appeals process and timeframes to include adverse determinations made through the lock-in program. These appealable determinations would include adverse

decisions related to the designation of at-risk as well as prescriber and/or pharmacy selection for lock-in, beneficiary-specific POS claim edits for frequently abused drugs, and information sharing for subsequent plan enrollments.

First, PhRMA would like to urge caution with the use of the general Part D benefit appeals process with respect to the CARA provisions described herein. As noted in previous comments, we have concerns with regards to patient access barriers created by the appeals process. According to MedPAC, Part D beneficiaries are not always aware of their exceptions and appeals rights and many do not understand how the process works.⁶⁴ CMS program audits have also shown “unacceptably high rates of non-compliance” with certain coverage determinations and appeals requirements, which have resulted in inappropriate delays or denials of medications. CMS has previously reported that fewer than 17 percent of all negative coverage determinations in 2013 were appealed to Part D plans for redetermination, but that on appeal, nearly 80 percent of denials were overturned.⁶⁵ We are concerned that the relatively low proportion of coverage denials that are appealed reflects a lack of transparency in the appeals process or excessive administrative burden for beneficiaries and providers. We are additionally concerned that these same challenges will be extended to those who may be inappropriately identified as at-risk and may in turn be subject to unnecessary access restrictions to needed medications.

Furthermore, we urge caution with respect to the lack of appeals process for LIS and dually-eligible beneficiaries identified as *potentially* at-risk who may be prevented from utilizing the SEP. Per the proposed interpretation of CARA, these beneficiaries are immediately removed of the right to any SEP, an act that is explicitly not appealable. Undoubtedly, some beneficiaries will be erroneously identified as potentially at-risk and subsequently not confirmed as at-risk, whether through proactive response by the beneficiary or from plan or prescriber action that invalidates the original identification. PhRMA believes these beneficiaries should not lose access to an important patient protection as a result of poor data, plan error, or some other reason potentially unrelated to the beneficiary’s action.

And lastly, CMS proposes not to require automatic escalation to the independent review entity (IRE) of at-risk determinations, citing efficiencies for beneficiaries and the Medicare program. However, as noted above, we have concerns with the existing appeals process and thus, we encourage CMS to conduct analysis to determine which option would best prevent or reduce bias against beneficiaries, as well as minimize the timeframe by which the review process occurs. Should CMS maintain its approach on at-risk redeterminations, PhRMA urges CMS to closely monitor adverse redeterminations of at-risk status by Part D plans compared to adverse reconsiderations issued by IREs to ensure Part D plans make decisions in the best interest of beneficiaries.

⁶⁴ Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy, Status Report on Part D. March 2014. http://www.medpac.gov/docs/default-source/reports/mar14_entirereport.pdf?sfvrsn=0

⁶⁵ Centers for Medicare & Medicaid Services. Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter. February 20, 2015. <http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2016.pdf>.

A.2: Flexibility in the Medicare Advantage Uniformity Requirements [p. 56360]

Description: CMS is proposing to modify its interpretation of uniformity requirements that apply to Medicare Advantage (MA) plans. Currently MA plans must offer all enrollees access to the same benefits at the same level of cost sharing. Under the newly proposed requirements, MA plans would be permitted new flexibility to reduce cost-sharing for certain covered benefits, offer specific tailored supplemental benefits, and offer lower deductibles for enrollees that meet specific medical criteria, provided that similarly situated enrollees are treated the same.⁶⁶

Comments:

PhRMA supports CMS's proposal to expand flexibility under the uniformity requirements. We agree with CMS' new interpretation that the MA uniformity of benefit requirements generally do not preclude offering enrollees, who meet specific medical criteria, tailored supplemental benefits or reduced deductibles as long as all similarly situated individuals (i.e., all enrollees who meet the specified medical criteria) are treated the same and as long as the MA benefit package does not violate MA nondiscrimination principles by discouraging enrollment by Medicare beneficiaries with higher-cost health conditions—e.g., a plan would not be permitted to offer targeted cost-sharing reductions and supplemental benefits for large number of disease conditions while excluding other, higher-cost conditions. The new flexibility could expand implementation of value-based insurance design (VBID) in the MA program, offering plans the opportunity to better align incentives and help ensure health care financing and delivery are designed to improve access to high value care. VBID also complements health plans' interest in exploring value-based arrangements, because both VBID and value-based arrangements encourage consideration of how the value of a medicine varies between different patients.

PhRMA appreciates and supports the proposed rule's many patient protections to guard against VBID being used in a discriminatory way. These protections include requiring that similarly situated enrollees are treated the same, requiring that plans ensure that cost sharing reductions and targeted supplemental benefits are for healthcare services that are medically related to each disease condition, and ensuring that MA plans do not provide supplemental benefits for many disease conditions, while excluding other higher-cost conditions. These protections are critical to ensuring that VBID approaches in MA do not discriminate against or discourage enrollment of beneficiaries with certain conditions.

Beyond the protections already proposed, PhRMA suggests that CMS should also adopt the following measures to help ensure that VBID can facilitate access to a full range of high-value care:

- VBID should not lead to cost sharing increases for other covered items or services or reductions in the number of medicines on a health plan's formulary
- VBID cost-sharing must be based on an appropriate assessment of value, not price

⁶⁶ 82 Fed. Reg. 56360.

- Value assessments should be based on the full body of available evidence, based on a range of study designs
- Value must incorporate relevant clinical quality and patient-centered measures and account for changes in evidence, medical practice, and innovations

Finally, PhRMA urges CMS to consider extension of this additional plan flexibility to Part D benefits in future rulemaking. We recognize the programmatic complexity of doing so, but also note the absurdity of plans offering diabetic enrollees zero cost sharing for endocrinologist visits (adopting the proposed rule's example),⁶⁷ but charging 33 percent coinsurance for a biopharmaceutical anti-diabetic agent that could avoid the need for some physician or hospital visits all together. Because VBID can complement plans' efforts to implement value-based arrangements – and plans may use the same infrastructure to support both efforts – allowing plans greater flexibility to pursue VBID designs may also encourage more value-based arrangements between plans and biopharmaceutical companies.

We believe CMS has leeway to entertain application of the proposed flexibilities to Part D benefits. The Part D program has uniformity of benefit requirements that are very similar to those that apply to MA plans, and very similar non-discrimination requirements. The basic requirement is set forth in 42 CFR section 423.104(b), providing that a Part D sponsor must offer the plan to all Part D eligible beneficiaries residing in the plan's service area; and "[a]t a uniform premium, with uniform benefits and level of cost-sharing throughout the plan's service area."⁶⁸ Likewise Part D and MA have substantially identical non-discrimination requirements, which prohibit plan benefit designs that discourage enrollment by certain beneficiaries.⁶⁹

Given these similarities in the uniformity of benefit and non-discrimination rules that apply to Part D and Medicare Advantage, we think the same basic logic that CMS articulates in the proposed rule—allowing tailored offerings for individuals with certain serious medical conditions, provided that the offering is available to all enrollees with that condition and these tailored offerings are not aimed at attracting enrollment by individuals with lower-cost health conditions—would generally apply in the same manner to Part D benefits, and thus permit somewhat greater flexibility in Part D benefit designs. Therefore, we were surprised that the proposed rule stated that “the benefit and cost-sharing flexibility we have discussed here applies to Part C and not Part D benefits,”⁷⁰ without further discussion. We request that in the preamble to

⁶⁷ *Id.*

⁶⁸ CMS guidance also elaborates on these principles and provides, for example, that Part D plans must provide the same negotiated prices to enrollees in all phases of the Part D benefit, and must not apply preferential utilization management criteria, DUR rules, or transition policies to a subset of their enrollees for non-medical reasons. Medicare Prescription Drug Benefit Manual, Chapter 5, sections 20.6, 50.5.3. To preclude discriminatory cost-sharing on individual items and services, CMS caps the cost-sharing on certain items and services in the annual Call Letter process. For 2018 and in previous years, CMS has limited the cost-sharing for most Part B drugs to 20 percent or \$50 (both for MA plans that use the mandatory MOOP and for those that use the lower, voluntary MOOP). See, e.g., CMS, Announcement of Calendar year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter and Request for Information, at 126 (Apr. 3, 2017), <https://www.cms.gov/Medicare/healthPlans/MedicareAdvgtgSpecRateStats/Downloads/Announcement2018.pdf>. We strongly encourage CMS to maintain this 20%/\$50 cap on Medicare Advantage cost-sharing for Part B drugs.

⁶⁹ See SSA 1860D-11(d)(2)(D)(Part D); SSA 1852(b)(1)(A)(MA).

⁷⁰ 82 Fed. Reg. at 56360.

the final rule CMS specifically address the underlying similarities in the MA and Part D uniformity of benefit and non-discrimination rules. This includes identifying any differences in these rules that it sees as calling for less flexibility to offer tailored cost-sharing or supplemental benefits on the Part D side and the specific ways in which CMS thinks that flexibilities might differ in Part D. We hope that CMS ultimately will include a proposal extending its new approach permitting somewhat more flexible benefit designs to Part D in its next rulemaking cycle.

A.4: Maximum Out-of-Pocket Limit for Medicare Parts A and B Services [p. 56361]

Description: Current law requires MA plans to apply a maximum out-of-pocket (MOOP) limit on annual patient cost-sharing for Part A and B covered services. CMS sets this mandatory MOOP (currently \$6700) at approximately the 95th percentile of projected out-of-pocket spending for Part A and B services (i.e., only about 5 percent of Medicare fee-for-service beneficiaries are expected to incur annual Part A and B cost-sharing charges exceeding \$6700).⁷¹ CMS proposes to amend the MA regulations to specify that it may vary the MOOP from year to year as necessary to “strike a balance between limiting maximum beneficiary out-of-pocket costs and potential changes in premiums, benefits, and cost-sharing with the goal of ensuring beneficiary access to affordable and sustainable benefit packages.”⁷²

Comments:

PhRMA supports this proposal, and we strongly support the Part A/B MOOP: a critical feature of the MA program that helps to protect MA patients against excessive annual cost-sharing. The MOOP has important consequences both for the MA program and its enrollees. The MOOP helps to ensure that MA benefit designs do not discourage sicker Medicare patients from enrolling in an MA plan—which is why CMS established the MOOP—and it also helps to improve enrollees’ adherence to treatment regimens and thus to improve their health, as studies have repeatedly shown that higher cost-sharing leads to reduced or

⁷¹ 82 Fed. Reg. at 56361. In addition to the mandatory MOOP, CMS sets a lower voluntary MOOP; Medicare Advantage plans may adhere to this lower MOOP in order to obtain greater flexibility on cost-sharing for individual Part A and B services.

⁷² 82 Fed. Reg. at 56495 (proposed 42 C.F.R. §§ 422.100(f)(4), 422.101(d)(2), (3)(ii)).

delayed initiation of treatment⁷³ and lower adherence rates,⁷⁴ which in turn may result in worse outcomes for patients as well as higher overall Medicare spending.⁷⁵

Given the important functions the MOOP performs, we urge CMS to extend the MOOP to Part D. Extending the MOOP to all of the benefits offered by MAPD plans could improve adherence to Part D prescribed drug regimens; curb spending on many Part A and B services, including hospitalizations, the use of which increases with poor adherence to drug regimens; and help MAPDs to better coordinate Part A, B, and D-covered care for their enrollees.

Moreover, CMS relied on two MA provisions in establishing the MOOP for local MA plans,⁷⁶ both of which have Part D counterparts: (1) the prohibition on discriminatory MA benefit designs in Social Security Act (SSA) § 1852(b)(1)(A), which closely resembles the Part D non-discrimination provision in SSA § 1860D-11(d)(2)(D); and (2) the authority in SSA § 1857(e)(1) to add “necessary and appropriate” terms to contracts with MA plans, which is incorporated into Part D via § 1860D-12(b)(3)(D).⁷⁷ Therefore CMS’ legal authority for establishing the MA MOOP is just as relevant to a Part D MOOP.

While CMS has never denied its authority to establish a Part D MOOP, CMS has previously dismissed the idea of a Part D MOOP as not “practical or appropriate,” stating in 2010 that:

We do not believe that a regulatory overall liability limit for Part D would be practical or appropriate given the current design of Part D benefits (such as the coverage gap). We also note that, under

⁷³ See, e.g., Doshi JA, Li P, Huo H, et al. High Cost Sharing and Specialty Drug Initiation under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia. *American Journal of Managed Care*. 2016;22(4 Suppl):s78-86.

⁷⁴ See, e.g., Doshi JA, Takeshita J, Pinto L, et al. Biologic Therapy Adherence, Discontinuation, Switching, and Restarting Among Patients with Psoriasis in the US Medicare Population. *Journal of the American Academy of Dermatology*. 2016;74(6):1057-1065.e4.; Doshi JA, Hu T, Li P, Pettit AR, Yu X, Blum M. Specialty Tier-Level Cost Sharing and Biologic Use in the Medicare Part D Initial Coverage Period Among Beneficiaries with Rheumatoid Arthritis. *Arthritis Care Research*. 2016; 68(11):1624-1630; Gibson T et al., Cost-Sharing Effects on Adherence and Persistence for Second-Generation Antipsychotics in Commercially Insured Patients. *Managed Care*. 2010; 19(40):40-47. Iuga AO, McGuire MJ. Adherence and Health Care Costs. *Risk Management and Healthcare Policy*. 2014;7:35-44. doi:10.2147/RMHP.S19801 (literature review finding that “Reducing out-of-pocket costs leads to better medication adherence across many diagnoses. There is a linear relationship between the magnitude of patient cost sharing and the level of adherence. This relationship persists from low to higher income levels”)(citation omitted).

⁷⁵ See, e.g., Eaddy MT, Cook CL, O’Day K, Burch SP, Cantrell R. How Patient Cost-Sharing Trends Affect Adherence and Outcomes. *P&T*. 2012;37:45–55. [PubMed] (literature review concluding that “increased patient cost-sharing was associated with declines in medication adherence, which in turn was associated with poorer outcomes”; the authors found that 85 percent of the articles that evaluated the relationship between changes in cost-sharing and adherence found that an increasing patient share of medication costs was significantly associated with a decrease in adherence, and that the majority of the articles that investigated the relationship between adherence and outcomes found that increased adherence was associated with a statistically significant improvement in outcomes); MacEwan JP, et al. The Relationship Between Adherence and Total Spending Among Medicare Beneficiaries with Type 2 Diabetes. *American Journal of Managed Care*. 2017; 23(4):248-252. Stuart B, Davidoff A, Lopert R, Shaffer T, Shoemaker JS, Lloyd J. Does Medication Adherence Lower Medicare Spending among Beneficiaries with Diabetes? *Health Services Research*. 2011;46(4):1180-1199. doi:10.1111/j.1475-6773.2011.01250.x.

⁷⁶ The statutory provisions governing regional MA plans have an explicit MOOP requirement.

⁷⁷ 74 Fed. Reg. 54634, 54657 (Oct. 22, 2009) (proposed MA and Part D rule for 2011, proposing mandatory MOOPs for local Medicare Advantage plans); 75 Fed. Reg. 19678, 19710-11 (April 15, 2010) (final rule for 2011, finalizing MOOP proposal).

the Part D benefit, there is protection afforded to a beneficiary once they enter into the catastrophic phase of the benefit where there is nominal cost-sharing.⁷⁸

While we hope that this passage does not reflect CMS' current thinking, it has two key flaws that are important to examine, because they suggest incorrectly that a MOOP is not necessary or feasible in Part D.

First, CMS' 2010 statement understates the cost-sharing charges that beneficiaries incur in catastrophic coverage. Cost-sharing in catastrophic coverage is not "nominal." Instead, catastrophic coverage cost-sharing for non-LIS enrollees is generally the greater of a nominal copayment or 5 percent coinsurance.⁷⁹ Moreover, the coinsurance is based on a price for the drug that generally does not take negotiated rebates and manufacturer discounts into account.

A recent Kaiser Family Foundation report found that, far from being "nominal," catastrophic coverage cost-sharing amounted to 40 percent of total annual Part D cost-sharing, on average, for non-LIS enrollees who reached catastrophic coverage.⁸⁰ Examining catastrophic spending in 2015 (the most recent year for which data were available), the study found that one million non-LIS enrollees reached catastrophic coverage that year; they incurred average Part D cost-sharing charges of \$1215 in catastrophic coverage alone; and 1 in 10 of these beneficiaries had total cost-sharing of at least \$5200 over the course of the year.⁸¹ Unless enrollees qualified for low-income subsidies, the report noted, "the absence of an annual out-of-pocket spending limit under Part D exposes enrollees to significant costs."⁸²

In short, non-LIS Part D enrollees who reach catastrophic coverage may face substantial and continuing cost-sharing charges—as long as the individual keeps taking his or her medication. Without a cap on Part D cost-sharing the risk of non-adherence and worsened health outcomes for individuals in catastrophic coverage is apparent. Beneficiaries can still incur significant out-of-pocket costs in catastrophic coverage, and this is after the beneficiary has already incurred high out-of-pocket costs on Part D drugs to reach catastrophic coverage,⁸³ and may have incurred high out-of-pocket costs for Part A and B services as well. Therefore the theory that a Part D MOOP is not needed, unfortunately, is not reality.

Second, CMS' 2010 statement also suggested incorrectly that a Part D MOOP was not "practical or appropriate" due to Part D benefit design provisions. Certainly Part D has a different benefit design than the Part A and B services covered by MA plans, which could create additional complexities. Importantly, however, for MAPDs at least, any legal impediments to limiting Part D out-of-pocket spending are easily addressed. The Part D statute (specifically, SSA § 1860D-21(c)(2)) states that CMS shall waive Part D

⁷⁸ 75 Fed. Reg. at 19714 (final MA and Part D rule for 2011).

⁷⁹ SSA § 1860D-2(b)(4)(A).

⁸⁰ Kaiser Family Foundation Issue Brief, "No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending," 1-4 (Nov. 2017).

⁸¹ No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending, supra, at 1-4.

⁸² No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending, supra, at 9.

⁸³ For example, the catastrophic coverage threshold for 2018 is \$5,000 in TROOP (which includes manufacturer coverage gap discounts as well as beneficiary out-of-pocket spending) for an "applicable beneficiary" who receives coverage gap discounts. April 3, 2017 Part D final call letter for 2018 at 48 (Appendix VI, listing final updated Part D benefit design parameters for 2018).

provisions to the extent they duplicate or conflict with Part C provisions, or as may be necessary to improve coordination of Part C and D benefits. As CMS explained at the inception of Part D, this provision provides for CMS to “waive any Part D requirement for an MAPD plan that conflicts with or duplicates a requirement of Part C or the waiver of which is necessary to promote coordination between benefits provided under Parts C and D.”⁸⁴

SSA § 1860D-21(c)(2) applies here because permitting unlimited cost-sharing on an MAPD plan’s Part D benefits undercuts the purpose of establishing a Part A/B MOOP: preventing benefit designs that discourage enrollment by certain Medicare beneficiaries. In establishing the Part A/B MOOP, CMS explained that “requiring such a limit on plan design is necessary in order to avoid discouraging enrollment by individuals who utilize higher than average levels of health care services (that is, in order for a plan not to be discriminatory in violation of [SSA] section 1852(b)(1)).”⁸⁵ Yet unlimited Part D cost-sharing can just as easily discourage individuals who use higher-than-average levels of services from enrolling in an MAPD, and thus conflicts with the cap on Part A/B cost-sharing.

Section 1860D-21(c)(2) also applies here because the lack of a Part D MOOP creates distortions that undercut an MAPD plan’s ability to coordinate Part C and Part D benefits. Sicker enrollees may cut back on Part D medications—skipping doses or just not filling Part D prescriptions—as their out-of-pocket costs increase without limit on the Part D side, which in turn may cause avoidable complications and increase their use of Part C services such as hospitalizations.⁸⁶ In addition, in cases where a particular disease may be treated with Part B or D drugs, the Part A/B MOOP and the absence of a Part D counterpart may create incentives for beneficiaries with high healthcare costs to use the Part B drug even if it may not be the best choice from a clinical perspective. These scenarios may all reflect rational behavior by patients who are protected by a cap on the costs of certain healthcare services, but faced with the possibility of unlimited cost-sharing liabilities for other healthcare services that are key to managing and curing diseases—and they illustrate the potential for this asymmetric cost-sharing scheme to thwart good care management by MA plans and their providers. In particular, they illustrate the problems this perverse incentive system can create for coordinating the Part C and D benefits covered by MAPDs.

Accordingly, CMS has the authority to waive Part D benefit design provisions to the extent they would otherwise impede its ability to limit Part D cost-sharing under MAPD plans. From a legal and healthcare policy perspective, a Part D MOOP would be an appropriate and sound strategy offering substantial benefits to the MA program and its enrollees and prospective enrollees. Given the flexibility of its SSA

⁸⁴ 70 Fed. Reg. 4194, 4275. See also 42 C.F.R. 423.528(b) (“CMS waives any provision of [Part D] otherwise applicable to MAPD plans or MA organizations under paragraph (a) of this section [generally applying Part D rules to Part D benefits provided by MAPDs] to the extent CMS determines that the provision duplicates, or is in conflict with, provisions otherwise applicable to MA organization or MAPD plans ... or as may be necessary in order to improve coordination of [Part D] with the benefits under Part C”).

⁸⁵ 74 Fed Reg. at 54657. Under SSA § 1852(b)(1)(A), CMS may not approve an MA plan if “the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals”).

⁸⁶ See, e.g., Congressional Budget Office, Offsetting Effects of Prescription Drugs Use on Medicare’s Spending for Medical Services. November 2012 (“policy changes that influence Medicare beneficiaries’ use of prescription drugs, such as those altering the cost-sharing structure of the Part D drug benefit, probably affect federal spending on their medical services”).

§ 1860D-21(c)(2) authority, CMS could either establish a separate Part D MOOP that would apply in addition to the MOOP for Part A/B services, or (if operationally feasible) could consider a single unified MOOP that applied to all Part A, B, or D services covered by an MAPD plan (e.g., a MOOP that set at the projected 95th percentile of Part A, B, and D spending, mirroring the current A/B MOOP model).

We encourage CMS to include a MOOP on Part D spending in its next MA rulemaking and would welcome the opportunity to work with CMS on fleshing out this approach in the interim.

A.9: Part D Tiering Exceptions [p. 56371]

Description: CMS is proposing to revise its Part D tiering exceptions policy, including the limitations that plan sponsors may apply to tiering exception requests. The proposed rule clarifies that requests for tiering exceptions should be granted at the lowest applicable cost-sharing for the tier containing preferred alternative drugs for the treatment of a beneficiary’s health condition, irrespective of tier labels. Specifically, while a Part D plan sponsor would not be required to offer a tiering exception for a brand name drug to a preferred cost-sharing level that applies only to generic alternatives, Part D plan sponsors would be required to offer a preferred cost-sharing level that applies to tiers that contain both branded and generic alternatives, even if the tier is labeled “generic.” Additionally, plans would be required to approve tiering exceptions for non-preferred generic drugs when the plan determines that the enrollee cannot take the preferred generic alternative(s), including when preferred generic alternative(s) are on tier(s) that include only generic drugs or when the lower tier(s) contain a mix of brand and generic alternatives. CMS also proposes new limitations on tiering exceptions. Specifically, for brand medicines, approved tiering exceptions would generally be assigned to the lowest cost-sharing for the tier associated with brand alternatives; for biologic medicines, approved tiering exceptions would generally be assigned to the lowest cost-sharing tier associated with biologic alternatives; for non-preferred generic drugs, approved tiering exceptions would generally be assigned to the lowest cost-sharing tier associated with either brand or generic alternatives. The proposed rule would also maintain the current policy exempting specialty tiers from tiering exceptions.

Comments:

1. Beneficiaries Should Have Access to the Lowest Applicable Cost-Sharing Irrespective of Tier Label

PhRMA supports CMS’ proposal to clarify that requests for tiering exceptions should be granted at the lowest applicable cost-sharing for the tier containing preferred alternative drugs for the treatment of a beneficiary’s condition irrespective of tier labels. We agree that the increasing complexity of formulary tiers, with multiple “generic” tiers and tiers containing both branded and generic drugs, has resulted in Part D plans restricting tiering exceptions more stringently than is appropriate. This proposal will ensure that beneficiaries receive the benefit of lower cost sharing where the preferred drug(s) are judged by their physician not to be medically appropriate.

2. High Cost-Sharing Adversely Impacts Beneficiary Access and Adherence to Medicines

PhRMA has significant concerns that CMS intends to continue exempting specialty tiers from tiering exceptions and allowing plan sponsors to use blended coinsurance tiers containing both brand and generic medicines. These policies result in high-cost sharing for patients, which a growing body of research demonstrates can adversely impact beneficiary access and adherence to needed therapies:

- A recent analysis by Amundsen Consulting, a division of IQVIA (formerly QuintilesIMS), shows that in 2016, 38 percent of all new prescriptions for specialty medicines filled by Part D beneficiaries beginning therapy for the first time were abandoned at the pharmacy. The likelihood of abandonment was strongly associated with patient out-of-pocket cost. When beneficiary cost-sharing exceeded \$250, 71 percent of new specialty prescriptions were abandoned. This level of cost-sharing was not uncommon, as nearly 40 percent of all new Part D prescriptions for specialty medicines had cost-sharing of more than \$250.⁸⁷
- Analysis by Avalere Health shows that a large share of PDP and MAPD plans placed all medicines in certain therapeutic classes on the specialty tier in 2017, a practice known as adverse tiering. For example, 97 percent of PDPs placed all medicines in two therapeutic classes used to treat cancer—antiangiogenic agents and molecular target inhibitors—on the specialty tier. MAPD plans were less likely to engage in this behavior, but for these two respective classes, 87 percent and 73 percent of all MAPDs included all medicines on the specialty tier. For multiple sclerosis agents, no MAPDs engaged in adverse tiering, while 26 percent of PDPs placed all medicines in this class on the specialty tier.⁸⁸
- One peer-reviewed study examined the impact of high cost-sharing on specialty drug initiation under Part D, focusing on access to tyrosine kinase inhibitors (TKIs) that have revolutionized the treatment of chronic myeloid leukemia (CML). The analysis found that Part D beneficiaries who did not receive the low-income subsidy (LIS) and were diagnosed with CML were less likely than beneficiaries who did receive subsidies (and pay only nominal out-of-pocket costs) to have a claim for a TKI within six months of diagnosis (45.3 percent vs. 66.9 percent). Additionally, non-LIS beneficiaries took twice as long to fill one claim for a TKI (an average 50.9 days vs. 23.7).⁸⁹
- Another peer-reviewed study found that among Part D enrollees with psoriasis, fewer than 40 percent were adherent and almost half discontinued biologic treatment within 12 months of

⁸⁷ Amundsen Consulting. Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment. November 2017.

⁸⁸ Avalere Health, analysis for PhRMA. December 2017.

⁸⁹ Doshi, JA, Li, P, Huo, H, et al. Medicare Part D Cost Sharing and Specialty Drug Initiation In Newly Diagnosed Chronic Myeloid Leukemia Patients. *Value in Health*. 2016;19(3): 78-86.

initiation. Further, Part D beneficiaries with psoriasis who did not receive the LIS were twice as likely to discontinue treatment relative to beneficiaries receiving subsidies.⁹⁰

- A third peer-reviewed study found that for Part D beneficiaries with rheumatoid arthritis (RA), high cost-sharing was associated with treatment interruptions. Among beneficiaries who used a Part D biologic in the prior year, those facing high cost-sharing were less likely to continue using a Part D biologic relative to those beneficiaries receiving cost-sharing subsidies. When beneficiaries with RA did fill a Part D biologic, those facing high cost-sharing were twice as likely to experience an interruption in treatment (defined as a gap of more than 30 days) compared to beneficiaries receiving subsidies.⁹¹

3. Barriers on Part D Tiering Exceptions Are Not Consistent with the Statute

The proposed rule would retain the “specialty tier” provision permitting plans to cut off patients’ rights to seek tiering exceptions for high-cost drugs,⁹² and add new barriers to tiering exceptions. We believe these barriers to tiering exceptions are not consistent with the statute, which provides that:

a Part D eligible individual who is enrolled in [a plan with a tiered formulary] may request an exception to the tiered cost-sharing structure. Under such an exception, a non-preferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for the treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h) [concerning appeals].⁹³

Thus, the statute gives beneficiaries a right to request tiering exceptions for any non-preferred drug if there is a preferred drug with lower cost-sharing to treat the same condition and the beneficiary’s physician

⁹⁰ Doshi, JA, et al. “Biologic Therapy Adherence, Discontinuation, Switching, And Restarting Among Patients with Psoriasis In The US Medicare Population”. *Journal of the American Academy of Dermatology*. 2016;74(6):1057-1065.

⁹¹ Doshi, JA, Hu, T, Li, P, et al. Specialty Tier-Level Cost Sharing and Biologic Agent Use in the Medicare Part D Initial Coverage Period among Beneficiaries with Rheumatoid Arthritis. *Arthritis Care & Research*. 2016;68(11):1642-1630

⁹² 42 C.F.R. § 423.578(a)(7) (proposed to be redesignated as § 423.578(a)(6)(iii)). The definition of the “specialty tier” would be in proposed 42 C.F.R. § 423.560 and would largely focus on specialty tier drugs being “very high cost.”

⁹³ SSA § 1860D-4(g)(2) (emphasis added). The MMA conference report similarly states that “[a] beneficiary in a plan that provides for tiered cost-sharing can request coverage of a non-preferred drug on the same conditions applicable to preferred drugs, if the prescribing physician determines that the preferred drug for the treatment of the same condition is not as effective for the enrollee or has adverse effects for the enrollee.” H.R. Conf. Rep. 108-391 (2003), reprinted in 2004 U.S.C.C.A.N. 1808, 1834.

⁹³ 149 Cong. Rec. S15882, S15888 (Nov. 25, 2003) (emphasis added).

determines that the preferred drug would be less effective or have adverse effects for the beneficiary; in these circumstances, the plan must at least consider the request.

4. The Current Regulation Permits Plans to Make Drugs on Specialty Tiers “Ineligible” for Tiering Exceptions

The statutory language quoted above is inconsistent with CMS’ regulation allowing plans to declare that drugs on a “specialty tier” are simply ineligible for a tiering exception—the statute gives no indication that plans could simply refuse to entertain certain exception requests even though the prescribing physician had determined that the preferred drug would be less effective or have adverse effects for the beneficiary. And the statute authorizes CMS to create guidelines for plans to “mak[e] a determination with respect to such a [tiering exception] request,” not guidelines allowing plans to refuse to make determinations with respect to tiering exception requests.

Moreover, the tiering exception provision is part of Social Security Act (SSA) § 1860D-4, “Beneficiary Protections for Qualified Prescription Drug Coverage,” and a beneficiary would likely have the greatest need for the protection of this provision in the specialty tier context where he or she is taking a “very high cost” non-preferred drug. In fact, referencing tiering exceptions in the Senate floor debate on the Medicare Modernization Act (MMA), Senator Grassley, the chief Senate negotiator on the MMA Conference Committee, stated that: “I am pleased with the backup protections in this bill. That if a plan doesn’t carry or doesn’t treat as preferred a drug needed by, say, a person with AIDS, a simple note from a doctor explaining the medical need for that particular drug could get that drug covered.”⁹⁴ Senator Grassley’s example of HIV/AIDS drugs, which are often considered specialty drugs and placed on Part D plans’ specialty tiers, demonstrates that the congressional architects of Part D intended tiering exceptions to help patients needing high-cost specialty products. Allowing plans to deny beneficiaries with the greatest need for tiering exceptions the right to seek one contravenes the statute’s text and purpose.

PhRMA is not aware of any other benefit design that so aggressively differentiates patient out-of-pocket costs based on a patient’s non-elective need for more costly services. For instance, the costs of hospitalizations vary widely; many patients have lower cost hospitalizations and some patients have comparatively high cost hospitalizations.⁹⁵ Yet we are not aware of plan benefit designs in which patients with the most costly hospital stays are charged a dramatically higher “specialty tier” hospital coinsurance percentage as compared to patients needing less expensive hospital care. Indeed, such a practice would run counter to the very purpose of insurance.

In the 2017 Call Letter, CMS indicated it would analyze the impact of tiering exceptions for specialty tier drugs, but it has yet to provide an update on these results or the status of the analysis. We strongly encourage CMS to provide an update on the status of these analyses, and an opportunity for stakeholders to review and provide input on next steps. We believe the findings of these analyses will be critical to

⁹⁴ 149 Cong. Rec. S15882, S15888 (Nov. 25, 2003) (emphasis added).

⁹⁵ S.R. Machlin and K. Carper, “Statistical Brief #164: Expenses for Hospital Inpatient Stays, 2004” Agency for Healthcare Research and Quality.

informing future policy directions for the specialty tier to ensure beneficiaries have appropriate access to medically necessary medicines.

We realize that the proposed rule did not propose to eliminate the regulation permitting plans to refuse to consider tiering exception requests for specialty tier drugs. We urge CMS to propose to eliminate this provision (and then do so) in its next Part D rulemaking. It is neither fair nor reasonable to require patients to pay cost-sharing as high as 33 percent coinsurance when they can demonstrate that they must take a specific medicine and have no reasonable alternative. To impose a very high and un-appealable level of cost-sharing in such circumstances amounts to discrimination based on a particular patient's clinical needs or health status. Beneficiaries who have previously undergone step therapy and/or have demonstrated that drugs on lower tiers are not clinically appropriate should pay cost-sharing as if the drug were available on a more favorable tier. Requiring these beneficiaries to pay cost-sharing up to 33 percent coinsurance singles them out based on their specific prescription drug needs or specific conditions without any clinical or utilization management rationale. Based on the Part D benefit design, it also concentrates these individuals' spending early in the year, with little if any opportunity to spread that spending out. Eliminating the specialty tier exemption from the formulary exceptions process could help to mitigate financial hardship and also align CMS' specialty tier policy with the statute.⁹⁶

5. The Proposed Rule Would Impose New Barriers to Tiering Exceptions

CMS also proposes several new barriers to tiering exceptions. First, CMS would limit the exceptions process to patients seeking the lower cost-sharing on a preferred drug for their condition of the "same type" as the non-preferred drug they are taking. Specifically, CMS would permit plans:

- to limit tiering exceptions for brand name drugs (as defined under 42 C.F.R. § 423.4⁹⁷) to cost-sharing for an alternative brand name drug for the patient's condition; and
- to limit tiering exceptions for biologicals (including biosimilars) to cost-sharing for an alternative biological for the patient's condition⁹⁸

⁹⁶ Social Security Act § 1860D-4(g)(2).

⁹⁷ "Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(c)), including an application referred to in section 505(b)(2) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(b)(2))." 42 C.F.R. § 423.4 (emphasis added). A similar CMS proposal would provide that plans can refuse to consider tiering exception requests if the patient is taking a brand name drug or biological and the only preferred drugs for the patient's condition are generics (approved under Section 505(j) of the Food, Drug, and Cosmetic Act (FDCA)) or authorized generics (as defined in FDCA § 505(t)(3)(21 U.S.C. § 355(t)(3), which means a drug approved under FDCA § 505(c) that is marketed under different labeling or packaging, a different labeler code, product code, trade name or trademark than the "brand name" version). 82 Fed. Reg. at 56372. As a result of this related proposal, CMS' proposal to limit tiering exceptions for brand name drugs to the cost-sharing for other brand name drugs (defined as drugs approved under FDCA § 505(c)) actually would limit the drugs that could be the basis for an exception request to other drugs for the patient's condition approved under FDCA § 505(c) minus authorized generics.

⁹⁸ 82 Fed. Reg. at 56372. Patients seeking a tiering exception for a generic drug could seek the cost-sharing for a generic or brand name drug for treating their condition.

CMS states that this new restriction would “achieve needed balance” and “align[] with how many plan sponsors already design their tiering exceptions criteria.”⁹⁹ The statute does not impose this “same type” restriction on tiering exceptions; under its terms the Food and Drug Administration (FDA) approval pathway for the preferred drug that provides the basis for the exception request is irrelevant.

CMS also proposes to revise the requirement that the preferred drug that provides the basis for an exception request must treat the “same condition.” CMS instead would interpret “same condition” as the same condition “as it affects the enrollee—that is, taking into consideration the individual’s overall clinical condition, including the presence of comorbidities and known relevant characteristics of the enrollee and/or the drug regimen, which can factor into which drugs are appropriate alternative therapies for that enrollee.”¹⁰⁰

Nothing in the statute permits these limitations. By law, enrollees whose physician determines that the “preferred drug for treatment of the same condition” would be ineffective or have adverse effects can seek exceptions, so that the drug they take is made available at the same cost-sharing as a “preferred drug for treatment of the same condition.” By contrast, the approach CMS proposes would reduce tiering exception requests to seeking the cost-sharing on a very small (or non-existent) set of preferred products that treat a subset of the patient’s condition specific to individuals with the general condition plus all of the patient’s comorbidities and other clinical characteristics.

One result of this proposal would be that a patient who needs a non-preferred drug because all the preferred drugs for his or her condition are not clinically inappropriate (due to some comorbidities or other characteristics of the patient) could not—for this very reason—seek a tiering exception. Under this proposal, once the physician decides that a preferred drug would be less effective or have adverse effects for the individual, then the individual could not request a tiering exception based on the cost-sharing for that preferred drug (since that preferred drug would not treat the relevant subset of the individual’s condition).

CMS justifies this odd limitation by saying that section 1860D-4(g)(2) “requires that coverage decisions subject to the exceptions process be based on the medical necessity of the requested drug for the individual for whom the exception is sought. We believe that requirement reasonably includes consideration of alternative therapies for treatment of the enrollee’s condition, based on the facts and circumstances of the case.”¹⁰¹ But CMS is taking the “for the individual” language out of context. The statute provides that the tiering exceptions process is available when a prescribing physician determines that a preferred drug for the treatment of the same condition “would not be as effective for the individual.”¹⁰² Thus, the individualized determination contemplated by the statute is one made by the prescribing physician in prescribing the non-preferred drug instead of a preferred drug, and is unrelated to the plan’s exceptions process.

⁹⁹ 82 Fed. Reg. at 56372.

¹⁰⁰ 82 Fed. Reg. at 56372-73 (emphasis added).

¹⁰¹ 82 Fed. Reg. at 56373 (emphasis in original).

¹⁰² SSA § 1860D-4(g)(2).

Accordingly, we urge CMS: (1) to delete the regulation allowing plans to refuse to consider tiering exceptions for specialty tier drugs (in a future rulemaking where CMS proposes such a change); and (2) not to finalize the proposed new barriers to tiering exceptions. Congress sought to create a simple and crucially important beneficiary protection in enacting the tiering exception provision. That statutory protection must be given effect.

6. CMS Should Continue to Monitor Trends Related to Non-Preferred Drug Tiers

Cost-sharing on non-preferred tiers is not restrained to a maximum 33 percent coinsurance or \$100 copay as it is on the specialty tier. According to the Kaiser Family Foundation, 98 percent of PDPs used coinsurance for their non-preferred drug tiers in Part D in 2017. The typical coinsurance on this tier is 40 percent, but can also be as much as 50 percent.¹⁰³ This high cost-sharing burden raises the same access concerns noted above. CMS' current policy related to tier labeling and composition, which allows mixing brand and generic medicines on a non-preferred tier, may serve to exacerbate the out-of-pocket cost burden placed on beneficiaries, with lower average cost-sharing for generic products masking the disproportionate cost-sharing that beneficiaries would face for brand products placed on the same tier. For example, if a beneficiary needs a brand drug placed on the "non-preferred tier," and this brand drug does not have a generic alternative, at 40 percent coinsurance, that patient's actual out-of-pocket costs will likely be higher than the non-discriminatory \$100 threshold—creating an access barrier for that beneficiary to get treatment. This is an outcome of plans being allowed to put generics on the non-preferred tier to lower the average out-of-pocket cost for that tier.

A.10: Establishing Limitations for the Part D Special Election Period (SEP) for Dually Eligible Beneficiaries [p. 56375]

Description: Under current policy, most beneficiaries dually-eligible for Medicare and Medicaid and those receiving the low-income subsidy (LIS) can change enrollment monthly through a Special Election Period (SEP). CMS is proposing to modify the current continuous SEP to permit dual-eligible and LIS beneficiaries to use the SEP only once per calendar year, with limited exceptions: dual-eligible and LIS beneficiaries who have not been identified as potentially at-risk or at-risk who have been auto-assigned to a plan would have access to an additional SEP before the assignment becomes effective or within two months of their enrollment into that plan, and those who experience a change in their Medicaid or LIS status would have an additional SEP to change enrollment within two months of the eligibility change, or of notification of the change, whichever is later.

Comments:

¹⁰³ *Op. cit.* Hoadley & Cubanski

In the proposed regulation, CMS asserts that the majority of auto-assigned beneficiaries do not switch plans, and that fewer than 10 percent use a SEP outside of the Annual Election Period (AEP).¹⁰⁴ Similarly, a Kaiser Family Foundation study shows that only 3 percent to 4 percent of LIS beneficiaries changed plans outside of the AEP each year from 2007 to 2010.¹⁰⁵ However, the Kaiser study also found that most changes made using a SEP occurred in February or March, suggesting that a change in plans may be easier to navigate for some beneficiaries than the exceptions or appeals process. Thus, if so few LIS beneficiaries use the continuous SEP as currently structured, it is logical to assume that beneficiaries are not using the SEP to take advantage of the transition policy or use the Part D program in other concerning ways. In short, PhRMA questions the rationale for CMS proposing this change.

Further, PhRMA argues it is reasonable to assume that the minority of beneficiaries who use this SEP could have healthcare needs that require off-cycle plan switches to ensure they have the best coverage. A CMS-sponsored Acumen study shows that LIS beneficiaries subject to reassignment who made an active enrollment decision had greater prevalence of the 30 top diagnoses in Part D, suggesting that those who expect high drug utilization are more likely to actively select a plan rather than accept reassignment.¹⁰⁶

Given the clear data that beneficiaries with LIS are not abusing the flexibility afforded to them by the continuous SEP, along with the disproportionate need for enrollment flexibility for that population, PhRMA urges CMS to modify the proposed policy to allow beneficiaries to request additional SEPs beyond the limited options CMS has outlined.

A.11: Medicare Advantage and Part D Prescription Drug Plan Quality Rating System [p. 56375]

Description: CMS proposes to codify many aspects of the existing Star Ratings System for the MA and Part D programs in an effort to provide greater stability and transparency to the program. These proposed changes include establishing clearer rules governing the adding, updating, and removal of measures. CMS believes this is the appropriate time to codify the Star Ratings methodology, due to the maturity of the quality rating program and lower likelihood for extensive changes on an annual basis.

Comments:

PhRMA supports CMS' continued commitment to improving the MA and Part D quality performance measurement system. Quality measures convey critical information about plan and provider performance, can inform quality improvement strategies, and most importantly, improve patient care. Therefore, we support the use of measures, whether structural, process, or outcome that are well-grounded in evidence;

¹⁰⁴ 82 Fed. Reg. at 56373.

¹⁰⁵ Kaiser Family Foundation. To Switch or Be Switched: Examining Changes in Drug Plan Enrollment among Medicare Part D Low-Income Subsidy Enrollees. July 2015. Available at: <http://files.kff.org/attachment/report-to-switch-or-be-switched-examining-changes-in-drug-plan-enrollment-among-medicare-part-d-low-income-subsidy-enrollees>.

¹⁰⁶ Marrufo G, O'Brien-Strain M, Theobald N, Lau T, Verhulst E, Moin N. Evaluation of the Medicare Part D Demonstration to Transition Enrollment of Low Income Subsidy Beneficiaries. June 2009. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Marrufo_PartD_LIS_2009.pdf.

have successfully undergone the rigor of careful testing, validation, and scrutiny to ensure they provide accurate, reliable, and meaningful results; have been subjected to external review; and presented for public review and comment. Ideally, measures should not be adopted for use unless they have undergone this type of process and been endorsed through a multi-stakeholder consensus development process, such as that of the National Quality Forum (NQF), working in close concert with measure stewards.

1. Guiding Principles to Enhancements to MA and Part D Star Ratings

PhRMA commends CMS for applying a set of well-established guiding principles in making enhancements to the MA and Part D Star Ratings. PhRMA supports these principles because they lay an important foundation for quality improvement and accountability for plan sponsors, as well as ensure that beneficiaries are receiving safe, high quality, and timely care. In addition, we encourage CMS to further explore how the recently announced “Meaningful Measures” initiative¹⁰⁷ can also help to prioritize and harmonize quality measures within the Star Ratings program. This could include streamlining of measures, filling measure gaps, removing topped out measures, improving alignment between the Star Ratings and provider-level measures, and transitioning more measures towards outcomes.

2. Proposed Codification of Star Ratings System

Currently, proposed changes to the Star Ratings System are communicated and modified through the annual Advanced Notice and Rate Announcement process. Based on stakeholder feedback on enhancements to program stability and improved transparency, CMS proposes to codify many aspects of the existing Star Ratings System for the MA and Part D programs.

For certain processes for which there are well-established measure specifications and methodologies, PhRMA agrees that these aspects should be codified via rulemaking, as these changes are minimal over time. This includes those processes and rules pertaining to data integrity and sources, criteria for substantive and non-substantive measure changes, and removal of measures in which there are data reliability issues or changes in clinical guidelines in which the measure is no longer relevant. Additionally, the current measure weighting system for the Star Ratings has remained stable and we believe places the right emphasis and importance on the measure types to reflect plan performance and incentivize continuous quality improvement. These criteria and procedures are well-accepted and applied across quality measures in other CMS payment programs, and so we agree that they could be codified in regulation.

As we will discuss in greater detail below, PhRMA does not support CMS’ proposal to require rulemaking for the addition of new measures to the Star Ratings. The proposed codification for measure additions is duplicative and adds an unnecessary regulatory layer to the already lengthy process that current measures undergo for inclusion in the Star Ratings program which would not increase transparency, and in fact could hinder prompt adoption of better measures for safety and care quality.

¹⁰⁷ <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-10-30.html>

3. Measure Maintenance: Measure Additions, Updates, Removals

Given the time-intensive nature of measure development, endorsement and adoption, we strongly believe that CMS should retain the flexibility to make changes through sub-regulatory action and do not believe it is appropriate to require rulemaking in order to add a new measure to the program. CMS states that the rulemaking process will create longer lead time for changes to the measure set. Therefore, PhRMA does not support the proposal that new measure additions undergo rulemaking. Subjecting new measure additions to rulemaking will exacerbate an already lengthy process for current measures to be added to the Star Ratings Program, and we are concerned that this policy would hinder CMS' ability to more quickly add measures that promote evidence-based practices, reduce adverse events, and encourage quality care. We believe the current process appropriately balances opportunities for comment and lead time to gain experience with new measures with the need to keep the measure set current. In the event CMS finalizes this proposal, there should be an accompanying framework or policy guiding measure prioritization that addresses care gaps or circumstances where the regular rulemaking process would be exempted, for instance to address an urgent public health need.

PhRMA agrees that it is important to have multiple opportunities for the public to provide input and preview measures as they are being considered for inclusion in any payment program, and that plan sponsors have adequate lead time to know which new measures or adjustment to existing measures are being considered. Compared to other quality payment programs, the Star Ratings program is unique in that CMS has historically provided a separate solicitation and comment period regarding the Star Ratings and display measures to review and evaluate comments prior to the Call Letter process. This has been done to ensure that the agency has time to review and consider input from stakeholders on proposed methodology changes for measures, and to provide advance notice of potential changes to the Star Ratings and display measures. There is another opportunity to comment in response to the draft Call Letter each year, and prior to addition to the Star Ratings, measures under consideration for addition are placed on the Display page for plans to gain familiarity with the measure before they are moved into the performance ratings. Display measures are not part of the Star Ratings, and they could include measures in transition to or from the Star Ratings or new measures that are tested before inclusion into the Star Ratings. CMS provides organizations and plan sponsors with the opportunity to preview their data on the display measures prior to release on CMS' website.

PhRMA appreciates the ample opportunities and transparent process CMS has created for interested parties to review the measures and provide comment, and we believe these mechanisms are sufficient. The advance notice provided by CMS regarding measures considered for implementation in either the Star Ratings or display measures, additional comment opportunities and the incremental, stepwise process to measure addition should provide all stakeholders with adequate time to prepare without the need for formal rulemaking.

Additionally, CMS has not addressed or included any potential exceptions to the proposed rulemaking regarding measure additions. Situations could arise where CMS wants to more promptly implement a Star Ratings measure in order to address a known patient safety issue. For example, the National Action Plan

for Adverse Drug Event Prevention (ADE Action Plan)¹⁰⁸ identifies drug adverse events that are considered to be common, clinically significant, preventable, and measurable. Requiring rulemaking in order to add a measure to the Star Ratings could unnecessarily delay implementation of measures to address these preventable safety issues. Should CMS decide to codify the addition of new measures to the Star Ratings moving forward, PhRMA strongly urges CMS to consider granting exceptions in circumstances which there are urgent public health and patient safety issues that could be addressed through quality measures.

Quality measure development and maintenance is a dynamic process that evolves with the science and discovery of new therapeutics, as well as improved technology and data collection capabilities to support these measures with a greater focus on patient outcomes. The measure development process itself, when thoughtfully conducted through a patient-centered, clinically-driven and validated process that is transparent and accountable, can take several years. Additionally, there is currently a two-year lag in the data collection periods to any corresponding performance year, so measures are not a current reflection or representation of plan performance and we should strive to reduce this delay without compromising the measurement development process so patients can make informed decisions about their care. As CMS considers further modifications to its procedures for the Star Ratings, we encourage the agency to explore ways to shorten the timeframe between measure development, endorsement, and adoption in the Star Ratings in order to further speed adoption of evidence-based quality measures.

4. Measure Weighting

PhRMA supports codification of the current weighting of measures in the Part C and D Star Ratings by assigning the highest weight to improvement measures, followed by outcome and intermediate outcome measures, then by patient experience/complaints and access measures, and lastly process measures. We believe these appropriately prioritize measure types that best reflect plan improvement and performance, and have been stable over time to warrant codification. PhRMA supports maintenance of the current methodology and we believe that outcome and intermediate outcome measures should be weighted more than process measures, as achieving improved outcomes, including improved clinical outcomes, functional status, and quality of life, is the goal.

Along with codification, CMS is also considering increasing the weight of patient experience measures. PhRMA believes it is critical to capture the patient's voice in quality measures, and share in CMS' commitment to better serve Medicare beneficiaries, by including their assessment of the care provided by plans. We believe there is merit to placing a greater weight on these measures to bring them closer into alignment with intermediate outcome measures, but caution that there could be issues with data reliability and encourage CMS to work closely with measure stewards on reducing survey bias and strengthening the integrity of the data.

We would also like to reiterate our support for maintaining the current medication adherence measures at a weight of 3. Medication adherence measures address the intermediate outcome that is clearly linked with better health for Medicare beneficiaries, and adherence remains below optimal levels for many high-priority

¹⁰⁸ <https://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf>

conditions. Patients who were more adherent to prescribed medications for four chronic conditions (congestive heart failure, hypertension, diabetes, and dyslipidemia) had savings of \$3 to \$8 in non-drug spending for each additional dollar spent on medicines, and significantly fewer emergency department visits and inpatient hospital days.¹⁰⁹ To underscore the importance of adherence in Medicare, since the introduction of the Part D drug benefit, increased access to medicines for those previously without drug coverage resulted in reduced medical spending and an overall savings of \$13.4 billion in the first full year of the benefit.¹¹⁰ Part D enrollees with diabetes who are adherent to therapy save the Medicare program between 15-20% per month in spending on Medicare Part A and Part B services in the second year following initiation.¹¹¹

PhRMA also supports the development of additional clinical outcome measures for medication adherence, but as we've previously stated, measure development is a lengthy process. In the interim, it is essential that CMS continue to measure adherence in the Part C and D programs and provide plans with strong incentives to improve (i.e., a 3x weighting for these measures). There is evidence that shows plan sponsors continue to have strong incentives to address medication adherence with the ultimate goal of improving management of chronic conditions across MA-PDs and PDPs.¹¹²

5. Categorical Adjustment Index (CAI)

As an interim means to account for the potential variation and within-contract disparities due to socioeconomic status, CMS applied the Categorical Adjustment Index (CAI) beginning with the 2017 Star Ratings. CMS is now proposing to continue the use of the CAI and codify the calculation of CAI values while the agency continues to work with measure stewards and evaluate the evidence generated by other stakeholders. CMS is also seeking comment on how the agency should account for low socio-economic status (SES) and other social risk factors in the Part C and D Star Ratings.

PhRMA appreciates CMS' attention to the potential impact of low income subsidy/dual eligible (LIS/DE) and disabled beneficiary enrollment on Star Rating performance and commitment to an open process as it evaluates this issue.

PhRMA agrees that use of the CAI as an interim adjustment is consistent with CMS' goals for addressing the potential impact of LIS/DE and disabled beneficiary enrollment on Star Rating performance. However, this was intended to be applied as a temporary analytical adjustment only, and thus we do not believe codification of the calculation or use of CAI is appropriate given the original intent of the adjustment, and in the absence of overwhelming evidence, this has detrimental effects on beneficiaries and plan sponsors.

¹⁰⁹ Roebuck MC, et al. Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending. *Health Affairs*. 2011;30(1):91-9.

¹¹⁰ McWilliams JM, et al. The Economic Impact of Medicare Part D and Nondrug Medical Spending for Elderly Adults with Limited Prior Drug Coverage. *JAMA*. 2011; 306(4):402-9.

¹¹¹ Stuart B, Loh FE, Roberto P, Miller L. Incident User Cohorts for Assessing Medication Cost-Offsets. *Health Services Research*. 2014;49(4):1364-1386.

¹¹² Ta JT, Erickson SC, Qiu WA, Patel BV. Is there a Relationship Between Part D Medication Adherence and Part C Intermediate Outcomes Star Ratings Measures? *J Manag Care Spec Pharm*. 2016 Jul;22(7):787-95

CMS notes that even through its own research, the impacts of SES on quality are modest, do not always negatively impact the measures, and would only affect a small subset of measures.

Therefore, it is critical that CMS proceed with caution to avoid either creating a double standard of care or inappropriately lowering standards for chronic disease management. Additionally, CMS should continue to closely monitor the effect of any adjustment to the Star Ratings for potential unintended consequences – such as declining quality of care for LIS/DE and disabled enrollees, or the potential risk of disincentivizing plans from enrolling these populations. As an additional interim approach, CMS could also consider including structural measures in the Star Ratings program to evaluate if plans have appropriate supports in place for LIS/DE and/or disabled beneficiaries to achieve optimal outcomes.

We strongly urge CMS to continue working closely with the measures stewards to develop any permanent specification changes as determined appropriate. PhRMA agrees that the best approach to risk adjusting the Star Ratings measures is to facilitate rigorous analysis, development, and testing of measure-specific adjustments by the measure stewards, the Pharmacy Quality Alliance and the National Committee for Quality Assurance.

6. Additional Areas for Feedback

CMS is interested in stakeholder feedback on additional opportunities to improve measures so that they better reflect the quality of health outcomes under the rated plans, adding measures that evaluate quality from the perspective of adopting new technology, and the potential inclusion of survey measures of physicians' experiences.

Looking ahead, as CMS continues to make changes to maintain and improve the Star Ratings, we encourage the agency to consider the development of comprehensive measure sets to assess and report on plan quality. These sets include a mix of measure types, i.e., outcomes and processes, disease-specific and cross-cutting, and clinical and patient-reported data sources, to ensure that measure sets provide a complete picture of the quality of patient care.

Furthermore, as the Star Ratings program evolves, inclusion of additional outcome measures addressing a broader range of conditions would strengthen the program and help assure that it achieves its goals. A shift to more granular, outcomes-focused measures that are aligned to current clinical guidelines can help advance the current standard of care in ways that would meaningfully improve patient health and reduce costs associated with ongoing complications. Measuring the outcomes of care delivered by health plans is particularly essential to ensure that plans deliver high quality care to patients and do not restrict patient access to essential treatments as plans seek to manage the cost of care.

It is essential that quality measures be reflective of the health needs of Medicare beneficiaries, and include the conditions most prevalent in this population. In particular, gaps in currently available measures related to cancer treatment and symptom management, pain, autoimmune disorders, respiratory conditions, mental illness, dementia/cognitive impairment, and multiple co-morbidities hamper the ability of the program to

appropriately measure quality of care for these conditions. There are also measure gaps that address public health needs, such as those addressing opioid-related use or guideline-recommended vaccines in older adults that are not currently included in quality measures in the Medicare Advantage and Part D programs. In order to holistically address opioid misuse and abuse, there also needs to be adequate quality measures in place that address the application of non-addictive alternatives to pain management, whether in the form of pharmacotherapeutics, medication-assisted treatment, or non-pharmacological options. With respect to vaccines, the Measures Application Partnership (MAP) has recently recognized the importance of adult immunizations, and emphasized the need for such a composite measure.¹¹³ With continual scientific advances in both development of new therapies and diagnostics, many patients are able to manage diseases that were once considered life-threatening chronic conditions. As this panel of patients continue to age into the Medicare benefit, we urge CMS to consider quality measures that anticipate the health needs of these patients, particularly as the prevalence of those living with these chronic conditions continues to grow.^{114,115}

We also encourage CMS to give particular attention to patient-centered measures, e.g., those that reflect patients' priorities for measuring and reporting on quality of care. Measure types such as quality of life, functional status, and patient-reported outcomes, which provide an important patient perspective on care, should also be included as additional outcome measures. CMS should encourage measure developers to focus resources in disease areas and measure types mentioned, and work to include new measures as they are endorsed. Both patient-reported outcomes and clinical outcomes are important, and PhRMA supports CMS seeking ways to incorporate these types of measures in future Star Ratings. There have also been advances in health care delivery that incorporate the use of mobile health or technology as a complementary component to aid beneficiaries and their providers in shared decision making or better managing their disease. We are supportive of using such technologies to inform current or future quality measures.

CMS notes that the agency is considering developing a survey tool for collecting standardized information on physicians' experience with health and drug plans and their services. Gathering feedback from providers on their interactions with plan sponsors, such as through processes like prior authorization for medications, could provide valuable information that complements patient experience data, particularly if there is a correlation with beneficiary access to care.^{116,117} As CMS further considers this approach, it will

¹¹³ National Quality Forum Measures Application Partnership. MAP 2018 Considerations for Implementing Measures in Federal Programs: MIPS and MSSP. Draft Report for Comment. December 2017.

¹¹⁴ Centers for Disease Control and Prevention. HIV Among People 50 and Over: <https://www.cdc.gov/hiv/group/age/olderamericans/index.html>. Accessed January 9, 2018.

¹¹⁵ Alzheimer's Association. 2017 Alzheimer's Disease Facts and Figures. *Alzheimers Dement* 2017;13:325-373.

¹¹⁶ Morra, D, Nicholson, S, Levinson, et al. US Physician Practices Versus Canadians: Spending Nearly Four Times As Much Money Interacting With Payers. *Health Affairs*. 2011;30(8):1443-1450.

¹¹⁷ American Medical Association. 2016 AMA Prior Authorization Physician Survey. <https://www.ama-assn.org/sites/default/files/media-browser/public/government/advocacy/2016-pa-survey-results.pdf>. Accessed January 5, 2018.

be important for the agency to work with providers on the development of the survey so that it can be seamlessly integrated into their workflow and does not add to provider reporting burden.

A.12: Any Willing Pharmacy Standards Terms and Conditions and Better Define Pharmacy Types [p. 56408]

Description: CMS is proposing a number of clarifications and changes around any willing pharmacy (AWP) requirements, pharmacy types, and what constitutes “reasonable and relevant” pharmacy terms and conditions. CMS is concerned that the balance between maintaining standard terms and conditions and permitting preferred networks has resulted in some plan sponsors developing a set of standard terms and conditions that may inappropriately exclude pharmacies from network participation and circumvent AWP requirements.

Comments:

In considering these clarifications and changes, PhRMA applauds CMS’s effort to ensure that all beneficiaries have adequate access to pharmacies and pharmacy services. PhRMA particularly appreciates the clarification that the current pharmacy benefit manager (PBM) practice of requiring non-PBM-owned specialty pharmacies to obtain additional accreditation as a condition of network participation is not reasonable.

Given concern that plans are limiting the number of specialty pharmacies in their networks, PhRMA urges CMS to monitor whether beneficiaries have appropriate access to products that are distributed through specialty pharmacies. Especially given these potential changes, CMS should ensure that beneficiaries have adequate access to accurate and public information about their plan’s pharmacy network and appropriate advance notice of changes to specialty pharmacy networks.

A.14: Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes [p. 56413]

Description: CMS is proposing to allow plans to immediately—at any time of the year and without 60-day notification—remove a brand medicine from the formulary or increase brand cost-sharing when adding a newly available, therapeutically equivalent generic. Though CMS would require plans to provide general notification that such changes are possible, it would no longer require direct advance notice to affected beneficiaries when making a change. CMS is also proposing to decrease the amount of direct notice for other mid-year changes from 60 to 30 days and to limit the 60-day refill upon notice to one month.

Comments:

PhRMA believes that appropriate generic substitution can be beneficial for patients, plan sponsors, and the Part D program. However, PhRMA has serious concerns about the proposal to change the advance notice requirement and urges CMS not to eliminate or reduce this requirement for mid-year changes.

CMS states in the proposed rule that this change was supported by recommendations made by MedPAC. Although MedPAC proposed a policy change that would allow plans to remove brand drugs upon addition of therapeutically equivalent generics, the proposal did not also recommend the elimination of advance notice for beneficiaries affected by these types of changes.

No sound reason exists for the elimination of advance notice of these changes. The timing of newly available generics is widely available and known to plan sponsors well in advance of the release of these medicines. Therefore, eliminating the advance notice requirement for these types of formulary changes only serves to reduce plan administrative tasks.

In addition, PhRMA is concerned that lack of advance notice could harm beneficiaries. Advance notice offers beneficiaries the opportunity to discuss options with their prescribers, whether to request an exception, to change medications, or to accept the change in formulary. Beneficiaries who receive no notice could be alarmed upon filling a prescription if the name, color, and/or shape of the drug is different than the one they have been receiving. These changes—without notice even from the pharmacy—could result in beneficiary confusion and/or therapy disruption.

In addition to this policy change not being supported by MedPAC and potentially leading to beneficiary confusion and therapy disruption, it would also be inconsistent with the National Association of Insurance Commissioners (NAIC) model guidelines. NAIC's multi-stakeholder process on its Prescription Drug Benefit Management Model Act (#22) has thus far reached consensus on a minimum 60-day advance notice for generic and non-generic substitutions, rather than 0-day and 30-day notifications, respectively.¹¹⁸

A.15: Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost-Sharing [p. 56416]

Description: Generics and multiple source drugs have lower maximum copays for LIS enrollees, and for non-LIS enrollees in catastrophic coverage. In 2015 guidance on Part D biosimilar issues, CMS concluded that biosimilars were not “generics” under the Part D regulatory definition in 42 C.F.R. § 423.4 (because it is limited to drugs approved under section 505(j) of the Food, Drug, and Cosmetic Act) or “multiple source drugs” (because the relevant Part D provisions reference a Medicaid rebate statute provision defining

¹¹⁸ NAIC, Health Carrier Prescription Drug Benefit Management Model Act (#22), November 7, 2017 draft, available at http://www.naic.org/documents/cmte_b_mod_22_sg_exposure_health_carrier_prescription_drug_benefit_proposed_revisions.pdf

“multiple source” drugs as those having therapeutic equivalents listed in FDA’s Orange Book).¹¹⁹ Therefore biosimilars currently are treated as brand drugs for purposes of the maximum LIS and catastrophic coverage copays. The proposed rule would revise the definition of a “generic” in 42 C.F.R. § 423.4 such that biosimilars would be classified as generics solely for purposes of the maximum LIS and catastrophic coverage copays.

Comments:

The proposed rule does not explain why a biosimilar could logically be categorized as a “generic,” but states that classifying biosimilars as brands for purposes of the maximum LIS and non-LIS catastrophic coverage copays has “generated a great deal of confusion and concern for plans and advocates alike, and that CMS received numerous requests to redefine a generic drug at 423.4.”¹²⁰ CMS is proposing this change because it agrees with stakeholders’ concerns that treating biosimilars as brands for purposes of the maximum LIS and catastrophic coverage copays could create a disincentive to choose lower-cost alternatives.¹²¹

Under Social Security Act (SSA) § 1860D-14(a)(1)(D), the maximum LIS copay for the lowest-income-dual eligibles (before catastrophic coverage) equals \$1 for a “generic” or preferred “multiple source” drug and \$3 for any other drug (or, if less, the maximum catastrophic coverage copay for non-LIS beneficiaries, which is described below).¹²² The \$1 and \$3 amounts apply in 2006 and are adjusted annually by the percentage increase in the consumer price index (CPI); for 2018 the adjusted amounts are \$1.25 and \$3.70.¹²³ Under SSA § 1860D-2(b)(4), the maximum catastrophic coverage copay (for non-LIS enrollees) is the greater of: (1) \$2 for a generic or preferred “multiple source” drug and \$5 for any other drug; or (2) 5 percent coinsurance. The dollar amounts apply in 2006 and are annually adjusted based on average annual increase in per capita Part D spending; for 2018 the adjusted amounts are \$3.35 and \$8.35.¹²⁴ Under this provision, the dollar amounts will fall below 5 percent coinsurance for medium and higher-cost drugs, in which event beneficiaries’ cost-sharing is based on 5 percent coinsurance instead of the dollar amounts; therefore classifying biosimilars as “generics” under this provision might not significantly affect patient cost-sharing in catastrophic coverage.

In addition, this proposal would further complicate the already inconsistent treatment and definition of biosimilars across the Medicare and Medicaid programs. While we recognize the challenges before CMS, consistent treatment of biosimilars both within CMS regulations and with the FDA regulatory scheme for these products is important to avoid confusion around the regulatory status and use of these products.

¹¹⁹ March 30, 2015 Memo from Amy K. Larrick to Part D Sponsors, “Part D Requirements for Biosimilar Follow-On Biological Products.”

¹²⁰ 82 Fed. Reg. at 56417.

¹²¹ 82 Fed. Reg. at 56417.

¹²² Certain higher-income LIS enrollees have maximum copays before catastrophic coverage that apply to non-LIS enrollees in catastrophic coverage; these copays are described below.

¹²³ CMS, Final Updated Part D Benefit Parameters for 2018, for Defined Standard Benefits, Low Income Subsidies, and Retiree Drug Subsidies.

¹²⁴ Id.

Treating biosimilars as generics for the purposes of LIS cost-sharing and non-LIS catastrophic cost-sharing in Part D would be inconsistent with the approach to biosimilars in other government reimbursement statutes and policies. For example, CMS now proposes to treat biosimilars as “generics” for the purposes of LIS cost-sharing and non-LIS catastrophic cost-sharing in Part D, but CMS treats biosimilars as different from their reference biologic for purposes of the Part D transition policy and the mid-year formulary changes policy, and in the context of the Medicaid Drug Rebate Program, where manufacturers pay rebates based on the formula for single source brand drugs, rather than the formula for multiple source drugs.¹²⁵ Moreover, CMS recently revised its Part B reimbursement policy to treat biosimilars covered under Medicare Part B as single source medicines (abandoning its previous policy of blending the payment rates for biosimilars with the same reference biologic).¹²⁶ Meanwhile, in the Part D coverage gap, by statute biosimilars are considered not “applicable drugs” for the purposes of the Coverage Gap Discount Program, and are ineligible for the 50 percent discount paid by pharmaceutical manufacturers on brand medicines, including innovator biologics.¹²⁷

PhRMA strongly supports efforts to promote the development of a vibrant biosimilar marketplace that promotes greater competition and cost savings for patients and the program overall; these are critically important objectives we have addressed in many previous comment letters to CMS. Therefore, we appreciate the intent of this CMS proposal and hope CMS will continue to analyze potential steps to encourage appropriate biosimilar utilization in Medicare Parts B and D. At the same time, we are not certain what the rationale would be for classifying biosimilars as generic drugs, even in limited circumstances, as there are no existing CMS or FDA definitions of generics (or even the broader term “multiple source drug”) that encompass biosimilars, and the proposed rule does not suggest a rationale.

We also share CMS’ concerns that classifying biosimilars as generics could cause confusion. Specifically, CMS stated that:

we propose to limit inclusion of follow-on biological products in the definition of generic drug to purposes of non-LIS catastrophic cost sharing and LIS cost sharing only because we want to avoid causing any confusion or misunderstanding that CMS treats follow-on biological products as generic drugs in all situations. We do not believe that would be appropriate because the same FDA requirements for generic drug approval (for example, therapeutic equivalence) do not apply to biosimilar biological products, currently the only available follow-on biological products. Accordingly, CMS currently considers biosimilar biological products more like brand name drugs for purposes of transition or midyear formulary changes because they are not interchangeable. In these contexts, treating biosimilar biological products the same as generic drugs would incorrectly signal that CMS has deemed biosimilar products (as differentiated from interchangeable biological

¹²⁵ CMS, Medicaid Drug Rebate Program Notice: Biosimilars and Medicaid Drug Rebate Program (Mar. 30, 2015), [available at https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-092.pdf](https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/MFR-Releases/mfr-rel-092.pdf).

¹²⁶ 82 Fed. Reg. at 53182.

¹²⁷ SSA § 1860D-14A(g)(2).

products) to be therapeutically equivalent. This could jeopardize Part D enrollee safety and may generate confusion in the marketplace through conflation with other provisions due to the many places in the Part D statute and regulation where generic drugs are mentioned.¹²⁸

Given the potential risks CMS identified, the lack of a logical or statutory basis for categorizing biosimilars as generics, and the fact that the proposal (if adopted) may have little impact on patient cost-sharing in catastrophic coverage, we suggest that CMS reconsider this proposal and instead take a comprehensive look at the full range of tools that could be used to encourage biosimilar utilization in Part D. Addressing high patient cost-sharing is a top priority and we appreciate CMS' efforts to develop solutions. We would welcome the opportunity to work with you on this important issue to identify alternative proposals that strike a better balance between risks and benefits.

A.16: Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings with Meaningful Differences [p. 56417]

Description: CMS is proposing to eliminate the meaningful difference requirement between enhanced alternative (EA) Prescription Drug Plans (PDPs). CMS also intends to revisit the use of the out-of-pocket cost (OOPC) model as method for determining meaningful difference between basic and enhanced PDPs.

Comments:

PhRMA supports CMS in its aim to lower Part D premiums and increase beneficiaries' choice of coverage options. PhRMA has previously opposed limits on the number of sponsors' offerings, since such policies can be arbitrary and potentially harmful to the competitive Part D market. Choice of plans is important to beneficiaries and allows for beneficiaries to find enrollment options that meet their needs.

If CMS moves forward with allowing plan sponsors to submit more enhanced plan offerings, PhRMA urges CMS to ensure that distinctions between plans are clear to beneficiaries when they are considering enrollment options. Revising the Plan Finder and the *Medicare and You* handbook to include a flag for the type of enhancement each plan uses (e.g., reduced cost-sharing on tiers, coverage of additional drugs, improved benefit design, additional gap coverage) would help beneficiaries distinguish plans and make better plan choices. Additionally, PhRMA encourages CMS to monitor how changes in the number of Part D plans available each year impact competition in the marketplace.

In terms of revisiting the OOPC model for determining meaningful difference, PhRMA continues to have significant concerns with the well-documented shortcomings of the OOPC model, which we have raised

¹²⁸ 82 Fed. Reg. at 56417.

with CMS several times in the past.¹²⁹ These shortcomings have created several unintended consequences for the program, such as:

- Providing incentives for sponsors to create a basic plan formulary that covers fewer drugs than its enhanced plan formulary, even if there are no financial or clinical objectives to do so other than meeting the meaningful difference requirement. For example, in the OOPC Tool, actuaries at Milliman tested the impact of removing medications from formulary with a representative benefit design and found that there are several products valued at \$5 or more in the OOPC tool, making up a large portion of the overall OOPC requirement between basic and enhanced plans to achieve meaningful difference compliance for that plan year.¹³⁰
- Placing certain medications (e.g., older medicines with high utilization in the base data) at a disadvantage over others in basic PDP formularies due to the long lag time between the data used in the OOPC model and the time period for which it is applied. This existing data lag was further exacerbated by the delayed update of the Medicare Current Beneficiary Survey (MCBS) data used in the 2016, 2017, and 2018 OOPC models.
- Disproportionately impacting low-income beneficiaries because the vast majority of these members enroll in basic plans where the OOPC model drives more formulary exclusions.
- Potentially disrupting beneficiary access to needed medicines when the OOPC model contributes to negative formulary changes from one plan year to the next (e.g. if a market-leading product is dropped from a basic plan formulary in order to create a meaningful difference relative to the enhanced plan).

Many of these shortcomings can be addressed, but CMS has not finalized any solutions to date. In the 2014 draft Call Letter, CMS considered a change to the OOPC model to “have the MCBS cohort drugs which are non-formulary priced at the cost-sharing of the Part D sponsor’s exceptions tier.”¹³¹ PhRMA’s comments on the 2014 draft Call Letter supported this proposed change, noting that it would improve the ability for CMS and beneficiaries to judge true differences across plan offerings. However, CMS did not take action on this proposal for CY 2014 and instead stated that it would consider the comments received for CY 2015.¹³² CMS did not take up this proposed change in the 2015 draft Call Letter, and it has not been addressed since then.

Analysis from actuaries at Milliman has shown that the change proposed in the 2014 Call Letter would eliminate any differential between drugs being off the formulary (otherwise treated as 100 percent cost-

¹²⁹ Milliman. “Impact on Formulary Design from Medicare Part D Meaningful Difference Regulations,” Prepared for PhRMA, November 2014. *This report has been shared with CMS previously.*

¹³⁰ Milliman analysis of the CMS CY2017 OOPC Model, prepared for PhRMA, February 2017.

¹³¹ Advance Notice of Methodological Changes for Calendar Year (CY) 2014 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2014 Call Letter, February 15, 2013, p. 144.

¹³² Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2013, p. 156.

sharing) or on the exception tier (generally at the non-preferred cost-sharing level) and could limit incentives for plans to narrow the basic plan formulary based on the OOPC model.¹³³ PhRMA once again strongly urges CMS to explore implementing this proposed change from the 2014 draft Call Letter for the 2019 plan year. At a minimum, we request that CMS provide further explanation as to why it has not pursued this previously proposed change further.

As an alternative, we suggest that CMS explore options for moving away from use of the OOPC tool in evaluating meaningful differences between plan offerings. For example, CMS could consider requiring plans to establish that average member cost-sharing in the initial coverage phase have a minimum difference between basic and enhanced plans (e.g., 20 percent average member cost-sharing for an enhanced plan vs. 25 percent average member cost-sharing for a basic plan). A second enhanced plan could further reduce average member cost-sharing in the initial coverage period and/or offer extra gap coverage. This alternative approach to meaningful difference requirements is based on existing information provided by plan sponsors on bid forms each year and therefore may be relatively straightforward to implement.

B.8: E-Prescribing and the Part D Prescription Drug Program: Updating Part D E-Prescribing Standards [p. 56438]

Description: CMS is proposing to adopt the NCPDP SCRIPT 2017071 as the official Part D electronic prescribing (e-prescribing) standard for certain specified transactions within the Part D program, and to retire the current version of the standard (NCPDP SCRIPT 10.6) effective January 1, 2019. If finalized, plan sponsors, prescribers, dispensers, and other entities that electronically transmit prescription and certain other information for covered drugs prescribed for Medicare Part D eligible beneficiaries would be required to use the proposed standard to convey information about prescriptions and other medication-related data.

Comments:

PhRMA supports technological advancements that promote a safer, more efficient, and interoperable health care system, and we are supportive of CMS' proposal to adopt NCPDP SCRIPT 2017071 as the new e-prescribing standard. In particular, we are pleased with the enhancements in the new standard that will improve patient safety and access, and encourage the appropriate use of medicines. While we support the use of standards for e-prescribing, we also want to stress the importance of the transmission of timely, accurate, un-biased data that protects patient privacy, does not interfere with patient/provider communications, nor negatively impact clinical care decisions that could restrict patient access to appropriate therapies. High quality e-prescribing should support improvements in patient care by providing

¹³³ Milliman. "Impact on Formulary Design from Medicare Part D Meaningful Difference Regulations," prepared for PhRMA, November 2014, p. 2.

a neutral and balanced platform for the exchange of prescription-related information and efficient delivery of medications.

In addition to the specified transactions that would be required in the rule, we encourage CMS to explore whether there are additional transactions within the SCRIPT standard that would be beneficial to adopting in the Part D program, such as the electronic prior authorization (ePA) transaction. The utilization of this transaction aligns with CMS' goals of improving customer experience and supporting innovative approaches to improving quality, accessibility, and affordability. Prospectively addressing prior authorization issues through the ePA transaction decreases administrative burden for providers, reduces the wait time for approvals and potential for prescription abandonment, thereby improving beneficiary access to innovative medicines and adherence.

CMS also requests comment on the impacts of the proposed effective date to adopt NCPDP SCRIPT 2017071 on January 1, 2019 as the official e-prescribing standard. PhRMA notes that the beginning of the plan year can present several processing and administrative changes for providers and their vendors to prepare for. To reduce the risk of health care delivery delays, we encourage CMS to work with affected stakeholders to identify a timeline for a smooth transition process to implementing the new e-prescribing standard that minimizes beneficiary disruption.

B.10: Part D Prescriber Preclusion List [p. 56441]

Description: In lieu of requiring prescribers to enroll in or opt out of Medicare in order for a Part D drug pharmacy claim to be covered, CMS is proposing to establish a "Preclusion list" of prescribers from which scripts will not be covered. CMS proposes to compile a preclusion list of prescribers who:

1. Are currently revoked from Medicare, are under a reenrollment bar, and CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the program; or
2. Have engaged in behavior for which CMS could have revoked the prescriber to the extent applicable if he or she had been enrolled in Medicare, and CMS determined the underlying conduct that would have led to the revocation is detrimental to the best interest of the Medicare program.

Comments:

PhRMA applauds CMS' efforts to address fraud and abuse in the program—particularly given the urgency of the opioid crisis and the need to ensure that unscrupulous prescribers are prevented from evading program integrity efforts. In particular, we appreciate the steps CMS has taken to ensure that pharmacy claims for covered Part D drugs include a valid National Provider Identifier (NPI) and consideration of additional penalties to deter fraud and abuse related to illegal use of such identifiers. We

encourage CMS to also consider how to mitigate potential access challenges created for patients when claims with invalid NPIs are submitted in error.

PhRMA also applauds CMS' proposed risk-based approach to focus on demonstrably problematic prescribers by establishing a preclusion list based on Prescription Drug Event (PDE) data updated each month. As CMS transitions to this approach, we want to ensure there is an appropriate balance between efforts to target problematic prescribers in the program and the need to preserve legitimate patient access to needed medicines. Likewise, we appreciate CMS' efforts to provide provisional coverage of needed medicines to patients once they are notified that their prescriber appears on CMS' preclusion list so that they may appropriately transition their care. In addition, in cases where timely access to needed opioids is medically appropriate, we urge CMS to take steps to require Part D sponsors to provide timely transfer to a new provider when the first provider is on the preclusion list. Such an approach will ensure that patients can obtain timely access to pain management while also allowing for an appropriate assessment for substance use disorder and referral to treatment as needed. Moving forward, we also urge CMS to expand efforts to coordinate and expand sharing of information with other federal public programs, state medical boards and other entities on potentially problematic prescribing to help inform the identification of prescribers who should appear on the preclusion list.

C.1: Reducing the Burden of the Medicare Part C and Part D Medical Loss Ratio Requirements [p. 56456]

Description: The proposed rule would change the medical loss ratio (MLR) requirements with respect to the treatment of expenses for fraud reduction activities and clarify that medication therapy management (MTM) services always count as quality improvement activities for the purposes of MLR calculations.

Comments:

In past comments, PhRMA has urged CMS to clarify that MTM activities undertaken by plan sponsors always count as "quality-improving activities" (QIA) for purposes of MLR calculations. MTM has been an important aspect of Part D since its inception and plays an important role in improving quality, care coordination, and medication adherence. We thank CMS for this proposed clarification, which will help to ensure that incentives are aligned for plans to continue expanding and enriching their MTM offerings.

* * * *

On behalf of PhRMA and our member companies, thank you for consideration of these comments. We look forward to working with you to improve these and other hallmarks of success for Part D and would be pleased to provide such additional information as may be useful or appropriate.

Best regards,



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