



July 16, 2018

Submitted electronically via <http://www.regulations.gov>

The Honorable Alex Azar II
HHS Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 600E
Washington, DC 20201

Dear Secretary Azar:

RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs Request for Information [RIN 0991-ZA49]

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to provide the attached comments on *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (the "Blueprint RFI") as published in the Federal Register on May 16, 2018.

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

We appreciate the Administration's interest in reducing drug prices and costs, as expressed in the options and questions raised in the Blueprint RFI. We agree on the need to encourage competition by curtailing REMS abuses and other schemes to discourage use of generics and biosimilars. We support using PBM tools in Medicare Part B and expanding available formulary tools in Medicare Part D and Medicaid. We also support the Administration's efforts to expand value-based purchasing.

We urge the Administration to focus on proposals that are likely to reduce costs and move beyond those that CMS has already determined will raise costs. For example, CMS calculated that imposing point-of-sale rebates in Medicare Part D would increase taxpayer costs \$42 billion. That proposal should no longer be considered a credible means to accomplishing the President's goals.



Also, at a time of rising drug prices, we think it would make no sense to undermine plans' ability to negotiate rebates or other price concessions from drugmakers. That would raise costs while offering no corresponding benefit to either consumers or taxpayers. A study by Oliver Wyman commissioned by PCMA and referenced in our comments found that Part D premiums would have been 52.4 percent higher in 2018 without rebates.

It should be noted that there's no evidence drugmakers set prices based on rebates they negotiate with plans in Medicare. Drugmakers – not any other industry – are solely responsible for the prices they set.

Some of the highest priced drugs are found in Medicare Part B, where neither rebates nor PBMs play any meaningful role. Therefore, we see no reason to believe that simply eliminating rebates or supplanting them with an unproven fixed-priced discounting concept would reduce costs or prices. That said, we remain open to alternative ways to reduce net costs.

Our comments on the Blueprint RFI also address the proposal to revise the Anti-Kickback Statute safe harbors to potentially limit or eliminate the use of rebates, and the concept of imposing upon PBMs a fiduciary duty toward consumers or health plans. Such proposals would decrease competition and increase costs for consumers without addressing the underlying problem of high drug prices.

We look forward to working with the Administration and Congress on policies to address high drug costs, and urge you to focus on increasing competition among prescription drugs and avoid policies that increase costs for consumers and taxpayers.

PCMA appreciates the opportunity to share this feedback and we look forward to working with HHS to address any aspects of our comments. Please feel free to contact Wendy Krasner at 202-756-5731 or by email at wkrasner@pcmanet.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Mark Merritt", written in a cursive style.

Mark Merritt
President and CEO

Enclosures

cc: Kristin Bass, PCMA
Andy Cosgrove, PCMA
Wendy Krasner, PCMA



HHS Blueprint to Lower Prices and Reduce Out-of-Pocket Costs Request for Information

TABLE OF CONTENTS	PAGE
Index Subject Matter	
Executive Summary	i
I. Previous Actions by the Trump Administration	
A. Increasing Competition	
<ul style="list-style-type: none"> • Prevent Generic “Parking,” i.e., Prevent Companies from Using their 180-day Exclusivity to Indefinitely Delay Real Competition 	1
<ul style="list-style-type: none"> • New Medicaid Demonstration Authority 	2
<ul style="list-style-type: none"> • Improved Data Sharing 	5
<ul style="list-style-type: none"> • Acceleration of Bringing Generics to Market 	7
<ul style="list-style-type: none"> • Part B Biosimilar Payment 	8
<ul style="list-style-type: none"> • Close Loopholes Allowing Brand-name Drug Companies to “Game” FDA Rules to Forestall Generic Competition: Evergreening <i>See also III (A): Access to Product Samples and Ending Risk Evaluation and Mitigation Strategies (REMS) Abuses</i> 	9 42
B. Better Negotiation	
<ul style="list-style-type: none"> • Use of Part D tools in Part B and creation of CAP for Part B Drugs 	10
D. Reducing Patient Out-of-Pocket Spending	
<ul style="list-style-type: none"> • Eliminating Cost-sharing on Generic Drugs for Low-Income Beneficiaries 	15
II. Responding to President Trump’s Call To Action	
B. Better Negotiation	
<ul style="list-style-type: none"> • One Drug Per Category/Class 	17
<ul style="list-style-type: none"> • Indication-based payments (<i>see III (B)</i>) 	57
<ul style="list-style-type: none"> • Protected Classes (<i>see III (C)</i>) 	114
<ul style="list-style-type: none"> • Value-based Transformation and DIR 	21
<ul style="list-style-type: none"> • Part B Drugs to Part D (<i>see III (B)</i>) 	63
<ul style="list-style-type: none"> • Sole Source Generic Price Increases 	25
<ul style="list-style-type: none"> • Updating the Methodology Used to Calculate Drug Plan Customer Service Star Ratings 	27
<ul style="list-style-type: none"> • Use of Demonstration Projects 	31
C. Creating Incentives to Lower List Prices	
<ul style="list-style-type: none"> • Evaluating the Inclusion of List Prices in Direct-to-Consumer Advertising 	34
<ul style="list-style-type: none"> • CMS Drug Pricing Dashboard 	38
<ul style="list-style-type: none"> • Improve Price Transparency / Tools to Make Prices More Transparent (<i>see III (B)</i>) 	49
III. Solicitation of Comments	
A. Increasing Competition	
<ul style="list-style-type: none"> • Underpricing of Generic Drugs 	39
<ul style="list-style-type: none"> • Affordable Care Act Taxes and Rebates 	40

• Access to Product Samples and Ending Risk Evaluation and Mitigation Strategies	42
• Promoting Access to Interchangeable Biologics and Biosimilars	44
• Improving the Purple Book	46
• Role of State Pharmacy Practice Acts	47
B. Better Negotiation	
• Improve Price Transparency / Tools to Make Prices More Transparent	49
• Value-based Arrangements and Price Reporting	50
• Federal Preemption of Contracted Pharmacy Gag Clause Laws	55
• Indication-based Payments	57
• Long-term Financing Models	60
• Part B Drugs to Part D	63
• OECD pricing for Part B Drugs	69
• Fixing Global Freeloading	71
• Site Neutrality of Physician-administered Drugs/Site Neutrality Between Inpatient and Outpatient Setting	72
• Accuracy of National Spending Data	74
C. Creating Incentives to Lower List Prices	
• Reducing the Impact of Rebates (See also Exhibit I p. 139)	76
• Fiduciary Duty for Pharmacy Benefit Managers	94
• Inflationary Rebate Limits	105
• Exclusion of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price	107
• HCPCS Codes and Part B	110
• Copay Discount Cards/Coupons	112
• Protected Classes	114
• 340B Program	119
D. Reducing Patient Out-of-Pocket Spending	
• Informing Beneficiaries About Price changes, Cost-sharing and Lower-cost Alternatives	120
E. Additional Feedback	
• Assuring Reasonable Costs for Drugs Developed with Federal Support	125
• Formulary Issues	127
- Formulary Integrity	127
- Midyear Formulary Changes	128
- Transition Fill	129
- Ability of Plans to NOT include Certain drugs on Formularies	129
- Brand/Generic	129
- Coverage for Compounds	130
- Partial Fills	130
- Fifth and Sixth Tier	131
- Facilitate Inclusion of Biosimilars in Formularies	131
- Prorated cost-sharing	132
• Issues Other Than Formulary	133
- Specialty Pharmacy Networks	133



- Medicare Plan Finder	133
- Compendia	134
- Quantity Prescribed	134
- Mail-Order Auto-Refills	135
- Allowing a Mandatory Mail-Service Pharmacy Benefit Option	135
- Part D Plan Access to Part A and Part B Claims Data	136
- Section 1557 Notice and Tagline Requirements	137
Exhibit I – Antitrust Considerations of Proposals to Limit Rebates	139



HHS Blueprint to Lower Prices and Reduce Out-of-Pocket Costs Request for Information

SUBJECT MATTER INDEX	PAGE
1557 (Section):	
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Section 1557 Notice and Tagline Requirements 	137-138
340B Drug Pricing Program:	
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Value-based Arrangements and Price Reporting 	50
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Exclusions of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price 	108-109
<ul style="list-style-type: none"> - 340B Program 	119
Administration FY2019 Budget:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - Prevent Generic “Parking,” i.e., Prevent Companies from Using their 180-day Exclusivity to indefinitely Delay Real Competition - New Medicaid Demonstration Authority - Part B Biosimilar Payment 	1 2-3 8
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> - Use of Part D tools in Part B and Creation of CAP for Part B Drugs 	10
<ul style="list-style-type: none"> ▪ I(D): Previous Actions by the Trump Administration: Reducing Patient Out-of-Pocket Spending: <ul style="list-style-type: none"> - Eliminating Cost-Sharing on Generic Drugs for Low-Income Beneficiaries 	15
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> - One Drug Per Category/Class - Value-based Transformation and DIR 	17-19 24
Affordable Care Act:	
<ul style="list-style-type: none"> ▪ III(A): Solicitation of Comments: Increasing Competition: <ul style="list-style-type: none"> - Affordable Care Act Taxes and Rebates 	40-41
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Inflationary Rebate Limits - Exclusion of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price 	105-106 108
Antitrust Issues:	
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Value-Based Transformation and DIR - Use of Demonstration Projects 	24 32
<ul style="list-style-type: none"> ▪ III(A): Solicitation of Comments: Increasing Competition: <ul style="list-style-type: none"> - Access to Product Samples and Ending Risk Evaluation and Mitigation Strategies (REMS) Abuses 	42



<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Value-Based Arrangements and Price Reporting 	52-54
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Reducing the Impact of Rebates - Fiduciary Duty for Pharmacy Benefit Managers 	76-93 98
<ul style="list-style-type: none"> ▪ Exhibit I – Antitrust Considerations of Proposals to Limit Rebates 	139-144
Bipartisan Budget Act of 2018:	
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Issues Other Than Formulary (Plan D Access to Part A and Part B claims data) 	136
Biosimilars:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - Acceleration of Bringing Generics to Market - Part B Biosimilar Payment 	7 8
<ul style="list-style-type: none"> ▪ I(D): Previous Actions by the Trump Administration: Reducing Patient Out-of-Pocket Spending: <ul style="list-style-type: none"> - Eliminating Cost-Sharing on Generic Drugs for Low-Income Beneficiaries 	15
<ul style="list-style-type: none"> ▪ II(B): Responding to President’s Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Protected Classes 	117-118
<ul style="list-style-type: none"> ▪ III(A): Solicitation of Comments: Increasing Competition: <ul style="list-style-type: none"> - Promoting Access to Interchangeable Biologics and Biosimilars - Improving the Purple Book - Role of State Pharmacy Practice Acts 	44-45 46 47-48
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Site Neutrality of Physician-administered Drugs/Site Neutrality Between Inpatient and Outpatient Setting 	73
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Protected Classes 	117-118
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Formulary Issues 	128-129, 131-132
Center for Medicare & Medicaid Innovation (CMMI)	
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Use of Demonstration Projects 	31-32
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Reducing the Impact of Rebates 	92
Competitive Acquisition Program (CAP), Medicare Part B	
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> - Use of Part D tools in Part B and Creation of CAP for Part B Drugs 	10-14
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Part B Drugs to Part D 	68
<ul style="list-style-type: none"> ▪ III(B): Responding to President Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Part B Drugs to Part D - Site Neutrality of Physician-administered Drugs/Site Neutrality Between Inpatient and Outpatient Setting 	68 73

<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - HCPCS Codes and Part B 	111
Data Integrity and Sharing:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - Improved Data Sharing 	5-6
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Use of Demonstration Projects - Indication-based Payments 	31 58
<ul style="list-style-type: none"> ▪ II(C): Responding to President's Trump's Call to Action: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - CMS Drug Pricing Dashboard 	38
<ul style="list-style-type: none"> ▪ III(A): Solicitation of Comments: Increasing Competition: <ul style="list-style-type: none"> - Improving the Purple Book 	46
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Value-based Arrangements and Price Reporting - Indication-based Payments - OECD Pricing for Part B Drugs - Accuracy of National Spending Data 	50-54 58 69 74-75
<ul style="list-style-type: none"> ▪ III(D): Solicitation of Comments: Reducing Out-of-Pocket Spending: <ul style="list-style-type: none"> - Informing Beneficiaries About Price Changes, Cost-sharing and Lower-cost Alternatives 	120-124
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Issues Other Than Formulary: 	134-136
Direct and Indirect Remuneration (DIR):	
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Value-Based Transformation and DIR 	21-24
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Reducing the Impact of Rebates - Fiduciary Duty for Pharmacy Benefit Managers 	80, 84, 91-92 94-104
Drug Classes: Protected and Therapeutic:	
<ul style="list-style-type: none"> ▪ I(D): Previous Actions by the Trump Administration: Reducing Patient Out-of-Pocket Spending: <ul style="list-style-type: none"> - Eliminating Cost-Sharing on Generic Drugs for Low-Income Beneficiaries 	15
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - One Drug Per Category/Class - Part B Drugs to Part D - Protected Classes 	17-20 66-67 114-118
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Part B Drugs to Part D: - OECD Pricing for Part B Drugs 	66-67 69
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Fiduciary Duty for Pharmacy Benefit Managers - Protected Classes 	98 114-118
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Formulary Issues 	127, 132

FDA National Drug Code (NDC):	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - Part B Biosimilar Payment 	8
<ul style="list-style-type: none"> ▪ II(B): Responding to President's Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Indication-based Payments 	57-58
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Indication-based Payments 	57-58
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - HCPCS Codes and Part B 	111
<ul style="list-style-type: none"> ▪ III(D): Solicitation of Comments: Reducing Out-of-Pocket Spending: <ul style="list-style-type: none"> - Informing Beneficiaries About Price Changes, Cost-sharing and Lower-cost Alternatives 	123
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Formulary Issues 	130
Fiduciary Duty:	
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Fiduciary Duty for Pharmacy Benefit Managers 	94-104
"Fixed-Price Discount" Policy Proposal	
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Protected Classes 	114
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Reducing the Impact of Rebates - Fiduciary Duty for Pharmacy Benefit Managers - Protected Classes 	76-93 99 114
<ul style="list-style-type: none"> ▪ Exhibit I – Antitrust Considerations of Proposals to Limit Rebates 	140
Formulary Issues:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - New Medicaid Demonstration Authority - Improved Data Sharing 	2-4 5
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> - Use of Part D tools in Part B and creation of CAP for Part B Drugs 	10
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - One Drug Per Category/Class - Sole Source Generic Price Increases - Updating the Methodology Used to Calculate Drug Plan Customer Service Star Ratings - Use of Demonstration Projects - Part B Drugs to Part D - Protected Classes 	17-20 25-26 27-30 32 65-68 114-118
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Value-Based Arrangements and Price Reporting - Part B Drugs to Part D - OECD Pricing for Part B Drugs 	51 65-68 69
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Reducing the Impact of Rebates 	76, 79-83, 88-89

<ul style="list-style-type: none"> - Fiduciary Duty for Pharmacy Benefit Managers - Copay Discount Cards/Coupons - Protected Classes 	<p>94, 98, 101-103 112-113 114-118</p>
<ul style="list-style-type: none"> ▪ III(D): Solicitation of Comments: Reducing Out-of-Pocket Spending: <ul style="list-style-type: none"> - Informing Beneficiaries About Price Changes, Cost-sharing and Lower-cost Alternatives 	120-124
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Formulary Issues - Issues Other Than Formulary 	127-132 133-136
Generic Drugs:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - Prevent Generic “Parking,” i.e., Prevent Companies from Using their 180-day Exclusivity to Indefinitely Delay Real Competition - Acceleration of Bringing Generics to Market - Close Loopholes Allowing Brand-Name Drug Companies to “Game” FDA Rules to Forestall Generic Competition: Evergreening 	1 7 9
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> - Use of Part D Tools in Part B and Creation of CAP for Part B Drugs 	10
<ul style="list-style-type: none"> ▪ I(D): Previous Actions by the Trump Administration: Reducing Patient Out-of-Pocket Spending: <ul style="list-style-type: none"> - Eliminating Cost-Sharing on Generic Drugs for Low-Income Beneficiaries 	15-16
<ul style="list-style-type: none"> ▪ II(B): Responding to President’s Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Value-Based Transformation and DIR - Sole Source Generic Price Increases - Updating the Methodology Used to Calculate Drug Plan Customer Service Star Ratings - Protected Classes 	22-23 25-26 29 115, 117
<ul style="list-style-type: none"> ▪ II(C): Responding to President Trump’s Call to Action: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Evaluating the Inclusion of List Prices in Direct-to-Consumer Advertising 	36
<ul style="list-style-type: none"> ▪ III(A): Solicitation of Comments: Increasing Competition: <ul style="list-style-type: none"> - Underpricing of Generic Drugs - Access to Product Samples and Ending Risk Evaluation and Mitigation Strategies (REMS) Abuses - Promoting Access to Interchangeable Biologics and Biosimilars - Improving the Purple Book 	39 42-43 44-45 46
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Site Neutrality of Physician-administered Drugs/Site Neutrality Between Inpatient and Outpatient Setting 	73
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Inflationary Rebate Limits - Copay Discount Cards/Coupons - Protected Classes 	105 112-113 115, 117



<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Formulary Issues 	128-130
Health Insurance Portability and Accountability Act of 1996 (HIPAA):	
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - HCPCS Codes and Part B 	110
<ul style="list-style-type: none"> ▪ III(D): Solicitation of Comments: Reducing Out-of-Pocket Spending: <ul style="list-style-type: none"> - Informing Beneficiaries About Price Changes, Cost-sharing and Lower-cost Alternatives 	121-123
Healthcare Common Procedure Coding System (HCPCS) Codes:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - Part B Biosimilar Payment 	8
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> - Use of Part D tools in Part B and creation of CAP for Part B Drugs 	12
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - HCPCS Codes and Part B 	110-111
House of Representatives, United States:	
<ul style="list-style-type: none"> ▪ Committee on Appropriations: Subcommittee on Labor, Health and Human Services, Education, and Related Agencies: <ul style="list-style-type: none"> - II(B): Responding to President's Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> ◆ Value-Based Transformation and DIR - III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> ◆ Reducing the Impact of Rebates 	24 85, 90
Independent Review Entity (IRE):	
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Updating the Methodology Used to Calculate Drug Plan Customer Service Star Ratings 	27-30
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Formulary Issues 	127
Mail-service Pharmacies:	
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Reducing the Impact of Rebates 	88
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Issues Other Than Formulary 	134-135
Market Exclusivity Abuse:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - Prevent Generic "Parking," i.e., Prevent Companies from Using their 180-day Exclusivity to Indefinitely Delay Real Competition - Close Loopholes Allowing Brand-Name Drug Companies to "Game" FDA Rules to Forestall Generic Competition: Evergreening 	1 9
<ul style="list-style-type: none"> ▪ II(B): Responding to President's Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Sole Source Generic Price Increases 	25-26
<ul style="list-style-type: none"> ▪ III(A): Solicitation of Comments: Increasing Competition: <ul style="list-style-type: none"> - Access to Product Samples and Ending Risk Evaluation and 	



Mitigation Strategies (REMS) Abuses	42-43
- Improving the Purple Book	46
▪ III(B): Solicitation of Comments: Better Negotiation:	
- Fixing Global Freeloading	71
▪ III(E): Solicitation of Comments: Additional Feedback:	
- Assuring Reasonable Costs for Drugs Developed with Federal Support	125-126
Medicaid:	
▪ I(A): Previous Actions by the Trump Administration: Increasing Competition:	
- New Medicaid Demonstration Authority	2-4
▪ I(B): Previous Actions by the Trump Administration: Better Negotiation:	
- Use of Part D tools in Part B and Creation of CAP for Part B Drugs	10
▪ II(B): Responding to President Trump's Call to Action: Better Negotiation:	
- Indication-based Payments	57-59
▪ II(C): Responding to President's Trump's Call to Action: Creating Incentives to Lower List Prices:	
- CMS Drug Pricing Dashboard	38
- Improve Price Transparency/Tools to Make Prices More Transparent	49
▪ III(A): Solicitation of Comments: Increasing Competition:	
- Affordable Care Act Taxes and Rebates	40-41
▪ III(B): Solicitation of Comments: Better Negotiation:	
- Value-Based Arrangements and Price Reporting	50-54
- Improve Price Transparency/Tools to Make Prices More Transparent	49
- Federal Preemption of Contracted Pharmacy Gag Clause Laws	56
- Indication-based Payments	57-59
- Long Term Financing Models	60-62
- Site Neutrality of Physician-administered Drugs/Site Neutrality Between Inpatient and Outpatient Setting	72
- Accuracy of National Spending Data	74-75
▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices:	
- Reducing the Impact of Rebates	85-86, 89
- Fiduciary Duty for Pharmacy Benefit Managers	95-96, 99
- Inflationary Rebate Limits	105-106
- Exclusions of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price	107-109
- Copay Discount Cards/Coupons	112-113
▪ III(E): Solicitation of Comments: Additional Feedback:	
- Formulary Issues	129
Medicaid Best Price:	
▪ II(B): Responding to President Trump's Call to Action: Better Negotiation:	
- Indication-based Payments	57-59
▪ III(B): Solicitation of Comments: Better Negotiation:	
- Value-Based Arrangements and Price Reporting	50-54
- Indication-based Payments	57-59
- Long-term Financing Models	62

<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Exclusions of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price 	107-109
Medicare Part A:	
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> - Use of Part D tools in Part B and creation of CAP for Part B Drugs 	12, 14
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Part B Drugs to Part D 	66
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Part B Drugs to Part D - Site Neutrality of Physician-administered drugs/Site Neutrality Between Inpatient and Outpatient Setting 	66 72
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Issues Other Than Formulary (Plan D Access to Part A and Part B claims data) 	136
Medicare Part B:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - Part B Biosimilar Payment 	8
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> - Use of Part D tools in Part B and creation of CAP for Part B Drugs 	10-14
<ul style="list-style-type: none"> ▪ II(B): Responding to President's Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Part B Drugs to Part D - Value-based Transformation and DIR - Indication-based payments 	63-68 21-22 57-59
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Indication-based payments - Part B Drugs to Part D - OECD Pricing for Part B Drugs - Site Neutrality of Physician-Administered Drugs/Site Neutrality Between Inpatient and Outpatient Setting 	57-59 63-68 69-70 72-73
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Fiduciary Duty for Pharmacy Benefit Managers - HCPCS Codes and Part B 	96, 98 110-111
<ul style="list-style-type: none"> ▪ III(D): Reducing Patient Out-of-Pocket Spending: <ul style="list-style-type: none"> - Informing Beneficiaries About Price Changes, Cost-sharing and Lower-cost Alternatives 	120
National Council for Prescription Drug Programs (NCPDP) Standards:	
<ul style="list-style-type: none"> ▪ II(B): Responding to President's Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Indication-based payments 	58
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Indication-based payments 	58
<ul style="list-style-type: none"> ▪ III(D): Solicitation of Comments: Reducing Out-of-Pocket Spending: <ul style="list-style-type: none"> - Informing Beneficiaries About Price Changes, Cost-sharing and Lower-cost Alternatives 	121-124
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Issues Other Than Formulary: 	135

Non-Interference Clause – Part D:	
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> – Use of Demonstration Projects ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> – Reducing the Impact of Rebates – Fiduciary Duty for Pharmacy Benefit Managers 	<p>32-33</p> <p>77, 81, 83, 90-93</p> <p>97, 100, 102-103</p>
Point of Sale (POS), Price Concessions and Consumer Experience:	
<ul style="list-style-type: none"> ▪ II(B): Responding to President’s Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> – Value-Based Transformation and DIR – Part B Drugs to Part D 	<p>21-24</p> <p>66</p>
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> – Part B Drugs to Part D 	<p>66</p>
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> – Reducing the Impact of Rebates 	<p>80, 91</p>
<ul style="list-style-type: none"> ▪ III(D): Solicitation of Comments: Reducing Out-of-Pocket Spending: <ul style="list-style-type: none"> – Informing Beneficiaries About Price Changes, Cost-sharing and Lower-cost Alternatives 	<p>120-124</p>
Preferred Pharmacy Networks:	
<ul style="list-style-type: none"> ▪ II(B): Responding to President’s Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> – Part B Drugs to D 	<p>65</p>
<ul style="list-style-type: none"> ▪ III(B): Responding to President’s Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> – Part B Drugs to D 	<p>65</p>
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> – Fiduciary Duty for Pharmacy Benefit Managers 	<p>102-103</p>
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> – Issues Other Than Formulary 	<p>134</p>
Price Transparency:	
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> – Use of Part D tools in Part B and creation of CAP for Part B Drugs 	<p>14</p>
<ul style="list-style-type: none"> ▪ II(C): Responding to President’s Trump’s Call to Action: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> – Evaluating the Inclusion of List Prices in Direct-to-Consumer Advertising – CMS Drug Pricing Dashboard – Improve Price Transparency/Tools to Make Prices More Transparent 	<p>34-37</p> <p>38</p> <p>49</p>
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> – Improve Price Transparency/Tools to Make Prices More Transparent – Value-based Arrangements and Price Reporting – Federal Preemption of Contracted Pharmacy Gag Clause Laws – Accuracy of National Spending Data 	<p>49</p> <p>50</p> <p>74-75</p>
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> – Reducing the Impact of Rebates – HCPCS Codes and Part B 	<p>78-79</p> <p>110</p>

<ul style="list-style-type: none"> - Copay Discount Cards/Coupons 	112
<ul style="list-style-type: none"> ▪ III(D): Solicitation of Comments: Reducing Out-of-Pocket Spending: <ul style="list-style-type: none"> - Informing Medicare Beneficiaries with Medicare Part B and Part D about Cost Sharing and Lower-cost Alternatives 	120-124
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Issues Other Than Formulary 	134
Pricing Indexes:	
<ul style="list-style-type: none"> ▪ Average Manufacturer Price (AMP): 	
<ul style="list-style-type: none"> • I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> ◆ Use of Part D tools in Part B and creation of CAP for Part B Drugs 	11
<ul style="list-style-type: none"> • III(A): Solicitation of Comments: Increasing Competition: <ul style="list-style-type: none"> ◆ Affordable Care Act Taxes and Rebates 	40-41
<ul style="list-style-type: none"> • III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> ◆ Value-Based Arrangements and Price Reporting 	50-51
<ul style="list-style-type: none"> • III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> ◆ Reducing the Impact of Rebates ◆ Inflationary Rebate Limits ◆ Exclusions of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price ◆ Copay Discount Cards/Coupons 	89 105 107-109 112
<ul style="list-style-type: none"> ▪ Average Sales Price (ASP): 	
<ul style="list-style-type: none"> • I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> ◆ Use of Part D tools in Part B and creation of CAP for Part B Drugs 	10-11
<ul style="list-style-type: none"> • II(B): Responding to President's Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> ◆ Indication-based Payments 	57-59
<ul style="list-style-type: none"> • III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> ◆ Value-Based Arrangements and Price Reporting ◆ Indication-based Payments ◆ Site Neutrality of physician-administered drugs/Site Neutrality between inpatient and outpatient setting 	50 57-59 73
Rebates:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - New Medicaid Demonstration Authority - Improved Data Sharing 	2-4 5
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> - Use of Part D tools in Part B and creation of CAP for Part B Drugs 	10-11

<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> – Indication-based payments – Protected Classes – Part B Drugs to Part D 	58 114, 117 65
<ul style="list-style-type: none"> ▪ II(C): Responding to President’s Trump’s Call to Action: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> – CMS Drug Pricing Dashboard – Improve Price Transparency/Tools to Make Prices More Transparent 	38 49
<ul style="list-style-type: none"> ▪ III(A): Solicitation of Comments: Increasing Competition: <ul style="list-style-type: none"> – Affordable Care Act Taxes and Rebates 	40-41
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> – Improve Price Transparency/Tools to Make Prices More Transparent – Indication-based payments – Long-term Financing Models – Part B Drugs to Part D – Value-based Arrangements and Price Reporting – Accuracy of National Spending Data 	49 58 62 65 50-54 74-75
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> – Reducing the Impact of Rebates – Protected Classes – Fiduciary Duty for Pharmacy Benefit Managers – Inflationary Rebate Limits – Exclusions of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price 	76-93 114, 117 94-104 105-106 107-109
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> – Formulary Issues 	130-131
Senate, United States:	
<ul style="list-style-type: none"> ▪ Committee on Finance: 	
<ul style="list-style-type: none"> – I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> ◆ Use of Part D tools in Part B and creation of CAP for Part B Drugs 	10-11
<ul style="list-style-type: none"> ▪ Health, Education, Labor & Pensions (HELP) Committee: <ul style="list-style-type: none"> – II(B): Responding to President Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> ◆ Part B Drugs to Part D – III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> ◆ Part B Drugs to Part D – III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> ◆ Reducing the Impact of Rebates ◆ Fiduciary Duty for Pharmacy Benefit Managers 	63 63 76, 84 95
<ul style="list-style-type: none"> ▪ Exhibit I – Antitrust Considerations of Proposals to Limit Rebates 	142

Specialty Drugs and Specialty Pharmacies:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - New Medicaid Demonstration Authority 	2
<ul style="list-style-type: none"> ▪ III(A): Solicitation of Comments: Increasing Competition: <ul style="list-style-type: none"> - Access to Product Samples and Ending Risk Evaluation and Mitigation Strategies (REMS) Abuses 	42
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Value-based Arrangements and Price Reporting - Long-term Financing Models - Site Neutrality of physician-administered drugs/Site Neutrality between inpatient and outpatient setting. 	50 60-62 73
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Copay Discount Cards/Coupons 	113
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Assuring Reasonable Costs for Drugs Developed with Federal Support - Formulary Issues - Issues Other Than Formulary 	126 130-131 133
Star Ratings – Part D:	
<ul style="list-style-type: none"> ▪ II(B): Responding to President Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Value-Based Transformation - Updating the Methodology Used to Calculate Drug Plan Customer Service Star Ratings - Use of Demonstration Projects - Protected Classes 	23 27-30 32-33 117
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Protected Classes 	117
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Issues Other Than Formulary 	134
Utilization Management Tools:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - New Medicaid Demonstration Authority - Improved Data Sharing 	2-4 5
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> - Use of Part D tools in Part B and Creation of CAP for Part B Drugs 	10-14
<ul style="list-style-type: none"> ▪ I(D): Previous Actions by the Trump Administration: Reducing Patient Out-of-Pocket Spending: <ul style="list-style-type: none"> - Eliminating Cost-Sharing on Generic Drugs for Low-Income Beneficiaries 	15
<ul style="list-style-type: none"> ▪ II(B): Responding to President’s Trump’s Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Sole Source Generic Price Increases - Updating the Methodology Used to Calculate Drug Plan Customer Service Star Ratings - Indication-based Payments - Part B Drugs to Part D - Protected Classes 	25 27-28 58 63-68 115, 117

<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Part B Drugs to Part D - OECD Pricing for Part B Drugs - Site Neutrality of physician-administered drugs/Site Neutrality between inpatient and outpatient setting. 	65-68 69 73
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Reducing the Impact of Rebates - Fiduciary Duty for Pharmacy Benefit Managers - - Protected Classes 	82 94, 98, 101-104 115, 117
<ul style="list-style-type: none"> ▪ III(D): Solicitation of Comments: Reducing Out-of-Pocket Spending: <ul style="list-style-type: none"> - Informing Medicare Beneficiaries with Medicare Part B and Part D about Cost Sharing and Lower-cost Alternatives 	122
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Formulary Issues 	127
Value-Based Contracting and Indicated Based Payments:	
<ul style="list-style-type: none"> ▪ I(A): Previous Actions by the Trump Administration: Increasing Competition: <ul style="list-style-type: none"> - New Medicaid Demonstration Authority - Improved Data Sharing 	4 5
<ul style="list-style-type: none"> ▪ I(B): Previous Actions by the Trump Administration: Better Negotiation: <ul style="list-style-type: none"> - Use of Part D tools in Part B and creation of CAP for Part B Drugs 	11-12
<ul style="list-style-type: none"> ▪ II(B): Responding to President's Trump's Call to Action: Better Negotiation: <ul style="list-style-type: none"> - Value-Based Transformation and DIR - Use of Demonstration Projects - Protected Classes - Indication-based Payments 	21-24 31-32 107 57
<ul style="list-style-type: none"> ▪ II(C): Responding to President's Trump's Call to Action: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Improve Price Transparency/Tools to Make Prices More Transparent 	49
<ul style="list-style-type: none"> ▪ III(B): Solicitation of Comments: Better Negotiation: <ul style="list-style-type: none"> - Improve Price Transparency/Tools to Make Prices More Transparent - Value-Based Arrangements and Price Reporting - Long Term Financing Models 	49 50-54 60-62
<ul style="list-style-type: none"> ▪ III(C): Solicitation of Comments: Creating Incentives to Lower List Prices: <ul style="list-style-type: none"> - Reducing the Impact of Rebates - Fiduciary Duty for Pharmacy Benefit Managers - Exclusion of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price - Protected Classes 	80, 82 104 107 117
<ul style="list-style-type: none"> ▪ III(E): Solicitation of Comments: Additional Feedback: <ul style="list-style-type: none"> - Assuring Reasonable Costs for Drugs Developed with Federal Support - Formulary Issues - Issues Other Than Formulary 	126 127-129 136

Executive Summary

The Blueprint RFI asks questions reflecting the Administration’s priorities in tackling the problem of rising prescription drug prices. It identifies four main strategies that HHS may use to decrease drug prices – increased competition, better negotiation, incentives to lower list prices and lower consumer out-of-pocket costs. PCMA commends the Administration for addressing the issue of high drug prices largely in a way that works with—rather than against—the market. Making the way for more competition in the marketplace is far preferable to resorting to market-distorting price controls, which inevitably misalign demand and supply. The Administration has previously noted myriad ways where the market for prescription drugs can be made more competitive and we offer several more suggestions in this response to the Blueprint RFI.

However, we believe that the premises of some of the questions posed in the RFI suggest policies that could do great harm to the drug market and have the opposite of the intended effect; that is, they could result in higher, rather than lower, drug spending. Specifically, we highlight questions related to the following two areas:

- Eliminating negotiated rebates on brand drugs; and
- Encumbering PBMs with “fiduciary duty.”

The Role of Rebates in Lowering Drug Spending

The Administration asks what CMS should do to restrict or reduce the use of rebates and seeks comment on whether Medicare Part D should prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers to reduce drug costs. Here, the possibility of ending the safe harbor for drug rebates under the federal Anti-Kickback Statute is raised. We reject the premises of these questions in their entirety. In short, absent a proven, viable, alternative method to extract pricing concessions from manufacturers, rebates must remain as a viable option. They are currently the only proven way for PBMs to negotiate lower drug costs with manufacturers.

Operating in a competitive environment, PBMs reduce brand drug costs primarily using manufacturer rebates. As part of manufacturer-PBM negotiations, brand drug manufacturers compete for formulary placement by offering rebates for moving market share, which are typically calculated and paid weeks or months after a drug is dispensed. As a result of these negotiations, PBMs can recommend benefit designs that stretch payers’ finite dollars and reduce premiums and cost-sharing. These designs include cost-sharing incentives for patients to use the most affordable drugs, which often are generics. The highest cost-sharing is typically reserved for drugs with the least competitive price concessions, or in the case of many high-



priced, single-source drugs, no price concessions at all. PCMA supports benefit designs that ensure patients do not pay more in cost-sharing than the actual cost of the drug and innovations like electronic prior authorization that reduce physicians' administrative burden.

Any suggestion that PBMs act in the market in some way other than to obtain the lowest possible net price for drugs is just that—a suggestion, but one not born out by facts. By contrast, detailed analyses discussed in our comments show that PBMs do in fact harness competition to negotiate lower drug costs and that rebate levels are correlated with competition, not launch prices or price increases.

Recognizing there have been proposals to change the current rebating system, we have yet to see a viable, market-based proposal that would take as much cost out of brand drug spending as negotiated rebates do today. While publicly singling out and criticizing drug manufacturers for raising list prices may produce some effect in the short run, the force of market competition will be the only effective tool in the long run. Strengthening competition under the current system is the best way to help lower drug spending in the long term.

While negotiated, after-the-fact rebates may be the most efficacious way today to lower drug spending, PCMA and the PBM industry would be open to any idea that could use a market-based approach to lower drug costs and we would be happy to work in good faith with stakeholders and policymakers to explore improved ways to bring about lower drug costs.

HHS should follow the evidence with respect to rebates and focus its policies on the list prices set by manufacturers. Manufacturer rebates produce significant savings in the Part D program in the form of overall lower costs and lower premiums. Restricting or prohibiting rebates would increase overall net drug costs, plan premiums, and administrative costs, and result in higher government spending and unclear effects on consumers at the pharmacy counter. We urge HHS to recognize that any fixed-price discount approach would require a major restructuring of Part D, including reconstructing and revising bids. Even were changes to the current rebate structure appropriate, which PCMA does not concede, HHS both lacks the authority to subject rebates to AKS scrutiny, and must also contend with the significant antitrust concerns regarding up-front discounts. Finally, the contemplated policy raises significant concerns under both the Part D non-interference clause and the Administrative Procedure Act.

Fiduciary Duty Is Inappropriate for PBMs

Our second major concern is the concept of imposing a fiduciary duty on PBMs. Such a concept is wholly inconsistent with how the term fiduciary has been used both in common law and the Employee Retirement Income Security Act (ERISA). Additionally, it would both implicate, and conflict with, existing Part D statutory authority, including the noninterference clause.



PBMs are third party administrators that lack the discretionary authority of fiduciaries: under current practice, PBMs typically serve in administrative and advisory roles for health plans, performing claims processing and other administrative tasks, but do not exercise discretionary authority over plan assets or make decisions about the scope and design of benefits being offered. While PBMs and plan sponsors have the freedom to engage in a variety of contractual relationships with each other (including with a wide range of duties and obligations), an independent fiduciary obligation also raises significant concerns and questions. For example, if a PBM were a legal fiduciary to its contracted plan sponsor, could a PBM still negotiate rebates and price concessions across multiple books of business or would it have to negotiate separately for each plan, thus not taking full advantage of its scale and its customer base? What would happen when the fiduciary duty conflicted with HHS' requirements (e.g., when HHS' interest varied from that of the plan)? These are only a few of the many important, detailed operational questions that would have to be addressed to understand the ramifications of imposing a fiduciary obligation on PBMs.

Indeed, the Blueprint RFI appears to be suggesting a PBM fiduciary duty as a way to end any remuneration between pharmaceutical manufacturers and PBMs, including rebates but also for legitimate service fees that have long been permitted under Medicare Part D and which serve to reduce premiums for beneficiaries. Prohibiting this remuneration would reduce the ability of PBMs to negotiate with manufacturers and administer the Part D benefit, and increase overall plan costs. Given that existing regulations already restrict PBMs from profiting from these fees in Part D, it makes little sense to eliminate this type of remuneration.

The inconsistencies under current law and complex questions related to operation and policy argue strongly against any question to impose fiduciary duty on PBMs. Doing so would likely disrupt the market and increase costs for plan enrollees and payers, including taxpayers, unnecessarily.

PCMA encourages HHS to focus on the root cause of rising drug prices – the list prices set by manufacturers. Imposing costly, new legal duties on PBMs will merely increase Part D programmatic costs and reduce the overall beneficiary experience by prohibiting payment for necessary services. In addition, eliminating remuneration between PBMs and manufacturers will restrict necessary transactions in the Part D program, reduce PBM negotiating power, and do little to reduce manufacturer incentives to maintain and raise high list prices.



Other Important Issues Raised in the Blueprint RFI

Below we briefly highlight some of our key comments and suggestions to questions posed in this RFI.

Medicare Part B

- **Use of Part D Tools in Part B and Creation of CAP for Part B Drugs:** HHS should assess how to implement its proposal to leverage Part D plan sponsors' negotiating power and UM tools for certain drugs under Part B under current authorities. Two potential ways to accomplish this are to 1) allow the Medicare Administrative Contractors, which process Medicare Part A and B claims, to subcontract with PBMs with Part D experience to apply UM tools, and 2) withdraw the HPMS memo dated September 17, 2012 to facilitate the application of PBM UM tools under Part B. CMS should instead replace it with authorization for the application of reasonable UM tools in this arena.
- **Part B Drugs to Part D:** HHS should adopt the following recommendations:
 1. Identify one or two drug classes for use in a pilot for moving drugs from Part B to Part D, focusing on classes that will bring operational benefits to providers and beneficiaries in addition to bringing savings to the Medicare program. Such a change should be implemented first in the MA-PD setting;
 2. Maximize the use of PBM UM and negotiation tools by using PBMs and Part D tools in the Part B program; and
 3. Include insulin, anti-emetics, inhalants, immunosuppressants and anticancer drugs in the report that HHS will send to the President on this topic.

Medicare Part D

- **Value-based Transformation and DIR:** CMS should maintain the DIR construct in its current form to promote value-based payments in Part D (similar to how value-based payments are encouraged in FFS Medicare). PCMA encourages CMS to assess its current policies and make appropriate changes, including adding a safe harbor from the anti-kickback limitations for value-based payments, to assure that there are no barriers to the ability of plan sponsors and PBMs to negotiate value-based payments with pharmacies under Part D.
- **Protected Classes:** HHS should provide Part D plan sponsors and their PBMs "full flexibility" to manage high drug costs where manufacturers do not provide rebates or negotiate, including in protected classes. HHS should adopt options for Part D plan sponsors and their PBMs to meaningfully incentivize manufacturers to lower their prices for protected class drugs (as well as others). HHS should address biosimilars in protected

classes by providing that the innovator product does not need to be covered where there is a biosimilar in the class and should narrow the scope of protected classes to apply only to the indications within the scope of the protected class rather than to all indications.

- **One Drug Per Category/Class:** CMS should adopt the policy proposed in the FY2019 Administration Budget to change Part D formulary standards to require a minimum of one drug per category or class rather than two.
- **Eliminating Cost-Sharing on Generic Drugs for Low-Income Beneficiaries:** PCMA supports modifying the cost-sharing structure for LIS beneficiaries in Medicare Part D to encourage the use of lower-cost drugs, including generics.
- **Sole Source Generic Price Increases:** HHS should issue guidance to provide Part D plan sponsors and their PBMs with the authority to respond quickly to price increases from sole source drugs whose patents have expired by removing such a medication from a plan formulary or moving the medication to a non-preferred tier.
- **Updating the Methodology Used to Calculate Drug Plan Customer Service Star Ratings:** HHS should modify the Appeal Upheld star ratings measure to exclude IRE overturns based on information not available at the time of plan decision. HHS should focus on improving the IRE process and communication and decreasing excessive and inaccurate IRE overturns.
- **Informing Beneficiaries About Price Changes, Cost-sharing and Lower-cost Alternatives:** HHS should:
 1. Authorize Part D plan sponsors to add additional information to the EOB statement that educates beneficiaries as to where to find out if prices for their drugs have changed.
 2. Make updating the HIPAA regulations to implement the NCPDP electronic prior authorization standard a priority as part of its drug pricing efforts.
 3. Examine current real-time benefit inquiry (RTBI) technology and consider how it can be better integrated into the normal flow of a prescriber's work, how prescribers may be encouraged to adopt such technology, and how HHS might encourage or require competing RTBI technologies to be seamlessly interoperable with one another.
 4. Help facilitate the development of systems that provide pharmacists with all information available about lower-cost options, primarily through development of an NCPDP standard, recognizing that the information is most useful at the point of prescribing.
 5. Improve the Medicare Plan Finder (MPF) tool and the timeliness of the information to reduce inconsistencies between the pricing data submitted by Part D plan sponsors for the MPF listing and the price at the time a prescription is filled.

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

Medicaid

- **New Medicaid Demonstration Authority:** PCMA broadly supports efforts by HHS to introduce private-sector formulary management techniques into the Medicaid program, and would welcome new demonstration projects. HHS should review its waiver authority to grant states maximum flexibility in the administration of the benefit. Any new Medicaid demonstration authority should give MCOs the flexibility and responsibility for actively managing the prescription drug benefit.
- **Inflationary Rebate Limits:** HHS should eliminate the cap on the inflationary penalty in the Medicaid Drug Rebate Program to discourage drug manufacturers from imposing excessive increases to list prices.

Additional CMS Issues

- **Use of Demonstration Projects:** HHS should consider smaller, shorter-term pilots through CMMI that can be more rapidly tested on more flexible terms than through a longer-term project. HHS should not take any action through CMMI that would waive the non-interference clause.
- **Affordable Care Act Taxes and Rebates:** In general, PCMA opposes price controls which inhibit competition in the marketplace and would welcome changes that grant drug supply chain actors the full freedom to conduct arm's length negotiations. PCMA strongly urges HHS to keep in place the rebate exclusions.
- **Improve Price Transparency/Tools to Make Prices More Transparent:** HHS should resist any transparency proposals that include disclosure of confidential rebate information. Public disclosure of privately negotiated rebate information would enable tacit collusion among manufacturers and have a dampening effect on the level of rebates offered, thereby increasing costs.
- **Value-based Arrangements and Price Reporting:** To the extent that HHS does have existing authority to exempt certain value-based arrangements from anti-kickback liability, PCMA would support such efforts. HHS should also work with Congress to amend the underlying statute to support these efforts.
- **Indication-based Payments:** HHS should address policy issues related to Medicaid best price and Average Sales Price (ASP) regarding indication-based pricing. This could include,



for drugs with multiple indications whose price varies by indication, exempting the lowest-cost indication from the Medicaid best price and establishing separate ASPs for each indication.

- **Accuracy of National Spending Data:** All rebates should be reported in an aggregated way, separately for small molecule drugs, biologics and high-cost drugs, as suggested by HHS. The price concessions labeled as “rebates” by manufacturers should be broken out separately for Medicare Part D, Medicaid statutory and supplemental rebates, and the commercial market. These rebates should be separately reported in the national health spending accounts. HHS must strike a balance to ensure that public disclosure of information does not lead to a disincentive for manufacturers to offer deep discounts.
- **Exclusion of Certain Payments, Rebates, or Discounts from the Determination of Average Manufacturer Price and Best Price:** HHS should continue to exclude PBM rebates from AMP and best price so as to incentivize competition.

FDA/Drug Development

- **Prevent Generic “Parking” Where Companies Use their 180-day Exclusivity to Indefinitely Delay Real Competition:** PCMA endorses the policy proposal to begin the period of exclusivity at the time of approval of a subsequent generic drug application and recommends the Administration work with Congress to enact it.
- **Close Loopholes Allowing Brand-Name Drug Companies to “Game” FDA Rules to Forestall Generic Competition: Evergreening:** The FDA should encourage the Federal Trade Commission, which has argued that tactics aimed at “gaming” FDA rules may be anti-competitive and unlawful, to (1) continue to take action when drug companies employ unlawful tactics that delay widespread use of lower-cost generic options; and (2) support plaintiffs who present legal challenges regarding such anti-competitive behaviors.
- **Promoting Access to Interchangeable Biologics and Biosimilars:** While we support the general concept advanced for judging interchangeability of biosimilars, FDA should not erect any unnecessary barriers to achieving interchangeability as it moves to finalize the guidance.



I. Previous Actions by the Trump Administration

**Increasing Competition – I (A) p. 22693
Prevent Generic “Parking,” i.e., Prevent Companies from Using their 180-day Exclusivity to Indefinitely Delay Real Competition**

Background

The Food, Drug, and Cosmetic Act provides an incentive to generic drug applicants by granting a 180-day period of exclusivity to the applicant that is first to file a substantially complete application to FDA. Increasing the availability of generic drugs helps to create competition in the marketplace, which then helps to make treatment more affordable and increases access to health care for more patients. However, some “first filers” can block subsequent generic competitors from receiving approval under this exclusivity provision. Similarly, first filers that receive tentative approval but then intentionally delay seeking final approval can block subsequent competitors. As a result, first filers can “park” their exclusivity, and consumers are denied access to generic products and must keep paying brand price. The FY2019 Administration Budget proposed ending the ability of generic filers to “park” their exclusivity.

Discussion

A legislative proposal in the FY2019 Administration Budget makes the tentative approval of a subsequent generic drug applicant that is blocked solely by a first applicant’s 180-day exclusivity, where the first applicant has not yet received final approval, a trigger of the first applicant’s 180-day exclusivity. This means the period of exclusivity would immediately begin for the first filer. This proposal will enhance competition and facilitate more timely access to generic drugs. This proposal is estimated by the Administration to create \$1.8 billion in Medicare savings over 10 years.

PCMA Recommendation: We endorse the policy proposal to begin the period of exclusivity at the time of approval of a subsequent generic drug application and recommend the Administration work with Congress to enact it.

Background

In the Blueprint RFI, HHS references the President’s FY2019 Administration Budget proposal to add new Medicaid demonstration authority for up to five states to test drug coverage and financing reforms that build on private sector best practices. Under this model, participating states would determine their own drug formularies and negotiate drug prices directly with manufacturers.

Discussion**High-cost specialty drugs have underscored the limits of the Medicaid Drug Rebate Program (MDRP) as a mechanism for controlling Medicaid prescription drug cost:**

Prescription drug costs are a major contributing factor to the growth of Medicaid spending, particularly high-cost specialty drugs. While a little over one percent of patients in the Medicaid FFS program used specialty drugs in 2015, they accounted for approximately 37% of total drug expenditures and are expected to reach 50% by 2020.¹

These high-cost specialty drugs have highlighted the limits of the MDRP as a mechanism for controlling Medicaid prescription drug costs. According to a Kaiser Family Foundation survey of Medicaid State Directors, the majority of states identified high-cost and specialty drugs as a significant cost driver for state Medicaid programs.² In addition, many state officials cite federal law as limiting their ability to use private-sector formulary management techniques that are needed to run a cost-efficient Medicaid drug benefit program.³ To help accomplish this difficult task, states and Medicaid managed care organizations (MCOs) need the flexibility to administer and manage the prescription drug benefit using proven pharmacy benefit management tools. PCMA broadly supports efforts by HHS to introduce private-sector formulary management techniques into the Medicaid program, and would welcome new demonstration projects like the model proposed in the FY2019 Administration Budget.

- **HHS has the clear legal authority to approve the demonstration:** In October 2017, PCMA submitted comments to CMS in support of MassHealth’s section 1115 waiver request, which would have enabled the program to use all available tools to manage the rapid growth of drug costs—including a closed formulary to facilitate the negotiation of advantageous supplemental rebates with manufacturers, while also working to ensure

¹Magellan Rx Management. 2017 Medicaid Pharmacy Trend Report. Available at:

<https://www1.magellanrx.com/media/671872/2017-mrx-medicaid-pharmacy-trend-report.pdf>.

²Health Management Kaiser Family Foundation. “Medicaid Reforms Expand Coverage, Control Costs and Improve Care.” October 2015. Available at: <http://files.kff.org/attachment/report-medicaid-reforms-to-expand-coverage-control-costs-and-improve-care-results-from-a-50-state-medicaid-budget-survey-for-state-fiscal-years-2015-and-2016>.

³National Academy for State Policy. States and the Rising Cost of Pharmaceuticals: A Call to Action. October 2016. Found at: <http://nashp.org/wp-content/uploads/2016/10/Rx-Paper.pdf>.



patients have the highest standard of care available.⁴ In those comments we noted the clear legal authority for HHS to waive *all* or *some* of the requirements imposed under section 1927 of the Social Security Act (the authority for the MDRP) through a waiver of section 1902(a)(54).⁵ In those same comments, PCMA also cited numerous examples of past waiver approvals that supports HHS' clear authority to waive requirements in section 1927.⁶

On June 27, 2018, CMS sent a letter to Assistant Secretary of MassHealth, Daniel Tsai, approving an amendment to Massachusetts' section 1115 waiver, but denying approval for the requested formulary flexibility. In the letter, CMS set forth its belief that while states could in fact waive the requirements in section 1927 through a waiver of section 1902(a)(54) so that drug coverage need not be provided in accordance with the requirements of the MDRP, a state could do so only if it were to forgo all manufacturer rebates available under the MDRP program. In other words, CMS took the position that a waiver of section 1927 is all or nothing; if a state wants to impose additional requirements on drug coverage, it loses access to federally mandated rebates.

PCMA disagrees with CMS' reasoning and urges HHS to reconsider the HHS Secretary's waiver authority in this arena. As previously noted, CMS has in the past permitted states to waive *some*, but not *all*, of the requirements detailed in section 1927. We see no distinction here, nor are we aware of any legal rationale for limiting a state's ability to waive individual requirements in section 1927.

As to the demonstration contemplated in the FY2019 Administration Budget, we believe the MassHealth waiver approval makes clear that HHS does in fact have the authority to waive state compliance with section 1927, allowing states to operate alternative prescription drug programs and still receive a federal match. Further, and as noted above, we believe there is ample authority to permit a "state compact" to collect mandatory rebates while otherwise operating outside the confines of the MDRP program.

- **New formulary tools must be coupled with new flexibility for MCOs:** As noted above, PCMA supports the FY2019 Administration Budget proposal to add a new Medicaid demonstration authority to test drug coverage and financing reforms that build on private-sector best practices. However, for these tools to have the most impact, they must be coupled with the ability of MCOs to have responsibility for the administration and delivery of the Medicaid pharmacy benefit.

In an increasing effort to maximize Medicaid rebates, a number of states have implemented state-mandated formularies for their Medicaid managed care programs. Under these

⁴ See PCMA comments on MassHealth's section 1115 Waiver Application dated October 20, 2017.

⁵ SSA, § 1115(a)(1). As part of this authority, the Secretary may "waive compliance with any of the requirements of section ... 1902 ... to the extent and for the period he finds necessary to enable such State or States to carry out such project..."

⁶ For example, in reviewing recently approved section 1115 waivers, states, such as Arkansas, have received waivers under section 1902(a)(54) insofar as it incorporates section 1927(d)(5), to permit the state to request that prior authorizations be addressed in 72 hours, rather than 24 hours.

arrangements, managed Medicaid plans are required to follow the state FFS formulary and are prohibited from collecting supplemental rebates. This could be viewed as limiting the range of tools available to MCOs and their PBMs. Additionally, according to a comprehensive analysis of CMS Medicaid data, the full use of PBM tools in addition to those related to benefit design, and similar to those used in the commercial market, could result in \$33.4 billion in federal savings and another \$17.7 billion in savings for the states in the Medicaid program.⁷

MCOs have little pricing leverage outside of the federally mandated rebates. Excluding drugs through a closed formulary would allow MCOs to lower drug costs through increased negotiation power, enabling them to extract additional rebates from drug manufacturers than they could without this tool. Drug exclusions would also enable MCOs to reduce costs by further steering utilization to more cost-effective alternatives than can be achieved through a prior authorization process. In fact, a recent study found that the majority of drug exclusion policies were reported to reduce costs and with no negative impact on patient outcomes.⁸

A closed formulary would also pave the way for MCOs to pilot alternative payment models that would allow these stakeholders to manage prescription drug costs in a manner that connects coverage, payment, value, and health outcomes (i.e. value-based purchasing). Prescription drugs have mostly been excluded from value-based payment models that have been developed for other services in the Medicaid program.

PCMA Recommendation: PCMA broadly supports efforts by HHS to introduce private-sector formulary management techniques into the Medicaid program, and would welcome new demonstration projects. In light of the recent MassHealth waiver demonstration decision, PCMA encourages HHS to review its waiver authority to grant states maximum flexibility in the administration of the benefit. In addition, PCMA recommends that any new Medicaid demonstration authority give MCOs the flexibility and responsibility for actively managing the prescription drug benefit.

⁷ "Medicaid Pharmacy Savings Opportunities: National and State-Specific Estimates," The Menges Group (October 2016).

⁸ Chambers JD, Rane PB, Neumann PJ. "The impact of formulary drug exclusion policies on patients and healthcare costs." *Am J Manag Care*. 2016 Aug; 22(8):524-31.

Background

HHS notes in the RFI its ongoing desire to facilitate opportunities for enhanced information sharing among manufacturers, doctors, patients and insurers to improve patient access to medical products, including through value-based insurance. In 2017, FDA released draft guidance entitled, “Drug and Device Manufacturer Communications with Payers, Formulary Committees, and Similar Entities – Questions and Answers.” PCMA and its members largely supported the contents of the guidance.

Discussion

We support the need for timelier and more proactive sharing of pre-approval and post-approval healthcare economic information (HCEI) between drug and device manufacturers and insurers, PBMs, and others. The need for this proactive communication is especially important now as our health care system evolves from a fee-for-service payment system that rewards volume to a modernized system rewarding quality, improved patient outcomes, and value.

PCMA members believe access to timely HCEI is critical to the work they undertake on behalf of clients and patients to encourage the appropriate and cost-effective use of medicines. Specifically, our members are engaged daily in the work of developing formularies, negotiating rebate agreements, establishing cost-sharing, creating utilization management protocols, providing clinical support such as through medication therapy management programs, and crafting other programs to assist prescribers and patients in making choices among many prescription drugs. While there are many sources of information our members access in doing this work, information from manufacturers and other product sponsors is one of the most important.

In addition, our members are increasingly engaged in discussions with product sponsors to create contracts that condition pricing on value—the actual clinical benefits that patients realize from a medicine’s use. These contracts are an important tool in achieving value for our members’ clients and the patients they serve. HCEI is especially critical in these discussions that can involve clinical and economic outcomes that relate to an approved indication.

With regard to investigational drugs, early and complete information on pipeline products is essential to our members’ work. Such information enables them to anticipate the clinical and economic impact of new drugs. In turn, this allows them to more accurately project costs and, for programs such as Medicare Part D, establish premiums for future benefit periods. Our members negotiate contracts with their health plan clients and establish premiums well in



advance of a plan year. Therefore, prescription drugs that are approved over a subsequent 12 - 24 months can have a direct, and sometimes dramatic, impact on current contracts and premiums.

In general, we believe that the recent guidance is a significant positive step in the direction of properly implementing the legal mandates of section 114 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) and section 3037 of the 21st Century Cures Act. The guidance it provides should give product sponsors additional assurance that they can communicate HCEI with our members. In addition, the guidance on communications about investigational drugs should enhance our members' ability to anticipate and plan for new drugs to improve patient access to new therapies.

PCMA Recommendation: We thank the FDA for finalizing the HCEI guidance.

**Increasing Competition – I (A) p. 22693
Acceleration of Bringing Generics to Market**

Background

The RFI discusses a number of policy proposals planned or underway to accelerate the FDA approval of generic drugs. In addition to generally improving the agency's review efficiency, the document specifically mentions publishing names of drugs with no competition and maximizing scientific and regulatory clarity with respect to complex generic drugs.

Discussion

We thank the FDA Commissioner for his recent statement recognizing that, while FDA does not control drug pricing, its decisions affect competition, which drives pricing in the market. FDA has undertaken a number of steps to be more open and accessible to stakeholders and has shown a commitment toward increasing competition by getting more generics and biosimilars onto the market. We support all these measures and thank the FDA for these initiatives.

PCMA Recommendation: PCMA commends the FDA for publicly recognizing that its actions affect competition in the market, which, in turn, drives pricing. Additionally, we thank the agency for all the measures it is undertaking to enhance competition.

**Increasing Competition – I (A) p. 22697
Part B Biosimilar Payment**

Background

HHS notes it plans to finalize a policy in which each biosimilar for a given innovator biologic gets its own billing and payment code under Medicare Part B, to incentivize development of additional lower-cost biosimilars. Prior approaches to biosimilar coding and payment would have created a race to the bottom of biosimilar pricing, while leaving the branded product untouched, making it an unviable market that few producers would want to enter.

Discussion

PCMA commends the Administration on its proposal for biosimilar payment in Part B. We believe assigning each biosimilar its own HCPCS code will, as the FY2019 Administration Budget posits, incubate a vital growing industry and incentivize development of important new products.

In addition, because National Drug Codes (NDCs) are not required for providers to receive payment for drugs in Part B, assigning unique HCPCS codes will help the health community keep better track of which specific drugs are administered to patients, allowing for better care coordination.

PCMA Recommendation: PCMA commends the Administration on its proposal for biosimilar payment in Part B to assign a unique HCPCS code to each biosimilar and urges implementation as soon as practicable.

**Increasing Competition – I (A) p. 22693
Close Loopholes Allowing Brand-Name Drug Companies to “Game” FDA Rules to
Forestall Generic Competition: Evergreening**

Background

Drug manufacturers use tactics such as “product hopping” or “evergreening,” submitting applications to the FDA for approval of a “new” product that is essentially the same as the original product. Through such strategies, drug manufacturers have found ways to prolong patent protections past their original expiration dates. To evergreen a drug, a manufacturer simply creates a slightly adjusted follow-on drug through methods such as making small changes to the chemical composition, adjusting the dosage, combining formulas, or making a timed-release version of the existing drug.

Discussion

These product lifecycle management tactics artificially extend drug exclusivity periods and delay the take-up of lower-cost generics. Peer-reviewed research has found that evergreening strategies developed by drug manufacturers to create follow-on drugs substantially contributed to an increase in overall healthcare costs.⁹ These findings also provide further evidence that policies encouraging prescribing of generic medicines could have substantial savings on health costs.¹⁰

PCMA Recommendation: We ask the FDA to encourage the FTC, which has argued that tactics aimed at “gaming” FDA rules may be anticompetitive and unlawful, to (1) continue to take action when drug companies employ unlawful tactics that delay widespread use of lower-costly generic options; and (2) support plaintiffs who present legal challenges regarding such anticompetitive behaviors.

⁹ Nathalie Vernaz et. al., “Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis,” Journal of the Public Library of Science: Medicine, June 4, 2013 <https://doi.org/10.1371/journal.pmed.1001460>

¹⁰ Ibid.

Better Negotiation – I (B) p. 22694, p. 22695
Use of Part D tools in Part B and Creation of CAP for Part B drugs

Background

PBMs are third party administrators of prescription drug programs (including the Medicare Part D benefit, managed Medicaid programs, and other public and private prescription drug benefits). PBMs develop and maintain the formularies, negotiate discounts and rebates, and process prescription drug claims. They use a variety of drug utilization management (UM) tools to reduce drug costs, including prior authorization, step therapy, mandatory generic substitution, and others. Currently, the Medicare program utilizes PBMs and their UM tools only within the Medicare Part D benefit, and does not include PBMs in the Part B program (which covers physician-administered drugs). However, the Blueprint RFI suggests that expanding Part D tools into Part B for certain drugs may reduce Medicare costs. Further, in the FY 2019 Administration Budget, the Administration proposes authorizing HHS to leverage Medicare Part D tools (e.g., formularies, UM, rebates) in the Part B program.

The Blueprint also proposes to leverage the existing authority of the Part B Competitive Acquisition Program (CAP) (created by the Medicare Modernization Act of 2003 (the MMA) and in effect between 2006 and 2008 but with limited success) to provide physicians a choice between obtaining drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the current ASP methodology. The Blueprint RFI suggests that this model may provide savings for aggregate bid prices below the 106 percent of ASP currently paid for drugs under Medicare Part B, as well as opportunities for physicians who do not wish to bear the financial or administrative burdens associated with being in the business of drug acquisition.

Discussion

PCMA welcomes the recognition that use of Part D tools and PBMs to negotiate price concessions would be an important addition to the Part B program. We appreciate HHS Secretary Alex Azar’s comments during a June 26, 2018, hearing at the Senate Committee on Finance that: “We also want to bring negotiation to Medicare Part B, physician-administered drugs. Right now, HHS just gets the bill, and we pay it. This system may actually be driving doctors to prescribe more expensive drugs, while potentially tempting manufacturers to develop drugs that fit into Part B rather than D. We are going to look at ways to merge Part B drugs into Part D and leverage existing private-sector options within Part B.”¹¹

¹¹ Written Testimony by Alex M. Azar II, Secretary, U.S. Department of Health and Human Services on President Trump’s Drug Pricing Plan, United States Senate Committee on Finance, June 26, 2018.
<https://www.finance.senate.gov/imo/media/doc/26JUN2018AzarSTMNT.pdf>

The value of adding a rebate component to the Medicare Part B program was recognized by the HHS Office of the Inspector General (OIG) in a September 2013 report titled “Medicare Could Collect Billions if Pharmaceutical Manufacturers were Required to Pay Rebates for Part B Drugs.” In the report, the OIG found that the Medicare program would have collected either \$2.7 or \$3.1 billion in rebates on 60 high-expenditure drugs if pharmaceutical manufacturers had been required to pay rebates in 2011, depending on whether rebates were based on Average Sales Prices (ASP) or Average Manufacturer Price (AMP). This would represent from 20 to 22 percent of spending for those drugs. However, as part of its recommendation, the OIG noted that CMS would need to address administrative issues that would hinder rebate collection in the current system.¹²

The importance of adding prior authorization (PA) to Part B as a UM tool has been recognized in other areas of the Part B benefit. CMS has begun using PA in Part B in one permanent program and through a series of demonstrations designed to measure its effectiveness. A recent General Accountability Office (GAO) report to the Senate Committee on Finance indicated that expenditures decreased for items and services subject to the demonstration, with estimated savings from all PA Part B demonstrations through March 2017 in the range of about \$1.1 to \$1.9 billion. While these demonstrations were not related to prescription drugs, the analysis led GAO to recommend that CMS take steps to continue PA efforts to reduce spending.¹³ MedPAC, in its recent report to Congress, noted that PA is one of the six tools that Medicare could consider using to address the use of low-value care, stating that, “Expanding prior authorization, which requires providers to obtain approval from a plan or payer before delivering a product or service, could help reduce the use of low-value care. Although CMS has tested this approach to reduce unnecessary use of power mobility devices, nonemergent ambulance transports, and hyperbaric oxygen therapy, it has not been widely adopted by Medicare.”¹⁴

While PCMA fully supports the introduction of cost-saving Part D tools in the Part B program, we believe the Part B CAP program, absent changes to its underlying regulations, is not the appropriate vehicle to introduce competition into Part B. While we appreciate the interest of HHS in reviving the CAP program, we remain concerned that the Part B CAP program (at least under existing regulations) will not facilitate the use of Part D tools in Part B.

Under the CAP model (as specified in section 1847 of the Social Security Act), CAP vendors ship products to participating physicians, rather than physicians ordering products directly from wholesalers. The MMA provision creating the CAP program notably states that a CAP vendor must “acquire and deliver competitively biddable drugs and biologicals *within such category* in the area specified in the contract.” In regulation, CMS has interpreted this to require a vendor to

¹² HHS OIG, “Medicare Could Collect Billions if Pharmaceutical Manufacturers Were Required to Pay Rebates for Part B Drugs,” September 2013. <https://oig.hhs.gov/oei/reports/OEI-12-12-00260.asp>

¹³ GAO, Report to the Senate Finance Committee, “CMS Should Take Actions to Continue Prior Authorization Efforts to Reduce Spending,” April 2018. <https://www.gao.gov/assets/700/691381.pdf>

¹⁴ MedPAC, June 2018 Report to Congress, Chapter 10: Medicare coverage policy and use of low-value care. http://medpac.gov/docs/default-source/reports/jun18_medpacreporttocongress_sec.pdf?sfvrsn=0

offer at least one drug per HCPCS code. As a result, a CAP vendor's ability to drive down prices through competition among potentially substitutable drugs is significantly limited given the large number of HCPCS codes, relative to the more limited range of recognized categories and classes such as those promulgated by the U.S. Pharmacopeia (USP).

The current regulations also require the vendor to actually hold title to the drug, and allow a physician to opt out of the program and, if applicable, to request an exception to the CAP drug under a "furnish as written" exception, and do not permit a vendor to offer ancillary services to physicians tied to individual products.

HHS could of course amend the CAP program or create a more user-friendly program (modeled on MedPAC's Drug Value Program)¹⁵ which would more clearly allow use of existing private sector tools to introduce competition into the Part D program.

We believe a more viable way to demonstrate the value of Part D tools in Part B would be to allow Medicare Administrative Contractors (MACs), which process Medicare Part A and B claims, to subcontract with PBMs to manage the utilization of Part B drugs. MACs have a statutory ability to subcontract:

- 42 U.S.C. § 1395kk-1, Contracts with Medicare Administrative Contractors, outlines MACs' role. The statute permits CMS to "enter into contracts with any eligible entity to serve as a Medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (**or, to the extent provided in a contract, to secure performance thereof by other entities**)." § 1395kk-1(a)(1) (emphasis added).
 - This suggests that MACs may subcontract to carry out their statutory functions.
- § 1395kk-1(a)(4) outlines these statutory functions as (a) determination of payment amounts; (b) making payments; (c) assisting and educating beneficiaries; (d) providing consultative services; (e) communicating with providers and facilitating communication with providers and suppliers; (f) educating and assisting providers; (g) implementing an improper payment outreach and education program; and (h) ***additional functions as necessary to carry out the Medicare program***. (emphasis added)
 - *PBM administration of drug programs could fall under (h), the catch-all provision.*

However, it appears that while MACs may subcontract with PBMs to manage the utilization of Medicare Part B drugs, PBMs' ability to apply UM tools will be somewhat limited by Part B's coverage requirements and by the limits on plans from applying UM to Part B. In other words,

¹⁵ MedPAC, Chapter 2, Report to the Congress: Medicare and the Health Care Delivery System, June 2017. http://www.medpac.gov/docs/default-source/reports/jun17_ch2.pdf?sfvrsn=0

PBMs could employ UM tools, but without the scope of authority available under the Part D program. For example, Section 1861(t) of the Social Security Act requires relatively broad coverage of certain chemotherapeutic agents. A PBM could not employ UM so as to interfere with that level of coverage.

That said, there is action that CMS could take that would help, at least directionally, in terms of clarifying that PBMs may in fact provide UM services under Part B. Specifically, on September 17, 2012, CMS issued an HPMS memo entitled “Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services”.¹⁶ This memo stated that, for Medicare Advantage Organizations (MAOs), and others, “the imposition of additional requirements for access to certain Part B drugs or services, such as step therapy requirements, is not permitted unless also required through Original Medicare.” The memo does not cite a statutory basis for this statement but takes the position that MAOs must cover all services covered by Medicare Part B. Unfortunately, this memo has stifled the ability of MAOs to conduct UM on Part B services for their enrollees and could be cited as the basis for saying that even if MACs could contract with PBMs to administer Part B drugs, PBMs could not use UM tools. This would undermine the HHS initiative to make Part B more cost-effective. Fortunately, the action needed to address this barrier is very straightforward: CMS could withdraw this memo and reissue a new memo with direction as to what constitutes acceptable UM in this arena. At a minimum, the withdrawal would allow MA-PD plans to use a more holistic approach to their oversight and management of all drugs taken by their enrollees.

Finally, another strategy not addressed in Part B is how pharmacists and others could make beneficiaries aware of cost-saving alternatives for Part B drugs. Part D tools (both current and those discussed below in section III (D) (p. 120): Informing Beneficiaries about Price Changes, Cost-sharing, and Lower-cost Alternatives) are not used in Part B today because, while PBMs often manage the use of medical benefit drugs in private-sector medical benefits, the current Part B framework is not built to use PBM management tools. Incorporating Part D PBMs and PBM tools to help administer drugs in Part B would help with beneficiary education as well. Some of the ideas that could be considered include:

- CMS could produce a formulary-type document for Part B drugs (perhaps including icons signaling high-cost drugs where there are alternatives) and possibly include a preferred drug list.
- CMS could set up something similar to a Medicare Plan Finder (MPF) for Part B drugs, where FFS beneficiaries could find out the most current prices (and their applicable coinsurance) for Part B drugs, as well as information on whether the drug or an alternative might be available under Part D, and if so, allow them to click right on to MPF.

¹⁶ CMS memo posted on HPMS from Danielle R. Moon regarding “Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services.” September 17, 2012.

- CMS could revise “The Medicare & You Handbook” to include a clear explanation of Part B drug coverage with as much pricing, transparency and coverage information to facilitate the ability of beneficiaries to understand the extent to which they have options to utilize lower-costs drugs under Part B.
- If UM functions are contracted to PBMs as part of the MAC contract approach, PBMs should be able to apply existing methods of sharing information on coinsurance and drug pricing with beneficiaries, along with those tools in development as described elsewhere in our comments.

PCMA Recommendation: As a way to implement the HHS proposal to leverage Part D plans’ negotiating power and UM tools for certain drugs under Part B, PCMA recommends that HHS assess how to do this under current authorities. Two potential ways to accomplish this are to 1) allow the MACs, which process Medicare Part A and B claims, to subcontract with PBMs with Part D experience to apply UM tools, and 2) withdraw the HPMS memo dated September 17, 2012 to facilitate the application of PBM UM tools under Part B. Because that memo could be read to prohibit Part D plans from applying UM to Part B drugs, CMS should instead replace it with authorization for the application of reasonable UM tools in this arena.

Reducing Patient Out-of-Pocket Spending – I (D) p. 22694 Eliminating Cost-Sharing on Generic Drugs for Low-Income Beneficiaries

Background

The maximum cost-sharing amounts that LIS beneficiaries can pay out-of-pocket are set in statute and Part D plan sponsors cannot modify those amounts. As a result, financial incentives to enrollees to use lower-cost drugs via differential cost-sharing are not as strong for LIS enrollees and Part D plan sponsors therefore have limited ability to manage the drug spending for this population.¹⁷ President Trump's 5-part plan in the FY2019 Administration Budget to modernize the Medicare Part D program includes a proposal to eliminate cost-sharing on generic drugs for low-income beneficiaries.¹⁸

Discussion

The Medicare Payment Advisory Commission (MedPAC) has examined this issue and made recommendations regarding LIS cost-sharing over the years. In 2016, MedPAC noted that "LIS copayments provide much weaker financial incentives than those faced by non-LIS enrollees."¹⁹ MedPAC observed that differences in generic dispensing rates among groups of beneficiaries may be in part explained by "the difference in financial incentives faced by LIS and non-LIS enrollees."²⁰ MedPAC recommended that the HHS Secretary consider moderately increasing financial incentives for LIS enrollees to use lower-cost drugs, including generic drugs, preferred multisource drugs and biosimilars.

The Secretary also would have the authority to select the therapeutic classes for which the policy would apply and review those classes at least every three years. Plan sponsors would be required to ensure that their prior authorization and appeals and grievance processes allowed enrollees to receive necessary medications in cases where therapeutic substitution was not clinically appropriate. MedPAC noted that if a Part D plan sponsor's enrollees switched to lower-cost generic drugs, the plan could experience a decrease in the costs of providing the Part D benefit, leading to decreased premiums for all enrollees and reduced subsidy payments from Medicare to Part D plan sponsors. These analyses show that there should be savings generated by increasing the difference in cost-sharing between brand and generic drugs, for those drugs that have generics.

¹⁷ See MedPAC Report to the Congress: "Medicare and the Health Care Delivery System" (June 2016): <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>

¹⁸ "Lowering the Price of Drugs by Reforming Payments: 2019 Budget Fact Sheet." https://www.whitehouse.gov/wp-content/uploads/2018/02/FY19-Budget-Fact-Sheet_Reforming-Drug-Pricing-Payment.pdf

¹⁹ MedPAC, Op. Cit.

²⁰ MedPAC, Op. Cit.



PCMA Recommendation: PCMA supports modifying the cost-sharing structure for LIS enrollees in Medicare Part D to encourage the use of lower-cost drugs, including generics.

II. Responding to President Trump’s Call to Action

Better Negotiation – II (B) p. 22693 One Drug Per Category/Class

Background

HHS notes that it has proposed, as part of the FY2019 Administration Budget, a five-part plan to modernize Part D, and that one portion includes enhancing Part D plan sponsors’ negotiating power with manufacturers by changing Part D formulary standards to require a minimum of one drug per category or class rather than two. We believe CMS has the authority under the statute to reverse the rules to accommodate this change and it need not await legislative authority to take this action.

Discussion

For Part D plan sponsors to offer a clinically sound, cost-effective formulary, CMS should allow more flexibility in formulary constructs. The requirement that plans include two drugs per therapeutic class or category is a significant barrier to the development of a cost-effective therapy. The mandatory coverage of two drugs in each category or class has negative effects on competition and fundamentally undermines the development of evidence-based formularies. The mandate overrides the activities of Pharmacy and Therapeutic (P&T) committees, which make their own assessments on clinical appropriateness and therapeutic alternatives based on clinical guidelines, peer-reviewed literature, and the compendia, thus undercutting a critical component of a well-managed drug plan offering. The mandate also undercuts the competitive aspect of the marketplace, where plans compete with each other based on drug coverage, including appropriate access to a wide range of drugs. Simply put, the requirement to cover a certain number of medications allows pharmaceutical manufacturers to name their price. With the additional formulary checks that CMS has established and utilizes, the rigid enforcement of the two drugs per class requirement is no longer necessary.

In a June 20, 2018, Issue Brief²¹ on the Administration’s plan for Medicare Part D, the Kaiser Family Foundation noted the Congressional Budget Office’s (CBO’s) estimate that relaxing Part D formulary standards would reduce federal spending by \$6.3 billion over 10 years.²² The Issue Brief states that “[b]y relaxing the current two-drug standard for Part D formulary coverage and allowing plans to limit coverage to only one drug per class, plans could have greater leverage in price negotiations. If plans are able to negotiate steeper discounts on the drugs they choose to cover, that could lower plan costs, generate savings for enrollees in the form of lower premiums, and lower Medicare spending.”

²¹ KFF, Issue Brief: What’s in the Administration’s 5-Part Plan for Medicare Part D and What Would it Mean for Beneficiaries and Program Savings?, June 2018. <http://files.kff.org/attachment/Issue-Brief-Whats-in-Administrations-5-Part-Plan-for-Medicare-Part-D>

²² CBO, Proposals Affecting Medicare—CBO’s Estimate of the President’s Fiscal Year 2019 Budget, June 5, 2018. <https://www.cbo.gov/pub>

PCMA engaged Oliver Wyman Actuarial Consulting, Inc. (Oliver Wyman) to estimate the savings that could be achieved if higher price concessions were negotiated with drug manufacturers if only one drug per class was allowed. The analysis was limited to brand drugs in the following drug classes:

- AHFS classes – insulin, dipeptidyl peptidase-4 (DPP-4) inhibitors, incretin mimetics, sodium-glucose co-transporter 2 (SGLT2) inhibitors, phosphodiesterase type 5 inhibitors, anti-hepatitis C (HCV) replication complex inhibitors
- USP classes – anti-hepatitis C (HCV) agents, respiratory tract agents/other, gastrointestinal agents/other, sleep disorders/other

Oliver Wyman estimated that Part D expenditures could be reduced between 1.2% and 3.5% if Part D plan sponsors and their PBMs were able to negotiate higher price concessions with brand drug manufacturers in these drug classes. In aggregate for 2015, this equates to a \$1.0 billion to \$3.1 billion decrease in costs. At these savings rates (1.2% to 3.5%), the Part D program could save between \$2.3 billion and \$6.8 billion in 2026. The Medicare program would realize 74.5% of these savings, while beneficiaries would realize 25.5% of the savings. Furthermore, the savings could be larger if all drug classes were considered.²³

Importantly, we believe this change can be made through the regulatory process whereby CMS proposes a revised interpretation of the language in the Medicare Modernization Act of 2003 (the MMA). Specifically, although it did not do so in 2005, CMS could reasonably interpret the language of section 1860D-4(b)(3)(C) of the MMA that “the formulary must include drugs within each therapeutic category and class of covered part D drugs” as requiring Part D formularies to include at least one drug per category or class, not a minimum of two. As an initial matter, the fact that “drugs” is in the plural is of limited assistance in ascertaining the correct meaning of the statute. An elementary rule of statutory construction is that the singular includes the plural and vice-versa. See, e.g., 1 U.S.C. §1 (“unless the context indicates otherwise . . . words importing the singular include and apply to several persons, parties, or things; words importing the plural include the singular”).

Furthermore, other provisions of Part D make it clear that Congress knows how to specify two or more of something when it so desires. See, e.g., *Central Bank of Denver v. First Interstate Bank*, 511 U.S. 164, 184 (1994) (“when Congress wishes to provide a private damages remedy, it knows how to do so and does so expressly”). In the section immediately preceding the formulary requirements, section 1860D-3(a)(1), Congress requires that “[t]he Secretary shall ensure that each Part D eligible individual has available . . . a choice of enrollment in at least 2 qualifying plans . . . in the area in which the individual resides, at least one of which is a

²³ Oliver Wyman, “Impact of Allowing One Drug Per Drug Class in the Medicare Part D Program,” September 18, 2017. <https://www.pcmnet.org/wp-content/uploads/2018/07/OW-Part-D-One-Drug-per-Class-v3.pdf>

prescription drug plan” (emphasis added). Likewise, section 1860D-131(g)(5)(B) requires the Secretary to ensure that “pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations . . . have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 States and the District of Columbia where such a pharmacy operates” (emphasis added).

In light of these other provisions, it would not be unreasonable for CMS to conclude that Congress’ failure to specify that at least two drugs per category or class are required in Part D allows for Part D plans to include a minimum of one drug per category or class. See *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 844 (1984) (“Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency.”).

Indeed, the Council of Economic Advisers’ February 2018 report²⁴ on “Reforming Biopharmaceutical Pricing at Home and Abroad” states that the two-drug requirement “eliminates the ability of Part D plan sponsors to negotiate for lower prices when there are only two drugs on the market since drug manufacturers know that CMS must cover both. The two-drug requirement leads to more spending.”

Specifically, the rule could provide that Part D plans must cover at least two drugs in each duly determined category or class of drugs, except that: 1) Part D plans may cover only one drug in a category or class where there are two drugs in the category or class that are of comparable clinical quality, and 2) Part D plans may cover only one drug in a category or class if that drug is as good or better than all other drugs in the category or class, regardless of the number of drugs in the category or class.

PCMA Recommendation: *We recommend that CMS adopt the policy it proposed in the FY2019 Administration Budget to change Part D formulary standards to require a minimum of one drug per category or class rather than two. This could be accomplished by changing CFR §423.120(b)(2) so that it reads:*

Provision of an Adequate Formulary. A Part D plan's formulary must -

(i) Except as provided in paragraphs (b)(2)(ii) and (v) of this section, include within each therapeutic category and class of Part D drugs at least two Part D drugs that are not therapeutically equivalent and bioequivalent, with different strengths and dosage forms available for each of those drugs, except that only one Part D drug must be included in a particular category or class of covered Part D drugs if the

²⁴ Council of Economic Advisers, *Reforming Biopharmaceutical Pricing at Home and Abroad*, February 2018. <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>



category or class includes only one Part D drug.

(ii) Include at least one Part D drug within a particular category or class of Part D drugs to the extent the Part D plan demonstrates, and CMS approves, the following:

(A) That only two drugs of comparable clinical quality are available in a category or class of Part D drugs; or

(B) That at least one drug is clinically comparable or clinically superior to the other drugs in a category or class containing more than two Part D drugs.

Background

HHS acknowledges that “value-based transformation of an entire system is a top HHS priority.” We wanted to use this opportunity to reiterate how the current DIR construct for payments to pharmacies under Part D is grounded on value-based principles and that any effort to restructure or eliminate this type of DIR would undermine the Department priority as noted above.

Discussion

As CMS has recognized, “Value-based pricing for pharmaceuticals involves linking payment for a medicine to patient outcomes, quality performance and cost-effectiveness rather than solely the volume of sales.... The market today uses the term “value-based” to encompass a wide variety of different options designed to improve clinical results, quality of care provided, and reduce costs.”²⁵ The concept of paying for value and quality can be seen in numerous value-based payment models in the private and public sectors, including those implemented or proposed by CMS. For example, the shared savings concept of the CMS Accountable Care Organizations (ACOs) or the upfront discount applied in the Comprehensive Care for Joint Replacement (CJR) Model are emerging value-based models developed by CMS. While no repayments to Medicare were required in Performance Year 1 in the CJR model, downside risk applies beginning in Performance Year 2.²⁶

Part D plan sponsors and their PBM partners seek to provide value-based care under Part D based on quality performance; indeed, the above CMS statement on value-based care describes precisely what they view as a main goal of the Part D program. Yet, the last few years have seen a significant movement in the Part D regulatory arena toward mandating that any amounts that can be determined at point-of-sale (POS) be passed through at the POS to pharmacies, and not accounted for as direct and indirect remuneration (DIR), even though DIR has been the construct through which plans and PBMs make value-based payments since the program was implemented in 2006.

Indeed, as the 2017 CMS report on DIR noted, higher levels of DIR can reduce beneficiary premiums and lower some government costs through lower Part D premiums.²⁷

²⁵ “Medicare Program; Part B Drug Payment Model; Proposed Rule,” 81 *Federal Register* 48 (March 11, 2016), p. 13243. <https://www.gpo.gov/fdsys/pkg/FR-2016-03-11/pdf/2016-05459.pdf>

²⁶ CMS Innovation Center website, Comprehensive Care for Joint Replacement Model. <https://innovation.cms.gov/initiatives/CJR/>

²⁷ CMS website, Medicare Part D – Direct and Indirect Remuneration (DIR) <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html>



Cost as a Measure of Value

Both MedPAC and CMS recently identified the value of payment for managing beneficiary and program costs:

- In its June 2018 Report to Congress, MedPAC concluded that, “Establishing new payment models that hold providers accountable for the cost and quality of care ... creates incentives for organizations to reduce low-value services.” Further in the report, MedPAC notes “Medicare could also use new payment models that encourage delivery system reform to reduce low-value care. Payment models that hold providers accountable for the cost and quality of care may create incentives for the efficient delivery of care, including decreased use of low-value services.”²⁸
- Pharmacy DIR promotes value similar to the way CMS recognizes cost as a value measurement in the Part B program. In the MACRA Merit-based Incentive Payment System (MIPS) program, CMS supports payment to clinicians based on their ability to manage costs. Included in the CY 018 Updates to the Quality Payment Program, issued by CMS on November 16, 2017, was a reinstatement of the original cost component. CMS confirmed that this component will be 10 percent of the MIPS Composite Score for 2018 and will increase to 30 percent in 2019.²⁹

DIR Payments to Encourage Value

Part D plan sponsors have incorporated the emerging value-based models by contracting with pharmacies in various ways to reward value. Quality measures incorporated into DIR payments include:

- a. Greater MTM Program participation to increase the number of eligible beneficiaries that receive completed Comprehensive Medication Reviews and MTM consultations;
- b. Appropriate dispensing and administration of Part B and D vaccines for at-risk beneficiaries;
- c. Engagement and reporting of metrics related to diabetes disease management programs;
- d. Appropriate reduction of High Risk Medications in the senior population;
- e. Active engagement in medication adherence programs;
- f. Active engagement in customer satisfaction and service programs; and
- g. Use of generic medications to provide therapy at lowest cost to beneficiaries.

²⁸ MedPAC, June 2018 Report to Congress, Chapter 10: Medicare coverage policy and use of low-value care. http://medpac.gov/docs/default-source/reports/jun18_medpacreporttocongress_sec.pdf?sfvrsn=0

²⁹ Federal Register, Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year, November 16, 2017. <https://www.federalregister.gov/documents/2017/11/16/2017-24067/medicare-program-cy-2018-updates-to-the-quality-payment-program-and-quality-payment-program-extreme>



Many of the quality measures used in the Medicare Part D Star Ratings System and listed above are based on measures developed by the Pharmacy Quality Alliance (PQA), an alliance of which CMS is member and on which the CMS medical director serves as a member of the PQA Board.³⁰ Part D plan sponsors include Star Rating/PQA measures as part of the standardized, achievable and proven criteria used as contractual incentives with pharmacies that serve as part of the DIR payments. Through CMS' involvement and leadership in PQA (along with the American Pharmacists Association, the National Association of Chain Drug Stores and the National Community Pharmacists Association), CMS and organizations representing community pharmacies have significant influence on PQA to develop measures that these stakeholders agree demonstrate value for patients and provide an incentive to pharmacies to use the most cost-effective therapy. Until an alternate measure is developed, some Part D plan sponsors appropriately use generic dispensing rate (GDR) as the measure identified to encourage pharmacy providers to support use of the most cost-effective therapy.

The current Part D regulatory construct does not allow for pharmacy DIR payments at POS to encourage higher value service for beneficiaries—in fact, it would encourage the opposite. Indeed, to pass through such payments would incentivize beneficiaries to use relatively poorer performing pharmacies.

Consider the following example. A plan pays \$1 more per prescription for pharmacies that meet certain quality targets related to the plan's quality rating measures. Pharmacies that do not meet the quality standard get paid \$1 less per prescription from the base negotiated price. Pharmacy A hits the targets and Pharmacy B does not. Under a policy to move DIR payments to POS, a drug would cost \$2 more at Pharmacy A compared with Pharmacy B (base cost of drug \$10, Pharmacy A=\$10+\$1=\$11 and Pharmacy B=\$10-\$1=\$9). If the beneficiary cost-sharing must fully reflect payments to pharmacies, the beneficiary would be incentivized to go to Pharmacy B, the pharmacy that did not meet the quality standards, as seen in the chart below.

Pharmacy	Current DIR Policy		DIR at POS Policy	
	Pharmacy A	Pharmacy B	Pharmacy A	Pharmacy B
Net Drug Cost	\$10	\$10	\$10	\$10
Quality Bonus	+\$1	-\$1	+\$1	-\$1
Final Cost at POS	\$10	\$10	\$11	\$9

The first two columns of the chart reflect the current policy in which the quality bonus (upside or downside) payments do not impact the drug cost calculated at the time of dispensing/POS (because they are accounted for at a later time with DIR payment calculations). The second two columns reflect the situation if the quality bonus (upside or downside) payments are included into the payments to the pharmacy at the time of dispensing/POS, impacting any beneficiary coinsurance.

³⁰ See, https://pqaalliance.org/about/staff_biography.asp?bsbid=16



We also strongly reiterate all of our comments on the topic of otherwise changing the current construct for pharmacy DIR payments as set forth in detail in our response to the RFI contained in the proposed 2019 Part D rules.³¹ Apart from that proposal, which we understand at this point would be considered only as part of a five-point plan in the FY2019 Administration Budget taking all of the components into account, we urge CMS not to propose any other changes to pharmacy DIR. Indeed, as noted in the pending 2019 House Labor-HHS Appropriations report³² regarding DIR, “The Committee is aware that CMS has put forth a Request for Information as part of the 2019 proposed Part D rule. The Committee understands any specific policy changes must occur through a future notice and comment rulemaking and urges the Secretary to consider the impact this proposal will have on seniors’ premiums and the taxpayer, as well as its potential to reveal competitively sensitive information. The Committee requests an update on this topic in the fiscal year 2020 Congressional Justification.”

PCMA Recommendation: PCMA recommends that CMS maintain the DIR construct in its current form to promote value-based payments in Part D (similar to how value-based payments are encouraged in FFS Medicare). At the same time, PCMA encourages CMS to assess its current policies and make appropriate changes, including adding a safe harbor from the anti-kickback limitations for value-based payments, to assure that there are no barriers to the ability of plan sponsors and PBMs to negotiate value-based payments with pharmacies under Part D.

³¹ See PCMA comments filed January 16, 2018, to Seema Verma on the Medicare Program 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 Proposed Rule as published in the Federal Register on November 28, 2017.

³² Senate Labor-HHS Report: https://appropriations.house.gov/uploadedfiles/labor_report.pdf at page 90.

Better Negotiation – II (B) p. 22694
Sole Source Generic Price Increases**Background**

HHS indicates that it may support better negotiation by allowing Part D plan sponsors to adjust formulary or benefit design during the benefit year if necessary to address a price increase for a sole source generic drug. Part D plan sponsors and PBMs do not contract with generic drug manufacturers for the purchase of generic drugs and are not permitted under existing policy to implement negative formulary changes midyear in response to a price increase. HHS indicates that this change could ensure Part D plan sponsors can respond to a price increase by the only manufacturer of a generic drug.

Discussion

There is growing concern over pharmaceutical manufacturers' ability to set and raise drug prices. The price of a drug that has not been protected by a patent for decades can suddenly increase as much as 10,000 percent. The best-known example of a dramatic price increase for a sole source drug whose patent has expired is the Turing Pharmaceuticals/Daraprim example where Turing acquired an old, off-patent drug pyrimethamine (known by the brand name Daraprim) and then raised the drug's price roughly 55-fold. While Daraprim's patent had expired, there were no generic equivalents on the market.³³ Similar implications occur when there is only one generic manufacturer with a product available, especially if there is not competition from a brand-name product.

Because Part D plan sponsors and PBMs generally do not contract with generic drug manufacturers for the purchase of generic drugs, Part D plan sponsors need the ability to use all available utilization management tools to respond to such price increases. CMS should allow plan sponsors to respond quickly and strongly to dramatic price increases from sole source drugs whose patents have expired. Plan sponsors should be allowed to remove such a medication from a plan formulary or to move the medication to a non-preferred tier, after notifying CMS, but without being required to obtain CMS approval for the midyear formulary change. If there is no therapeutic alternative for the medication, a plan sponsor would be moving the medication to a non-preferred tier rather than completely removing from formulary. A change in formulary status is one of the few tools available to discourage the manufacturer of a sole source product from dramatic price increases. With the midyear formulary change, plans would provide beneficiaries with appropriate notice of the formulary change.

³³ US Senate Special Committee on Aging, Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Tax Payers, and the U.S. Health Care System, December 2016.
<https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf>



PCMA Recommendation: PCMA encourages HHS to issue a CMS guidance document to provide Part D plan sponsors and their PBMs with the authority to respond quickly to price increases from sole source drugs whose patents have expired by removing such a medication from a plan formulary or to move the medication to a non-preferred tier. Plan sponsors should be required to notify CMS of the change but should not be required to obtain CMS approval before making the change.

**Better Negotiation – II (B) p. 22695
Updating the Methodology Used to Calculate Drug Plan Customer Service Star Ratings****Background**

HHS indicates that it may support better negotiation by updating the methodology used to calculate Drug Plan Customer Service star ratings for plans that are appropriately managing utilization of high-cost drugs. Presently, if a Part D plan issues an adverse redetermination decision, the enrollee, the enrollee's representative or the enrollee's prescriber may appeal the decision to the Independent Review Entity (IRE). This process may discourage Part D plan sponsors from appropriately managing utilization of high-cost drugs. The proposed change could provide Part D plan sponsors with the ability to better use their formulary and prior authorization systems to manage high-cost changes while being held accountable for using other successful enforcement mechanisms.

Discussion

Impact of star rating on coverage decisions: The measure proposed for updating is D03 – Appeals Upheld (Fairness of Drug Plan's Appeal Decisions, based on an Independent Reviewer), which reports how often an IRE determines the drug plan's decision to deny an appeal was fair. Currently, MAXIMUS Federal Services is the Part D IRE. The measure is defined as the percent of IRE confirmations of upholding the plans' decisions. In 2017, excluding cases that were dismissed, withdrawn, or remanded, and cases involving non-Part D drugs, the IRE reversed plan decisions in 27.65 percent of cases³⁴ (down from 29.81 percent in 2016³⁵). The top appeal types in 2017 are: 1) plan cost utilization tool disputed; 2) not covered under Part D; 3) not a medical accepted indication; and 4) request for drug not on formulary.³⁶

The inclusion of the current Appeals Upheld measure as part of the Star Ratings Quality Measurement System has a negative effect on a Part D plan sponsor's incentive to best manage prescription drug utilization. Achieving a high overall star rating is extremely important for both Medicare Advantage plans with prescription drug benefits (MA-PDs) and stand-alone prescription drug plans. MA-PD plans earning at least four stars qualify for federal bonus payments. Those that do not achieve that level lose out on those payments. For Part D plan sponsors, a five-star rating rewards plans with the opportunity for year-round enrollment of new enrollees. A low rating over three years keeps a Part D plan from being able to enroll beneficiaries via the Medicare Plan Finder (MPF). Therefore, all plans have a strong incentive to make coverage decisions that will maximize their overall star ratings. Avoiding appeals that might not be upheld by the Part D IRE may impact utilization management (UM) decisions

³⁴ CMS, Fact Sheet: Part D Reconsideration Appeals Data–2017

³⁵ CMS, Medicare 2018 Part C & D Star Ratings Technical Notes. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/2018-Star-Ratings-Technical-Notes-2017_09_06.pdf

³⁶ CMS, Fact Sheet: Part D Reconsideration Appeals Data–2017

related to covering a non-formulary drug or a drug that requires prior authorization (PA). Part D plan sponsors and their PBMs have a responsibility to encourage the use of the most safe, effective and cost-effective medications. Part D plan sponsors are aware that some decisions will be appealed, and that a plan's decision can be reversed by the IRE.

MAXIMUS in its role as the Part D IRE has a history of reversing decisions, and, therefore, keeps Part D plan sponsors trying to learn from and adjust behavior, even when the plan sponsor disagrees with an IRE decision. The threat and unpredictability of such a reversal impacting the Appeals Upheld star rating prevents plan sponsors from making what they believe to be the best quality, most appropriate decisions. Part D plan sponsors are concerned about their total inability to predict whether a decision will be reversed by the IRE.

The average 2018 Star Rating for D03 – Appeals Upheld was 3.5 for standalone PDPs and 3.9 for MA-PD plans.³⁷ These scores indicate that beneficiaries often prevail at the IRE level; that is, the IRE did not concur that the plan sponsor's decision to deny was appropriate. As noted, this leads to plans' reluctance to deny high-cost drugs, even when they believe the decision is appropriate and there is a more cost-effective alternative. Therefore, success on the Appeals Upheld star rating measure is achieved when plan sponsors change their UM practices to follow IRE decisions rather than recognized clinical practice guidelines or PA criteria established by Pharmacy & Therapeutics (P&T) committees. A previous IRE overturn can lead to a plan changing behavior and approving a high-cost drug over a cost-effective formulary alternative to prevent a future IRE overturn.

Several examples of IRE reversals, provided by PBMs from actual cases,³⁸ which discourage Part D plan sponsors from making the most appropriate decisions:

- **Methocarbamol:** Although methocarbamol is considered a high-risk medication (HRM) in patients over age 65 and is indicated for acute use, the IRE is accepting chronic use based on an outdated reference in Comparative Efficacy that identifies a seven-day course of therapy with methocarbamol as supportive for chronic musculoskeletal pain. A seven-day period should fall into the category of acute pain rather than chronic pain.
- **Amitiza (lubiprostone):** An IRE exception allows for the use of Amitiza when also taking methadone, despite this being a limitation of use specifically called out in the FDA-approved labeling. The limitation of use states that the effectiveness of Amitiza in the treatment of opioid-induced constipation in patients taking diphenylheptane (e.g., methadone) has not been established.

³⁷ Fact Sheet - 2018 Part C and D Star Ratings.
http://www.integratedcareresourcecenter.com/PDFs/2018_Star_Ratings_Fact_Sheet_2017_10_10.pdf

³⁸ More detail on each example can be provided upon request.

- **Budesonide Nebulizer Solution:** The IRE approved for nasal polyps despite the nebulizer formulation lacking support for this diagnosis; only budesonide nasal spray (Rhinocort) has support for this diagnosis.
- **Jakafi (ruxolitinib):** The IRE approved Jakafi for treatment of graft versus host disease (GVHD) related to a previous allogenic bone marrow transplant for acute myeloid leukemia (AML), indicating that the treatment of GVHD is a continuum of treatment of AML. GVHD is not a cancer diagnosis; therefore, only the FDA-approved label, DrugDex, and AHFS-DI should be used as references for supportive citations. The IRE referenced DrugDex, noting that Jakafi has orphan drug status for treatment of GVHD and also referenced a citation in a CMS-approved journal to support medically accepted indication for the use of Jakafi for GVHD. However, the documentation of orphan drug status for treatment of a condition in either DrugDex or AHFS-DI is not considered a supportive citation per CMS guidelines.³⁹
- **Seroquel XR (quetiapine fumarate XR):** The IRE approved a formulary exception for treatment of bipolar disorder with brand-name Seroquel XR because there was documentation that multiple formulary alternatives had been tried and failed; however, there was also documentation from the prescriber that the generic form of quetiapine fumarate XR, which was on formulary, could be taken by the enrollee.
- **PA exceptions:** Another area of significant concern is the IRE approval of PA exceptions. Part D plan sponsors and PBMs have noted that for cases in which a Part D plan's PA criteria are not met, there is a trend of IRE PA exception approvals that do not follow the appropriate CMS guidelines for PA exceptions as identified below, resulting in inappropriate favorable IRE reversals. The CMS guidelines are:
 - The prescriber states that all of the alternative drugs on the Part D plan's formulary for treatment of the enrollee's condition would not be as effective for the enrollee or would have adverse effects, and/or,
 - If the drug is not a new start, the prescriber states that the enrollee is stable on the requested drug and that a change in therapy would result in destabilization of the enrollee's condition or other adverse effects, with adverse effects specified.

IRE overturns based on information not available at the time of plan decision: In addition to concerns about the appropriateness of the measure, the current D03 – Appeals Measure methodology does not account for the change in a beneficiary's clinical status or the change in the prescriber request that can occur during the time period from when the Part D plan sponsor decisions a case for redetermination to when the IRE decides a case. Change in case status can result in a different decision by the IRE than the decision reached by the plan. While the

³⁹ It should be noted that this example was from earlier this year. DrugDex has since been updated with a supportive citation for the use of Jakafi for GVHD following allogenic stem cell transplantation, steroid refractory.

decisions are different, they may both be appropriate based upon the status of the case or the information available at the time of review. The measure methodology does not account for this appropriate difference in decisions. While PCMA supports the IRE making the most accurate and timely decision based upon information available at the time of its review, such an IRE decision should not count against the plan in the Appeals Measure methodology when there was a notable change in clinical status or in the prescriber request following the plan sponsor's decision. Examples of the IRE approval after significant changes include:

- New laboratory information was available to the IRE after the redetermination denial.
- The IRE reviews a request for a different regimen than was requested of the Part D plan.
- The IRE issues favorable decisions due to timing of compendia updates.
- Different information is supplied by the prescriber to the IRE versus information supplied by the prescriber to the Part D plan.

Better IRE/Part D plan sponsor communication: The ability of Part D plan sponsors to predict an IRE decision is challenged by the IRE's focus on the process of the decision rather than on the clinical quality of the decision. IRE decisions would be more impactful, and plans could refine and improve decision-making processes to align with the IRE, if there was better communication at the time of the IRE decision. Instead a plan sponsor is focused on a punishment for overturned decisions that has negative repercussions years later through the Star Rating measurement system.

CMS process to adjust star ratings: In the 2019 Policy and Technical Changes Final Rule, CMS clearly delineates the regulatory process for adding, updating and removing measures. With the new regulatory process, changes or removal of a measure could be proposed through the 2020 Policy and Technical Changes Proposed Rule. To avoid delaying a change that would encourage the use of more cost-effective medications, CMS could begin implementation of such a change through a pilot program even prior to a regulatory change.

PCMA Recommendation: PCMA encourages HHS to modify the Appeal Upheld measure (D03) to exclude IRE overturns based on information not available at the time of plan decision. PCMA also encourages HHS to focus on improving the IRE process and communication. HHS should work to decrease excessive and inaccurate IRE overturns.

**Better Negotiation – II (B) 22694
Use of Demonstration Projects****Background**

HHS notes that it may support better negotiation by directing CMS to develop demonstration projects “to test innovative ways to encourage value-based care and lower drug prices.” Among other goals, this should provide Medicare providers, payers and states with additional tools to manage spending for high-cost therapies.

Discussion

We believe the goals articulated by HHS for demonstration projects are appropriate, and we appreciate HHS’ willingness to engage in pilots which attempt to improve the overall competitiveness of the market. That said, we remain concerned about CMMI’s demonstration process and legal waiver considerations, as noted below.

- **Process considerations**

We appreciate that there are many considerations that CMMI needs to address in order to establish a meaningful demonstration project undertaking. That said, we urge HHS to consider how to best put into effect shorter and more manageable demonstrations so that it can test and learn, and then implement as appropriate on a larger scale at a later time.

Our concerns about implementing models initially on a larger scale are manifold. Bigger scale undertakings are much more difficult for Part D plan sponsors and their PBMs as it often means changes across some contracts and plans options, but not others. In light of the amount of time it takes to prepare bids, revise beneficiary materials, and also change provider and prescriber contracts, the effort involved in larger scale models can be counterproductive to assessing the effectiveness of a concept. Indeed, the administrative costs associated with larger scale pilots may cost more to test than it would save (in particular, it may cost more to collect data than any potential programmatic savings). Moreover, we believe Congress’ intent in creating CMMI was to encourage the uptake and test of *small* pilots prior to any larger rollout.

Likewise, while we appreciate that it may take several years for the agency to have confidence in the results of a test to universally adopt a change, we believe that the current length of many of the demonstrations actually undermines the likelihood of their adoption. Thus, parameters like a five-year test period, or a requirement that a model be tested throughout a whole region, and with all of the plans in the region, can be very restrictive. We believe HHS should consider flexibility in terms of the ability of CMMI and the plans to modify the demonstration over time, as it is counterproductive to have to continue with a flawed approach. We further believe that CMMI should be flexible in terms of allowing new participants to enter the model in subsequent years



as appropriate (e.g., within year two of a five-year demonstration). Finally, we strongly urge HHS to ensure that all participation in any demonstration is voluntary and not mandatory.

Those are some general precepts; we now turn to specific considerations for Part D plan sponsors and their PBMs regarding the implementation of innovation models, as follows:

1. Any costs incurred by Part D plan sponsors to implement projects anticipated by the RFI should be treated as a quality improvement activity for Medical Loss Ratio (MLR) purposes. It is not reasonable to essentially punish Part D plan sponsors for participating in innovations by counting costs incurred against them in terms of the MLR requirements.
2. Any innovations encouraged by CMMI through waivers provided under the projects anticipated by the RFI should be protected from prosecution under the Anti-Kickback Statute (AKS) and not subject to Civil Monetary Penalties (CMPs). CMMI should align its policies with the OIG and provide safe harbors for all innovations in financing, payment, and service delivery approved by CMMI that otherwise might implicate the AKS or result in CMPs. Elsewhere in these comments, we provide suggested legislative language should Congress opt to create a specific value-based arrangement safe harbor. See section III B. Value-based Arrangements and Price Reporting (p. 52).
3. Activities undertaken by a Part D plan sponsor under an innovation project should not result in reductions in star ratings if the Part D plan sponsor is implementing the agreed upon approach under the terms of the demonstration.
4. Finally, complaints filed by beneficiaries where the Part D plan sponsor is implementing the agreed upon approach under an innovation project should not be counted against the plan.

- **No waiver of non-interference**

As HHS considers ways to improve beneficiary access to care, and streamline and improve current care delivery models, we believe it is essential that certain key elements of the Part D program remain intact. As the Department is well aware, the Part D program continues to be remarkably popular, and to deliver on its original promise of providing seniors with cost-effective and convenient access to much needed medications in a market-driven system. One of the hallmarks of this market-driven system is the non-interference clause. The non-interference clause — Section 1860D-11(i) of the Social Security Act, codified at 42 U.S.C. § 1395w-111(i) — states that the Secretary “may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors” and “may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.” CMS has



previously interpreted the non-interference clause as applying to negotiations between pharmacies and manufacturers and Part D sponsors.

The non-interference clause ensures that the Part D program is truly market-driven – ensuring robust competition, lowering costs, and providing beneficiaries with the best service possible. While the authority to waive various statutory requirements in order to implement demonstration projects is expansive, Congress did specify some very broad parameters/goals that such demonstrations must seek to achieve: (1) CMMI demonstrations must select models where the Secretary determines “there is evidence that the model addresses a defined population for which there are *deficits in care* leading to poor clinical outcomes or potentially unavoidable expenditures;” (2) models must “preserv[e] or enhance[e] the quality of care received by individuals receiving benefits under such title;” and (3) models must go through two phases, and only in phase II may CMS expand a model nationally. A waiver of the non-interference clause cuts against the very grain of what Congress intended CMMI to do – to improve care, reduce costs, and preserve benefits. The intent of the Congress to feature private bidding in Part D is clear, and the CBO has repeatedly found that any waiver of the Part D non-interference clause would not result in savings unless CMS also placed access restrictions on Part D drugs.

PCMA Recommendation: PCMA recommends that HHS consider smaller, shorter-term pilots through CMMI that can be more rapidly tested on more flexible terms than a longer-term project. PCMA further recommends that models be voluntary and that the agency consider Part D plan/PBM specific issues if they are involved, including with respect to bids, star rating and compliance. PCMA also urges that HHS not take any action through CMMI that would waive the non-interference clause.

Background

The Blueprint RFI asks whether HHS should “call on the FDA to evaluate the inclusion of list prices in direct-to-consumer advertising.” Policymakers have reportedly been asking drugmakers to voluntarily add pricing information in their TV commercials and print ads. In letters to executives at Pfizer, AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Merck & Co., GlaxoSmithKline and Novartis, five Democratic and independent senators asked the drugmakers to immediately add drug prices to their direct-to-consumer promos.⁴⁰ Each of the drugmakers reportedly spends more than \$100 million on advertising every year.⁴¹

Discussion

PCMA does not have a position on whether list prices should be included in DTC ads, because PCMA opposes the existence of DTC ads for specific prescription drug products and believes that such ads should not be permitted in the media. While DTC drug ads may encourage some people to see a health professional, they unnecessarily drive up the cost of drug benefits. We therefore believe there should be a prohibition on DTC ads mentioning a specific drug product. We also believe, however, that list prices of drugs should be included in drug manufacturers’ communications with prescribers, for example in literature used for detailing.

DTC Ads Misinform or Mislead Patients

Although DTC advertising may educate patients, it also has the ability to misinform them, often by omitting important information.⁴² For example, in one study, 82% of DTC ads made some factual claims and rational arguments for use of the advertised drug; however, only 26% of the ads described risk factors or causes of the condition, and only 25% mentioned prevalence of risk.⁴³

DTC advertising also tends to suggest that health improvement comes from a medication, perhaps in combination with healthy activities, but never from behavior modification alone.⁴⁴ For example, one study found that although 19% of DTC ads mentioned lifestyle changes as an adjunct to medication, none mentioned them as an alternative to drug treatment.⁴⁵

⁴⁰ Fierce Pharma, “Senators to Big Pharma: Better Step up with Drug Prices In DTC Ads, or We’ll Make You,” May 21, 2018, <https://www.fiercepharma.com/pharma/senators-to-big-pharma-it-s-time-to-put-drug-prices-dtc-ads>

⁴¹ Ibid.

⁴² See: Almasi EA, Stafford RS, Kravitz RL, Mansfield PR. What Are the Public Health Effects Of Direct-To-Consumer Advertising? *PLoS Med.* 2006;3(3):e145.

⁴³ Frosch DL. Creating demand for prescription drugs: A content analysis of television direct-to-consumer advertising. *Ann Fam Med.* 2007;5(1):6–13.

⁴⁴ Shaw A. Direct-to-consumer advertising of pharmaceuticals: The DTC advertising debate. ProQuest. Mar, 2008.

⁴⁵ Frosch DL. Creating demand for prescription drugs: A content analysis of television direct-to-consumer advertising. *Ann Fam Med.* 2007;5(1):6–13

Moreover, consumers have also been found to place unwarranted trust in DTC ads.⁴⁶ One survey of consumers found that 50% of respondents thought that the ads were approved by the government, 43% thought that a medication had to be completely safe for it to be advertised, and 22% thought that a drug known to have serious side effects could not be advertised.⁴⁷ Finally, the commercial for cancer drug nivolumab stated it “significantly increased the chance of living longer versus chemotherapy” in patients with squamous cell lung cancer. But the ads glossed over the fact that it prolonged life just 3.2 months. The ad also did not note that it is indicated for stage-four cancer only after standard chemotherapy has failed. And the ad did not mention the drug’s price – \$157,000 per year.⁴⁸ Because of such an ability to mislead patients, we believe that DTC ads for specific drugs should end.

DTC Ads Overemphasize Drug Benefits and Minimize Drug Risks

DTC ads tend to emphasize drugs’ benefits over risks.⁴⁹ One study found that the average DTC television commercial devotes more time to benefits than to risks⁵⁰ and disciplinary action on drug manufacturers for violating FDA guidelines has confirmed that this has been a common problem.⁵¹ The same study found nearly 84% of the regulatory issue citations for DTC ads cited ads for either minimizing risks (e.g., omitting information about side effects) or exaggerating a drug’s effectiveness (e.g., portraying the indication too broadly or making unsubstantiated claims of superiority over other drugs), or both.⁵² This suggests that the penalties for DTC ad violations may not be robust enough to deter manufacturers from improperly overemphasizing benefits, and that manufacturers may view it as just the cost of doing business. For these additional reasons, we believe DTC ads for specific drugs should end.

DTC Ads Promote New Drugs Before Safety Profiles Are Fully Known

New drugs have been associated with previously unknown serious adverse events after they have been introduced to the market and have seen a substantial amount of use.⁵³ This is particularly true for “first-in class” drugs.⁵⁴ Clinical trials required for FDA approval are typically not designed to detect rare adverse effects, and current methods of post marketing surveillance often fail to connect adverse events that have a high rate of background prevalence with the use

⁴⁶ Connors AL. Big bad pharma: An ethical analysis of physician-directed and consumer-directed marketing tactics. *Albany Law Rev.* 2009;73(1):243–282.

⁴⁷ Connors AL. Big bad pharma: An ethical analysis of physician-directed and consumer-directed marketing tactics. *Albany Law Rev.* 2009;73(1):243–282.

⁴⁸ Asset Builder, “Why Direct-to-Consumer Pharmaceutical Advertising Should be Banned,” Jul 26, 2016.

<https://assetbuilder.com/knowledge-center/articles/why-direct-to-consumer-pharmaceutical-advertising-should-be-banned>

⁴⁹ Frosch DL, Grande D, Tarn DM, Kravitz RL. A decade of controversy: Balancing policy with evidence in the regulation of prescription drug advertising. *Am J Public Health.* 2010;100(1):24–32.

⁵⁰ Shaw A. Direct-to-consumer advertising of pharmaceuticals: The DTC advertising debate. ProQuest. Mar, 2008.

⁵¹ Donahue JM, Cervasco M, Rosenthal MB. A decade of direct-to-consumer advertising of prescription drugs. *N Engl J Med.* 2007;357(7):673–681.

⁵² Donahue JM, Cervasco M, Rosenthal MB. A decade of direct-to-consumer advertising of prescription drugs. *N Engl J Med.* 2007;357(7):673–681.

⁵³ Schuchman M. Drug risks and free speech: Can Congress ban consumer drug ads? *N Engl J Med.* 2007;356(22):2236–2239.

⁵⁴ Schuchman M. Drug risks and free speech: Can Congress ban consumer drug ads? *N Engl J Med.* 2007;356(22):2236–2239.

of a particular drug.⁵⁵ Drugs that are expected to be “blockbuster” sellers are also most heavily promoted early in the product’s life cycle, which can present a public health risk because the drug’s safety profile is not fully known at that point.⁵⁶

The safety problems with rofecoxib (Vioxx) are perhaps the most frequently cited example regarding this issue. Vioxx was among the most heavily promoted drugs in the U.S. from 1999 to 2004.⁵⁷ During that time, Merck spent over \$100 million per year to build the drug into a blockbuster seller, with annual sales of more than \$1 billion in the U.S.⁵⁸ Patients requesting Vioxx thought that they were advocating for themselves by asking for a drug that they thought was better than its competitors, not knowing that it could lead to stroke or myocardial infarction.⁵⁹ On September 30, 2004, Merck voluntarily withdrew Vioxx from the market. This illustrates that DTC can exacerbate safety problems with drugs, to the point of causing unnecessary patient deaths. This is another reason we believe DTC ads for specific drugs should be banned.

DTC Ads Unnecessarily Drive up Drug Costs

Manufacturers often use DTC ads to promote expensive drugs that might not offer any significant benefits over older and cheaper medications.⁶⁰ For example, two heavily promoted diabetes treatments, rosiglitazone and pioglitazone, were found to be no more effective—or safe—than older drugs, even though they were much more expensive.⁶¹ In another study, older drugs for the treatment of schizophrenia were found to be equally effective and to cost as much as \$600 per month less than olanzapine, quetiapine or risperidone.⁶² In this way, DTC ads help drive up the cost of drugs. Additionally, DTC ads can suppress generic fill rates since some consumers may insist on getting the brand advertised on TV. For these reasons, we believe DTC ads mentioning specific drug products should be banned.

PCMA Recognizes DTC Ads May Get Patients to See a Health Provider

PCMA recognizes that the research data show that DTC ads do encourage some patients who otherwise wouldn’t, to see a health provider.⁶³ For this reason, PCMA believes that only DTC ads that mention a specific drug product should be taken out of the media. Failing a direct ban on such ads, at the very least, the standard business tax deduction should not apply to

⁵⁵ Donahue JM, Cervasco M, Rosenthal MB. A decade of direct-to-consumer advertising of prescription drugs. *N Engl J Med.* 2007;357(7):673–681

⁵⁶ Liang BA, Mackey T. “Direct-to-Consumer Advertising with Interactive Internet Media: Global Regulation and Public Health Issues.” *JAMA.* 2011;305(8):824–825.

⁵⁷ Schuchman M. Drug risks and free speech: Can Congress ban consumer drug ads? *N Engl J Med.* 2007;356(22):2236–2239.

⁵⁸ Schuchman M. Drug risks and free speech: Can Congress ban consumer drug ads? *N Engl J Med.* 2007;356(22):2236–2239.

⁵⁹ Abel GA, Penson RT, Joffe S, et al. Direct-to-consumer advertising in oncology. *Oncologist.* 2006;11(2):217–226

⁶⁰ Shaw A. “Direct-To-Consumer Advertising of Pharmaceuticals: The DTC Advertising Debate.” *ProQuest.* Mar, 2008.

⁶¹ Shaw A. “Direct-To-Consumer Advertising of Pharmaceuticals: The DTC Advertising Debate.” *ProQuest.* Mar, 2008.

⁶² Shaw A. “Direct-To-Consumer Advertising of Pharmaceuticals: The DTC Advertising Debate.” *ProQuest.* Mar, 2008.

⁶³ Aikin KJ, Swasy JL, Braman AC. Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results. Washington, D.C: U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research; Nov, 2004.

expenses related to the production and airing of such ads. Ads that describe legitimate medical symptoms and encourage listeners to see a medical professional as a result of such symptoms—without mentioning a specific drug product by name—ought to continue to be published and broadcast for the positive effects they may have.

Drug Manufacturers Should Disclose List Prices in Communications to Prescribers

Drug manufacturers engage in several methods of direct marketing to prescribers.⁶⁴ These include:

- **Detailing:** This marketing approach refers to face-to-face promotional activities directed toward physicians and pharmacy directors.
- **Samples:** Providing free medication samples to physicians have been shown to cause significant increases in new prescriptions for the promoted drug.
- **Educational and Promotional Meetings:** Sales representatives invite doctors to meetings during which industry-paid physicians discuss the use of particular drugs.
- **Promotional Mailings:** Pharmaceutical companies send unsolicited promotional materials to most doctors' offices.
- **Journal and Web Advertisements:** These advertisements are standard promotional techniques and the accuracy of statements in such ads is regulated by the U.S. Food and Drug Administration.

We believe that prescribers would be better informed if the current list prices of promoted drugs were disclosed to them. Such information would help prescribers be more fully informed about the prescribing choices for their patients and help prescribers understand the financial tradeoffs patients face in choosing the right drug.

PCMA Recommendation: We have no position on including list prices in DTC advertising, because we believe there should be no DTC ads at all. We do believe, however, that drug list prices should be disclosed in manufacturer communications with prescribers so that prescribers are better informed about the treatment options for their patients.

⁶⁴ See, Pew Charitable Trusts, "Persuading the Prescribers: Pharmaceutical Industry Marketing and its Influence on Physicians and Patients: Fact Sheet," November 11, 2013. <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients>

Background

HHS states that it will direct CMS to “make Medicare and Medicaid prices more transparent, hold drug makers accountable for their price increases, highlight drugs that have not taken price increases, and recognize when competition is working with an updated drug pricing dashboard.” The Department notes that the drug pricing dashboard will also provide additional information to help individuals make informed decisions and predict their cost-sharing.

Discussion

In May, CMS released an updated version of its drug dashboard for Medicare Parts B and D, along with Medicaid. For the first time, the revised dashboards included year-over-year information on drug pricing and highlighted which manufacturers have been increasing their prices. The new version also reported the percentage change in spending on drugs per dosage unit and included an expanded list of drugs. The Part D dashboard also included high-level rebate summary information for 2014.

PCMA applauds CMS for making these positive changes to provide useful information and help empower individuals and prescribers to make decisions. PCMA notes, however, that the information presented in the dashboard does not contain current year data and therefore may be better suited to research and analysis than in helping beneficiaries make decisions about their current coverage.

PCMA Recommendation: PCMA commends CMS for the positive changes it recently made to the drug pricing dashboards. PCMA notes, however, that the lack of current-year information in the dashboards makes them less useful in helping beneficiaries make real-time decisions about their coverage.

III. Solicitation of Comments

Increasing Competition – III (A) p. 22695 Underpricing of Generic Drugs

Background

HHS questions whether its programs are comprised of the “correct incentives” to allow it to obtain affordable prices on safe and effective drugs. Specific to generic drugs, HHS asks whether government programs cause generic drugs to be underpriced and thereby reduce long-term generic competition.

Discussion

PCMA found no evidence suggesting that generic drugs are underpriced in government programs or that there are any long-term anticompetitive effects resulting from low generic drug prices. Vigorous competition among generic drug manufacturers under the Hatch-Waxman legislative architecture has worked as intended and has resulted in low generic drug prices, which benefits Medicare beneficiaries. For example, researchers found a strong association between the number of generic drug manufacturers and the relative price of the drug.⁶⁵ For brand-name drugs with just one generic manufacturer, researchers found that the prices of the generic and brand versions were similar. For drugs with two generic manufacturers, the relative price decreased by ten percentage points and by an additional 17 percentage points with a third generic manufacturer. In another study of generic drug prices, researchers found that generic drug prices rise when market competition drops.⁶⁶

PCMA Recommendation: We believe the Hatch-Waxman legislative architecture for producing and marketing generic drugs has worked well and resulted in a robust, competitive generic drug market. We see no reason for any significant policy changes.

⁶⁵ Chintan Dave, Abraham Hartzoma and Aaron Kesselheim, “Prices of Generic Drugs Associated with Numbers of Manufacturers” (Correspondence), *NEJM*, December 28, 2017. <https://www.nejm.org/doi/full/10.1056/NEJMc1711899>

⁶⁶ Chintan Dave, et al., High Generic Drug Prices and Market Competition: A Retrospective Cohort Study, *Annals of Internal Medicine*, August 1, 2017. <http://annals.org/aim/article-abstract/2636750/high-generic-drug-prices-market-competition-retrospective-cohort-study>

**Increasing Competition – III (A) p. 22695
Affordable Care Act Taxes and Rebates****Background**

The ACA included provisions to increase the minimum rebate percentage for brand drugs from 15.1% to 23.1% of AMP and extended the application of those rebates to Medicaid managed care organizations, which previously had been exempt from them. HHS seeks comment on the extent to which the increases in Medicaid drug rebate amounts and the extension of these rebates to Medicaid managed care under the ACA have impacted manufacturer list pricing practices. In particular, HHS asks whether the increase in the minimum rebate percentage in the Medicaid program has resulted in cross-subsidization by higher list prices and excess costs paid by individuals and employers in the commercial market.

Discussion

The mandatory Medicaid rebate is a form of price control. Price controls (in the form of mandatory discounts, minimum rebate percentages, or otherwise) in governmental programs often times result in a “cost shift” to those with private coverage to make up for the required discounts.⁶⁷ As we discuss elsewhere (See section III (C), Exclusion of Certain Payments, Rebates, or Discounts from the Determination of AMP and Best Price (p. 107)), soon after the creation of the Medicaid Drug Rebate Program (and the introduction of the ‘best price’ principle), manufacturers significantly increased their prices in the commercial sector in order to offset losses in the Medicaid program and to avoid “resetting” their best price.⁶⁸ To address these increases, both Congress and HHS have acted on a number of occasions to address this cross-subsidization effect by excluding certain prices, discounts, and rebates from the definition of AMP and best price.⁶⁹ Through these longstanding exclusions, HHS has largely avoided the negative impacts imposed by price control policies.⁷⁰

To the extent then that the increase in the minimum Medicaid base rebate percentage has resulted in cross-subsidization by higher list prices in the individual, employer, and commercial markets, we believe these effects have largely been offset by the flexibility afforded to manufacturers to increase rebate payments to plans. In other words, we believe the appropriate incentives exist under current policies to keep net drug prices *low*, even in the face of increased rebate liability in the Medicaid program.

⁶⁷ See Langwell, K. Price Controls: On the One Hand... And on the Other. Health Care Finance Review. 1993 (14)(3), available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/Downloads/CMS1191262dl.pdf>.

⁶⁸ GAO, Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals (GAO/HEHS-94-194FS, Aug. 5, 1994). Available at <http://archive.gao.gov/t2pbat2/152225.pdf>.

⁶⁹ Social Security Act § 1927(a)(5), 42 U.S.C. § 1396r-8(a)(5).

⁷⁰ Congressional Budget Office Letter to the Honorable Paul Ryan. Nov 4, 2010. The Effect of the March Health Legislation on Prescription Drug Prices. Available at: https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/116xx/doc11674/11-04-drug_pricing.pdf.



As we note below in section III (C) (p. 107), HHS is now contemplating a policy that would remove the exclusion for rebates, discounts and certain other prices (such as prices negotiated in the Part D program) from the definitions of AMP and best price. While we believe the market has largely been shielded from the effects of certain price controls in governmental programs (including the increase in the base Medicaid rebate percentage), to the extent that HHS removes or limits the exclusion for rebates, we believe drug prices would in fact increase significantly as the incentives for cross-subsidization (that existed in the early 1990s) are re-introduced into the marketplace.

PCMA Recommendation: In general, PCMA opposes price controls which inhibit competition in the marketplace and would welcome changes that grant drug supply chain actors the full freedom to conduct arm's length negotiations. Given the existing exclusions from AMP and best price for certain rebates and discounts, we think that manufacturer incentives to increase list prices due to cross-subsidization are largely tempered. However, PCMA strongly urges HHS to keep in place the rebate exclusions so as to avoid triggering this cross-subsidization response.

**Increasing Competition – III (A) p. 22695
Access to Product Samples and Ending Risk Evaluation and Mitigation Strategies
(REMS) Abuses**

Background

Generic companies are greatly aided by samples of branded drugs in order to perform necessary bioequivalence studies to gain FDA approval. However, some branded companies make it difficult for the generic firms to obtain them, even though the drugs are in commercial distribution, and even though a legitimate sale and a fair price could be agreed to. One tactic brand manufacturers use is to get a brand drug approved with a REMS program, which requires additional safeguards for how the drug is to be dispensed to patients. In the case of such a drug whose patent is near expiry, months can go by in frustrating negotiations and litigation in trying to obtain samples. Estimates show that such REMS generic delay tactics can cost \$5 billion annually.⁷¹

According to observers, there appear to be three distinct situations leading to the delays:⁷²

1. When a branded drug company has a closely controlled distribution system enabling it to simply choose whom to sell to;
2. When a drug has a REMS program, and the branded drug company invokes the terms of REMS program to “protect” clinical trial patients; and
3. When the details of the REMS program are claimed to be patented intellectual property, and not to be shared, resulting in generic manufacturers not being able to, or having great difficulty to, participate in the REMS.

The FTC argued that the Hatch-Waxman Act, which provides, among other things, the generic drug approval pathway, would be undermined if generic drugmakers are unable to access samples of brand products.⁷³ The FTC further noted that an innovator’s refusal to sell to its potential competitors may, under certain circumstances, violate the antitrust laws.⁷⁴

There are legitimate reasons to have restricted or exclusive distribution agreements, especially for specialty drugs for which patients benefit from extra attention and support. However,

⁷¹ Association for Accessible Medications, “REMS Abuses,” Accessed 6-6-18. <https://www.gphaonline.org/issues/remss#>

⁷² Pharmaceutical Commerce, “Enough Already with REMS Abuse in Generic Drug Development,” July 12, 2016. Accessed 6-6-18. <http://pharmaceuticalcommerce.com/opinion/enough-already-rems-abuse-generic-drug-development/>

⁷³ FTC, Amicus Curiae Brief for Actelion Pharmaceuticals Ltd. et al. v. Apotex Inc. et al. March 11, 2013. Accessed 6-6-18 https://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf

⁷⁴ FTC, Amicus Curiae Brief for Actelion Pharmaceuticals Ltd. et al. v. Apotex Inc. et al. March 11, 2013. Accessed 6-6-18 https://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf



unwarranted measures such as restricted distribution are an opportunity for abuse, as the infamous Turing Pharma situation of 2016 demonstrated.

Discussion

We recognize its action and thank the FDA for its pointing out such REMS abuses by brand drug manufacturers. Moreover, we are considering, and will comment upon, the draft guidances that FDA released in May that will attempt to ease generic manufacturers participation in existing REMS programs or provide generic manufacturers alternative pathways to comply with REMS requirements. The goal of the two draft guidances, to allow easier generic compliance with REMS requirements, should help accelerate generic market entry and spur greater competition.

We note, however, that there remain issues with generic manufacturers obtaining samples to conduct bioequivalency standards. Given that under current law, the FDA cannot compel a brand company to sell drug product and the FDA cannot impose monetary fines on a company for anticompetitive behavior, it suggests to us that legislative remedies may be necessary. We believe Congress should pass measures to compel samples from brand manufacturers and/or to enhance the leverage of generic manufacturers to seek legal remedies to obtain them, and encourage the Administration to so work with the Congress.

PCMA Recommendation: PCMA commends the FDA for recognizing and taking steps to correct REMS abuses by brand drug manufacturers by promulgating draft guidances to ease generic manufacturers' participation in existing REMS programs or provide generic manufacturers alternative pathways to comply with REMS requirements. FDA should work with Congress to pass legislation that would allow generic manufacturers easier access to samples of brand drugs.

**Increasing Competition – III (A) p. 22696
Promoting Access to Interchangeable Biologics and Biosimilars****Background**

In 2017, FDA issued draft guidance, “Considerations in Demonstrating Interchangeability with a Reference Product.” This long-awaited guidance proposed standards for developing a pathway for the FDA to judge whether a given biosimilar product is “highly similar” to a given reference product such that the two products are determined to be interchangeable with one another. In 2017, FDA also launched an educational campaign and published educational materials to help physicians understand the benefits of biosimilars. With better understanding of these treatment options, doctors will be more likely to prescribe the lower-cost option to their patients. The agency plans on continuing to do research on how best to inform healthcare providers about biosimilars.

Discussion

As with generic medicines, the authority for pharmacists to substitute interchangeable products will enhance the ease in which patients will access safe, more affordable medicines. The interchangeable designation will further increase the confidence of prescribers and patients in biosimilars. Further, the interchangeable designation will reduce the administrative costs and burdens on prescribers who must now review and approve each request for substituting a biosimilar product for a reference product. While in no way detracting from the safety and benefits of biosimilar products, the interchangeable designation will, where appropriate, further realize the vision of the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

For these reasons, PCMA applauded the FDA for publishing the draft guidance and urged it to move as expeditiously as possible to promulgate a final guidance. While we supported the approach taken by the FDA in the draft guidance, we also urged the FDA to ensure that the final guidance erects no inadvertent and unnecessary barriers to the expeditious and least-cost approval of interchangeable status. To accomplish this, FDA should seek every opportunity in this guidance to clarify that product sponsors can work with the FDA to minimize testing, especially clinical testing, and to encourage, whenever possible, a “one-step” process of establishing both biosimilarity and interchangeability.

Further, we commend FDA for undertaking a comprehensive program to educate clinicians on the benefits and saving biosimilars do—and interchangeables will—bring to patients. Any measures FDA or other offices within HHS can take to seek to increase awareness about these new treatments will be beneficial.



PCMA Recommendation: We support the general concept FDA put forward for judging interchangeability of biosimilars. However, we urge the agency not to erect any unnecessary barriers to achieving interchangeability as it moves to finalize the guidance. Additionally, we commend FDA for undertaking a comprehensive campaign to educate clinicians about the benefits and savings possible with biosimilars and interchangeables.

**Increasing Competition – III (A) p. 22696
Improving the Purple Book****Background**

The so-called “Purple Book” lists biological products, including any biosimilar and interchangeable biological products, licensed by FDA under the Public Health Service Act. It includes the date a biological product was licensed under FDA law and whether the FDA evaluated the biological product for reference product exclusivity. The Purple Book, in addition to the date licensed, also includes whether a biological product has been determined to be biosimilar to or interchangeable with a reference biological product.

Discussion

We believe that it would be informative for readers if FDA were to report whether a given biologic product is or has been the subject of a settlement or “pay-for-delay” agreement. In “pay-for-delay” settlements, innovators agree to pay potential generic or biosimilar competitors that challenge the brand or innovator company to delay entry of a generic or biosimilar product into the market. In the past decade, it has become increasingly common for pharmaceutical companies to pay would-be competitors to delay entering the market, thereby securing a longer period of exclusivity. In return for payments that may even exceed the profits the generic competitor would have earned if it had entered the market, the generic or biosimilar firm agrees to delay entry. These settlements have been criticized as anticompetitive and contrary to the public interest.⁷⁵

FDA should include the existence of such settlements and a brief summary of the terms of the settlement to the extent it can. Drug patent settlement information is disclosed to the Department of Justice and/or the Federal Trade Commission, but typically kept confidential, except for reports using aggregated data. We believe summary information for settlements for biologics should be published in the Purple Book, to include at least the end date of the settlement. Publishing such information need not disclose sensitive intellectual property information around the discovery and manufacture of such products, and will better inform all stakeholders in the health community.

PCMA Recommendation: FDA should publish, in the Purple Book, summary information of any “pay for delay” settlements to which an approved biologic product is subject.

⁷⁵ Gregory H. Jones et al., “Strategies that Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States,” *Blood*, January 27, 2016.

Increasing Competition – III (A) p. 22696 Role of State Pharmacy Practice Acts

Background

In a discussion about biosimilar development, approval, education, and access, HHS asks what role state pharmacy practice acts could play in advancing the utilization of biosimilar products.

Discussion

State pharmacy laws and pharmacy practice acts direct whether interchangeable biosimilars can be substituted: The FDA has indicated that interchangeable products will have the same clinical result as the reference product. However, even once the FDA determines interchangeability, that evaluation does not determine whether the biosimilar can be substituted for the reference product at the pharmacy. Substitution of a biosimilar for a reference product is a matter of state pharmacy law and is a decision that is outside of FDA’s regulatory role.

Some state laws discourage substitution of interchangeable biosimilars: Between 2013 and 2017, state legislation regulating the substitution of interchangeable biosimilars has been adopted in 35 states and Puerto Rico. In 2018, five states have enacted laws so far. The provisions of state legislation vary⁷⁶, but there are several features and requirements that may discourage substitution:

- **Prescriber Decides:** The prescriber would be able to prevent substitution by stating “dispense as written” or “brand medically necessary.”
- **"Notification" vs. "Communication:"** In bills enacted in 2013 and 2014, the language usually required that the prescriber "must be notified" of any allowable substitution made at a pharmacy. In 2015 bills, the language commonly was adjusted to say "communicate with," allowing a notation in an electronic medical record, PBM records or "pharmacy record that can be electronically accessible by the prescriber."
- **Patient Notification:** The individual patient must be notified that a substitute or switch has been made.⁷⁷

⁷⁶ See National Conference of State Legislatures (NCSL) website for list of all state biosimilar laws. “State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars.” <http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx>

⁷⁷ NCSL. “State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars.” Additional provisions include: Records: The pharmacist and the physician must retain records of substituted biologic medications.

- **Immunity:** Some states provide immunity for pharmacists who make a substitution in compliance with biologics state law.
- **Web Lists:** The state must maintain a public or web-based list of permissible interchangeable products.
- **Cost or Pricing:** Some legislation requires the pharmacist to explain the cost or price of the biologic and the interchangeable biosimilar. For example, the enacted laws in Colorado, Georgia, Illinois, North Carolina and Texas require that any authorized or allowable substitution must have the lowest cost.



The “notification” provision requiring that the prescriber “must be notified” creates additional work at the retail pharmacy level and can serve as a barrier to the uptake of interchangeable biosimilars. PCMA recognizes that, at this time, none of the FDA-approved biosimilars have been designated as interchangeable biosimilars. However, the Administration should encourage states to address and resolve this barrier to future use of lower-cost alternatives now, before the first interchangeable biosimilar is approved by the FDA.

PCMA Recommendation: PCMA suggests that HHS and the Administration encourage state legislatures and state boards of pharmacy to amend or rescind the “notification” provision and adopt regulations allowing the substitution of interchangeable biosimilars without barriers.

**Better Negotiation – II (C) p. 22695 and III (B) p. 22696
Improve Price Transparency/Tools to Make Prices More Transparent**

Background

HHS notes that it may direct CMS to make Medicare and Medicaid prices more transparent. The Department adds that it is considering “even bolder actions” to reduce drug prices such as new measures to increase transparency. HHS asks for input on the steps that can be taken to improve price transparency in Medicare, Medicaid and other forms of health coverage “so that consumers can seek value when choosing and using their benefits.”

Discussion

PCMA has long supported providing useful information to consumers to empower them to make the best choices for themselves about their healthcare. PCMA is concerned, however, that the wrong kind of transparency, such as public disclosure of confidential rebate information, would allow manufacturers to learn what type of price concessions other manufacturers are giving and disincentivize them from offering deeper discounts, which benefit plan sponsors and their beneficiaries. This transparency will not lead to better health care or lower health care costs. In fact, a recent analysis found that legislative transparency proposals would have resulted in higher drug prices, particularly in Medicare Part D, and would have increased federal direct spending of more than \$20 billion over the 10-year budget horizon of 2018-2027.⁷⁸

PCMA Recommendation: PCMA strongly encourages HHS to resist any transparency proposals that include disclosure of confidential rebate information. Public disclosure of privately negotiated rebate information would enable tacit collusion among manufacturers and have a dampening effect on the level of rebates they offered, thereby increasing costs.

⁷⁸ The Moran Company, *Assessing the Budgetary Implications of Increasing Transparency of Prices in the Pharmaceutical Sector*, (April 2017)

**Better Negotiation – III (B) p. 22696
Value-based Arrangements and Price Reporting****Background**

HHS asks what benefits would accrue to Medicare and Medicaid beneficiaries by allowing manufacturers to exclude from statutory price reporting programs discounts, rebates, or price guarantees included in value-based arrangements. In particular, HHS seeks feedback on a variety of price reporting rules and the interplay with value-based arrangements, including the impact of excluding value-based arrangements from AMP and best price; how these exclusions would affect average sales price (ASP) and 340B ceiling; the timeframe for manufacturers to restate AMP and best price; and potential changes to the regulatory definitions in the Medicaid Drug Rebate Program (MDRP). Finally, HHS seeks comment on whether there are particular sections of the Social Security Act (e.g., the anti-kickback statute) that must be revised to assist manufacturers and states in adopting value-based arrangements.

Discussion

PCMA broadly supports aligning reimbursement around value, instead of volume: PBMs and payers are committed to the affordability and sustainability of the healthcare system and recognize the importance of aligning reimbursement around value, instead of volume. Traditionally, risk-sharing agreements between payers and drug manufacturers have not been tied to the value that medications provide. However, the use of real-world clinical and financial outcomes is driving the acceleration of value alignment.

Value-based arrangements are being developed for drugs that have quantifiable, widely accepted outcomes metrics. Data collected to inform these arrangements continue to provide doctors and payers with unique insights that enhance clinical decision-making processes and increase competition across the marketplace.

PCMA believes there are two major barriers to wider adoption of value-based arrangements: (1) first and foremost, manufacturers must stand by their products in the real world and leverage the use of specialty pharmacies to provide the right support to patients and provider; and (2) as noted by HHS in the Blueprint RFI, certain price reporting and other legal risks may be hindering fuller adoption of value-based arrangements.

- **Broader adoption of value-based arrangements requires trust, collaboration, and a willingness to explore new pricing models:** In the midst of increasing expenditures, PBMs are asking manufacturers to stand by their products in the real world and leverage the use of specialty pharmacies to provide the right support to patients and providers. By paying for only what works through value and outcomes-based contracts, payers can lower overall costs and preserve valuable resources to fund future innovations in the drug pipeline.

While certain price reporting and regulatory barriers as discussed below present potential challenges to the adoption of value-based arrangements, evidence also suggests that some of these concerns *may* be overblown.⁷⁹ For example, selling a drug at a low price to Medicare Part D plans (as well as through Medicare Advantage) does not trigger the best-price rule, so reporting requirements would have no impact within the scope of Medicare Part D drugs, the absence of which (presumably) would give drug manufacturers more flexibility on their pricing negotiations with payers and encourage moving to value-based pricing in Medicare. Yet, in spite of these protections, manufacturer adoption of value-based arrangements in the Medicare program is still quite limited.

Likewise, the increasingly common use of state-mandated formularies for Medicaid managed care plans introduces significant disincentives for the adoption of value-based arrangements. While it has been suggested that MCOs have access to cost-containment tools to restrict access to drugs on an open formulary, they are not sufficient to truly control the cost of medications and do not provide plans with sufficient flexibility to exclude certain drugs from the formulary. The proliferation of Preferred Drug Lists and open formularies has removed incentives for manufacturers to enter into value-based arrangements where coverage is already ensured.

- **Medicaid ‘best price’ rules should be reformed:** As noted below (See p. 107, Section III (C): Exclusion of Certain Payments, Rebates, or Discounts from the Determination of AMP and Best Price), Medicaid best price rules (absent existing exclusions for PBM rebates) have the tendency to artificially inflate list prices. Under best prices rules, manufacturers with signed rebate agreements must offer the best or “lowest” price to Medicaid, and accordingly, might be incentivized to raise list prices.⁸⁰ This practice can drive up overall drug costs across private and public payers. Best price can impede the ability to negotiate lower prices in other markets, and therefore act as a ceiling for prescription drug discounts in other lines of business within the healthcare industry.

Medicaid best price rules *may* inhibit innovation in value-based arrangements (e.g., outcomes-based contracts). In an outcomes-based contract, a manufacturer enters into an agreement with a payer that if a drug does not deliver agreed-upon outcomes, it will pay out a larger discount to the payer. The resulting price could become the new benchmark when calculating best price which could then establish a new, lower price that must be offered to all state Medicaid programs. Manufacturers facing this scenario may be incentivized to increase list prices, making it more costly for everyone across the board.

PCMA would therefore support efforts to exclude from the definition of best price certain value-based arrangements. As we note below in our suggested legislative language,

⁷⁹ Rachel Sachs, Nicholas Bagley, Darius N. Lakdawalla, “Innovative Contracting for Pharmaceuticals and Medicaid’s Best-Price Rule,” *Journal of Health Politics, Policy and Law* 43, no. 1 (Feb. 1, 2018): 5–18. DOI: <https://doi.org/10.1215/03616878-4249796>.

⁸⁰ Section 1927(c)(1)(C) of the Social Security Act.

Congress (or potentially HHS), could readily amend the underlying best price rule to encourage broader adoption of value-based arrangements.

- **HHS should support Congressional efforts to establish a safe harbor for value-based arrangements:** The Anti-Kickback Statute is intended to prevent exchanges of value between manufacturers and other parties, which, especially in fee-for-service arrangements, create risks of inappropriate care. While “safe harbors” and statutory exceptions have been developed for some activities, current rules do not contemplate payment models for medical products in which reimbursement depends mainly on measures of value and not on volume of sales. This is challenging for the implementation of value-based arrangements since the potential for increased value often depends on some degree of coordination and sharing of data, analytics, and other care improvement resources between the contracting parties. Reflecting this, CMS and the OIG jointly issued broad fraud and abuse waivers for the viable operation of the Medicare Share Savings Program (MSSP) and its principal cost-saving mechanism known as an Accountable Care Organization (ACO).⁸¹

Although the current statutory framework may impede the development and expanded adoption of value-based arrangements (below we provide our suggestions on proposed statutory language), some flexibility may exist for HHS and OIG to enable such arrangements to proceed under certain circumstances. This potential flexibility includes the OIG’s “prudential” approach to evaluating contractual arrangements that may violate the AKS. In addition, some value-based payment arrangements are not implicated by the AKS, because it applies only to “federal health care programs.”

PCMA Recommendation: *To the extent that HHS does have existing authority to exempt certain value-based arrangements from anti-kickback liability, PCMA would support such efforts. As noted below, we also believe HHS could work with Congress to amend the underlying statute to support these efforts.*

- ***Draft statutory exemptions for value-based arrangements:*** *The language below is our suggested amendments to existing law which PCMA believes could encourage the adoption of value-based arrangements and limit potential risks.*

- ***Anti-Kickback Amendment.***

Section 1128B(b)(3) of the Social Security Act is amended by adding the following subparagraphs:

⁸¹ “Medicare Program; Final Waivers in Connection With the Shared Savings Program; Final Rule,” 80 *Federal Register* 209 (Oct. 29, 2015), p. 66726. https://oig.hhs.gov/authorities/docs/2015/Federal_Register_Waivers_Shared_Savings_10.29.2015.pdf

(K) a value-based arrangement pursuant to a written agreement in which each participant agrees to assume varying levels of financial risk (including but not limited to rebates, discounts, price reductions, contributions, reimbursements, guarantees, patient care, shared savings payments, withholds, or bonuses or anything of value) based on—

(i) the future performance of the goods or services described in the arrangement;
(ii) the achievement of measurable and defined patient outcomes or clinical circumstances;

(iii) a patient’s substantial compliance with a medication regimen prescribed by the patient’s health care provider; or

(iv) any other evidence-based outcome or circumstance as defined by the Secretary in guidance or regulation.

(L) a medication adherence support program pursuant to a written agreement (including a program that is part of a value-based arrangement and any agreement with respect to the collection and use of derived adherence data and information) that establishes the protocol for a patient’s substantial compliance with a covered medication regimen prescribed by the patient’s health care provider under title XVIII, a federal health care program, or a State health care program.

- **Physician Self-Referral Amendment.**

Section 1877(h)(1)(C) of the Social Security Act is amended by adding the following subclause:

(iv) Any amounts determined under a value-based arrangement as defined in section 1128(b)(3).

- **Medicaid Best Price Amendment.**

Section 1927(c)(1)(A) of the Social Security Act is amended by adding the following after “Except as provided in”:

paragraph (1)(C)(iv)(II) and

Section 1927(c)(1)(C)(i) of the Social Security Act is amended by adding the following:

(VII) any prices charged that are determined under a value-based arrangement.

Section 1927(c)(1)(C) of the Social Security Act is amended by adding the following:

(iv) VALUE-BASED ARRANGEMENT.—

(I) DEFINITION.—A value-based purchasing arrangement includes any arrangement documented in writing the extent to which the price of a drug (net of any discounts under the arrangement) is based on—

(a) the achievement of measurable and defined evidence-based patient outcomes;

(b) clinical circumstances or measures achieving defined evidence-based patient outcomes; or

(c) medically appropriate and cost-effective methods (including a medication adherence program and the collection and use of derived data and information).

(II) BASIC REBATE.—Where there is no best price for a rebate period as a result of the operation of paragraph (C)(i)(VII), paragraph (A)(ii)(I) shall not apply.

**Better Negotiation – III (B) p. 22695
Federal Preemption of Contracted Pharmacy Gag Clause Laws****Background**

HHS indicates that it believes that some contracts between health plans, PBMs and pharmacies do not allow the pharmacy to inform a patient that the same drug or a competitor could be purchased at a lower price off-insurance. HHS asks what purpose is served by these clauses other than to require beneficiaries to pay higher out-of-pocket costs.

Discussion

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

PCMA encourages CMS to recognize, however, that beneficiaries may not always come out ahead if they pay cash instead of using their insurance or Medicare benefit. While we recognize the need for beneficiaries to lower their out-of-pocket costs and are committed to providing access at the lowest possible cost, we are concerned about unintended financial and clinical consequences where Part D beneficiaries purchase drugs outside of their plans. For example, out-of-network prescription claims for urgent or emergency cases can count toward the beneficiary's deductible and True Out-of-Pocket (TrOOP) calculated expenses if the beneficiary submits the claim for reimbursement, but absent an urgent or emergency situation, beneficiaries are expected to use network pharmacies in their Part D plans for the prescription to count toward the beneficiary's deductible or TrOOP calculated expenses. Additionally, if a plan is not aware of a medication purchased by a beneficiary outside the benefit, it cannot effectively provide care coordination, or medication management and monitoring of high risk medications. In particular, accessing drugs outside of one's prescription drug benefit could limit Part D plan sponsors' ability to effectively monitor at-risk beneficiaries' use of opioids. PCMA has concerns that purchasing drugs outside of Medicare may leave beneficiaries out of programs like medication therapy management, as the drugs not covered through Medicare may not be visible to the Part D plan. As well, potential drug-drug interactions may be missed if the beneficiary fills prescriptions at more than one pharmacy. Thus, PCMA recommends that pharmacists alerting patients of a potential lower cash price also inform them of potential financial and clinical ramifications if they decide to pay cash instead of using their prescription drug benefit.



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

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

Background

HHS indicates that it is evaluating options to allow high-cost drugs to be priced or covered differently based on their indication. Presently, Part D plan sponsors must cover and pay the same price for a drug regardless of the indication for which it is prescribed. This change could permit plans to choose to cover or pay a different price for a drug, based on the indication. Prescription drugs have varying degrees of effectiveness when used to treat different types of disease; however, different indications are typically subject to the same price. HHS asks whether Medicare or Medicaid should pay the same price for a drug regardless of the diagnosis for which it is being used and how indication-based pricing could support value-based purchasing. HHS also asks whether there are unintended consequences of current low-cost drugs increasing in price due to their identification as high-value. Other questions include whether there is enough granularity in coding and reimbursement system to support indication-based pricing; whether changes are necessary to CMS' price reporting program definitions or how the FDA's National Drug Code (NDC) numbers are used in CMS price reporting programs.

Discussion

Pharmaceutical manufacturers often pursue FDA approval for multiple indications for a medication as chemical entities sometimes offer solutions for multiple related or unrelated ailments. Assuming a pricing system based on the value of a drug, the manufacturer may pursue a higher price for a drug that is highly efficacious for one condition, and a lower price for that same drug which may be less efficacious for another condition. However, the pricing for different indications presents logistical challenges. Orphan drugs are generally priced at a relatively high price, as the pharmaceutical manufacturers assert that the price of development needs to be recouped over a small prescription volume. A new indication in a larger patient population could be priced lower; however, government pricing rules create a strong negative economic incentive for manufacturers to pursue the follow-up indications or to price follow-up indications at a lower price.⁸²

Addressing Medicaid Best Price and the Medicare Average Sales Price (ASP): Barriers to a manufacturer providing a medication for a follow-up indication at a lower price include the Medicaid best price and the Medicare ASP calculation rules. Medicare Part B payments are based on ASP, a rate that is the average selling price across commercial customers. Both Medicaid best price and ASP would be negatively impacted or reduced by any sales at the lower price.

⁸² Ed Schoonveld, The Benefits and Misconceptions of Indication-Based Pricing. <http://info.zs.com/priceofglobalhealth/the-benefits-and-misconceptions-of-indication-based-pricing>



Operational challenges: In addition to the policy issues of Medicaid best price and ASP, operational challenges would need to be resolved.

- **Medicare Part B:**

- For the Medicare Part B program, CMS does not have systems in place today to purchase medications at different prices based on indications. As CMS gathers information through the RFI process on better ways to negotiate for Part B medications, a system should be developed that allows for a PBM-type entity to obtain indication from prescribers before paying for medications. Additionally, the entity should be empowered to negotiate variable prices for the same drug, depending on the efficacy of the drug for a given patient condition, as proposed by CMS in 2016.⁸³ We address this in the section I (D) above on using PBM Part D UM tools in Medicare Part B (p. 10).

- **Medicare Part D:**

- Part D plans and PBMs would need to obtain information on the indication for a specific patient and report data to manufacturers on prescription drug use by indication. Systems would need to be developed by which Part D plan sponsors could obtain information either via a prior authorization process to obtain data from prescribers or through the development of programs to transmit indication via NCPDP standards.
- There would also be a number of issues as to how the payments would work. For example, an orphan drug that has a list price of \$10,000 might be useful for a different, non-orphan indication and reimbursed at \$1,000. If the Part D plan sponsor can determine the different indications and know the patient is taking the drug for the less expensive indication, it would work best if they could reimburse the pharmacy at the lower price. This, however, can only be done cleanly if the pharmacy can buy at the lower price, which would require different NDC numbers (treating the drug as two separate products for orphan and non-orphan indications). As an alternative, the Part D plan sponsor could pay the pharmacy the \$10,000 list price, then recoup the difference between the \$10,000 list price and the \$1,000 negotiated price for the non-orphan indication via rebates from the manufacturer. However, that would require significant up-front reimbursement by the Part D plan sponsor to the pharmacy. Moreover, this could be a logistical quagmire if every PBM has a different price for every indication. PCMA would be pleased to work with CMS on specific details of such a proposal going forward.

⁸³ "Medicare Program; Part B Drug Payment Model: A Proposed Rule by the Centers for Medicare & Medicaid Services," 81 *Federal Register* 48 (March 11, 2016), pp. 13229-13261. <https://www.federalregister.gov/documents/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model>



- In Medicare Part D, an issue for the future would be made how best to communicate drug costs on Medicare Plan Finder when a drug has more than two indication-based prices.
- **Cross-cutting:**
 - Separate NDC numbers for orphan and non-orphan (or other different) indications would allow for two or more distinct reimbursement levels or systems to be developed. Separate NDC numbers would also be necessary for retail pharmacies to purchase drugs at different acquisition prices for different indications.
 - The implications of multiple NDCs for the same product on wholesalers, pharmacies and other entities in the distribution chain would also need to be assessed, as the concept adds complexity to the system. HHS must examine implications in the distribution chain and how multiple NDC numbers could provide an opportunity for providers in the distribution system to “game” the system.
 - Prescribers today are not required to communicate the indication being treated when prescribing a medication. If the dispensing pharmacist does not have the information, even updates to existing systems will not allow for information to be transmitted. HHS and the Administration will also need to work with state legislatures and state boards of medicine to require prescribers to communicate the indication along with other prescription drug information.

PCMA Recommendation: PCMA recommends that HHS address policy issues related to Medicaid best price and ASP regarding indication-based pricing. This could include, for drugs with multiple indications whose price varies by indication, exempting the lowest-cost indication from the Medicaid best price and establishing separate ASPs for each indication. HHS should also assess the range of operational downstream challenges posed by indication-based pricing and consider the use of multiple NDC numbers for products with multiple indications. HHS should begin work by focusing on systems that would provide payers (Part D plan sponsors, Medicare Advantage organizations, Medicare Part B, Medicaid) and PBMs with information on indications.

Background

The Blueprint RFI states that U.S. states and other payers typically establish budgets or premium rates for a given benefit year. As such, their budgets may be challenged when a new high-cost drug unexpectedly becomes available in the benefit year. Long-term financing models are being proposed to help states, insurers, and consumers pay for high-cost treatments by spreading payments over multiple years. The RFI asks if the state, insurer, drug manufacturer, or other entity bear the risk of receiving future payments? How should Medicare or Medicaid account for the cost of disease averted by a curative therapy paid for by another payer? What regulations should CMS consider revising to allow manufacturers and states more flexibility to participate in novel value-based pricing arrangements? What effects would these solutions have on manufacturer development decisions? What current barriers limit the applicability of these arrangements in the private sector? What assurances would parties need to participate in more of these arrangements, particularly with regard to public programs?

Discussion

The recent emergence of some very expensive specialty drugs, especially for hepatitis C, has sparked conversations suggesting a role for long-term or multiple-year financing arrangements for paying for such drugs. In the case of hepatitis C, the emergence of Sovaldi, the first essentially curative drug free of side effects, strained many healthcare budgets in both the public and private sectors. Sovaldi was unusual in the prescription drug market in that it had an extremely high (\$84,000) price as drugs for rare conditions often do, yet the potential hepatitis C patient population numbered in the millions. The combination of the extremely high price set by the manufacturer and the patient population in the millions strained health budgets. Indeed, some state Medicaid programs at the time recommended rationing the drug or denying coverage for all but the sickest patients.⁸⁴

Given the fiscal strains that the emergence of several (or even one) very expensive specialty drugs have been shown to create, we believe that long-term or multiple-year financing arrangements may be workable and beneficial under certain circumstances. Employers and governments typically operate under annual budgets; such alternative financing arrangements may serve to prevent unexpectedly exhausting health budgets early in the year or diverting funds previously allocated to other needs. However, we believe that the use of such instruments should only be made under limited circumstances, and be subject to certain conditions.

⁸⁴ Stephen Barlas, "Are Specialty Drug Prices Destroying Insurers and Hurting Consumers? A Number of Efforts Are Under Way to Reduce Price Pressure," *Pharmacy and Therapeutics*, August, 2014. P. 563-566.

- **Drugs subject to multiple-year financing instruments should be for short-term patient use.** If a drug is priced so high that it requires spreading the cost over multiple years, it would be unsustainable if the patient needed the drug for the long term or the rest of her life.
- **Drugs expensive enough to require multiple-year financing should be very high value.** Sovaldi and similar hepatitis C drugs essentially cure an often fatal disease. Patients rightly place a high value on such a drug. However, many drugs are not as efficacious. They may extend life only a short time or have side effects that reduce a patient's quality of life. We believe that drugs should be rigorously studied for their value and their cost, as the Institute for Clinical and Economic Review (ICER) does today. Only drugs of very high value should be afforded very high prices.
- **Manufacturers should hold the risk for such financing arrangements.** Implementing multi-year payment arrangements may make sense for very high-cost drugs that are curative or ward off disease or degeneration for many years. If, however, a drug subject to such an arrangement becomes no longer effective, payments for the drug should stop. For example, if a drug is expected to extend life 10 years and is subject to a 10-year payment plan but a patient dies in the third year, the payments on such a drug must stop.
- **A number of practical considerations about multiple-year financing need addressing before they would become a common feature of the health system.**
 - **Long-term Financing Does Not Address Underlying Cost Issues:** The spreading out of the financing does nothing to address the issue of high drug prices set by manufacturers. In fact, the lessening of annual payment pressures could encourage manufacturers of very expensive drugs to raise the prices even higher. Policymakers must not try to implement multi-year drug payments with the idea that they would be helping to control or mitigate high drug spending.
 - **Patients May Acquire Many Conditions Over a Lifetime:** Arguments that curative treatments provide value to patients, governments, and insurers over a long period have pivoted on the principle that if a patient is cured of a disease, the patient will then avoid other, perhaps more expensive treatments associated with that disease. Additionally, they argue the patient will be more economically productive over a lifetime and, if carrying an infectious disease, not go on to infect other individuals. However, that model fails to account for the fact that even if cured, a patient may subsequently acquire other conditions which may also require expensive treatments, or could even reacquire the same original condition in the case of hepatitis C. Under proposed financing arrangements, long-term financial obligations could continue building without limit, leaving the issue of specialty drug sustainability unaddressed.
 - **The Nation Already Has Significant Future Health Care Obligations:** Because of the pay-as-you go financing system for many government entitlements, including

Medicare, the U.S. already stands to encumber significant future debts for financing health care. Despite recent slowdowns in a number of areas of health spending, the Medicare actuaries still consider Medicare spending unsustainable under current law.⁸⁵ Therefore the wisdom of adding to these future fiscal burdens through long-term financing of specialty drugs is unclear, particularly since they may crowd out other spending over many years, if undertaken for many patients.

- **Like Other Value-Based Contracts, Medicaid Best Price Rules May Thwart Some Alternative Financing Arrangements:** The Medicaid best price rule mandates that a drug manufacturer must offer the Medicaid program the lowest price that it offers any private insurer. Intended to protect government finances, the best price rule may nevertheless hinder the development of alternative drug financing schemes elsewhere. For example, a drug manufacturer is likely going to be reluctant to offer a large rebate to an insurer under a pay-for-performance drug contract if it must also match that same price for the Medicaid program. This may be particularly true for drugs that treat conditions disproportionately prevalent in the Medicaid population, such as hepatitis C.

PCMA Recommendation: We believe multiple-year financing arrangements for very expensive drugs might be beneficial for certain patients and certain payers under certain circumstances. Drugs subject to such arrangements should be curative or should improve or maintain a patient's health for a long time. The case of hepatitis C in 2014 is an example where a very expensive, curative new drug for a large patient population strained health budgets and multiple-year financing arrangements may have been appropriate. Before making such arrangements common, policymakers should answer a number of practical questions and realize that multiple-year financing will do nothing to control drug spending in the long term and may even exacerbate it.

⁸⁵ See, 2018 Medicare Trustees Report, p. 29. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf>

Background

In discussing how HHS may support better negotiation, HHS indicates it will send the President a report identifying particular drugs or classes of drugs in Medicare Part B where there are savings to be gained by moving some Medicare Part B drugs to Medicare Part D and asks which drugs or classes of drugs might be candidates for moving from Part B to Part D. HHS also asks how this proposal could be implemented to help reduce out-of-pocket costs for the 27 percent of beneficiaries who do not have Medicare prescription drug coverage or those who have Medicare supplemental benefits in Part B. In the section on informing beneficiaries with Medicare Part B and Part D about cost-sharing and lower-cost alternatives, HHS asks about a number of tools being developed by health plans and PBMs and asked how these tools could reduce out-of-pocket spending for people with Medicare.

Discussion

HHS Secretary Alex Azar noted at a June 12, 2018, Senate Committee on Health, Education, Labor, and Pensions (HELP) hearing that cost savings are a key driver of moving drugs from Part B to Part D, saying that “right now, we're paying sticker price for these drugs, no discounting. We ought to be able to get 20 to 40 percent discounting, as we do in Part D, on those drugs. That's \$30 billion of spend.” While moving drugs from Part B to Part D presents challenges as to how to allow for changes to beneficiary cost-sharing, including such a move would allow for price discounting.⁸⁶

Challenges to be addressed if moving drugs from Part B to Part D: One point of concern that would need to be addressed in moving classes of drugs from Part B to Part D is the potential for increases in beneficiary cost-sharing. Estimates based on beneficiary cost-sharing differences between Part B and Part D suggest that whether beneficiaries would have higher or lower coinsurance depends on a number of variables. One Avalere Health analysis indicates that for high-cost therapies, many Medicare beneficiaries would pay more out-of-pocket under Part D, primarily because they purchase supplemental health coverage for Part B medical services and are not eligible for low-income subsidy (LIS) copayments in Part D. However, Medicare beneficiaries that do not have supplemental health coverage would pay less out-of-pocket under Part D, especially if they are LIS-eligible.⁸⁷

In 2011, Acumen, LLC issued a report to CMS on ““Estimating the Effects of Consolidating Drugs under Part D or Part B.” This report simulated the impact in 2007 of moving four types of

⁸⁶ Written Testimony by Alex M. Azar II Secretary, U.S. Department of Health and Human Services on President Trump's Drug Pricing Plan before Senate Committee on Health, Education, Labor, and Pensions, June 12, 2018. <https://www.help.senate.gov/imo/media/doc/Azar1.pdf>

⁸⁷ Avalere Health, Avalere Analysis Highlights Complexities of Transitioning Medicare Part B Drugs into Part D, May 21, 2018. http://avalere.com/expertise/life-sciences/insights/avalere-analysis-highlights-complexities-of-transitioning-medicare-part-b-d?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top

drugs – oral anticancer/antiemetic drugs, insulin, inhalants, and immunosuppressants – from Part B to Part D. In general, the analysis indicated that moving these types of drugs from Part B to Part D would result in minor decreases in Medicare expenditures, because “Medicare’s share of point-of-sale costs is greater in Part B than in Part D for all beneficiaries except those in the catastrophic phase.” However, beneficiary cost-sharing could increase.⁸⁸

Not all Medicare beneficiaries have Medicare Part D coverage. There are 59 million beneficiaries on Medicare eligible to enroll in the voluntary Medicare Part D program, with more than 42 million Medicare beneficiaries enrolled in a Part D plan in 2017.⁸⁹ It is important to note that some Medicare beneficiaries have other drug coverage. In March 2014, 2.8 million beneficiaries are in employer plans taking the Retiree Drug Subsidy; 5.7 million beneficiaries have other prescription drug coverage.⁹⁰

Additional operational challenges for physicians were identified by Avalere in a document reviewing learnings from Medicare coverage of vaccines. Physicians who prescribe and administer pharmacy benefit vaccines may be unable to verify beneficiary coverage and cost-sharing liability. A number of third-party vendors have emerged to offer services to providers to facilitate benefit verification and online billing for Part D vaccines. However, only nine percent of responding family physicians and general internists were aware of these services according to a recent survey. Physicians could face similar billing and reimbursement challenges if Part B drugs were covered under Part D without addressing associated barriers.⁹¹

As Secretary Azar noted during his comments at the HELP committee hearing, savings from using Part D plan negotiation for drugs moved from Part B to Part D could be applied to modify the Part D benefit. Any move of drugs from Part B to Part D could be tested initially in MA-PD plans (where by definition beneficiaries have Part B and Part D benefits and no supplemental plan) to quantify savings while minimizing the initial impact on beneficiary cost-sharing.

Operational benefits of moving Part B drugs to Part D: As noted in a 2005 report from HHS to Congress, some drugs covered under Medicare Part B have a competitor drug that is covered under Part D. Given differences in the cost-sharing structure for Part B and Part D, concerns exist as to whether cost-sharing or reimbursement differences will lead to medical decisions based on cost-sharing or reimbursement.⁹²

⁸⁸ Acumen, Estimating the Effects of Consolidating Drugs under Part D or Part B, September 2011. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/Acumen_B_to_D_Final_Report_2011.pdf

⁸⁹ Kaiser Family Foundation, The Medicare Part D Prescription Drug Benefit, October 2, 2017. <https://www.kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/>

⁹⁰ Kaiser Family Foundation, Medicare Prescription Drug Plans: Number of Medicare Beneficiaries with Creditable Prescription Drug Coverage, by Type, timeframe March 2014. <https://www.kff.org/medicare/state-indicator/medicare-rx-drug-coverage/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

⁹¹ Avalere, Shifting Drugs from Medicare Part B to Part D: Learnings from Medicare Coverage of Vaccines, June 2018. <http://avalere.com/expertise/life-sciences/insights/shifting-drugs-from-medicare-part-b-to-part-d-learnings-from-medicare-cover>

⁹² HHS, Report to Congress: Transitioning Medicare Part B Covered Drugs to Part D, 2005. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/RtC_PtBtoPtD_2005_4.pdf



Moving current Part B medications to Part D would result in the opportunity for Part D plans sponsors to negotiate for rebates, lowering the net cost of drugs for which there is currently no negotiation. In addition, use of Part D UM tools can assist beneficiaries by directing them to the more cost-effective alternatives. As discussed above (see discussion beginning on p. 10), these efficiencies could also be obtained by allowing for the use of PBMs within the Part B program, taking advantage of PBM UM tools and rebate negotiation experience.

In the section on informing beneficiaries with Medicare Part B and Part D about cost-sharing and lower-cost alternatives, HHS acknowledges that health plans and PBMs have found new ways in the commercial sector to inform prescribers and pharmacists about the formulary options, expected cost-sharing and lower-cost alternatives specific to individual patients. HHS asks how these tools could reduce out-of-pocket spending for people with Medicare. In the current Medicare Part B program, there is not the opportunity to use PBM tools, as PBMs do not play a role in the management of Part B drugs. However, by moving some drug classes from Part B to Part D, HHS could allow for PBMs and associated Part D plan sponsors to provide beneficiaries with information on cost-saving alternatives.

Specific drug classes that might be candidates: Each drug class that might be a candidate for moving from Part B to Part D brings operational and cost-sharing challenges. However, the movement of selected drugs from Part B to Part D coverage could ultimately reduce costs for the Medicare program. Cost savings would be achieved by accessing these drugs through Part D plan sponsors' pharmacy networks with PBM-negotiated manufacturer discounts.

Additional factors may lead to determining that a drug or drug class may be a more suitable candidate for Part D coverage. For example, some Part B drugs are dispensed directly to beneficiaries by pharmacies. For these drugs, operational challenges would be reduced by moving drugs to Part D and would allow for real-time claims adjudication. In addition, addressing operational challenges created by confusion as to Part B/Part D coverage would reduce administrative costs.

For the report that HHS indicates that it will send to the President regarding moving Part B drugs to Part D, drug classes worth exploring include insulin, anti-emetics, inhalants, immunosuppressants and oral anticancer medications:

- a. Insulin – Moving some drugs from Part B to Part D could cause operational issues; however, the opposite is true of moving all insulin to Part D. Insulin is covered under Part D, except when used with an insulin pump. As described on a CMS beneficiary website: “You pay 100% for insulin (unless used with an insulin pump, then you pay 20% of the Medicare-approved amount, and the Part B deductible applies). You pay 100% for syringes and needles, unless you have Part D.”⁹³ For beneficiaries obtaining insulin for use in an insulin pump, they must make sure that their pharmacy is enrolled in Part B. For retail pharmacies and

⁹³ CMS, “Your Medicare Coverage: Insulin.” <https://www.medicare.gov/coverage/insulin.html>

other providers, it is equally confusing. A pharmacy may incorrectly submit a claim for insulin to the beneficiary's Part D plan, when the insulin is being used with an insulin pump and should be billed to Medicare Part B.⁹⁴

- b. Anti-emetics – Moving oral anti-emetic drugs from Part B to Part D would also address operational issues that can become a barrier to optimal patient care. Oral anti-emetic medications are covered under Part B when given within 48 hours of chemotherapy and as a full replacement for IV anti-emetic therapy,⁹⁵ and under Part D in all other situations. This requires care to be delayed while the Part D plan sponsor determines precisely at what time chemotherapy took place and if the oral anti-emetic prescription is limited to 48 hours post-chemotherapy. Moving oral anti-emetic medications to Part D would significantly decrease administrative burden and prior authorization requirements for these medications.
- c. Inhalants – The Acumen report suggested that “consolidating nebulizer inhalants under Part D could facilitate the use of step therapy and coordination of care, since nebulizers are often prescribed for patients who could not successfully treat their conditions with metered-dose inhalers (MDIs).” The report estimates the 2007 impact of moving nebulizers from Part B to Part D with projected savings to the program of approximately \$90.4 million in 2007 with a \$287 increase in per beneficiary costs at the point of sale.
- d. Immunosuppressants – Consolidating immunosuppressants in Part D would facilitate pharmacy claims processing and eliminate the need for system edits. Currently, immunosuppressant medications are covered under Part B for a beneficiary who receives a transplant from a Medicare-approved facility, and who is entitled to Medicare Part A benefits at the time of transplant. If these conditions are not met, or if a drug is used for purposes other than immunosuppression, the drug must be covered under Part D. Immunosuppressant drugs are one of the six protected classes, so each immunosuppressant option must be on a Part D plan formulary. The Acumen report projected Medicare savings of approximately \$6.9 million with a \$418 increase in per beneficiary costs at the point of sale. MedPAC

⁹⁴ AMCP, Medicare Part D: Coverage of Drugs under Part B vs. Part D, February 2013.

<http://amcp.org/WorkArea/DownloadAsset.aspx?id=16632>

⁹⁵ CMS, “Your Medicare Coverage: Prescription drug (outpatient).” <https://www.medicare.gov/coverage/prescription-drugs-outpatient.html#collapse-5968>

recommended in its 2016 Report to Congress that the immunosuppressant drug class be removed from the list of protected classes,⁹⁶ a move that would allow Part D plan sponsors and their PBMs to negotiate discounts.

- e. Anticancer drugs – For oral cancer and antiemetic drugs, an Acumen report to CMS projected Medicare savings of approximately \$34.8 million in 2007 with a \$391 increase in per beneficiary costs. The Acumen report suggested that “consolidating all anticancer and antiemetic drugs under Part D would facilitate pharmacy drug processing and billing and eliminate the necessity of maintaining systems edits for Part D plans and Part B, which could improve beneficiary access.”

Some organizations, including the Academy of Managed Care Pharmacy (AMCP), have argued that the change is necessary for reasons that relate to “patient safety and the need to eliminate confusion, delay and unnecessary expenses.” In making its recommendations, AMCP noted the benefits of defining drug coverage status at a drug specific level rather than introducing the circumstances of delivery and accentuated the fact that oral chemotherapeutics can be self-administered.⁹⁷

The antineoplastic/anticancer drug class is currently one of the protected classes under Medicare Part D, which removes concerns about some medications currently covered under Part B not being included on a Medicare Part D formulary.

Timing issues related to moving Part B drugs to Part D: The impact on Part D plan sponsors’ bids and operations requires that any movement of Part B drugs to Part D must happen at the beginning of a benefit year with time to include in Part D bids. Therefore, any change could not be implemented before 2020. Plan sponsors would need to develop bids that accurately account for the new costs associated with any Part B drugs moved to Part D.

PCMA Recommendation: PCMA encourages HHS to adopt all of the following recommendations:

- 1. Identify one or two drug classes for use in a pilot for moving drugs from Part B to Part D, focusing on classes that will bring operational benefits to providers and beneficiaries in addition to bringing savings to the Medicare program. Such a change should be implemented first in the MA-PD setting, where one organization is responsible for coverage under both Part B and Part D;**

⁹⁶MedPAC, Report to the Congress: Medicare and the Health Care Delivery System, June 2016.

<http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf>

⁹⁷ AMCP, Medicare Part D: Coverage of Drugs under Part B vs. Part D, February 2013.



- 2. Maximize the use of PBM utilization management and negotiation tools by using PBMs and Part D tools in the Part B program, without the challenges related to increases in beneficiary cost-share or coverage issues, as recommended above in I (B): Use of Part D Tools in Part B and Creation of CAP for Part B drugs (p. 10);***
- 3. Include insulin, anti-emetics, inhalants, immunosuppressants and anticancer drugs in the report that HHS will send to the President; and***
- 4. Any changes related to moving Part B drugs to Part D should not be implemented before 2020.***

Background

The Blueprint RFI states that Part B drugs are reportedly available to Organization for Economic Cooperation and Development (OECD) nations at lower prices than those paid by Medicare Part B providers. It further states HHS is interested in receiving data describing the differences between the list prices and net prices paid by Medicare Part B providers, and the prices paid for these same drugs by OECD nations. Though these national health systems may be demanding lower prices by restricting access or delaying entry, the RFI asks whether Part B drugs sold by manufacturers offering lower prices to OECD nations should be subject to negotiation by Part D plans? Would this lead to lower out-of-pocket costs on behalf of people with Medicare? How could this affect access to medicines for people with Medicare?

Discussion

PCMA believes that in general, Part D-like drug price negotiations may be able to lower drug costs in Part B, so long as the full range of negotiating tools would remain at the disposal of the negotiator, including formulary placement and utilization management techniques, to name just a few. Additionally, the coverage mandates in Part D, including the six protected classes and the two drugs per category or class requirement, would likely need to be lifted to enable any chance at significant savings if private negotiators such as PBMs were to undertake any administration of the Part B drug benefit.

The RFI specifically references drug prices in OECD countries and suggests that such prices may be used in some form as reference prices to help control drug costs in Part B of Medicare. This is a creative idea, but one that raises many implementation questions, including:

- The OECD comprises 35 different countries, each with its own unique governmental and market structures for applying prescription drugs. Would there be an index of OECD drug prices as a benchmark? Would specific countries that would somehow be chosen as representative be chosen from the list as a comparator?
- How would specific international pricing risks be handled? For example, if one or more comparator countries underwent a currency shock that dramatically affected prices for all commodities in that country (or countries), how, if at all, would such risk be handled, which would have nothing to do with the underlying supply and demand for drugs.



- Many OECD countries have highly regulated drug pricing regimes compared with the U.S., which has a relatively free market. Would reference pricing to those countries essentially import their pricing controls to the U.S.? If so, what would be the effect on the rest of the drug market?

PCMA Recommendation: We believe that private-sector negotiation of drug prices in Part B may have a potential for savings if negotiators have a free hand to use all the tools at their disposal. If permission for private-sector entities to undergo such negotiation were tied to relative levels of international drug pricing, a thorough analysis of all the effects must be made. In particular, care must be taken to avoid directly or indirectly pegging to international prices subject to government control and to account for fluctuations in currency value unrelated to the normal supply and demand patterns for drugs.

Background

The Blueprint RFI states that U.S. consumers and taxpayers generally pay more for brand drugs than do consumers and taxpayers in other OECD countries, which often have reimbursements set by their central government. In effect, other countries are not paying an appropriate share of the necessary research and development to bring innovative drugs to the market and are instead freeriding off U.S. consumers and taxpayers. The RFI asks what can be done to reduce the pricing disparity and spread the burden for incentivizing new drug development more equally between the U.S. and other developed countries. What policies should the U.S. government pursue in order to protect IP rights and address concerns around compulsory licensing in this area?

Discussion

We generally agree with the premises of the questions in this section that the U.S. bears an inordinate burden in financing new drug discovery. We believe the United States Trade Representative (USTR) or other qualified body should undertake a comprehensive assessment of these questions and put forth recommendations to address the issues.

PCMA Recommendation: These important questions on global freeloading should be referred to the USTR or other qualified entity to study and put forth recommendations to address.

**Better Negotiation – III (B) p. 22697
Site Neutrality of Physician-administered Drugs/Site Neutrality Between Inpatient and Outpatient Setting****Background**

Site neutrality for physician-administered drugs. HHS points out that under current Medicare Part B and often in Medicaid, hospitals and physicians are reimbursed comparable amounts for drugs they administer to patients, but the facility fees when drugs are administered at hospitals and hospital-owned outpatient departments are many times higher than the fees charged by physician offices. HHS asks what effect a site neutral payment policy for drug administration procedures would have on the location of the practice of medicine and how this would change affect the organization of health care systems.

Site neutrality between inpatient and outpatient setting. Medicare payment rules pay for prescription drugs differently when provided during inpatient care (Part A) or administered by an outpatient physician (Part B). In addition, beneficiaries have different cost-sharing requirements in Part A and Part B. Some drugs can be administered in either the inpatient or outpatient setting, while others are currently limited to inpatient use because of safety concerns. HHS asks whether the differences between Medicare's Part A and Part B drug payment policies create affordability and access challenges for beneficiaries and what policies CMS should ensure that inpatient and outpatient providers are neither underpaid nor overpaid for a drug. HHS also asks how Medicare should encourage the shift to outpatient settings.

Discussion

Use of home-infusion therapy and self-administered drugs in non-medical settings: In addition to considering issues related to site neutrality between inpatient and physician office settings, HHS should also consider whether drugs can be administered at home, whether through a home infusion benefit or through self-administration.

Significant differences exist in the cost of care between infusion therapy provided from skilled nursing facilities, hospital outpatient departments, and physicians' offices and the cost of infusion treatment provided at home. The differences have been illustrated in an Avalere study which analyzed the differences in cost of care for anti-infective medications provided in the various settings. The study found that there would be an estimated savings over 10-years of 12.6 percent or \$80 million dollars, with a first-year savings of 17.7 percent or \$8.5 million dollars, when anti-infective medications are provided through home infusion.⁹⁸

⁹⁸ Avalere, Impact on Medicare Expenditures from Expanding Coverage of Infusion Therapy of Anti-Infective Drugs to the Home Setting, June 2014. <http://www.nhia.org/resource/legislative/documents/AvalereFinalHomeInfusionReport.pdf>



Moving drugs from Part B to Part D or using PBM tools in Part B: For Part B drugs, which are provided primarily in physician-offices, there is little price competition and little to prevent the rapid growth in Part B drug spending. Medicare pays for most Part B-covered drugs based on the average sales price plus 6 percent (ASP + 6 percent). CMS assigns generic drugs and biosimilars and their associated brand products to a single billing code creating some price competition. However, CMS pays for most single-source drugs and biologics under separate billing codes without price competition among products with similar health effects. Whether a Medicare beneficiary receives a Part B therapy in a hospital, in a hospital's outpatient clinic, in a physician's office or from a specialty pharmacy may be influenced by the benefit of high Medicare Part B payment.

Moving at least some Part B drugs to Part D or using PBM UM tools under Part B (as discussed above in Section I (B): Use of Part D Tools in Part B and Creation of CAP for Part B Drugs (p. 10)), would provide for more site-neutral reimbursement. Removing incentives for prescribers to make site of care decisions based on drug reimbursement rates will lower the cost of medications. As described in that section, CMS already has some authority to move drugs from Part B to Part D. Based on that existing authority, CMS could move some drugs from Medicare Part B to D to allow the use of PBM UM tools that have been effective under Part D to a greater range of drugs.

PCMA Recommendation: PCMA appreciates that HHS is seeking to make site neutral payment a goal. We support HHS efforts to encourage the use of lower-cost sites of care with home infusion and self-administered medications by removing financial incentives for drugs to be provided in medical settings.

Background

HHS has several questions related to the accuracy of national spending data, including asking whether annual reports of health spending are obscuring the true cost of prescription drugs. The Department also questions whether average Part D rebate amounts should be reported separately for small molecule drugs, biologics, and high-cost drugs. Further, HHS solicits suggestions for what innovation is needed in order to maximize price transparency without disclosing proprietary information or data protected by confidentiality provisions.

Discussion

Studies have shown that rebates lower government costs and lead to lower premiums for plan enrollees.⁹⁹ One study addressed the assertion that the rebate system has led manufacturers to increase their list prices above what they would be in the absence of the rebate system. The researchers concluded that if this is true, any offset to the positive results of rebates “is likely to be small.” The researchers also addressed the assertion that PBMs retain rebate payments without passing the savings on to plans or consumers and found that while PBMs have earned a profit, “the notion that they divert a large share of rebates to excess profits is not supported by our analysis.”

PCMA believes that all rebates should be reported in an aggregated way, separately for small molecule drugs, biologics and high-cost drugs, as suggested by HHS. This reporting will help illustrate the extent to which competition drives lower costs in the Medicare Part D program. In addition, the price concessions labeled as “rebates” by manufacturers should be broken out separately for Medicare Part D, Medicaid statutory and supplemental rebates, and the commercial market. These rebates should be separately reported in the national health spending accounts. While PCMA has long supported providing useful information to consumers to empower them to make the best choices for themselves about their healthcare, HHS must strike a balance to ensure that public disclosure of information does not lead to a disincentive for manufacturers to offer deep discounts. Disclosure of confidential trade secret information can lead to diminished rebates and higher prices for plans and beneficiaries.

PCMA Recommendation: PCMA believes that all rebates should be reported in an aggregated way, separately for small molecule drugs, biologics and high-cost drugs, as suggested by HHS. This reporting will help illustrate the extent to which competition drives lower costs in the Medicare Part D program. In addition, the price concessions labeled as “rebates” by manufacturers should be broken out separately for Medicare

⁹⁹ Roehrig, Charles, PhD. “The Impact of Prescription Drug Rebates on Health Plans and Consumers.” April 2018. https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf



Part D, Medicaid statutory and supplemental rebates, and the commercial market. These rebates should be separately reported in the national health spending accounts. In addition, while PCMA has long supported providing useful information to consumers to empower them to make the best choices for themselves about their healthcare, HHS must strike a balance to ensure that public disclosure of information does not lead to a disincentive for manufacturers to offer deep discounts. Disclosure of confidential trade secret information can lead to diminished rebates and higher prices for plans and beneficiaries.

**Creating Incentives to Lower List Prices – III (C) p. 22697-8
Reducing the Impact of Rebates****Background**

In the Blueprint RFI, HHS argues that higher rebates in Federal health care programs *may* be causing higher list prices in public programs (and also increasing the prices paid by consumers, employers, and commercial insurers). HHS asks what CMS should do to restrict or reduce the use of rebates. HHS seeks comment on whether Medicare Part D should prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers, and require these contracts to be based only on a “fixed price discount” for a drug over the contract term. HHS also asks what incentives or regulatory changes (e.g., removing the discount safe harbor) could restrict the use of rebates and reduce the effect of rebates on list prices. Finally, HHS also seeks comment on the impact and unintended consequences of a policy restricting the use of rebates on the behavior of drug manufacturers, PBMs, and insurers, and how it may impact formulary design, premium rates, and the overall structure of the Part D benefit.

Discussion

At the outset, as we describe in greater detail below, we note the supreme irony of HHS seeking comments on the prospect of limiting rebates in the Part D program in the very same month that the CMS in the 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund (“Medicare Trustees Report”), credited rebates with lowering costs in the Part D program. CMS said, “[t]his upward revision to projected rebates is a major reason for decreases in overall Part D costs compared to 2017.” The commentary also seems to strongly imply that the reason that the price for the new class of hepatitis C therapies has declined so rapidly is because of high rebates for those therapies.¹⁰⁰ So it defies logic that HHS would be soliciting comments for a solution to high drug prices when that very solution – the use of rebates to manage Part D costs – was validated in this year’s Medicare Trustees Report.

Our discussion below focuses first on the significant policy, operational, and technical issues presented by a fixed price discounting model for PBMs, as suggested by the Administration’s Blueprint and reiterated in comments by the HHS Secretary in recent weeks.^{101,102} We then turn

¹⁰⁰ 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (June 5, 2018) at 143.

¹⁰¹ “Rebates are allowed under an exception to the Anti-Kickback Statute, and that’s an exception that we believe by regulation we could modify, but of course if Congress were to take action, that would obviously shore up our authority and allow thoughtful consideration by Congress about what would be fairly far-reaching impacts of moving to a different system of using instead fixed price discounts.” Testimony of HHS Secretary Alex Azar before the Senate Health, Education, Labor and Pensions Committee (June 12, 2018).

¹⁰² In recent statements, HHS Secretary Azar has claimed manufacturers seeking to lower their price are confronting “hurdles from pharmacy benefit managers and distributors...where they might say ‘if you decrease your list price, I will take you off formulary compared to your competitor.’” Testimony of HHS Secretary Alex Azar before the Senate Health, Education, Labor and Pensions Committee (June 12, 2018). While PCMA is aware of no evidence of such behavior, if in fact this is occurring, we encourage HHS to work in tandem with the OIG and FTC to investigate any possible anti-trust violations. In a letter to the Secretary from Sens. Warren

to the very clear legal barriers that would prevent the adoption of a policy that would prohibit rebates, in whole or in part. In particular, we discuss the Anti-Kickback Statute’s protection for discounting arrangements, and the antitrust implications of a fixed price discounting model. We also note that current law, under the Part D statute, very clearly prevents this type of proposal via the non-interference clause.

While our comments below generally focus on the impact of a fixed price discounting model for PBMs in the Part D program, such a policy would also have severe consequences if it were applied to the commercial and employer marketplaces. Even if HHS intends for its policies to be limited to the Part D (or federal) marketplace, we are concerned about the significant ripple effects of making major changes to the drug supply chain.

A Fixed Price Discounting Model for PBMs Fails to Address the Root Cause of High Drug Prices – the List Price Set by Manufacturers: The policy contemplated by HHS in the Blueprint RFI fails to address the root cause of rising drug costs: high list prices. Rather than targeting the underlying problem, the Administration in its Blueprint has seemingly zeroed in on a policy that it believes may “create incentives for manufacturers to lower list prices.” Not only is there no data or underlying support for the proposition that rebates contribute to rising list prices (indeed, as we note below, in non-competitive classes where rebates are minimal – such as antineoplastic drugs – list price inflation often exceeds more competitive, rebate-driven classes), but the policy itself would have no direct impact on net drug prices and would likely lead to overall *higher* drug costs and *increased* premiums. Simply put, the proposed approach discussed in the Blueprint appears to be a distraction from true policy change, at the expense of actual policy solutions that will reduce the real beneficiary burden at the pharmacy counter. As Tony Lo Sasso (University of Illinois Chicago) and Ike Brannon (Cato Institute) noted in their recent analysis: “Prohibiting rebates would either result in higher health-insurance premiums and drug costs, or drug companies devising a similar program to accomplish approximately the same thing as drug rebates--if we’re lucky.”¹⁰³ Indeed, as noted below, since the implementation of the Part D program in 2006, the use of rebates to lower drug prices has demonstrated itself to be a powerful *tool* to drive competition and lower drug prices.

Underlying HHS’ policy perspective that rebates are problematic appears to be a theory that if rebates are removed from the system, the price of drugs will go down. However, a June 2017 study by Visante prepared on behalf of PCMA, based on an analysis of price growth and estimated rebate levels for the top 200 brand name drugs by 2016 U.S. sales, found no correlation between the prices that drug makers set on individual drugs and the rebates that they negotiate with PBMs on those products. In other words, the incentives targeted by HHS in the Blueprint RFI do not exist under real world analysis. For example, large price increases for

and Smith sent on June 26th, the Senators specifically ask if “the Administration is in possession of any specific evidence or information that any PBM or drug distributor is “pushing back on drug companies” or otherwise setting up a “hurdle” to reducing drug prices?” In line with this request, we *do not* believe that HHS should make wholesale policy changes based on anecdotal behavior of select companies.

¹⁰³ Lo Sasso, Anthony T. and Brannon, Ike, Drug Rebates Do Not Increase Costs to Consumers (May 29, 2018). Available at SSRN: <https://ssrn.com/abstract=3186918> or <http://dx.doi.org/10.2139/ssrn.3186918>.

rheumatoid arthritis drugs and anticonvulsants—two categories with relatively low rebates—have resulted in similarly high net price increases for those medications after rebates are deducted. So, too, despite relatively low rebates for multiple sclerosis drugs, from 2011 to 2016 manufacturers increased list prices an average of 125% in this class.

On June 5, 2018, the Medicare Trustees Report was released and contained a number of findings key to HHS’ ongoing efforts to lower drug prices.¹⁰⁴ The report found:

- Projected Part D costs in the 2018 report are lower than in the 2017 report. This difference is “primarily attributable to higher manufacturer rebates....”
- For 2017, per capita benefit costs “decreased sharply” as compared to recent historical years due to the projected rebates in the 2017 plan bids being significantly higher than in the 2016 plan bids, “offsetting the increase in drug costs.”
- So, too, “the 2018 per capita benefits are projected to decrease further because the rebates assumed in the 2018 plan bids were significantly higher than assumed for the 2017 bids.”
- In forward-looking projections, the Trustees anticipate ongoing increases in rebate amounts (up to 28.1% by 2027 from 25.3% in 2018), while plan administrative expenses and profits are expected to remain level and then slightly decrease (down to 10.7% by 2017 from 10.9% in 2018.)

What this non-partisan, highly respected data shows is that the *rebate negotiations* that the Blueprint RFI attempts to target are precisely the *tool* that is keeping Part D costs down. Absent rebates, Part D costs would skyrocket as Part D plans would lose access to significant tools that drive negotiations.

In the short-term, a fixed price discounting policy for PBMs raises a number of significant policy concerns and questions:

- **Fixed Price Discounting Will Result in Higher Net Drug Prices:** Restricting rebates will introduce the wrong kind of transparency into the program and thus significantly hamper negotiating leverage, leading to higher costs. Respected government bodies and universities have established that confidential negotiations result in more competition and lower costs for patients and plan sponsors. The Federal Trade Commission has stated that, “[i]f pharmaceutical manufacturers learn the exact amount of rebates offered by their competitors ... then tacit collusion among manufacturers is more feasible ... Whenever competitors know the actual prices charged by other firms, tacit collusion — and thus higher

¹⁰⁴ “2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds,” Letter of Transmittal (June 5, 2018).

prices — may be more likely.”¹⁰⁵ And researchers at the University of Pennsylvania found that, “[t]ransparency requirements that attempt to set actual reimbursement for drugs at the pharmacy’s or PBM’s actual cost or acquisition price may have unintended consequences, leading to higher real costs and/or manipulated prices.”¹⁰⁶ As CMS itself has noted, disclosure of actual prices in Part D “could undermine the competitive nature of the Part D program.”¹⁰⁷

Underlying the fixed price discount policy contemplated in the Blueprint RFI is the notion that HHS can merely ask manufacturers to lower their prices to “List price minus rebate amount” and that this will actually occur (and note that, even if it does, net drug prices remain the same.) Yet, there is no reason to believe that a policy restricting or prohibiting rebates will result in the same or similar net drug prices as we see today in the program. While presumably manufacturers will still negotiate for formulary placement and volume, restricting rebates would remove the central tool used today by manufacturers to drive access – and by PBMs to lower prices. In addition, introducing total price transparency will allow manufacturers to know, up-front, the prices of their competitors, reducing the likelihood that PBMs can leverage competition to drive down prices. In particular, if HHS were to require fixed price discounting, manufacturers of similarly classified products would be driven by basic laws of economics to move toward a standard fixed discount to avoid any “free rider effect” whereby manufacturers with high discounts subsidize manufacturers with low discounts.

Moreover, even if manufacturers were to voluntarily lower their net drug prices to current post-rebate levels via use of up-front discounts rather than after-the-fact rebates, HHS would still have not attained its goal of lower list prices. In other words, the Blueprint RFI appears to be chasing a policy that, even assuming it were successful, would still not result in a difference in net drug costs. Given ongoing manufacturer brand drug price increases,¹⁰⁸ HHS would be taking a major gamble that the supply chain could possibly function without a rebate.

- **Restricting Rebates Will Result in Higher Premiums:** The Part D market-based model is based on premium competition, and study after study has shown that beneficiaries prefer to shop for coverage based on premiums.¹⁰⁹ Indeed, many parts of the Part D program are based on the premium metric (e.g., auto-assignment for the LIS population is based on the premium structure). Absent changes to the statute and the underlying program, it is difficult to envision how CMS can take a system based on premiums, and change a single aspect to

¹⁰⁵ Letter to Assembly Member Greg Aghazarian, U.S. Federal Trade Commission Comments on AB 1960 (September 7, 2004).

¹⁰⁶ Danzon P. “Pharmacy Benefit Managements: Are Reporting Requirements Pro or Anti-Competitive?” The Wharton School, University of Pennsylvania (April 1, 2015).

¹⁰⁷ “Medicare Program; Medicare Part D Claims Data; Final Rule,” 73 *Federal Register* 103 (May 28, 2003), pp. 30664, 30666. <https://www.gpo.gov/fdsys/pkg/FR-2008-05-28/html/08-1298.htm>

¹⁰⁸ Wells Fargo. January 2018 Drug Pricing Report accessed at <https://www.wellsfargoresearch.com/Reports/ViewReport/6ce91008-4fe3-4b0e-a0a8-aa4f69eb71c3?source=WFR.COM&ght=df4e0a92-c7f5-43b8-99b8-2b20d43bf7f7>

¹⁰⁹ See Abaluck J, Gruber J. Choice inconsistencies among the elderly: evidence from plan choice in the Medicare Part D program. *Am Econ Rev.* 2011; 101 (4): 1180 – 210.

seek to make it about competing solely on individual drug prices. As CMS has already noted in its 2019 Part D Policy and Technical Rule released earlier this year, “under the current Part D benefit design, price concessions that are applied post-point-of-sale, as DIR, reduce plan liability, and thus premiums, more than price concessions applied at the point of sale.”¹¹⁰ In other words, to the extent HHS adopts a policy that prohibits or restricts rebates: (1) net drug prices will either remain stagnant or increase (likely); and (2) plan premiums *will* increase. Indeed, Oliver Wyman has just released a study on the premium impact of disallowing manufacturer rebates in Part D. The major findings of the study are that rebates have saved beneficiaries \$34.9 billion in premium costs from 2014 to 2018. Without rebates, premiums would have been 52 percent higher in 2018 without rebates and beneficiaries would have paid \$9.8 billion more for their Part D coverage in 2018 alone. In 2017, the average Part D monthly premium of \$35.63 would have been 45 percent, or \$16.07, higher without rebates.¹¹¹ Absent a method permissible under antitrust law by which to extract price concessions from manufacturers (as discussed in more detail below, starting on p. 88) Part D premiums would be significantly higher, leaving many beneficiaries unable to afford Part D coverage.

- **Discounts Will Not Produce Equivalent Savings as Rebates:** Even if manufacturers could, under antitrust law, offer price concessions that did not rely on rebates, without the PBMs and plans taking the risk for being able to move market share to a given drug, manufacturers will never offer up-front discounts as deep as the rebates they currently negotiate. After-the-fact rebates allow a range of price concessions that are contingent on the amount of market share a given PBM moves onto a given drug. They are, in effect, value-based contracting with respect to PBM performance. No manufacturer will give the deepest up-front discount that would match its deepest current rebate, as it will have no guarantee of the PBM’s performance on moving patients onto its drug. And thus, without rebates, price concessions will not be as large and Part D premiums will increase.
- **A Policy Restricting Rebates Could Hurt the Economies of Scale of PBM Negotiations:** Under the policy proposal discussed in the Blueprint RFI, it is unclear whether manufacturers would be permitted to maintain multiple fixed prices (for each PBM), or whether they would be required to offer a single, fixed price to all purchasers. To the extent the latter policy is HHS’ intention, costs (and thus, premiums) would increase significantly as the collective negotiations that are the hallmark of the PBM industry would be undermined. Under current practice, a PBM may negotiate rebates with manufacturers for dozens of Part D plan clients at a time, resulting in true economies of scale and significant negotiating leverage for the PBM. The result of these aggregate negotiations are lower net drug prices as PBMs use their scale to negotiate the deepest possible rebates,

¹¹⁰ “Medicare Program; 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; Final Rule,” 83 *Federal Register* 73 (April 16, 2018), pp. 16440-16757. <https://www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare>

¹¹¹ <https://www.pcmanet.org/wp-content/uploads/2018/07/OW-Part-D-Manufacturer-Rebate-Premium-Impact-FINAL.pdf>.

which also can vary based on the exact market share a PBM moved to a given product. This system produces premium savings across the board. To the extent a manufacturer would be required to offer only a single fixed price, this negotiating leverage would be significantly hampered, resulting in overall increases in net drug costs as manufacturers' default discount would not be the deepest discount a buyer with massive scale could achieve. This would result in higher premiums for beneficiaries (not to mention the major legal concerns raised by such a proposal).

- **Fixed Price Discounting Still Involves Rebating:** In both the Blueprint RFI and in subsequent statements by the Secretary, HHS has railed against the use of rebates in the Part D program and seemingly committed to prohibiting this common practice. Yet, in the event that manufacturers are permitted to negotiate separate fixed prices with different purchasers, it is unclear how HHS could completely exclude rebates from the system (again, putting aside clear issues involving non-interference). If fixed prices varied across different purchasers, wholesalers and pharmacies would need to use some other pricing standard (WAC or AWP, likely) given that the ultimate negotiated price of the drug would not be determined until the point-of-sale. How would the physical drug supply chain account for such market segmentation? In particular, how would the manufacturer, wholesaler, and pharmacies know where each beneficiary would present their prescriptions, so that the supply chain costs reflected discounts reasonably and accurately? In our assessment, it would be impossible for wholesalers and pharmacies to estimate accurately which plan participants would buy a given drug from a given pharmacy. And thus, either the physical supply chain participants would name winners and losers, or the system would still need rebates so that pharmacies would be fairly reimbursed, and PBMs would receive the net cost negotiated with manufacturers.

Clearly, a rebate-based payment would still be necessary to the extent the manufacturer would still have to provide after-sale payments in the case that the pricing standard used by or the reimbursement paid to wholesalers and pharmacies were different than the fixed price discount agreed upon by the plan and manufacturer.

Not only does this reality present a major barrier to the policy contemplated in the Blueprint RFI (particularly to the extent, as discussed below, HHS intends to employ the AKS to subject all rebates to scrutiny), it also illustrates the key role that rebates play in the drug supply chain in driving competition. Put another way, unless HHS desires to move to a government run pricing system where each drug has a single net price regardless of purchaser, rebates will *always* play a key role in the drug supply chain.

- **HHS Does Not Consider the Potential for Adverse Selection:** When the Part D program began in 2006, plans competed based on premiums (with consumers shopping for coverage based on premiums and total costs, as opposed to individual drug prices.) However, under a fixed price discounting model, beneficiaries could now (armed with information on net drug

prices) shop for coverage based on individual drug prices. While there may be merits to such a system from a consumer perspective, there are reasons that the system does not work this way today (in any part of the healthcare sector). If a consumer knows, up-front, the net price of a drug, adverse selection and risk pool distortion are introduced into the system, resulting in potential rapid increases in premiums as the Medicare risk adjuster does not adjust fully for very ill beneficiaries, or those taking very expensive drugs that otherwise have relatively few encounters with the health care system.

Fixed Price Discount Approach Would Require Major Effort, Including Recontracting and Revising Bids: Since the inception of the Part D program, Part D plans have relied upon rebate negotiations to drive competition, lower drug costs, and reward value. Thus, over the course of nearly 15 years, plans, PBMs, manufacturers and other key drug supply chain actors (wholesalers, GPOs, etc.) have developed systems, processes, and contracts built and reliant upon back-end rebates based on volume and formulary placement. Any efforts to restrict or undermine this underlying system must be seriously analyzed for both known and unintended costs. For example, given that both manufacturers and PBMs – and Part D plan sponsors and PBMs – operate under contracts based on a rebate-driven system, a complete restructuring of these arrangements would require a significant investment in time and dollars. In addition, and putting aside the very real substantive and legal flaws in HHS’ proposal, any changes to the existing rebate system must occur no earlier than 2020 and only after duly promulgated notice and comment rulemaking. Attempts to disrupt the 2019 plan year (given that bids take many months to calculate and were due in early June), would be devastating to the program and to beneficiaries.

- **PBM Contracts with Manufacturers Are Complex:** We remain very concerned that HHS is underestimating what is involved in manufacturer contracts with PBMs – and how these arrangements ultimately are reflected in PBM contracts with Part D plan sponsors. PBM-manufacturer contracts go well beyond the terms of the list price, the amount of the rebate, and the incentives (e.g., market share, tier placement, applicable UM), and include a wide range of other items related to price including contract term, limits on price changes, impact of new drug approvals, impact of FDA actions (e.g., REMS), and conditions for reopening (e.g., change in law by Congress or in regulation by HHS). Moreover, this list does not even include all of the provisions in these contracts directly related to price (e.g., arbitration, impact of mergers or acquisitions, liability, etc.). Even assuming that the fixed price discounting concept is comprehensible and feasible, it is unrealistic to expect that any major new construct can be negotiated quickly. PBM-manufacturer agreements are often multi-year with a range of contingencies that would need to be addressed, and a PBM might well have to renegotiate with several manufacturers all in the same short window of time (and then they would need to negotiate their contracts with their Part D plan clients to reflect the changes). Larger PBMs may have many Part D clients, which would require significant plan renegotiation when the manufacturer negotiations were completed. Finally, bids would then have to be recalculated, normally a seven-month process, and refiled. As noted further



below, all of these negotiations take place under the umbrella of “non-interference.” We urge HHS to take into account what is involved in renegotiating the wide range of contracts implicated by the fixed price discounting approach.

- **The Part D Bid Process is a Multi-Year Process Involving Multiple Parties:** As CMS knows, the official Part D bidding process starts in November of the year before the calendar year (CY) for the contract, when applicants are required to submit a Notice of Intent to Apply to CMS (i.e. this notice would have been filed in November of 2017 for a contract for CY2019). While the bids for CY2019 contract were due in early June, CMS must review bids, a process taking several weeks, and finalize the contracts, typically in August. Final contracts must be executed by the beginning of September, so that all plan documents can be completed and posted for beneficiary review by the end of September to accommodate open enrollment, which begins as of October 15.

Of course, much of the activity for PBMs and Part D plan sponsors begins well before the Intent to Apply is filed in November. Indeed, the formulary development process, which typically begins about two years before the formulary is due (close to the time of the bid submission), is already well underway for the CY2020 bid.

Even assuming the manufacturer contracts noted above were completed, the significant and interlocking actuarial, operational, information systems, pharmacy network, P&T committee actions, benefit construct, beneficiary materials, and related components of a 2019 bid resubmission to reflect manufacturer contract changes – which would be followed by a second 2019 bid review process by CMS cannot be underestimated. It is simply unreasonable and impractical to compress a nine-month 2019 bid development and CMS review process into the limited calendar days that remain before 2019 open enrollment. Thus, we would urge HHS, if it is to propose any kind of fixed price discounting approach, to provide as much time as possible after it is duly adopted, for implementation.

Further, we respectfully note that the idea that this kind of major change could be effectuated in very short order – i.e., in the middle of the 2019 bid process which is underway – is just not realistic. Indeed, Medicare beneficiaries would be the most adversely impacted by a rushed process. Beneficiaries are currently expecting information on their 2019 options to be available online as of October 1, with open enrollment starting as of October 15, which is only 10 weeks away. Beneficiaries would be extremely confused by the necessary delay in seeing the materials, and assessing their options. Since it is possible that the fixed price approach would not only increase premiums for most beneficiaries, but also impact which drugs are covered, there could be major changes not only in what drugs are on formulary, but also what tiers they are on and at what cost-sharing level. We urge HHS to make it a top priority to ensure that any new approaches to be undertaken do not adversely impact beneficiaries, not just with respect to coverage, costs, and choice, but also

with respect to understanding and being satisfied with the Part D benefit and the enrollment experience.

- **HHS Lacks the Authority to Subject Rebates to AKS Scrutiny:** In the Blueprint RFI, HHS asks what incentives or regulatory changes (e.g., removing the discount safe harbor) could restrict the use of rebates and reduce the effect of rebates on list prices. Following the release of the Blueprint RFI, in remarks to AEI on May 16, 2018, Secretary Azar explained this policy further, noting:

“We would welcome the PBM industry coming forth with broader proposals for moving away from today’s system, including a plan for implementation with the pharmaceutical industry. But we also have the administrative power to end this system ourselves—to eliminate rebates and forbid remuneration from pharmaceutical companies, align interests, and end the corrupt bargain that keeps driving list prices skyward.”

In his recent comments before the Senate Health, Education, Labor & Pensions (HELP) Committee, Secretary Azar went further, noting: “Rebates are allowed under an exception to the Anti-Kickback Statute, and that’s an exception that we believe by regulation we could modify.”

As we will discuss below, discounts and other price reductions (which necessarily include rebates) are not only protected by a regulatory safe harbor, but are shielded from AKS scrutiny by a statutory exception. Contrary to the remarks of the Secretary, HHS lacks the authority to subject rebates to AKS scrutiny, absent Congressional intervention.

- **The Statutory Exception for Discounts Is Broad:** The federal AKS, section 1128B(b) of the Social Security Act, 42 U.S.C. 1320a-7b(b), makes it a civil and criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. “Remuneration” is defined to include a “kickback, bribe, or rebate.”¹¹² Penalties under the statute apply to both parties in a “kickback” transaction, and include fines, prison terms of up to five years, civil monetary penalties, and/or exclusion from participation in federal healthcare programs.

Because, under the clear terms of a rebate arrangement, a manufacturer is offering “remuneration” to a MA or Part D plan in order to induce the purchase of its products – payment for which is ultimately reimbursable by a federal healthcare program – the AKS is plainly implicated. Indeed, the Office of Inspector General (OIG) has stated in guidance that “[a]ny rebates or other payments by drug manufacturers to PBMs that are based on, or otherwise related to, the PBM’s customers’ purchases **potentially** implicate the anti-

¹¹² Social Security Act, § 1128B(b)(1).

kickback statute.”¹¹³ However, the AKS has both statutory and regulatory exceptions that arguably protect these rebate agreements in certain circumstances.

Under current law, the AKS contains eight statutory exceptions. Of the eight, the exception most applicable to rebate agreements is the discount exception, which provides that the AKS does not apply to “a discount or other reduction in price obtained by a provider of services or other entity under [Medicare] or a State health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity.”¹¹⁴ Although the exception does not explicitly refer to rebates, its language is broad and appears to encompass *any* reduction in price obtained by *any* entity so long as it is properly documented—including rebates.

The exception’s legislative history supports this broad reading. Following passage of the Social Security Amendments of 1972 (which included the original anti-kickback legislation),¹¹⁵ in 1977 Congress added the exception as part of its first amendments to the AKS.¹¹⁶ According to the House Report language, the exception:

“... would specifically exclude the practice of **discounting or other reductions in price** from the range of financial transactions to be considered illegal under Medicare and Medicaid, but only if such discounts are properly disclosed and reflected in the costs for which reimbursement could be claimed. **The committee included this provision to ensure that the practice of discounting in the normal course of business transactions would not be deemed illegal.** In fact, the committee would encourage providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs.”

H.R. Report No. 95-393(II), at 53, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056 (emphasis added).

- **The Statutory Exception to the AKS for Discounts Protects Rebates:** As noted above, the wording of the statutory exception for discounts to the AKS is *broad* – protecting from scrutiny any “discount or other reduction in price,” so long as it is properly disclosed and appropriately reflected in the costs claimed or charged made by the provider.¹¹⁷ This interpretation is supported by both the legislative history of the AKS,¹¹⁸ as well as by the OIG

¹¹³ OIG, Compliance Program Guidance for Pharmaceutical Manufacturers, April 2003, *available at* <https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf> (emphasis in original).

¹¹⁴ Social Security Act, § 1128B(b)(3)(A).

¹¹⁵ See Social Security Amendments of 1972, Pub. L. 92-603, 86 Stat. 1329 (1972).

¹¹⁶ See Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. 95-142, 91 Stat. 1175 (1977).

¹¹⁷ Social Security Act, § 1128B(b)(3)(A).

¹¹⁸ H.R. Report No. 95-393(II), at 53, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056 (emphasis added) (“The committee included this provision to ensure that the practice of discounting in the normal course of business transactions would not be deemed illegal.”)

itself, which has previously taken the position that the safe harbor regulations merely replicate, and do not expand, the statutory language of the discount exception.¹¹⁹ If it is OIG's longstanding position that the safe harbor regulations "do not expand the scope of activities that the [AKS] prohibits" – and given that current rebate arrangements are protected by the plain language of the regulatory safe harbors – then the OIG lacks the regulatory authority to exclude rebates from the discount safe harbor.

The Administrative Procedures Act ("APA") is instructive here. In particular, there is a strong argument that the underlying language of the AKS (exempting from scrutiny any "discount or other reduction in price,") unambiguously indicates that Congress did not intend that rebates be subjected to AKS scrutiny. Indeed, the legislative history of the AKS makes clear a desire for "providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs."¹²⁰ As such, a reviewing court is likely to find such policy changes as substantively invalid because they would be promulgated *ultra vires* and/or would be "arbitrary, capricious, or manifestly contrary to the statute."¹²¹

Any attempt by HHS-OIG to amend the existing regulatory safe harbor to exclude discounts would be entitled to *Chevron* deference.¹²² Under *Chevron*, a court reviewing an agency's construction of a statute which it administers must examine two questions. The first is whether "Congress has directly spoken to the precise question at issue" ("*Chevron* Step One").¹²³ If the statute is unambiguous, then that is the end of the inquiry and the unambiguous text of the statute must be followed.¹²⁴ If, however, "the court determines Congress has not directly addressed the precise question at issue...the question for the court is whether the agency's [interpretation] is based on a permissible construction of the statute" ("*Chevron* Step Two").¹²⁵

Here, a reviewing court is likely to find that OIG's "shrinking" of the discount safe harbor would fail *Chevron* Step One as being promulgated beyond the agency's delegated authority, given the broad wording of the statutory exception for discounts, and therefore not be entitled to deference. As the D.C. Circuit observed in *Arent v. Shalala*,¹²⁶

Chevron is principally concerned with whether an agency has authority to act under a statute. Thus, a reviewing court's inquiry under Chevron is rooted in statutory analysis and is focused on discerning the boundaries of Congress' delegation of authority to the agency; and as long as the agency stays within that delegation, it is free to make policy choices in

¹¹⁹ "Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions; Final Rule," 56 *Federal Register* 145 (July 29, 1991), pp. 35952, 35954.

¹²⁰ H.R. Report No. 95-393(II), at 53.

¹²¹ See *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 844 (1984).

¹²² See *Nat'l Mining Ass'n*, 758 F.3d at 251 ("Legislative rules generally receive *Chevron* deference....").

¹²³ *Chevron U.S.A., Inc.*, 467 U.S. at 842.

¹²⁴ *Id.*

¹²⁵ *Id.* at 843.

¹²⁶ 70 F.3d 610, 615 (D.C. Cir. 1995).

interpreting the statute, and such interpretations are entitled to deference... In such a case, the question for the reviewing court is whether the agency's construction of the statute is faithful to its plain meaning, or, if the statute has no plain meaning, whether the agency's interpretation "is based on a permissible construction of the statute. (internal citations and quotations omitted) (alterations made).

Under this interpretation, HHS-OIG does not have the statutory authority to subject manufacturer rebates to AKS scrutiny. Congress *has* spoken to the precise issue of discounts *or any other reduction in price* (which clearly includes a rebate) and their relationship to the AKS. If Congress intended rebates to be subject to AKS scrutiny, it would have surely foreclosed that possibility by more narrowly defining discounts to only include "up-front discounts." However, Congress clearly did not do this.

Even assuming *arguendo* that HHS' suggested policies could advance to *Chevron* Step Two, a reviewing court would likely find them to be arbitrary, capricious, or manifestly contrary to the statute. The appropriate inquiry under *Chevron* Step Two is whether the exclusion of rebates from the definition of discounts is a "reasonable" interpretation of the statute.¹²⁷ The agency may be hard pressed to argue that a rebate is not somehow included in the broad statutory exception for discounts, and does not qualify as a "reduction in price."

- **The Secretary Lacks the Authority to Direct HHS-OIG to Take a Particular Legal Position:** It is important to note that the HHS-OIG (as well as other Inspectors General) is an independent office that operates outside of the orbit of normal agency policymaking. The HEW Inspector General Act of 1976, Pub. L. 94-505, mandated the creation of the Office of Inspector General under the Department of Health, Education and Welfare (now, HHS) Secretary. Under the 1976 law, the Act stipulated that the HHS-OIG "reports to and is under the general supervision of the Secretary...but shall not report to or be subject to supervision by any other officer,"¹²⁸ and went even further to specify that the Secretary may not "prevent or prohibit the Inspector General from initiating, carrying out, or completing any audit or investigation."¹²⁹

Since 1988, the Secretary has fully delegated to HHS-OIG authority over the anti-kickback statute, including rulemaking authority.¹³⁰ Thus, HHS-OIG exercises a significant amount of functional autonomy and is immune from political pressure from either HHS or the White House to pursue a particular policy with regard to its own regulatory authority. Simply put, to the extent HHS determines it supports a particular enforcement policy for HHS-OIG, it lacks the authority to direct the HHS-OIG to pursue such policy.

¹²⁷ See generally *Chevron U.S.A. Inc.*, 467 at 844; *Texas v. United States*, 497 F.3d 491, 506 (5th Cir. 2007) ("[C]hevron step two compels a judicial evaluation of congressional intent.")

¹²⁸ 5 U.S.C. App. § 6(a) (9), The Inspector General Act.

¹²⁹ *Id.*

¹³⁰ 53 Fed. Reg. 12,993 (April 20, 1988).

Fixed Price Discounting Present Serious Antitrust Concerns That Must Be Addressed:

The current rebate system dates back to the mid-1990s. Before that time, most manufacturers offered up-front discounts on their products in exchange for greater volume and formulary access. The current rebating practice became commonplace after the settlement of a major class action lawsuit alleging conspiratorial price-fixing and price discrimination practices by brand name drug manufacturers in the 1990s. The practice of rebating was designed to theoretically ensure that even retail pharmacies (as opposed to only managed care organizations, PBMs and mail-service pharmacies) could access beneficial discounts previously not offered to them. In order to settle the litigation, manufacturers eventually agreed that “retail pharmacies and buying groups that are able to demonstrate an ability to affect market share will be entitled to discounts based on that ability, to the same extent that managed care organizations would get such discounts.”¹³¹

The lawsuit was filed by hundreds of retail drugstore pharmacies (and was later certified into a class-action suit containing “tens of thousands of retail pharmacies, ranging in size from individual, small pharmacies to large, multi-state chains”¹³²) against essentially all the major brand manufacturers in the market at that time. The class of retailers argued that the drug manufacturers conspired together in violation of the Sherman Act to refuse to offer the retailers discounts on drug purchases that were offered to other purchasers, such as hospitals and health maintenance organizations. A subset of the original plaintiffs opted not to join the class but, nevertheless, asserted individual price discrimination claims against the brand drug manufacturers alleging violation of both the Sherman and Robinson-Patman Acts.

Eventually, many of the defendant manufacturers settled with the plaintiff retailers and, while not all of the specific terms of the settlement agreement are public, the judge presiding over the case approved an amended settlement agreement on June 21, 1996 that sufficiently addressed the plaintiff retailers’ concerns about the pricing conduct of the defendant drug manufacturers.¹³³ In approving the amended settlement agreement, the Court articulated “two commitments which it felt to be appropriate on the part of the settling defendants: (1) That a manufacturer shall not refuse to discount its goods based solely on the status of the buying entity and (2) To the extent that retail pharmacies and retail buying groups can demonstrate an ability to affect market share in the same or similar manner in which managed care entities are able, retailers will be entitled to the same types of discounts given to managed care entities for this reason.”¹³⁴ The court indicated that while “the language propounded by the amendment does not mirror precisely the language articulated by the court we believe that the amendment sufficiently addresses our stated concerns and in fact represents a firm commitment on the part of the settling defendants.”¹³⁵

¹³¹ Testimony of Sarah F. Jaggar, Director of Health Services Quality and Public Health before the House of Representatives Subcommittee on Oversight and Investigations Committee on Commerce (Sept. 19, 1996).

¹³² In re: Brand Name Prescription Drugs Antitrust Litigation, No. 94-C-897, 1996 WL 167350, at *1 (N.D. Ill. April 4, 1996).

¹³³ In re: Brand Name Prescription Drugs Antitrust Litigation, No. 94-C-897, 1996 U.S. Dist. LEXIS 8817 at *10 (N.D. Ill. June 21, 1996).

¹³⁴ *Id.* at 9-10.

¹³⁵ *Id.* at 9-11.

Since the 1996 settlement then, the predominant method by which manufacturers reduce their prices based on volume, formulary placement and other favored market treatment is through the use of back-end rebates. Now, more than 20 years later, HHS has put forth a policy that would undo this reasonable and viable compromise, and throw plans, manufacturers, and pharmacies into a world of legal uncertainties. As now FDA Commissioner Scott Gottlieb noted in a 2016 article in *Forbes*, it is Congress, and not HHS, that must undo the current rebate system if it so desires:

“Congress can enact legislation that would address the judicial precedent that gave rise to this purposely-intricate system of rebates. If insurers could demand up-front discounts, rather than back-ended rebates, and drug makers were free to offer them; then more of the markdown would come in the form of lower opening prices.”¹³⁶

While we believe Commissioner Gottlieb has misdiagnosed the problem (rebates are clearly a tool that benefits the Part D program, and not a problem), he correctly points out that until Congress acts to amend existing antitrust laws, any system that relies on mandatory fixed price discounting will not work. Attached as Exhibit I is a more in-depth discussion of the antitrust concerns presented regarding potential changes to the current rebate system.

Mandatory Fixed Price Discounting Would Disclose Confidential Information in Violation of the Trade Secrets Act: Under the Part D statute, Part D plan sponsors are required to provide CMS with information about prescription drug price concessions and rebates.¹³⁷ This provision applies the confidentiality protections from the Medicaid prescription drug rebate program (at 42 U.S.C. § 1396r8(b)(3)(D)) to all such information submitted to CMS. Specifically, these protections preclude disclosure of information submitted to CMS “in a form which discloses the identity of a specific manufacturer or wholesaler [or] prices charged for drugs by such manufacturer or wholesaler,”¹³⁸ subject to five exceptions. Only one exception allows CMS to make a public disclosure:

to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with [42 U.S.C. § 1396r-8(f)].

42 U.S.C. § 1396r-8(b)(3)(D)(v).

The SSA’s designation as “confidential” information from which “prices charged for drugs” can be derived makes disclosure of such information a crime unless specifically authorized by

¹³⁶ Scott Gottlieb, M.D., “How Congress Can Make Drug Pricing More Rational,” *Forbes*, September 12, 2016.

<https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/#59bc04853e3b>

¹³⁷ 42 U.S.C. § 1395w-102(d)(2).

¹³⁸ 42 U.S.C. § 1396r-8(b)(3)(D).



statute. In particular, the Trade Secrets Act at 18 U.S.C. § 1905 prohibits “disclosure of confidential information” by any “officer or employee of the United States or of any department or agency thereof.”

The arrangement contemplated by HHS would be contrary to the confidentiality provisions in the Part D program, and thus violate the Trade Secrets Act, because it would require public disclosure of “confidential” information. Under a fixed price discounting methodology, rebate amounts negotiated by and between manufacturers and PBMs (on behalf of their Part D plan sponsor clients) would necessarily become public if these amounts were forced to be recognized in up-front pricing. Under 42 U.S.C. §1396r-8(b)(3)(D), information reported by a Part D sponsor to CMS which allows a member of the public to derive “prices charged for drugs” to a Part D sponsor is confidential.

Fixed Price Discounting Violates the Non-interference Clause: Section 1860D-11(i) clearly prevents HHS from inserting itself into the negotiations between Part D plan sponsors and manufacturers. Preventing such interference was very clearly the intent of Congress when it created the Part D program, as evidenced by multiple Conference Report statements. This provision has long been understood as prohibiting CMS from interfering in payment negotiations between both Part D plan sponsors and pharmacies, and Part D plan sponsors and manufacturers.¹³⁹ Indeed, CMS has long taken an appropriate view of the non-interference clause’s applicability to negotiations between Part D plan sponsors and pharmacies and manufacturers, reflecting the understanding that the Part D program’s success is built upon free market competition.

A policy which specifies the very methodology by which plans, their contracted PBMs, and manufacturers negotiate over and pay for drug products is precisely the type of interference Congress intended to avoid, and which HHS has, since the creation of the Part D program, refused to take part in. Given its prior view on the plain meaning of the non-interference clause, HHS cannot now view the language differently and take action inconsistent with its plain meaning. Indeed, as noted in the pending 2019 House Labor-HHS Appropriations report,¹⁴⁰ “The Committee supports efforts to improve patient access to prescription drugs. The Committee is encouraged by recent proposals to lower costs for beneficiaries, generate savings for the federal government, and increase access to medication for Medicare beneficiaries. As CMS evaluates options for the Prescription Drug Benefit Program, the Committee expects adherence to the noninterference clause, which ensures robust competition and beneficiary value.”

¹³⁹ See House Conference Report No. 108-391 at 461 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 1840 (“In order to promote competition, the Secretary is prohibited from interfering with the negotiations between drug manufacturers and pharmacies and Part D plans.”) See also id. at 748-9 (Nov. 21, 2003), reprinted in 2003 U.S.S.C.A.N. 1808, 2105 (“[t]hese negotiations would be carried out by private plans, eager to capture market share through lower premiums, and manufacturers, willing to negotiate discounts for volume assurance. Such private sector entities are far better suited to achieve maximum discounts and lower premiums for plan participants than a disinterested Administrator.”)

¹⁴⁰ Senate Labor-HHS Report: https://appropriations.house.gov/uploadedfiles/labor_report.pdf at page 95.

As PCMA has noted elsewhere in these comments, as well as in our comments on the RFI to the 2019 Policy and Technical Changes Final Rule (seeking information on a policy that would require PBMs to pass all or some rebates on at point-of-sale), under a proposal that would require either a fixed price discounting methodology, or that all or a certain percentage of rebates or price concessions be passed through at POS, Part D plan sponsors and their PBMs will lose significant bargaining power in the negotiation of manufacturer rebates. In particular, Part D plans currently utilize rebates as negotiating tools – to lower drug prices, develop formularies that respond to consumer needs, reduce pharmacy costs, and improve the beneficiary experience at the pharmacy counter. Requiring that discounts be negotiated up-front, or in the alternative that rebates be entirely passed through at POS, would significantly hamper the ability of a PBM to negotiate with manufacturers. As a result of this *interference*, the total amount of price concessions negotiated on behalf of Part D plans by PBMs will decrease, resulting in higher prices for beneficiaries and lower cost-savings for the government.

In responding to the RFI on rebates at POS, several commenters cited the definition of “negotiated price” as supporting the notion that Congress actually intended that CMS regulate the extent to which discounts and rebates are reflected in the prices paid by beneficiaries. However, this is a fundamental misreading of the statute. More specifically, Congress has stated that negotiated prices “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations...”¹⁴¹ If Congress intended to dictate that negotiated price concessions must be passed through to beneficiaries at the POS or else fully reflective up-front of all discounts and rebates, it would have surely foreclosed the possibility that Part D plan sponsors could report negotiated price concessions used to reduce costs under the plan in other ways. As CMS previously noted, “had the Congress intended that all negotiated price concessions be passed through to beneficiaries, they would have used a phrase other than “take into account” in the definition of term ‘negotiated prices.’”¹⁴² However, Congress clearly did not do this.¹⁴³

Therefore, it is entirely unclear under what statutory authority CMS would justify its interference with Part D plan sponsors’ management of plan costs.

Any Changes Impacting Rebates Raised Significant Concerns under the Administrative Procedure Act (APA): Beyond our numerous substantive concerns, the APA presents both legal and procedural challenges to the adoption of such a policy. First, as noted below, the statutory definition of “negotiated price” contemplates the use of rebates in the Part D program, and as such, any policy that prohibits such payments would be substantively flawed under the APA. Moreover, to the extent that HHS pursues any changes in this topic area (and that they are legally permitted), the Department must still undergo notice-and-comment rulemaking procedures, as required by the APA, as such a policy would have the force and effect of law. In

¹⁴¹ 42 U.S.C. § 1395w-102(d)(1)(B).

¹⁴² 70 Fed. Reg. at 4194, 4244 (Jan. 28, 2005).

¹⁴³ See id. at § 1395w-102(d)(2).

addition, prior to finalization, all relevant subregulatory guidance would need to be developed with adequate public feedback, and all documents subject to the Paperwork Reduction Act of 1995 (e.g., reporting forms, bid tools) would require clearance from the Office of Management and Budget. Given both the known and (vast) unanticipated costs of any policy change impacting rebates, we believe it is essential that HHS conduct a thorough cost-benefit analysis to determine whether or not this proposal is consistent with the ongoing efforts by this administration to reduce regulatory costs and other burdens (consistent with a number of Executive Orders promulgated under this Administration). Moreover, CMS is surely aware that if it were to implement any proposed changes to rebate policy via its demonstration or waiver authority (CMMI, § 402 of the Social Security Act Amendments of 1967 or § 1115 of the Social Security Act), even if those statutes presented CMS with authorities to waive title XVIII or XIX provisions, they certainly do not grant CMS the authority to waive the APA.

- **The Statutory Definition of “Negotiated Price” Prohibits the Fixed Price Discounting Policy:** The Part D statute clearly requires that negotiated prices “shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations.” We are concerned that the policy changes discussed in the Blueprint RFI would be substantively flawed under the APA as arbitrary and capricious and not otherwise in accordance with law. In particular, the underlying statutory language (“take into account”) unambiguously indicates Congress intended that negotiated prices would and could be inclusive of rebates. If Congress intended to prohibit the use of rebates in the Part D program, clearly it would not have included that precise term in the definition of negotiated price, nor would they have used the language “take into account.” Moreover, even if the statutory language was found to be ambiguous, HHS’ policy changes would be inconsistent with Congress’ intent to provide Part D sponsors with flexibility in administering the Part D prescription drug benefit as a private market model. As such, a reviewing court is likely to find such policy changes as substantively invalid because they would be promulgated *ultra vires* and/or would be “arbitrary, capricious, or manifestly contrary to the statute.”

It is a settled principle of statutory construction that a court will “give effect, if possible, to every clause and word of a statute, avoiding, if it may be, any construction which implies that the legislature was ignorant of the meaning of the language that it employed.”¹⁴⁴

Applying this principle to the HHS proposal, a court could easily conclude that eliminating rebates as a factor in the calculation of negotiated price is effectively reading out of the statute a word that Congress clearly understood the meaning of. As the courts have noted more recently, a statute should be construed “so as to avoid rendering superfluous” any statutory language.¹⁴⁵

- **Restricting or Prohibiting Rebates Requires Notice-and-Comment Rulemaking To Comply with the APA:** As a threshold matter, even assuming *arguendo* that HHS can

¹⁴⁴ *Montclair v. Ramsdell*, 107 U.S. 147, 152 (1883).

¹⁴⁵ *Astoria Federal Savings & Loan Ass’n. v. Solimino*, 501 U.S. 104, 112 (1992).

change its negotiated prices policy to require that negotiated prices somehow exclude rebates (as discussed above, we believe it lacks the authority to do so), doing so would require HHS to undertake notice-and-comment rulemaking because such a change constitutes a legislative rule. CMS has already engaged in rulemaking to implement section 1860D-2(d)(1)(B) of the SSA, which requires that Part D plan sponsors provide beneficiaries with access to negotiated prices for covered Part D drugs. Although CMS defines the terms “negotiated prices” and establishes a requirement that qualified prescription drug coverage include access to negotiated prices in its implementing regulations, the agency has never taken the position that, despite the plain text of the statute, negotiated prices do not include rebates.

As a result, even assuming solely for purposes of these comments on the Blueprint RFI that the statute permitted HHS to adopt such a change, imposing it would be effectively introducing a new condition that Part D plan sponsors must satisfy in order to offer qualified prescription drug coverage. Restricting or eliminating the use of rebates in the Part D program constitutes a legislative rule and falls subject to the APA’s and the Social Security Act’s notice-and-comment rulemaking procedures. This type of requirement would effectively impose a “legally binding obligation” on Part D plan sponsors and their contracted PBMs to alter the way in which they currently negotiate drug prices with manufacturers. Because such a requirement would have the “force and effect of law,” HHS would need to adhere to the APA’s and SSA’s procedural strictures before finalizing it.¹⁴⁶

PCMA Recommendation: HHS should follow the data with respect to rebates and focus its policies on the list prices set by manufacturers. Manufacturer rebates produce significant savings in the Part D program in the form of overall lower costs and lower premiums. Restricting or prohibiting rebates would increase overall net drug costs, plan premiums, and administrative costs, and result in unclear benefits to consumers at the pharmacy counter. We urge HHS to recognize that any fixed price discount approach would require a major restructuring of Part D including recontracting and revising bids. Even assuming changes to the current rebate structure is appropriate, HHS both lacks the authority to subject rebates to AKS scrutiny, and must also contend with the significant antitrust concerns regarding up-front discounts. Finally, the contemplated policy raises significant concerns under both the Part D non-interference clause and the APA.

¹⁴⁶ See generally Social Security Act § 1871(a)(2).

**Creating Incentives to Lower List Prices – III (C) p. 22697-8
Fiduciary Duty for Pharmacy Benefit Managers****Background**

HHS asks whether rebates and fees based on a percentage of the list price of a drug create an incentive to favor high list prices. HHS also asks the degree to which beneficiaries are negatively impacted by these incentives, and how HHS could reset these incentives to prioritize lower out-of-pocket costs for consumers, better adherence, and improved outcomes for patients. HHS seeks comment on whether PBMs should be obligated to act solely in the interest of the entity for which they are managing pharmaceutical benefits, and whether they should be forbidden from receiving any remuneration from manufacturers. HHS also seeks comment on whether PBM contracts should be forbidden from including rebates or fees calculated as a percentage of list price, and on the impact and unintended consequences of imposing a fiduciary duty on PBMs on behalf of either the plan or the consumer.

Discussion

The Concept of Imposing a Fiduciary Duty on PBMs Reflects a Fundamental Misunderstanding of the Role of PBMs in the Drug Supply Chain: In the Blueprint RFI, HHS correctly identifies high list prices as a growing concern impacting both consumers at the pharmacy counter and federal healthcare coffers. However, rather than proposing policy solutions that would address the root cause of these list prices (prices that, as HHS readily admits,¹⁴⁷ are set at the total discretion of drug manufacturers),¹⁴⁸ HHS identifies what it perceives as incentives in the system for manufacturers and PBMs to conspire to raise list prices. Citing no evidence other than the growth in list prices, HHS both fails to recognize the role PBMs play in generating significant savings for consumers through formulary negotiations and utilization management tools (by way of lower negotiated drug costs, and low premiums), as well as the significant costs that would be forced on the system if a fiduciary duty were imposed on PBMs (whether in just the MA/Part D market, or across all health plans). As CMS itself just recognized – not one month ago, after the release of the Blueprint RFI: “[t]his upward revision to projected rebates is a major reason for decreases in overall Part D costs.”¹⁴⁹

At the outset we note that HHS’ policy proposal raises a number of immediate questions regarding the scope and meaning of the term “fiduciary.” First, HHS appears to contemplate a duty, on the one hand, to the plan (“Should PBMs be obligated to act solely in the interest of the entity for whom they are managing pharmaceutical benefits?”) and, on the other, to the

¹⁴⁷ “Well, listen, who sets their drug price? The drug company sets their drug price. So in the first instance, the drug company is to blame for the price they set. They’re setting the price, okay? Nobody’s controlling that.” Statements by Alex Azar to the Washington Post (June 20, 2018).

¹⁴⁸ “Now let’s start -- first, the drug companies set their list prices. OK? So first, they’re accountable for -- for setting their prices.” *The Cost of Prescription Drugs: Examining the President’s Blueprint ‘American Patients First’ to Lower Drug Prices: Hearing before the Committee on Health, Education, Labor & Pensions, Senate, 115th Cong. (2018)* (Testimony of Alex Azar).

¹⁴⁹ 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds at 143 (June 5, 2018). Emphasis added.



consumer (“What effect would imposing this fiduciary duty on PBMs on behalf of the ultimate payer (i.e., consumers) have on PBMs’ ability to negotiate drug prices?”). Second, in his recent testimony before the Senate Health, Education, Labor & Pensions (HELP) Committee, Secretary Alex Azar appeared to back-step on this proposal, noting:

“The word fiduciary was meant more directionally than in any type of incorporation or suggestion of state law type financial fiduciary obligations. It was meant to get at, as I said in my opening, just the receipt of compensation. Our view is that pharmacy benefit manager that has been hired by other employers, or individuals, or insurance plans to negotiate the best deal possible against the drug company, ought not to be getting any compensation from those drug companies. They shouldn't be getting the holdback of rebates. They shouldn't be getting administrative fees that are based as a percent of list price and they should not be getting other types of fees from Big Pharma. They ought to be looking only out for the interests of their clients. That's the proposal that we – that we want to get comment on.”¹⁵⁰

We therefore comment below on both this more nuanced policy, which would prohibit any remuneration from manufacturers to PBMs, as well as the concept in the Blueprint RFI of applying a common law *legal duty* of a fiduciary on PBMs.

Finally, HHS does not indicate in its Blueprint RFI whether this proposed policy is aimed solely at the Medicare Advantage and Part D marketplaces, or whether it intends to impose a fiduciary duty on PBMs in commercial markets, Medicaid managed care, and the Exchange-subsidized individual market as well. Given HHS’ limited authority to regulate plans in the commercial market, our comments below largely address issues specific to the Part D program.

Prohibiting Any Remuneration Between PBMs and Manufacturers Would Harm

Beneficiaries: As noted above, in his testimony to the Senate HELP Committee on June 12, Secretary Azar clarified to the Senators in attendance that, in using the term “fiduciary” in the Blueprint RFI, HHS was attempting to get at all of the remuneration that currently flows between PBMs and manufacturers. In particular, HHS believes that, as a contractor to the Part D plan sponsor, a PBM should not be receiving any compensation from manufacturers. However, rather than addressing the key problem identified by HHS (high list prices), such a policy would harm consumers by prohibiting fair market value payments by manufacturers and pharmacies for services currently performed by PBMs, increasing out-of-pocket spending and raising premiums in the long-term as Part D plan sponsors shoulder the financial burden of paying for necessary services currently funded by manufacturers, pharmacies, and other third parties.

Importantly, the policy appears to reflect a fundamental misunderstanding of how the Part D program operates. Inherent in Secretary Azar’s comments is a belief that PBMs, as contractors to Part D plan sponsors, are able to extract significant profit from the drug supply chain in a way

¹⁵⁰ *Id.* (emphasis added).

that is either opaque or not otherwise accounted for in existing price reporting mechanisms (such as Direct and Indirect Remuneration, or DIR). As discussed below, this is untrue.

- **PBMs Charge Manufacturers Fees for Services that Benefit Consumers:** Prohibiting remuneration between PBMs and manufacturers would directly harm beneficiaries as it would reduce the level and scope of services currently offered. For example, manufacturers currently are authorized to pay PBMs “bona fide service fees” for the provision of a range of services that benefit the overall Part D program. HHS already recognizes in its regulations (42 CFR § 423.501) and DIR Reporting Guidelines (see field entitled “Bona Fide Services Fees” in Medicare Part D Reporting Requirements for 2017¹⁵¹) the value and legitimacy of such fees, and also collects detailed reports on such amounts. HHS defines these fees as fees paid by a manufacturer to an entity and meeting all of the following conditions:
 - The fee must be paid for a bona fide, itemized service that is actually performed on behalf of the manufacturer;
 - The manufacturer would otherwise perform or contract for the service in the absence of the service arrangement;
 - The fee represents fair market value; and
 - The fee is not passed on, in whole or in part, to a client or customer of an entity, whether or not the entity takes title to the drug.

Prohibiting any and all remuneration between manufacturers and PBMs would de facto prohibit the performance of these vital services, reducing the ability of PBMs to negotiate and administer the Part D benefit, reducing negotiating tools, and increasing overall plan costs as Part D sponsors are forced to shoulder the cost of services currently funded by other entities in the drug supply chain.

HHS’ proposal also raises significant questions about the downstream impact of such a proposal on commercial and other healthcare markets, not to mention within the Medicare program itself, and the Medicaid program. Given the critical role that bona fide services fees play throughout the insurance industry, as well as the overall Medicare and Medicaid programs, what would be the impact of eliminating these fees in a single (but large) program? CMS has itself noted that bona fide service fees in the Part D context apply in the same manner as fees for such services apply in Medicare Part B (for Part B drugs) and Medicaid.¹⁵²

¹⁵¹ CMS memorandum from Jennifer Harlow, “Final Medicare Part D DIR Reporting Requirements for 2017.” May 30, 2018.

¹⁵² 77 Fed. Reg. 22072, 22095 (April 12, 2012).



Finally, and as discussed in more detail below, a policy which imposes restrictions on the types of arm's length transactions Part D sponsors and manufacturers can engage in is precisely the type of policy Congress intended to prohibit in enacting the non-interference clause.

- **HHS' Existing Regulations Already Prohibit PBMs from Profiting from Manufacturer Fees:** Simply put, there is no “runaway profit” opportunity in Part D for Part D plan sponsors or their contracted PBMs. Congress and CMS have put multiple mechanisms in place to prevent abuse in Part D, and thus it is unreasonable for HHS to argue that prohibiting all remuneration between PBMs and manufacturers is necessary to curb abuse. Some of the many other programmatic features that limit Part D plan sponsor and PBM profits include:
 - **Risk Adjustment.** Plan profitability is affected by the direct subsidy, which is a risk-adjusted, capitated payment. Drug-level plan liability before risk adjustment may not be fully indicative of a plan's actual profit or loss for members taking a particular drug.
 - **Risk Corridors.** Plan sponsors participate in the risk corridor program, which is a risk-sharing arrangement with CMS where a portion of gains or losses are shared with CMS. Unexpected windfalls that exceed 5% from a filed bid target amount, including higher-than-anticipated rebates, must be shared with CMS.
 - **Medical Loss Ratio (MLR) Rebates.** Part D plan sponsors that do not meet the 85% MLR requirements must remit funds back to CMS.
 - **Reconciliation.** Part D subsidies, such as federal reinsurance, are reconciled after the end of the plan year using actual expense and revenue items.
 - **Prescription Drug Plan Margin Requirement.** CMS has a corporate margin requirement that limits the margin on Part D business as compared to another line of the company's business. CMS requires plan sponsors' projected Part D gain/loss margin to be within 1.5% of the sponsor's corresponding Medicare Advantage margin. If the Part D sponsor's corporate margin requirement instead is based on its non-Medicare business, CMS requires the projected aggregate Part D margin as a percentage of revenue to be within 1.5% of the Part D sponsor's corporate margin requirement.
 - **Actual vs. Expected Margin.** Plan sponsors report actual vs. expected margin for a three-year period in the supporting documentation included in the initial bid submission. CMS desk reviewers rely on this comparison to evaluate proposed plan sponsor margin during the bid review process.

- **Related Party Arrangements.** CMS requires all plan sponsors in a related-party arrangement to demonstrate that the margin of the related party is reflected in the bid margin. Thus, a Part D plan's PBM margin cannot be significantly greater than the Part D plan margin without affecting its ability to meet its margin requirement.
- **One-Third Financial Audits.** One third financial audits specifically test the entire Part D rebate continuum from the Part D Bid to the Part D Payment Reconciliation for a given contract year.
- **Annual DIR Reporting.** This report includes detailed DIR which requires the Part D sponsors to report on plan and PBM – retained rebates. The process is transparent to CMS.
- **Desk Review / Bid Audit.** CMS contracts with independent third parties to review and audit bid submissions to evaluate compliance with bid requirements and applicable actuarial standards of practice.

Further, the HHS Office of the Actuary will not approve a bid if the plan sponsor is consistently off with its projections. Likewise, HHS performs audits to ensure proper bid protocols are followed.

- **HHS' Proposal Raises More Questions than Answers:** Perhaps most importantly, HHS' policy suggests a drug supply chain that functions under entirely different rules than the current one, raising a number of vital questions that must be first answered by HHS, including:
 - Given that HHS' proposal would entirely eliminate the current system of back-end rebates in which manufacturers and PBMs (on behalf of their Part D plan sponsor clients) negotiate for volume, formulary placement and utilization management, how else does HHS intend Part D plans to negotiate lower drug prices?
 - In the Blueprint RFI, on multiple occasions, HHS extolls the virtues of PBM negotiating tools to lower drug costs. For example, HHS contemplates utilizing Part D tools to lower drug costs in the Part B program. HHS also proposes to give PBMs even *more* flexibility to control drug costs through the use of enhanced formulary tools. How would eliminating all remuneration between PBMs and manufacturers impact HHS' simultaneous efforts to increase the use of PBM tools in other areas of the Medicare program?
 - Assuming HHS' desired price structure involves a fixed price discounting policy in lieu of back-end rebates (as discussed more fully above in III (C) (pp. 76-93)), how does HHS intend to circumvent the 1990s-era *In re Brand Name Prescription Drugs Antitrust Litigation* settlement under which the parties effectively agreed to eliminate

such discounts? Will the manufacturers that settled the class-action lawsuit 22 years ago and paid nearly half a billion dollars in damages agree to differential up-front discounts by class of trade?

- Does HHS' "fixed price discounting" proposal contemplate a single fixed price across all PBMs and plans? If yes, how would such a single discount be negotiated under current anti-trust laws? If yes, would NOT such a policy necessarily raise prices across the board given that all competition would be effectively eliminated? If not, and assuming PBMs can still negotiate unique net prices with manufacturers, then how would such a system eliminate rebates, given the need to reconcile payments across different purchasers and the likelihood that manufacturers would continue selling at a higher, or at least different, price to wholesalers and retailers?
- Would imposing a requirement that PBMs act solely in the interest of the Part D plan sponsor prohibit the practice of PBMs aggregating rebates across multiple plans? Under current practice, PBMs achieve savings through the use of economies of scale and purchasing power, negotiating with manufacturers across multiple Part D plans so as to achieve greater savings than a single plan could on its own. Assuming HHS intends to prohibit such a practice on the basis that it is not "in the interest" of the Part D plan sponsor, does HHS' proposal take into account the significant increase in drug costs that would result from reduced negotiating leverage?
- How is HHS' policy position consistent with ongoing efforts to introduce commercial-like tools in the Medicaid program? The recently approved Massachusetts Medicaid section 1115 waiver, under which CMS has suggested that a state could incorporate commercial-like negotiating tools (including closed formularies in exchange for forgoing all Federally mandated rebates under the Medicaid Drug Rebate Program), relies on the ability of payments to flow between PBMs and manufacturers. An initiative that would eliminate all remuneration between PBMs and manufacturers would make it impossible to implement programs such as Massachusetts' attempts to better control drug spending.

Imposing a Fiduciary Duty on PBMs Raises Significant Legal Concerns: While the Secretary in testimony recently appeared to back-pedal on HHS' proposal to impose a legal fiduciary duty on PBMs, given the proposal's inclusion in the Blueprint RFI, we are obligated to address the significant concerns raised by such a policy as it was this policy as set forth in the Federal Register, not the Secretary's testimony before Congress, on which the Department has solicited comments. Not only would imposition of a fiduciary duty be wholly inconsistent with how the term fiduciary has been used both in common law and the Employee Retirement Income Security Act (ERISA), it would also be inconsistent with the Administration's policies in other sectors not to impose additional and unnecessary costs on private sector entities.¹⁵³ A

¹⁵³ "Presidential Memorandum on Fiduciary Duty Rule," Memorandum for the Secretary of Labor (February 3, 2017).

fiduciary duty also plainly implicates and conflicts with existing Part D statutory authority, as we discuss below. Moreover, to the extent HHS adopts a policy which prohibits remuneration between manufacturers and PBMs, such a policy would very clearly violate the Part D non-interference clause at section 1860D-11(i) of the Social Security Act.

- **PBMs are Third Party Administrators that Lack the Discretionary Authority of Fiduciaries:** Under current practice, PBMs typically serve in administrative and advisory roles for health plans, performing claims processing and other administrative tasks, but do not exercise discretionary authority over plan assets or make decisions about the scope and design of benefits being offered. Indeed, under current rules (according to both the Department of Labor (DOL) and federal courts) PBMs are typically considered Third Party Administrators (TPAs) “who have no power to make any decisions as to plan policy, interpretations, practices or procedures, but who perform [certain] administrative functions for an employee benefit plan... .”¹⁵⁴ Yet, it is this type of discretionary decision-making – which is decidedly not present in the PBM context – that is precisely the behavior that defines a fiduciary under law.

In layperson’s terms, a fiduciary is an entity or person in a position of trust that acts in the best interest of the entity or person to whom the duty is owed.¹⁵⁵ ERISA, under which most modern day discussions of fiduciary duty operate, closely tracks (and relies upon), this common law definition of “fiduciary.”¹⁵⁶ By extension, ERISA defines a fiduciary as an entity or person as a de facto fiduciary if:

(i) he or she exercises any discretionary authority or discretionary control over the management of the plan or exercises any authority or control over management or disposition of plan assets; or

(ii) he or she renders investment advice for a fee or other compensation, direct or indirect, with respect to any moneys or other property of the plan; or

(iii) he or she has any discretionary authority or discretionary responsibility over the administration of the plan.

¹⁵⁴ 29 CFR 2509.75-8 - Questions and answers relating to fiduciary responsibility under the Employee Retirement Income Security Act of 1974.

¹⁵⁵ “The common law understanding of fiduciary status is not only the proper starting point in this analysis, but is as specific as it is venerable. Fiduciary status turns on the existence of a relationship of trust and confidence between the fiduciary and client... Indeed, “[t]he development of the term in legal history under the Common Law suggested a situation wherein a person assumed the character of a trustee, or an analogous relationship, where there was an underlying confidence involved that required scrupulous fidelity and honesty.” *Chamber of Commerce of the United States v. United States DOL*, 885 F.3d 360 (5th Cir. 2018).

¹⁵⁶ “[ERISA] regulations captured the essence of a fiduciary relationship known to the common law as a special relationship of trust and confidence between the fiduciary and his client. See, e.g., George Taylor Bogert, et al., *Trusts & Trustees* § 481 (2016 update).” *Chamber of Commerce of the United States v. United States DOL*, 885 F.3d 360 (5th Cir. 2018). “That Congress did not place “fiduciary” in quotation marks indicates Congress’s decision that the common law meaning was self-explanatory, and it accordingly addressed fiduciary status for ERISA purposes in terms of enumerated functions.” See *John Hancock Mut. Life Ins. v. Harris Tr. & Sav.Bank*, 510 U.S. 86, 96-97, 114 S. Ct. 517, 126 L. Ed. 2d 524 (1993).

29 U.S.C. § 1002(21)(A) (emphasis added.) This duty is not insignificant, requiring a fiduciary to act solely in the interests of the plan participant. ERISA imposes a “prudent man standard of care” upon fiduciaries, requiring a fiduciary to “discharge his duties with respect to a plan solely in the interest of the participants and beneficiaries.”¹⁵⁷ Fiduciaries are prohibited from hiring themselves or affiliates to provide services unless the fiduciary charges *no additional fee*, and imposes restrictions on the types of transactions that plans may have with “parties of interest” including fiduciaries and service providers.

PBMs do not provide the types of services, nor do they engage in the type of relationships, that are associated with fiduciaries in either the common law or ERISA contexts. PBMs are TPAs to health plans, providing administrative services pursuant to a written agreement. PBMs *do not* make plan benefit decisions, or exercise any of the discretionary authority typically associated with fiduciaries. Imposing this duty, accompanied by the extraordinary responsibilities, costs, and penalties, is thus inappropriate and misguided.

- **The Role of a PBM is Inconsistent with a Fiduciary Duty to the Consumer:** In the Blueprint RFI, HHS asks: “What effect would imposing this fiduciary duty on PBMs on behalf of the ultimate payer (i.e., consumers) have on PBMs’ ability to negotiate drug prices?” Given the existing contractual duty imposed upon PBMs to their client, the Part D plan sponsor, we find this idea both concerning and of questionable merit. A number of important questions for HHS to consider include:
 - Under existing Part D statutory authority at 1860D-4(b)(3) of the Social Security Act, Part D plans are explicitly afforded the ability to adopt a formulary which specifies which Part D drugs are generally available – and not available – under the plan (subject to the appeals and exceptions policies). If a PBM is a fiduciary to the end consumer, could a PBM maintain a formulary to the extent it limits any of the benefits available to a beneficiary? This proposal of undying fealty to the end consumer is especially suspect because in the Blueprint document released by the White House, the Administration raised the question whether the two drug per category or class rule, 42 C.F.R. § 423.120(b)(2)(i), should be replaced with a policy under which one drug per category or class should be required.¹⁵⁸
 - How could a PBM impose utilization management requirements on access to a covered Part D drug (such as through prior authorization or step therapy, to the extent permitted under the PBM’s contract) such that it would have the effect of denying a beneficiary access to a particular drug if it owes a fiduciary duty to a consumer?

¹⁵⁷ 29 U.S.C. § 1104(a).

¹⁵⁸ American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (May 2018) at 20. Please note that we fully support this concept, as addressed elsewhere in these comments.

- In the absence of these tools, what ability would PBMs still have available to control costs?
- Could a PBM maintain preferred pharmacy networks to the extent they impose additional costs on beneficiaries who seek to access their benefits at the pharmacy of their choice?
- How would a PBM reconcile the need to lower costs for beneficiaries (through the use of, for example, utilization management tools) with the competing need to provide beneficiaries with completely unhindered access to their benefits?
- **The Role of a PBM is also Inconsistent with a Fiduciary Duty to the Plan:** The Blueprint RFI also contemplates a similar (or alternative) duty to the plan sponsor. While PBMs and Part D plan sponsors have the freedom to engage in a variety of contractual relationships with each other (including with a wide range of duties and obligations), an independent fiduciary obligation also raises significant concerns and questions. For example:
 - If a PBM is a legal fiduciary to its contracted plan sponsor, could a PBM still negotiate rebates and price concessions across multiple books of business or would it have to negotiate separately for each plan, thus not taking full advantage of its scale and its full customer base?
 - What happens when the fiduciary duty conflicts with HHS' rules or guidance (e.g., what is in HHS' interest may not be in plan's interest)? For example, if HHS establishes reporting requirements for downstream contractors (including PBMs) that result in disclosure of information that is not in the best interest of the Part D plan sponsor, would a PBM be forced to breach its duty and thereby subject itself to liability under state common law principles of fiduciary relations?
 - Would a fiduciary duty outright prohibit any remuneration to a PBM from a manufacturer? Alternatively, would "self-dealing" concerns make it difficult to determine whether such remuneration is prohibited, creating pricing model uncertainties?
- **Imposing a Fiduciary Duty Violates the Non-Interference Clause:** As noted above, to the extent HHS intends to disrupt existing negotiations between Part D plan sponsors, their PBMs, and manufacturers, such action would plainly violate the non-interference clause. Under section 1860D-11(i) of the Social Security Act, HHS may not "interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors" and also may not "require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." By prohibiting remuneration between a manufacturer and a plan

sponsor's contracted PBM, HHS is clearly disturbing the very negotiations which result in cost savings for plans, and thus, the Part D program overall. Since the creation of the Part D program, CMS has carefully – and appropriately – avoided “direct interference” in the negotiations between manufacturers and plans, but by prohibiting a plan's subcontracted entity from negotiating rebates and price concessions on drugs, CMS would do precisely this.

Under a proposal that would prohibit Part D plan sponsors and PBMs from negotiating rebates with manufacturers, such sponsors and their PBMs will lose a significant amount of bargaining power in the negotiation of lower drug prices. Part D plans currently use rebates as negotiating tools – to lower drug prices and develop formularies. As recently as 2014, CMS has reiterated its position that “the intent of 1860D–11(i) is to ensure that we do not create any policies or become a participant in any discussions that could be expected to interfere with negotiations leading to the selection of drug products to be covered under Part D formularies.”¹⁵⁹ Yet, HHS is now proposing to step directly in between manufacturers and Part D plan sponsors, and dictate the very details of the pricing arrangements between the parties. This clear interference will have the very obvious result of impacting drug formulary development and placement. Simply put, under the plain wording of the statute, CMS may not interfere in these negotiations.

- **A Fiduciary Duty is Inconsistent with the Part D Statute:** As noted above, whether HHS chooses to impose a fiduciary duty on PBMs to their contracted plans, or directly to the consumer, imposing such legal obligations would conflict with numerous existing statutory provisions in the Part D program. Among other conflicts, a fiduciary duty could: (1) conflict with a Part D plan's statutory authority to create and develop (through their contracted PBMs) formularies (under section 1860D-2(b)(3) of the Social Security Act) to the extent a formulary limits the drugs available to a consumer; (2) conflict with a PBM's ability to implement medication therapy management programs and utilization management protocols (as authority under section 1860D-2(c)); and (3) conflict with a PBM's ability to establish preferred pharmacy networks (under section 1860D-4(b) of the Social Security Act).
- **A Fiduciary Duty Raises A Number of Major Policy Concerns:** In addition to being inconsistent with the legal duties traditionally associated with fiduciaries, as well as impermissible under current laws and regulations, imposing a fiduciary duty on PBMs raises significant policy concerns, including:
 - Imposing a fiduciary status on PBMs would create conflicting obligations for PBMs. For example, and as noted above, a PBM's use of UM tools that reduces costs overall, may result in higher costs or less access for *some* participants.

¹⁵⁹ 79 Fed. Reg. 29,844, 29,874 (May 23, 2014).

- Given the special duty imposed upon fiduciaries, as well as several penalties for failure to perform, legal liabilities and administrative costs for plans would necessarily increase, increasing overall costs in the Part D program.
- Increased legal liability and conflicting obligations between client contracts would result in much lower savings (through lower rebate and price concession negotiations) and much higher drug costs (through less use of UM tools).
- Value-based contracting would be undermined by fiduciary status for PBMs. In particular, to the extent a value-based arrangement resulted in “fiduciary self-dealing” (i.e. fees contingent on performance), these arrangements could be prohibited.

Finally, to the extent a fiduciary duty forced PBMs to negotiate only on a single book of business, administrative costs (revising contracts, etc.) would skyrocket as would drug costs, as manufacturers likely would be less willing to give as deep price concessions for the smaller populations in single plans.

- **Imposing a Fiduciary Duty on PBMs is Inconsistent with this Administration’s Vision for Private Sector Success:** On March 15, the Fifth Circuit vacated, in its entirety, amendments to Rule 29 C.F.R. § 2510.3-21 (“Fiduciary Rule”), codifying the Obama-era’s expansive definition of the term “investment advice fiduciary” as applied under ERISA and the Internal Revenue Code. The Trump administration strongly opposed the Fiduciary Rule, directing in a February 2017 Memo to the Secretary of Labor to rescind the rule if DOL determines the rule is a net negative. In light of the Administration’s position in the Fiduciary Rule case, imposing a new duty on PBMs would be inconsistent with its stated goals of: (1) Ensuring access to benefits; (2) Not disrupting current program offerings; and (3) Avoiding rising costs due to burdensome regulations and increased litigation.

PCMA Recommendation: PCMA encourages HHS to focus on the root cause of rising drug prices – the list prices set by manufacturers. Imposing costly, new legal duties on PBMs will merely increase Part D programmatic costs and reduce the overall beneficiary experience by prohibiting payment for necessary services. In addition, prohibiting remuneration between PBMs and manufacturers will restrict necessary transactions in the Part D program, reduce PBM negotiating power, and do little to reduce manufacturer incentives to maintain and raise high list prices.

**Create Incentives to Lower List Prices – III (C) p. 22698
Inflationary Rebate Limits****Background**

HHS is concerned about the impact of limiting manufacturer rebates on brand and generic drugs in the Medicaid program to 100% of AMP. In particular, HHS seeks comment on whether or not this policy allows manufacturers to take excessive price increases without facing the full effect of the inflationary penalty established by Congress in the Affordable Care Act.

Discussion

The statutory cap on the inflationary penalty incentivizes some manufacturers to impose extreme price increases: The statutory cap on the inflationary penalty encourages manufacturers that have already exceeded the 100% limit to impose unlimited price increases with no consequences. To help keep drug list prices in line, PCMA recommends that HHS work with Congress to remove this cap.

Under current law, as revised by the ACA, a drug manufacturer for most single-source and innovator multiple-source drugs must pay a “basic rebate,” which is defined as the greater of either: the minimum rebate percentage of 23.1 percent of AMP, or the difference between AMP and the “best price” per unit. In addition to a basic rebate, a manufacturer (of both brand and generic drugs) may also be required to pay an “additional rebate” (also referred to as the CPI Penalty) in certain cases, where the price for a drug increases at a rate that exceeds the inflation rate (referred to as CPI-U).¹⁶⁰ If a manufacturer has increased a product’s price faster than the CPI-U over the time the drug has been on the market, the manufacturer selling that product is required to rebate an additional amount to Medicaid that is equal to the amount by which the price of the product has exceeded the rate of inflation. In the ACA, Congress made a number of changes to manufacturer rebate obligations, including: (1) increasing the basic rebate from 15.1% to 23.1%; (2) changing the rebate obligations for manufacturers of “line extensions”; and of import for this discussion; (3) capping the unit rebate amount to 100% of the AMP.

As a result of this “cap” on inflationary penalties, manufacturers whose rebate obligations exceed 100% of AMP have no incentive in place to stem price increases. In recent years, the inflationary component of the Medicaid rebate has become an increasingly large portion of the overall brand drug rebate as manufacturers are no longer incentivized to keep list prices low for highly rebates drugs.¹⁶¹ To understand the magnitude of this growing problem, a recent OIG

¹⁶⁰ Social Security Act § 1927(c)(2). The “additional rebate” is designed to guarantee that prices of prescription drugs paid by Medicaid do not exceed the inflation rate, as measured by the CPI. Essentially, CMS “recaptures” the excess of the AMP for a covered outpatient drug over the price of the drug increased by the CPI. See also <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html>.

¹⁶¹ MACPAC. May 2018. Medicaid Payment for Outpatient Prescription Drugs. Available at: <https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf>



analysis found that more than *half* of total brand drug rebates for a sample of brand drugs in 2012 were attributable to the inflationary component.¹⁶²

Studies have looked at the impact of the ACA inflationary cap on drug prices, and found that the cap encourages manufacturers to institute “excessive” annual price increases, which previously were penalized by higher Medicaid rebates.¹⁶³ Together, these analyses suggest that the Medicaid program could benefit from removing the inflationary caps currently in place due to the ACA to keep list prices low and, in the case of price increases, to generate even more rebates for the Medicaid program. Indeed, the Medicaid and CHIP Payment and Access Commission (MACPAC) has already examined various approaches to encouraging lower drug prices in the Medicaid program and recommended “graduating” the CPI penalty.¹⁶⁴ Removing (or increasing) this cap would expose manufacturers to rebates for excessive inflationary increases and prevent manufacturers from raising their prices in Medicaid faster than the rate of inflation.

PCMA Recommendation: PCMA recommends removing the cap on the inflationary penalty in the Medicaid Drug Rebate Program to discourage drug manufacturers from imposing excessive increases to list prices.

¹⁶² See Office of the Inspector General (OIG). 2015. Medicaid rebates for brand name drugs exceeded Part D rebates by a substantial margin. Available at: <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>. The CBO has found similar levels of inflationary rebates. See <https://www.cbo.gov/budget-options/2013/44899>.

¹⁶³ T. Horn and S. Dickson., Modernizing And Strengthening Existing Laws To Control Drug Costs, Health Affairs Blog, March 31, 2017 (available at: <http://healthaffairs.org/blog/2017/03/31/modernizing-and-strengtheningexisting-laws-to-control-drug-costs/>)

¹⁶⁴ MACPAC. October 2016. Medicaid Prescription Drugs Spending: Approaches to Cost Containment. Available at <https://www.macpac.gov/wp-content/uploads/2016/10/Medicaid-Prescription-Drugs-Spending-Approaches-to-Cost-Containment.pdf>.

**Creating Incentives to Lower List Prices – III (C) p. 22698
Exclusion of Certain Payments, Rebates, or Discounts from the Determination of Average
Manufacturer Price and Best Price**

Background

HHS is interested in learning more about the effect of excluding payments received from, and rebates or discounts provided to PBMs, from the determination of Average Manufacturer Price (AMP) and best price and the impact it would have on list prices, and public and private payers.

Discussion

PCMA believes there are both strong legal and policy grounds to keep in place the current treatment of rebates for purposes of calculating AMP and best price: The current exclusion of certain manufacturer rebates and discounts from AMP and best price plays a critical role in keeping in place incentives for manufacturers to negotiate steep discounts with payers (and their contracted PBMs). Absent these exclusions, manufacturers would face significant incentives to *increase* their prices, counter to the goals of HHS' Blueprint RFI to *lower* drug pricing. In particular, and as discussed in more detail below, removing or altering the exclusion of rebates from best price and AMP would have negative consequences throughout the drug supply chain as manufacturers would be exposed to a system (problematically) designed to penalize discounts, competitive pricing, and value-based purchasing. As a result, rather than incentivizing lower list prices, such changes would hamper the ability of PBMs to negotiate discounts and rebates and drug prices would increase.

- **The History of the Medicaid Drug Rebate Program Offers a Cautionary Tale for HHS' Proposal:** Congress created the Medicaid Drug Rebate Program under the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) to ensure that Medicaid receives a net price that is consistent with the lowest or best price for which manufacturers sold the drug.¹⁶⁵ In particular, under the program, manufacturers participating in the program must offer a basic rebate equal to: (1) 23.1% of AMP; or (2) AMP minus best price (statutorily defined as the lowest price available to any wholesaler, retailer, provider, or paying entity excluding certain governmental payers), whichever is greater.¹⁶⁶

One unintended consequence of the program was the incentives it introduced for manufacturers to raise, rather than lower, their prices (so as to avoid implicating best price and paying a rebate greater than 23.1%). Thus, following the enactment of the rebate program, manufacturers began raising their prices and the federal and state savings achieved through the Medicaid rebate program were offset by increased government

¹⁶⁵ "Medicaid Payment for Outpatient Prescription Drugs," MACPAC Issue Brief (May 2018).

¹⁶⁶ Social Security Act § 1927(c)(1)(C).

spending on drugs purchased by other federal – and state – supported providers.^{167,168} To correct this situation, Congress included in the Veterans Health Care Act of 1992 legislation intended to extend relief from increased prices to other governmental payers of drugs.¹⁶⁹ As a result of the 1992 legislation (as well as subsequent legislative efforts in 2003¹⁷⁰ and 2010¹⁷¹), manufacturer prices to government payers decreased as PBMs were able to negotiate significant discounts and rebates with manufacturers, without the manufacturer resetting best price and increasing rebate liability.

As HHS now looks to make changes to a nearly 30-year-old system, it should consider the perverse incentives changes to AMP and best price rules could re-introduce into the system, and remember the important history lesson of the early 1990s.

- **Changes to AMP and Best Price Will Have Significant Impacts throughout the Drug Supply Chain:** As noted above, PBM rebate exclusions from AMP and best price are critical to the success of rebate negotiations, as without them, manufacturers might be reluctant to offer rebates at the risk of setting a new best price or impacting AMP. For example, to the extent that rebates are *included* in the calculation of AMP and best price, both the price that a manufacturer must offer state Medicaid programs, as well as the amount of rebates a state will collect, will decrease. While HHS may believe that such a policy will reduce the incentives for rebates and increase the incentives for manufacturers to simply offer lower list prices, there is no evidence that manufacturers will “make up” for the reduced rebates through lower list prices. Instead (and as noted elsewhere in these comments), absent an HHS policy that directs manufacturers to lower their list prices, the most logical result of a policy that removes the rebate exclusion from best price is an increase in net drug prices as manufacturers reduce rebates and leave existing list prices intact.

So, too, a policy which removes the rebate exclusion from best price will replicate the same behavior we saw from manufacturers following the creation of the Medicaid Drug Rebate Program in 1990: price increases as manufacturers seek to avoid increased rebate liability.

Finally, to the extent that increased rebate payments to PBMs *do* implicate best price and AMP under a new policy, there are also implications under the 340B Drug Pricing Program. Under the 340B program, a manufacturer must agree to charge covered entities an amount

¹⁶⁷ See, for example, *Bristol-Myers Cuts Cost of Drugs Used By Federal Plans*, Wall Street Journal (January 8, 1992) (“The drug industry has come under fire of late because drug prices over the past few years have jumped at three times the rate of inflation for all consumer products. As a result of complaints, Merck & Co. recently promised that price increases of its products won’t rise faster than the inflation rate, and the drug industry’s trade group also asked its members to consider expanding the Medicaid rebate to all federal agencies.”)

¹⁶⁸ GAO, Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals (GAO/HEHS-94-194FS, Aug. 5, 1994). Available at <http://archive.gao.gov/t2pbat2/152225.pdf>.

¹⁶⁹ Social Security Act § 1927(a)(5), 42 U.S.C. § 1396r-8(a)(5). Note that § 1927(c)(2) requires manufacturers to pay an additional rebate when the AMP for a brand-name drug increases more than a specified inflation factor, thereby controlling the effect of drug prices generally. However, until 1992 most Federal health care programs were unable to take advantage of the drug rebate provisions.

¹⁷⁰ Medicare Prescription Drug Improvement and Modernization Act of 2003, P.L. 108-173.

¹⁷¹ Patient Protection and Affordable Care Act, P.L. 111-148, as amended.

that does not exceed the AMP for the drug in the preceding calendar quarter, reduced by the basic Medicaid rebate percentage.¹⁷² The rebate percentage, in turn, is equal to the greater of 23.1% of average manufacturer price, or AMP minus best price. Thus, to the extent that additional rebate payments to PBMs *lower* a manufacturer's best price for a particular product, there could be a similar downward trend on the ceiling price charged to covered entities under the 340B drug pricing program. Again, given the lessons we have already learned from past manufacturer behavior, any changes to the system that incentivize higher, rather than lower, prices will result in what we expect: higher drug prices.

- **HHS Has Limited Authority to Change the Treatment of Rebates:** Under existing law and regulations, HHS has limited authority to impact the treatment of rebates on AMP and best price: the former excludes, in statute, rebates from its definition, and the latter excludes all prices paid in the Medicare Advantage and Part D programs. Specifically, section 1927(k)(1)(B)(IV) excludes from the definition of AMP “payments received from, and rebates or discounts provided to, pharmacy benefit managers.” Section 1927(c)(1)(C)(i)(VI) excludes from the definition of ‘best price’ any prices negotiated by a Part D or Medicare Advantage plan. By way of regulation at 42 C.F.R. § 447.505(c)(17), CMS has excluded “PBM rebates” from the definition of ‘best price’.

Therefore, absent Congressional intervention, HHS’ ability to impact the AMP and best price treatment of rebates is limited.

PCMA Recommendation: *Given the interaction between the AMP and best price provisions and reduced prescription drug discounts, including rebates in the calculation of AMP and best price would lead manufacturers to refuse to enter into such negotiations with PBMs, or offer only modest concessions, on the grounds that such concessions would adversely affect their AMP and best price calculations. HHS should continue to exclude PBM rebates from AMP and best price so as to incentivize competition.*

¹⁷² Public Health Service Act §340B(a)(1) 42 U.S.C. § 256b(a)(1).

Background

In discussion options to provide incentives to lower or not increase list prices, HHS points out that the Healthcare Common Procedure Coding System (HCPCS) codes for new Part B drugs are not typically assigned until after they are commercially available. HHS asks whether HCPCS codes should be available immediately at launch for new drugs from manufacturers committing to a price over a particular lookback period. HHS also asks what CMS should consider doing under current authorities to create incentives for Part B drug manufacturers committing to a price over a particular lookback period and how long the lookback period should be.

Discussion

Each year in the United States, health care insurers process over five billion claims for payment. For Medicare and other health insurance programs, standardized coding systems are essential to ensure that these claims are processed in an orderly and consistent manner, the HCPCS Level II Code Set is one of the standard code sets used for this purpose. The regulation that CMS published on August 17, 2000 (45 CFR 162.10002) to implement the HIPAA requirement for standardized coding systems established the HCPCS level II codes as the standardized coding system for describing and identifying health care equipment and supplies in health care transactions that are not covered by the CPT code set jurisdiction. Level II codes are also referred to as alpha-numeric codes because they consist of a single alphabetical letter followed by four numeric digits.¹⁷³

The national codes are updated annually. Coding requests have to be received by January 3 of the current year to be considered for the next January 1 update of the subsequent year. PCMA supports actions to strengthen price competition for physician-administered drugs covered under Part B. Making HCPCS codes for new Part B drugs available immediately at launch would promote price competition and support Medicare Advantage organizations, PBMs and the Part B program in efforts to better manage Part B drugs and would bring additional transparency and administrative efficiency to the Part B drug benefit.

When a provider has identified an overpayment from the Medicare program, the provider is responsible for reporting and returning the self-identified overpayment. The Medicare Program: Reporting and Returning Overpayments rule issued on February 12, 2016, reduces the “lookback” period, within which CMS will go after provider overpayments to six years from the date the payment was made (down from the previous limit of ten years).¹⁷⁴ More timely updates

¹⁷³ HCPCS – General Information, CMS website. <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html>

¹⁷⁴ “The Medicare Program: Reporting and Returning Overpayments; Final Rule,” 81 *Federal Register* 29 (February 12, 2016), pp. 7653-7684. <https://www.federalregister.gov/documents/2016/02/12/2016-02789/medicare-program-reporting-and-returning-of-bOverpayments>



of HCPCS codes should reduce the need for the lookback period. As an alternative, billing for drugs using PBMs or PBM-like systems (as discussed above in Section I (B): Use of Part D Tools in Part B and Creation of CAP for Part B Drugs , p. 10) would allow for drugs to be billed using NDC codes. With NDC codes updated on a more-timely basis, overpayments addressed by the lookback period provision would be further reduced or eliminated.

PCMA Recommendation: PCMA recommends that CMS update codes at least twice annually. With the current fluctuation in drug prices, annual updates cannot accurately reflect the current price of drugs. Ideally, HCPCS codes for new Part B drugs should be available immediately at launch for a new drug, with no need for a lookback period. PCMA recommends that CMS consider billing for Part B drugs using NDC codes, allowing CMS to benefit from pricing files that are updated on a more timely basis.

Background

The Blueprint RFI asks if the use of manufacturer copay cards helps lower consumer cost or actually drive increases in manufacturer list price, and if use of copay cards incents manufacturers and PBMs to work together in driving up list prices by limiting the transparency of the true cost of the drug to the beneficiary? What data would support or refute the premise described above? CMS regulations presently exclude manufacturer sponsored drug discount card programs from the determination of AMP and the determination of best price. The Blueprint RFI asks what the effect of eliminating this exclusion would have on drug prices? Would there be circumstances under which allowing beneficiaries of federal health care programs to utilize copay discount cards would advance public health benefits such as medication adherence, and outweigh the effects on list price and concerns about program integrity? What data would support or refute this?

Discussion

We appreciate that HHS has raised these questions about drug couponing. There are some schemes that masquerade as patient assistance programs that are really marketing schemes. Such programs will tend to help patients purchase only one specific drug, and may not be means tested. Drug coupons are the most common form of this activity.

Considered illegal in federal health programs, copay coupons are banned in Medicare and Medicaid, but are still allowed in the commercial market in most instances. Drug companies rely on financial subsidy programs to increase product uptake among insured patients, without consideration of whether there are similarly effective, but more affordable options to treat the patients' conditions. By targeting drugs with sub-optimal formulary placement, drug manufacturers use these programs to rapidly increase product utilization outside the boundaries of traditional insurance processes.

In addition, health policy experts argue that in contrast to the charitable enterprises drug manufacturers may attempt to portray, couponing enterprises are often used to steer patients to higher-priced medicines when cheaper options are available. Harvard and Yale researchers writing in the *New England Journal of Medicine* stated, "the majority of drug coupons are for therapies for which lower-cost and potentially equally effective alternatives exist."¹⁷⁵ The HHS OIG also described the problem clearly, that:

¹⁷⁵ Joseph S. Ross, M.D., and Aaron S. Kesselheim, M.D., J.D., M.P.H. "Prescription-Drug Coupons — No Such Thing as a Free Lunch," *NEJM*, September 26, 2013.



“the availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices.”¹⁷⁶

Moreover, couponing schemes have raised serious suspicions of fraud. One drug maker recently reached a \$210 million settlement with the Justice Department over its handling of a drug coupon program, accusing it of violating the False Claims Act by paying kickbacks to induce Medicare patients to purchase the company's drugs.¹⁷⁷ Further, at least four other major drug manufacturers have received subpoenas recently about their relationships with charities.¹⁷⁸

We are supportive of programs that facilitate patient access to specialty and high-cost drugs when appropriate, such as when a patient of limited means needs an expensive drug for which there is no more affordable substitute. However, we do not support programs that undermine formulary design, since additional expenditures do not necessarily provide patients with additional health benefits. Employer costs rise dramatically when enrollees choose expensive drugs over more affordable options, and since the use of copay coupons reduces the utilization of these more affordable options, restrictions on copay coupon use can be part of a solution to help slow the rising cost of prescription drug coverage.

PCMA Recommendation: We suggest that the Administration should forbid the use of drug manufacturer coupon programs in the Exchanges, as is the case in Medicare and Medicaid. Additionally, the Administration should thoroughly examine manufacturer coupon actions to eliminate any further fraudulent activity.

¹⁷⁶ HHS OIG, “Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons,” September 2014 https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/sab_copayment_coupons.pdf

¹⁷⁷ Politico, “Justice Settlement May Be First Of Many On Drug Coupons,” December 20, 2017.

¹⁷⁸ Ibid.

Better Negotiation – (II) (B) p. 22695
Creating Incentives to Lower List Prices – (III) (C) p. 22698
Protected Classes

Background

The Blueprint RFI notes, in the section on what HHS may do to support better negotiations, that it might take action to provide “plans full flexibility to manage high-cost drugs that do not provide Part D plans with rebates or negotiate fixed prices, including in the protected classes.” Later, the Blueprint RFI requests comments on incentives to lower or not increase list prices and specifically asks, “Should manufacturers of drugs who have increased their prices over a particular lookback period or have not provided a discount be allowed to be included in the protected classes? Should drugs for which a price increase has not been observed over a particular lookback period be treated differently when determining the exceptions criteria for protected class drugs?”

Discussion

Medicare Part D plans are required to cover at least two drugs in each therapeutic class. However, for six therapeutic classes, plans are required to cover “[all or substantially all](#)” drugs. These so-called “protected classes” include antiretrovirals, immunosuppressants used for organ transplants, antidepressants, antipsychotics, anticonvulsant agents, and antineoplastics. As you know, PCMA has recommended for some time that CMS move forward on the changes proposed in the draft 2015 rule and remove the following classes from the so-called protected classes: antidepressants, immunosuppressants for treatment of transplant rejections, and antipsychotics.¹⁷⁹ PCMA also continues to recommend that CMS review the other three “classes of clinical concern” for possible removal from the list. While we do not belabor in this filing all of our ongoing concerns with the current policy, we do reiterate a few compelling studies on its adverse impact on drug pricings.

- A 2011 OIG report describing Part D sponsors’ frustration with the program, and their assertions that “they received either no or minimal rebates for the drugs in these six classes,” that “there is little incentive for drug manufacturers to offer rebates for these six classes of drugs because they do not need to compete for formulary placement.”¹⁸⁰

¹⁷⁹ In 2014, CMS noted in a [proposed rule](#) that they were concerned the policy “presents both financial disadvantages and patient welfare concerns for the Part D program as a result of increased drug prices and overutilization.” The agency also noted that protected status may “substantially limit Part D sponsors’ ability to negotiate price concession in exchange for formulary placement of drugs in these categories or classes.” In support, CMS cited several reports, including: Centers for Medicare & Medicaid Services, “CMS-4159-P: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs,” 79 Fed. Reg. 1918–2073 (Jan. 10, 2014), <https://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf>.

¹⁸⁰ HHS OIG, Concerns with Rebates in the Medicare Part D Program, March 2011. <https://oig.hhs.gov/oei/reports/oei-02-08-00050.pdf>

- A 2008 study conducted by Milliman found that the protected classes accounted for between 16.8% and 33.2% of drug expenditures among surveyed sponsors. The report estimated that affected drug costs were on average 10 percent higher than they would be in the absence of the protected class policy, representing \$511 million per year in excess costs to beneficiaries and the Part D program.¹⁸¹
- A 2010 study, which suggested that the Medicare Part D program led to average prices for brand name drugs increasing by significantly less from 2003 to 2006 for drugs sold differentially to Medicare recipients, while drugs given market power by being in protected classes raised their prices.¹⁸²
- Chapter 6 of MedPAC's Report to Congress (June 2016) titled "Improving Medicare Part D," discusses curtailing the protected classes policy. MedPAC states that it continues to support CMS's two-part test for protected classes from the 2015 Proposed Rule, and also supports specifically remove antidepressants and immunosuppressant from protected status because both classes "have a number of generic versions" available.¹⁸³

We appreciate the ideas offered by HHS in the RFI on possible ways to narrow the scope of protected classes in light of the urgent need to provide Part D plan sponsors with better negotiation tools. Initially, however, we note that Chapter 6 of the Medicare Prescription Drug

Manual currently allows UM on protected class drugs, except with respect to HIV/AIDS drugs, where the guidance notes that UM tools such as PA and ST are not generally employed as a best practice. See Section 30.2.5. That said, we understand from PCMA members that proposed UM tools on protected class drugs are often not approved by CMS during the formulary review process. We would urge the agency to assess its practice of denying UM tools in this regard, as the ability of Part D plan sponsors and their PBMs to apply appropriate UM tools as they do for all other classes would be a step forward in controlling the impediments otherwise imposed by the protected class construct.

Beyond allowing reasonable implementation of UM tools on protected classes as authorized in current CMS guidance, there is a range of regulatory action that CMS could take in the protected class arena (as well as with respect to any high-cost drug where the manufacturer

¹⁸¹ Milliman, Potential Cost Impacts Resulting from CMS Guidance on "Special Protections for Six Protected Drug Classifications" and Section 176 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (P.L. 110-275), October 16, 2008. <http://amcp.org/WorkArea/DownloadAsset.aspx?id=9279>

¹⁸² Mark Duggan and Fiona Scott Morton, "The Effect of Medicare Part D on Pharmaceutical Prices and Utilization," American Economic Review, 2010, 100:1, 590-607. <http://faculty.som.yale.edu/FionaScottMorton/documents/TheEffectoftheMedicareDrugBenefitonPharmaceuticalPricesandUtilization.pdf>.

¹⁸³ MedPAC, Report to Congress: Medicare and the Health Care Delivery System, Chapter 6, June 2016. <http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf>



will not negotiate lower prices) to discourage price increases and refusal to negotiate price concessions. Specifically, Part D plans could employ tools with respect to protected class drugs to address actions by manufacturers to:

- significantly increase prices;
- not provide significant pricing concessions;
- not commit to limits on price increases over a particular period;
- refuse to negotiate to lower drug prices; or
- take other actions that result in high drug prices.

We understand, of course, that it would be desirable to develop a definition or formula that would trigger the determination that a specific drug should be subject to remedies along the lines that we suggest below. However, our concern is that if a specific formula is offered, then the manufacturer would implement price increases right up to, but short of, the maximum (e.g., if the formula is price increase of no more than 10% a year, then the price increase will inevitably come in at 9.9%). One alternative to avoid this inevitable outcome would be to treat unreasonable pricing as if it were a negative formulary change, and allow plans to submit a justification to CMS as to why they are deeming a drug to no longer qualify for all of the protected class special treatment. Unless CMS disapproves the request, the plan could proceed with the applicable options discussed below, even midyear.

Options to such manufacturer intransigence on pricing of specific drugs in protected classes (or beyond) would include allowing Part D plan sponsors to utilize some or all of the following tools:

- Disqualify the drug from being eligible for tiering exceptions and transition requirements.¹⁸⁴
- Place the drug on a newly created tier for high-cost drugs in the classes of clinical concern where the manufacturer negotiation is insufficient and require that all drugs on that tier be automatically subject to prior authorization, step therapy and quantity limits (as well as being excluded from the tiering exceptions).¹⁸⁵
- Allow for partial fills for the drug upon initial prescription (e.g., 15-day supply) to make sure the patient can tolerate the medication before continuation. Patient cost-sharing for a partial fill could be prorated concomitant to the cost-sharing for a 30-day.¹⁸⁶
- Allow plans to communicate in explanation of benefits (EOBs) documents, member handbooks, on Medicare Plan Finder, the Drug Dashboard, and elsewhere that the

¹⁸⁴ CMS could modify its requirements for the exceptions process at 42 C.F.R. § 423.578 and the transition process at 42 CFR §423.120 (b)(3).

¹⁸⁵ CMS could add a new section to the Medicare Prescription Drug Benefit Manual, similar to the section on Specialty Tiers; <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>

¹⁸⁶ CMS could add a new section to the Medicare Prescription Drug Benefit Manual, similar to the section on Transition Requirements (See link above.)



manufacturer will not negotiate to reduce the price on a given protected class drug. This would be similar to the “icon” concept that CMS utilizes in star ratings where a plan fails to achieve certain star ratings for a defined period of time.¹⁸⁷

- For drugs where the manufacturer triggers the threshold for the application of options, plans and their PBMs should be provided the flexibility to exclude such drugs from a formulary where there is an absence of outcomes data that shows evidence of their value.

In addition, CMS could help narrow the scope of protected classes by addressing biosimilars in protected classes. Specifically, with antineoplastic biosimilar products expected to be launched in the near future, CMS should interpret Chapter 6 guidance (30.2.5 – Protected Classes) to mean that Part D sponsors are not required to include all or substantially all protected class drugs on the formulary where biosimilars are available. In other words, similar to the treatment of generics, Part D sponsors should not be required to cover both the reference innovator product AND its biosimilar, but only at least one or the other, for a protected class.

Finally, PCMA has identified another opportunity that CMS should implement to narrow the scope of protected classes when applicable. Under the current protected class construct, a medication should be “protected” only when it is being prescribed specific to the indication defined by the protected class. As an example, a medication with multiple indications including preventing seizures should be subject to the protections provided when it is being used as anticonvulsant to prevent seizures (i.e. one of the protected classes). However, if the same medication is being used for a different indication, such as diabetic peripheral neuropathic pain or fibromyalgia, it is not being used for an indication subject to the protected class provision. Therefore, the medication should not be treated as “protected” for those indications. Part D plan sponsors should be able to use UM tools as appropriate and to consider including drugs on the formulary for only the protected indication. We understand that this change would involve operational challenges and would appreciate the opportunity to work with CMS on the best way to implement this change.

PCMA Recommendation: PCMA urges HHS to take action to provide Part D plan sponsors and their PBMs “full flexibility” to manage high drug costs where manufacturers do not provide rebates or negotiate, including in protected classes. We recommend establishment of a definition of what triggers the ability to address the situation, perhaps through a process similar to how negative midyear formulary changes can be made, and the adoption of a list of options available to Part D plan sponsors and their PBMs to meaningfully incentivize manufacturers to lower their prices. We also recommend that HHS address biosimilars in protected classes by providing that the innovator product does not need to be covered where there is a biosimilar in the class,

¹⁸⁷ CMS could modify its Part D Marketing Requirements at 42 C.F.R. § 423, Subpart V. (<https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol3/pdf/CFR-2011-title42-vol3-part423.pdf>)



and that it narrow the scope of protected classes to apply only to the indications within the scope of the protected class rather than to all indications.



**Creating Incentives to Lower List Prices – III (C) p. 22698-22699
340B Program**

Background

The Blueprint RFI raises a number of questions about the growth, eligibility rules, and operation of the 340B Drug Discount Program.

PCMA Recommendation: We support the intended purpose of the 340B program, but believe HHS should have the necessary resources to better and more consistently manage the program.

**Reducing Patient Out-of-Pocket Spending – III (D) p. 22699
Informing Beneficiaries About Price Changes, Cost-sharing and Lower-cost Alternatives****Background**

In discussing drug price changes during the benefit year, HHS asks if information could be added to the explanation of benefits (EOB) documents that Part D plan sponsors provide to their enrollees. HHS also asks whether pharmacists could be empowered to inform beneficiaries when prices for their drugs have changed and whether this information could best be distributed by pharmacists at the point of sale (POS) or by some other means. HHS then asks what other communication barriers are in place between pharmacists and patients that could be impeding lower drug prices, out-of-pocket costs, and spending and whether pharmacists could be required to ask patients in federal programs if they would like information about lower-cost alternatives. HHS also requests other strategies that might be most effective in providing price information to consumers at the POS.

In discussing informing Medicare beneficiaries with Medicare Part B and Part D cost-sharing and lower-cost alternatives, HHS mentions that health plans and PBMs have found new ways to inform prescribers and pharmacists about the formulary options, expected cost-sharing and lower-cost alternatives specific to individual patients. HHS asks how these tools could reduce out-of-pocket spending for people with Medicare and specifically asks:

- Whether this technology is present in all or most electronic prescribing or pharmacy dispensing systems;
- Whether Medicare should require the use of systems that support providing this information to patients;
- What existing systems could support the creation of these tools;
- Whether the technology exists for this approach to be quickly and inexpensively implemented;
- Whether this would increase costs for the Medicare program; and,
- Whether this creates unreasonable burden for prescribers or pharmacists.

Discussion

Additional information to be added to EOB about the rate of change in prices: Medicare beneficiaries currently receive an EOB statement from their Part D plan sponsor that includes information about the negotiated price for each dispensed prescription, and what the plan, enrollee, and others paid. As suggested by HHS, Part D plan sponsors could be authorized to include additional information that educates beneficiaries as to when prices for their drugs have changed. This additional information would inform beneficiaries as to price changes that they pay through increases in cost-share payments, although not in real-time. It would also educate beneficiaries about the price increases that fixed copayments do not reflect. Most beneficiaries do not notice the price increases that impact them only indirectly through subsequent changes



in premiums or benefits. Making the significant changes to add such information to the EOB statement will require additional administrative costs. In addition, CMS will need to allow an appropriate time for the system changes necessary to implement the new EOB information.

While information added to the EOB statement could provide price increase data to be viewed when the EOB statement arrives in the beneficiary's mail, HHS must recognize that this is not real-time information and would not change real-time decisions about the most cost-effective option. Options that would allow for real-time information are described below.

Empowering prescribers to inform beneficiaries with Medicare Part D information: HHS efforts should primarily focus on providing prescribers with information to be acted upon at the point of care (time of prescribing). While input at the pharmacy POS on formulary alternatives or prior authorization requirements would inform beneficiaries, such information is most actionable at the point of care. Information about formulary alternatives provided after the prescriber/beneficiary interaction is less likely to result in a change to a more cost-effective formulary alternative.

Electronic prior authorization (ePA) is the electronic transmission of information between a prescriber and payer to determine whether or not a prior authorization can be granted. The National Council for Prescription Drug Programs (NCPDP) has developed technical standards to support this electronic transmission and accelerate the exchange of prior authorization information. As of 2018, 17 states have adopted the NCPDP ePA standard.¹⁸⁸ By automating the process and connecting all industry participants, ePA provides real-time information to support e-prescribing. If fully implemented, ePA could reduce administrative costs and burdens, while assisting efforts to direct prescribers to cost-effective, clinically-appropriate medications. In the preamble of the 2019 Policy and Technical Changes Final Rule, CMS indicated that the ePA standard requires a modification to the HHS HIPAA standard and cannot be effectuated in a CMS regulation. Specifically, CMS indicated: "In order for CMS to adopt the 2017071 for use in the Part D e-prescribing program, the HIPAA standard transaction would need to be modified to allow for use of an NCPDP SCRIPT ePA standard. Such HIPAA changes will need to occur in a Departmental regulation and cannot be effectuated in a CMS regulation. If the HIPAA regulations are modified, CMS will be able to propose adoption of the NCPDP SCRIPT ePA for use in the Part D e-prescribing program."¹⁸⁹

¹⁸⁸ covermyeds, "ePA National Adoption scorecard." 2018. <https://www.covermyeds.com/main/pdf/cmm-scorecard-2018.pdf>

¹⁸⁹ CMS, Medicare Program; 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, Federal Register, Vol. 83, No. 73, April 16, 2018, p. 16636. <https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf>



Clinical decision support has long been recognized as a set of tools that can improve clinical decision making and patient safety, both as functionalities in electronic health records (EHRs) and electronic prescribing (eRx) systems. One of the newest is the real-time benefit inquiry (RTBI), whose value lies in its potential for providing real-time, patient-specific formulary and benefit information at the point of care.

RTBI can be a key step in the eRx process because it helps the clinician know if a drug will be covered under a patient's insurance and how much the patient is responsible for paying. Today's eRx systems and EHRs with eRx modules already have the ability to perform formulary and benefit checks. RTBI provides real-time information about patient-specific utilization management programs (such as prior authorization and step therapy), true out-of-pocket costs for a drug (specific copay/coinsurance amount and deductible information), alternative pharmacy pricing (such as for a 90-day supply) and which pharmacy will be most cost-effective, based upon the patient's pharmacy benefits. RTBI should help the prescriber identify the most cost-effective drug at the point of prescribing, resulting in a cleaner prescription and minimizing treatment delays and unnecessary out-of-pocket costs to the patient.

Incorporating RTBI into EHRs and into the practice of medicine requires prioritization of making existing technologies available and integrating them into prescribers' routine. HHS can encourage the development of systems that provide prescribers with all information available about lower-cost options, primarily through development of an NCPDP communication standard. Additionally, HHS can require that competing technologies in the market be interoperable with one another and encourage or require the use of proven RTBI technology by payers, insurers, and clinicians to streamline the patient experience to create better health outcomes and savings for patients.

Empowering pharmacists to provide information: A lack of information is the primary barrier to pharmacists' ability to best provide patients with information on drug costs. All pharmacy dispensing systems provide information transmitted by payers on what copayments should be charged or when claims are rejected due to eligibility, prior authorization requirements, formulary status or some other reason. The current NCPDP communication standard and pharmacy dispensing systems do not provide the information needed by pharmacists to assist Medicare beneficiaries by letting them know about various formulary alternatives that could be more cost-effective for the patient.

Working with a pharmacy chain connected to an EHR system, we are aware of a PBM that is able to share information at the pharmacy POS that is similar to that shared with the prescriber. Options for broadening to other Part D plan sponsors without an NCPDP standard would require technology investment, possibly including the use of an EHR system, which is not a standard part of PBM operations or retail pharmacy operations. Incorporating this into part of the pharmacy workflow would require a similar technology investment by retail pharmacies.



HHS can encourage the development of systems that provide pharmacists with all information available about lower-cost options, primarily through development of an NCPDP standard. However, information about lower-cost alternatives provided after the prescriber/beneficiary communication has concluded is less likely to result in a change to a more cost-effective alternative.

Improvements to Medicare Plan Finder (MPF): An improved version of the MPF is essential to provide Medicare beneficiaries with needed information on the coinsurance they can expect to be charged for their prescriptions. The MPF tool should be improved both in the way information is shared with beneficiaries and the timeliness of the information being shared.

Pricing differences between data available on the MPF and the price at the time the prescription is dispensed occur due to CMS timelines for MPF updates. Files are prepared and submitted by Part D plan sponsors according to the CMS-issued calendar and guidelines which do not allow submissions outside the specified bi-weekly schedule. CMS posts files two weeks after submission which are then displayed for two weeks. When a beneficiary views drug pricing data on MPF, the data are typically between 19 to 31 days old. In addition, pricing data for the MPF display are based on a single reference/proxy National Drug Code (NDC) and may be different than the actual NDC assigned to a specific strength or package size. Drug costs vary by NDC, even for those with same strength or dosage form, and drug prices can change daily. This variability leads to unavoidable inconsistencies between the pricing data submitted by a Part D plan sponsor for the MPF listing and the price at the time a prescription is filled.

Additional tools to share drug pricing comparisons: HHS should consider other options to provide beneficiaries with communication on prescription drug pricing through the Medicare.gov website, MPF, and the CMS Drug Pricing Dashboard. Most useful to beneficiaries at the time of dispensing could be access to an MPF or Medicare.gov price comparison tool, perhaps at a kiosk available at pharmacies.

PCMA Recommendation: *PCMA encourages HHS to take all of the following steps:*

- 1. Authorize Part D plan sponsors to add additional information to the EOB statement that educates beneficiaries as to where to find out if prices for their drugs have changed.***
- 2. Make updating the HIPAA regulations to implement the NCPDP ePA standard a priority as part of its drug pricing efforts.***
- 3. Examine current RTBI technology and consider how it can be better integrated into the normal flow of a prescriber's work, how prescribers may be encouraged***

to adopt such technology, and how HHS might encourage or require competing RTBI technologies to be seamlessly interoperable with one another.

- 4. Help facilitate the development of systems that provide pharmacists with all information available about lower-cost options, primarily through development of an NCPDP standard, recognizing that the information is most useful at the point of prescribing.*
- 5. Improve the MPF tool and the timeliness of the information to reduce inconsistencies between the pricing data submitted by Part D plan sponsors for the MPF listing and the price at the time a prescription is filled.*
- 6. Make a drug pricing comparison tool available to beneficiaries via either the medicare.gov website or MPF to provide pricing for multiple formulary alternatives, rather just the price in response to a one drug query as is currently available.*

**Additional Feedback – III (E) p. 22699
Assuring Reasonable Costs for Drugs Developed with Federal Support****Background**

Historically, the federal government has been a major funder of academic research, providing approximately 60% of funds spent by academic institutions (through the American Association for the Advancement of Science and the National Science Foundation). However, not until the enactment of the Bayh-Dole Act did federally funded inventions have a clear path to commercialization. To encourage the development and commercialization of federally funded research and stimulate the economy, the Bayh-Dole Act gives academic institutions and small companies first rights to ownership (and control of the commercialization process) of inventions developed with the assistance of federal research dollars.

In return for receiving title to such inventions, the academic institution or company agrees to abide by several provisions, such as patent application filing provisions, reporting provisions and manufacturing provisions. One such provision, commonly referred to as the federal government's "march-in" right, allows the government to "march in" to the commercialization process and require licenses for a federally funded invention to be granted, or to grant licenses itself, if certain circumstances are met or not met.

In recent years, the government's march-in right has been discussed as the cost of drugs continues to increase. Proponents for the government to use march-in rights to control drug costs argue that the high-cost of drugs limits the availability of federally funded products, and thus such inventions are not available to the public on reasonable terms. Opponents argue that the federal march-in rights were never intended to be a cost-controlling measure, but instead were intended to stimulate the commercial development of federally funded inventions.¹⁹⁰ In one such case, observers have noted that the drug nusinersen, sold by Biogen under the trade name Spinraza for treating spinal muscular atrophy, was invented partly using research at the University of Massachusetts Medical School and funded in part by grants from the National Institutes of Health (NIH).¹⁹¹ Biogen received FDA approval in December 2016 to sell Spinraza and set a price of \$750,000 for the first year of treatment and \$375,000 for each year thereafter.¹⁹²

Under Bayh-Dole march-in rights, the government could, on its own initiative or at the request of a third party, ignore the exclusivity of a patent and grant additional licenses to other "reasonable applicants." However, that has never been done with a patent since the passage of Bayh-Dole in 1980.

¹⁹⁰ Intellectual Asset Management, "The federal government's march-in right: what does it mean for your intellectual property?" Dec. 7, 2016. <http://www.iam-media.com/reports/Detail.aspx?g=2272ce68-2009-4293-86fd-38ecb26ed349>

¹⁹¹ Tech Transfer Central, "Cold Spring Case Illustrates Bayh-Dole Risk in Midst of Drug Price Controversy," January 24th, 2018

¹⁹² *Ibid.*

Discussion

As the prices of branded drugs and specialty drugs that manufacturers set continue trending upward, payers and governments need creative solutions to control drug spending. A possible use of and variant on Bayh-Dole march-in rights would be to require that from a certain date forward, all new branded drugs approved by FDA developed with federal funding should be subject to certain reasonable pricing conditions for entering the market.

For example, if a drug whose development had federal support were to earn FDA approval and enter the market, the federal support would be noted, and such a drug would need to be priced reasonably. To achieve a reasonable level of pricing, the drug could be examined for value by a credible body that would estimate a reasonable range of price for a given drug, based on the value it is expected to bring to patients. One such entity is the Institute for Clinical and Economic Review (ICER), which has performed such work for years. ICER's valuations are helpful for health plans, payers, and drug manufacturers when assessing the value of drugs. Another approach to a reasonable pricing standard could be to estimate the pricing for such a drug as if it had at least two additional market alternatives.

If the drug manufacturer refused to abide by an established initial pricing standard, or increased the price of the drug over time to unreasonable levels, the government could invoke its march-in right to authorize one or more additional manufacturers to also produce the drug, despite its having been granted market or data exclusivity, thus generating competition to put downward pressure on prices.

A reasonable pricing standard that assesses a drug's value would be a strong tool to help stop unreasonable and unfounded launch prices and price increases, while still allowing drug manufacturers a fair return on their products. At the same time it could ameliorate the unfairness to Americans that results from a drug developed with federal funding priced unreasonably high, straining health budgets and potentially sending individual patients into bankruptcy.

PCMA Recommendation: All new brand drugs developed with federal funding and approved by the FDA after a future date certain should be subject to a reasonable pricing standard. The price of such drugs should be limited to their value, as assessed by a qualified, independent, expert body. If manufacturers failed to meet such a pricing standard, the government would be empowered to exercise march-in rights to allow additional manufacturers to produce the drug, despite any market or data exclusivities.

Background

The Blueprint RFI notes that HHS is interested in all suggestions to improve the affordability and accessibility of prescription drugs. It further asks “what other government policies may be increasing list prices, net prices, and out-of-pocket spending?”

We offer a range of regulatory and subregulatory actions that CMS could take to improve the affordability and accessibility of Part D benefits. For ease of reference, we divide the suggestions into two parts: this first section addresses suggestions related to the Part D formulary (in addition to the specific topics otherwise referenced in the Blueprint RFI such as protected classes and one drug per category and class), and the second section below addresses suggestions related to other aspects of Part D.

Discussion

- 1. Formulary Integrity (Chapter 18, §30.2.2.1).** We wanted to raise the concept of formulary integrity under Medicare Part D, and how certain stringent CMS actions/policies may be undercutting the ability of Part D plan sponsors to meaningfully offer cost-effective formularies. Limits on robust formularies show up through many paths, particularly through CMS’ increased rigidity around supporting statements that are part of the coverage determination process. Indeed, we are concerned that the constraints could be impacting premiums as plans need to account in their bids for the additional costs related to CMS policies on coverage determinations, IRE overturns, formulary exceptions (e.g., Chapter 18, Sec. 30.2.2.1 on supporting statements) and appeals, etc. We would urge CMS to consider an initiative addressing how to best allow Part D plans to maintain the integrity of the formulary and the utilization management process (e.g., to actually be able to not cover certain drugs).

As an initial step, CMS should revise the supporting statement guidance in Chapter 18, which currently provides a very low bar for coverage. The goal should be for the supporting statement to include more rigor, evidence based information and value. This contrasts with the current content which is very thin. Some supporting statements reference an adverse event but do not provide evidence to support. The goal should not be to try to get rid of the exceptions process altogether, but to require the provision of information to make it more supportable. This request is intended to improve quality and drive value. The formulary is a value-based tool and device. If HHS is trying to move to value-based approach, formulary integrity is a critical component to value-based design going forward.

The questions on the supporting statement are too simple, allowing the prescriber to simply check ‘yes’ every time. If the supporting statement does not require clinical justification, plans should not grant exceptions. Our consensus is that this is an issue only with the manual, and that the rules themselves do not need to be changed. Chapter 18 should be revised so that the prescriber must provide justification, rather than just check a box. We are not seeking the establishment of different criteria; rather, we seek to have the prescriber explain why other formulary drugs do not work (e.g., what adverse events are of concern). When our PBM members look at supporting statements and the pilots that they have managed over the years, they find that the opportunity for dialogue is removed by the way the supporting statements are used today.

PCMA’s PBM members are making an effort to create value, improve negotiation tools, and make available formulary drugs. Duly formed and operated P&T committees exclude drugs from the formulary, and work to assure that there are appropriate options that are on the formulary. One approach for HHS to consider is to return to the CMS model forms. If all the content on that form was provided, this issue would be largely resolved. Finally, another data point to address is that manufacturers have learned how to play this game. PBMs see the supporting statement being submitted via a generic form that is basically a cut and paste as to why that drug is better than alternative.

PCMA Recommendation: PCMA recommends that HHS work with CMS to take several short-term steps such as revising or clarifying Chapter 18 and the model forms regarding supporting statements and consider longer-term strategies to help maintain and improve formulary integrity.

- 2. Midyear Formulary Changes.** (Chapter 6, §30.3) Current CMS sub-regulatory guidance provides barriers to midyear negative formulary changes. CMS requires plans to submit and receive prior approval for all negative maintenance formulary changes, even those that CMS would generally approve. Plans can make requests only during certain time periods and may not proceed unless and until CMS approves the request, and beneficiaries already taking the drug must be grandfathered. Instead, CMS should allow Part D plans greater flexibility to make midyear formulary changes when there are developments including (a) market events such as the availability of new generic, brand or biosimilar drug entrant to the market that increases competition, (b) significant manufacturer price increases, including where there is a significant price increase for a single source generic, or (c) the emergence of new clinical evidence related to the safety and/or efficacy of a prescription drug. This expanded flexibility to make midyear formulary changes would provide beneficiaries quicker access to more effective or lower-cost medications. This idea is also addressed earlier in section II (B): Sole Source Generic Price Increases, p. 25.

PCMA Recommendation: PCMA recommends that CMS remove barriers to midyear formulary changes by allowing negative formulary changes in specified

circumstances upon notice to CMS, without requiring additional delays for CMS approval. The specified circumstances should include where there is a significant price increase for a single source generic.

- 3. Transition Fill.** (Chapter 6, §30.4.1). As stated in regulation at §423.120(b)(3) and in Chapter 6, Part D plans must provide for an appropriate transition process for new and current beneficiaries prescribed Part D drugs that are not on its formulary. This provision has been in place since the start of the Part D benefit and served its original purpose as dual-eligible beneficiaries were transitioning from Medicaid coverage of prescription drugs to the Medicare Part D program. The current policy creates situations where a beneficiary automatically receives coverage for a non-formulary medication, when another medication may be more clinically appropriate and/or more cost-effective. With the formulary exception protections in place with the Part D benefit, the transition fill requirement is no longer necessary.

PCMA Recommendation: PCMA recommends that CMS eliminate the transition fill requirements. If CMS leaves the transition fill in place, PCMA recommends that CMS, at a minimum, allow Part D plans to require prior authorization for transition fills costing more than a certain amount to prevent the Medicare Part D benefit from covering high-cost medications being dispensed when other options are clinically appropriate.

- 4. Ability of Plans to NOT Include Certain Drugs on Formularies.** The use of drug formularies enables Part D plans to promote clinically sound, cost-effective medication therapy options and positive therapeutic outcomes. As demonstrated in the recent MedPAC examination of the use of H.P. Acthar Gel, drugs may experience rapid growth in Medicare spending despite weak evidence that it is effective for adult indications.¹⁹³ Industry stakeholders would be pleased to provide CMS a list of drugs that plans should be able to exclude where there is no outcomes data that shows evidence of their value.

PCMA Recommendation: PCMA recommends that CMS should provide more flexibility to allow plans to not include drugs on their formulary where there is an absence of outcomes data that shows evidence of their value.

- 5. Brand/Generic.** The landscape of generic drug pricing has changed, and price differences between brands and generics are blurring. The assumption that generics are cheap and brands are expensive is often no longer the case. As PCMA communicated to CMS in a document, “Technical Complications in Brand or Generic Definitions for Purposes of Formulary Tier Composition,” submitted in October 2016, it is highly improbable that any

¹⁹³ MedPAC, Report to Congress: Medicare and the Health Care Delivery System, Chapter 10, June 2018. http://www.medpac.gov/docs/default-source/reports/jun18_ch10_medpacreport_sec.pdf?sfvrsn=0

multi-tier Part D formulary approved to date has a generic, preferred generic or non-preferred generic tier comprised entirely of ANDA approved NDCs which would result in such a tier being protected from tier lowering of a brand drug, approved under an NDA or BLA, into said tier. PCMA provided CMS with examples illustrating that there is no clear technical solution to structuring formulary tiers in a way that is consistent with the existing tier exceptions policy. Part D formulary tier labels must be flexible enough to allow plans to evolve their tiering structures to reflect these changes in the market. CMS tiers of brand vs. generic, preferred generic and preferred brand, non-preferred, etc., do not reflect terms that both are understandable to consumers but also tie to out-of-pocket costs, which can be used to make smarter purchasing decisions. Tiers should be reformulated to be more understandable to beneficiaries and be based on cost, not the underlying manufacturer terminology. Industry representatives would be open to engaging in a dialogue with CMS around this topic and look forward to clarification and guidance as to how to proceed.

We further query whether other tiering alternatives might be possible, in a high-cost, high-rebate class with significant competition (e.g., drugs are essentially commoditized to treat the drugs more like generics). Possible ideas to achieve this include tiering (as noted above), reference pricing, and working with states to liberalize substitution by pharmacists.

PCMA Recommendation: PCMA encourages CMS to utilize tier labeling that does not depend on “brand” or “generic” as part of the label and recognize that both brands and generics can appropriately be placed on all tiers.

- 6. Coverage for Compounds.** CMS published guidance in Chapter 6 of the Prescription Drug Manual does not specifically address whether medically-accepted indication (MAI) is intended to encompass a medically-accepted route of administration. The current language in Chapter 6 is subject to a range of interpretations. For example: cyclobenzaprine, gabapentin, and OxyContin are often added to Voltaren gel. The three drugs have MAIs but do not have topical delivery as a medically-accepted route of administration. PCMA has expressed its concerns on this issue to CMS and has requested that CMS provide written guidance, to provide clarification for both Part D plans and for the IRE, confirming that a MAI includes a medically-accepted route of administration.

PCMA Recommendation: PCMA continues to recommend that CMS provide written confirmation via published guidance that the Chapter 6 requirement for a medically-accepted indication includes a medically-accepted route of administration in order to be considered a Part D drug.

- 7. Partial Fills.** As more specialty and high-cost medications enter the marketplace, there are increasing frequencies of situations where a patient may have an adverse reaction to a first fill of a specialty drug. A partial fill also allows for better use of expensive medications that might otherwise go unused, wasted, or unnecessary for continued treatment.

In a study conducted on partial fill strategies for oral oncolytics to reduce waste and drive persistency. The authors demonstrated that 261 of 1,069 patients discontinued therapy in the first month of the program, and 7.7% could have saved at least one-half of the prescribed month of therapy. Overall, 33.8% of patients could have been prevented from wasting the prescribed oral chemotherapy medications through implementation of a partial fill program. Average savings per patient was \$934.20. The study also demonstrated that hospitalizations were reduced by 2.9%, resulting in average savings of \$439.87, in patients that received interventions within the partial fill program. The author of the study noted that the purpose of partial fill oral oncolytic programs is not to reduce access to potentially lifesaving therapies. The goal is to allow more frequent direct intervention and tracking of patients and their therapies by personnel specifically trained in oncology.¹⁹⁴

PCMA Recommendation: *PCMA recommends that to better manage costs and avoid waste, Part D plans should be allowed to provide coverage for only a 15-day supply for a first fill of a specialty drug to make sure the patient can tolerate the medication before continuation.*

8. **Fifth and Sixth Tier.** CMS should update the Part D cost-share tiering structure to permit a sixth tier that would allow for preferred and non-preferred specialty drug tiers. Updating the cost-share tiering structure would increase the ability of Part D plans to negotiate with pharmaceutical manufacturers for rebates related to formulary status and also avoid the current process where patients using the exception process and pay a lower tier cost-share for a specialty drug. In addition, as more biosimilar products are approved by the FDA, this two-specialty tier structure could encourage Medicare beneficiaries to substitute lower-cost biosimilar products for the corresponding reference product. In its June 2016 Report to Congress, MedPAC recommended that CMS revise its Part D guidance to allow for two specialty tiers, and indicated that if used appropriately, this tier structure could reduce the need for non-formulary exceptions as less cost-effective options could be placed on the non-preferred tier rather than excluded from the plan's formulary.

PCMA Recommendation: *PCMA recommends that CMS permit Part D plans to adopt a sixth tier in the specialty tier area. We also recommend that CMS revise the tiering exception guidance to permit beneficiaries to obtain a sixth tier non-preferred drug at the fifth tier preferred drug cost-sharing level when the sixth tier drug is medically necessary.*

9. **Facilitate Inclusion of Biosimilars in Formularies.** We urge CMS to ensure that Medicare Part D formulary rules and policies enable timely access by beneficiaries to biosimilars. CMS should review all formulary requirements to ensure that biosimilars – once they have

¹⁹⁴ Atheer Kaddis, Partial Fill Strategies for Oral Oncolytics to Reduce Waste and Drive Persistency, *American Journal of Managed Care*, February 26, 2013. <https://www.ajmc.com/journals/evidence-based-oncology/2013/2013-1-vol19-sp1/partial-fill-strategies-for-oral-oncolytics-to-reduce-waste-and-drive-persistency>.

been approved by the FDA and are on the market – are available to beneficiaries without delay. For example, CMS should allow lower-cost biosimilars to replace innovator products on a formulary as soon as biosimilars are available in the market. These midyear additions to a formulary should not need CMS advance review. As recommended earlier in section III (C): Protected Classes (p. 114), HHS should address biosimilars in protected classes by providing that the innovator product does not need to be covered where there is a biosimilar available.

PCMA Recommendation: PCMA recommends that CMS adopt policies that clearly facilitate and encourage the coverage of biosimilars in Part D formularies.

10. Prorated Cost-Sharing. Current regulations require Part D plans to make available prorated cost-sharing for less than 30-day supplies to reduce medication waste and promote medication synchronization. The same requirements do not currently apply to supplies greater than 30 days, which prevents medication synchronization from being a cost-effective option for beneficiaries taking 90-day supplies of chronic medications.

PCMA Recommendation: PCMA recommends that CMS permit prorated daily cost-sharing for prescriptions that are for more than 30-day supplies.

Background

The Blueprint RFI notes that HHS is interested in all suggestions to improve the affordability and accessibility of prescription drugs. It further asks “what other government policies may be increasing list prices, net prices, and out-of-pocket spending?”

We offer a range of regulatory and sub-regulatory actions that CMS could take to improve the affordability and accessibility of Part D benefits. For ease of reference, we divide the suggestions into two parts: the first addresses suggestions related to the Part D formulary and this section addresses suggestions related to other aspects of Part D.

Discussion

- 1. Specialty Pharmacy Networks:** (Chapter 5, §50.3) Currently, the Part D program provides limited tools for Part D plan sponsors to manage specialty medications. In order to appropriately manage both complex therapies for chronically ill and the associated increased program costs and premiums, Part D plan sponsors should have the flexibility to dispense specialty drugs through a subset of accredited specialty pharmacies (e.g., Utilization Review Accreditation Commission accredited or accredited by similar body). A 2015 survey of 400 physicians showed that two-thirds of those who work with specialty pharmacies think that only some or none of traditional drug stores have the expertise to provide the range of specialty medications to patients.¹⁹⁵ For Part D plan sponsors to appropriately manage specialty medications, they should be permitted to limit the dispensing of specialty drugs to those network pharmacies that demonstrate the requisite services and technology infrastructure to properly and economically dispense them. By providing this flexibility for Part D plan sponsors, they will work with these specialty pharmacies to work with patients to address clinical concerns related to the specialty drugs (e.g., side effects that may keep them from staying adherent).

PCMA Recommendation: PCMA recommends that CMS provide the opportunity for Part D plan sponsors to contract with accredited specialty pharmacy networks and/or to require that certain specialty medications be dispensed only by pharmacies that are accredited as a specialty pharmacy.

- 2. Medicare Plan Finder (MPF):** PCMA recognizes that the MPF should be improved to be of most benefit for Medicare beneficiaries. CMS should consider initiatives

¹⁹⁵ North Star Opinion Research, “Key findings from the survey of New York physicians regarding specialty medications,” April 2015.



on how to improve the MPF to better display pharmacy costs and options to assure that beneficiaries understand the various Part D offerings. Some of the target areas might include:

- *Preferred pharmacy networks.* A demonstration could test language that could be added to clearly and simply explain the difference between preferred and other network pharmacies.
- *Plan design/availability of mail-order.* CMS could consider approaches to add elements to the MPF tool to ensure that beneficiaries understand their plan design choices. Most beneficiaries using the MPF cannot select a mail-order pharmacy as their primary pharmacy.
- *Other information needed.* MPF should be improved to appropriately calculate the cost of a drug when not on formulary and to provide beneficiaries with information as to what the cost of a drug will be when they move from one phase of the benefit to the next phase of the benefit.
- *Price accuracy.* PCMA believes that the MPF Price Accuracy Star Ratings measure is technically limited because the MPF price file reports are submitted and updated every two weeks when, in reality, prices are updated daily. CMS should include language on the MPF that indicates that the pricing data may be up to two weeks old and thus may not reflect the prices that beneficiaries experience at the time a prescription is dispensed.

PCMA Recommendation: PCMA recommends that CMS focus on updating and improving the MPF to better provide information needed by beneficiaries.

3. **Compendia.** Part D coverage for off-label indications is dictated by Section 1861(t)(2)(B) of the Social Security Act, which indicates that a drug must be covered in Part D for any off-label indication, so long as there is one entry in any of several recognized drug compendia. Evidence has shown that the CMS-specified compendia suffer from many conflicts of interest and have many instances of unreproducible studies. Reports produced by the government and in the medical literature have noted a lack of transparency in the production of drug compendia, which may hide conflicts of interest. Higher standards of evidence should be adopted before requiring coverage.

PCMA Recommendation: PCMA recommends that CMS test ways to strengthen the current compendia disclosure requirements for financial conflict of interest.

4. **Quantity Prescribed.** PCMA is concerned with the number of Recovery Audit Contractor (RAC) audit findings regarding refills on controlled substances, which threaten appropriate

beneficiary access to controlled substances. RAC audits have systematically misidentified multiple “partial fills” as multiple refills, and flagged these transactions for review. This is a direct result of CMS’s failure to approve the ‘Quantity Prescribed’ (460-ET) field in the National Council for Prescription Drug Programs (NCPDP) Telecommunications standard. Immediate availability of this field would permit appropriate claims editing, ensuring beneficiary access while reducing the administrative burden on the part of Part D plan sponsors and PBMs – as well as RACs – in conducting retrospective reviews of these claims.

PCMA Recommendation: PCMA requests that CMS provide an immediate update on the regulatory status of the ‘Quantity Prescribed’ field. In the meantime, we ask that CMS provide Part D plan sponsors and PBMs with a viable, workable alternative so as to permit RACs to differentiate between permissible, multiple partial fills, and impermissible multiple refills of controlled substances. Moreover, we believe that CMS should advise the RACs that it is developing a policy in this area and that duplicative and unnecessary requests for information from Part D plan sponsors is overly burdensome and inappropriate, especially in light of the agency’s failure to adopt the NCPDP Telecommunications standard proposed program field.

- 5. Mail-Order Auto-Refills.** The requirement established by a 2013 HPMS guidance mandated that Part D plan sponsors call beneficiaries every time for an auto-refill has been found to be ineffective and annoying to beneficiaries and provides obstacles to the convenience of mail-order pharmacy. As CMS noted in the 2019 Call Letter, it is now appropriate that CMS requirements in this area be revisited.

PCMA Recommendation: PCMA recommends that current barriers to the use of home delivery in Part D, such as mandatory beneficiary authorization for each specific prescription, should be removed. Instead, a one-time initial authorization for mail-service should be adopted.

- 6. Allowing a Mandatory Mail-Service Pharmacy Benefit Option.** Under Part D plan design today, incentives for use of mail-service are lacking, resulting in relatively low utilization of mail-service as compared with other programs. Increasing the use of mail-service pharmacies could yield significant savings to beneficiaries and the federal government. If CMS allowed more flexibility on mail-service benefit design, Medicare beneficiaries would be able to choose a plan that incentivizes use of mail-service pharmacy. Savings from increased flexibility in plan design and the increased use of mail-service pharmacies in plan networks could significantly reduce Part D costs to both the Medicare program and beneficiaries. CMS should consider an initiative which would allow Part D plan sponsors to offer beneficiaries the option of mandatory mail for maintenance medications once the beneficiary is stabilized.

PCMA Recommendation: PCMA recommends that CMS allow Part D plan designs that provide opportunities for Medicare beneficiaries to choose a money-saving Part D plan that uses home delivery for all maintenance drugs once the beneficiary is stabilized.

7. **Part D Plan Access to Part A and Part B claims data.** The Bipartisan Budget Act of 2018 (BBA) provided Part D plans with access to Parts A and B claims data as of 2020 to promote the appropriate use of medication and improve health outcomes. The statute requires HHS to establish a process under which a Part D plan sponsor may submit a request to CMS for such claims data, including claims as recent as possible. The Secretary is authorized to determine additional purposes for which the data may be used, and also to determine purposes beyond those listed in the statute for which it may not be used. The lack of Part A and B medical claims data is a primary barrier that Part D plans face in negotiating and administering value-based contracts for stand-alone PDP members. We appreciate that Congress addressed this problem in the BBA, although we have some concerns about some of the restrictions on use in the authorizing language which we look forward to addressing with CMS. In the meantime, we encourage CMS to begin sharing Medicare Parts A and B data with Part D plan sponsors as soon as possible, but in no event later than the 2020 implementation date mandated by Congress. PCMA looks forward to providing input into CMS on the manner and technical specifications for how such data should be accessed, received, and utilized by Part D plans as broadly as possible, within the limitations of the BBA.

PCMA Recommendation: We encourage CMS to begin sharing Medicare Parts A and B data as authorized by the BBA with Part D plan sponsors as soon as possible.

Additional Feedback – III (E) p. 22699
Section 1557 Notice and Tagline Requirements

In response to the statement that “HHS is actively working to reduce regulatory burdens,” we once again ask HHS to address a major regulatory burden that can readily be changed, resulting in immediate cost-savings across health programs. Specifically, in the Nondiscrimination in Health Programs and Activities final rule, the Office of Civil Rights (OCR) declined to strictly define a list of significant documents in order to “maximize covered entities’ flexibility.”¹⁹⁶ We realize that this concern may not fall directly under the topic of reducing drug prices, but the breadth and costs of the requirement should compel HHS to consider all options for relief.

The burdens and costs associated with the nondiscrimination notice and taglines are particularly acute for PBMs, which handle millions of claims, operate in many different states, and thus face multiple, diverse notice and tagline requirements across their portfolio of plans. Because PBMs are not “issuers,” they are only partially helped by guidance that allows a multi-state issuer to establish a single aggregate “Top 15” list for its service areas. Further, because of the quantity of drug benefit transactions and utilization decisions, the costs of reprinting notices and redistributing notices and developing new web-content for taglines are vastly higher for a PBM than an issuer, at least on a per capita basis. These added costs have not been reflected in HHS’s regulatory burden cost estimates, despite PCMA’s prior communications on this topic.¹⁹⁷

Although the text of the regulations refers to “significant publications,” neither the regulation nor the preamble defines what constitutes “significant.” Instead, OCR defined “significant” through subregulatory guidance in the form of a series of FAQs that were published on the agency’s website.¹⁹⁸ Unfortunately, this definition was written in a broad way so as to make virtually every document sent to an individual “significant.”

According to PCMA research (as shared with OCR and throughout HHS), the resulting burden imposed upon PBMs— and ultimately borne by all participants in the marketplace, including enrollees— by the nondiscrimination notices and taglines was estimated to cost the industry between \$500 million to nearly \$5 billion in 2017 (and is on track to be comparable in 2018), despite lack of evidence of their effectiveness. Indeed, the costs imposed on the industry are increasing exponentially.

PCMA, along with other industry stakeholders, provided OCR with a draft FAQ in May 2017, which stays faithful to the intent of the nondiscrimination rule, while significantly reducing the burden imposed on covered entities.

¹⁹⁶ 81 Fed. Reg. 31,376, 31,402 (May 18, 2016)

¹⁹⁷ These costs are in fact in direct contradiction to the OMB cost estimates which provided for “no resource costs related to including updated notices in the publications.” “Nondiscrimination in Health Programs and Activities; Final Rule,” 81 Federal Register 31,376, 31,453 (May 18, 2016).

¹⁹⁸ “Section 1557: Frequently Asked Questions,” Question 26 (accessed March 29, 2017), available at <https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/>.



As we have noted in several previous conversations, OCR has considerable regulatory flexibility under the underlying statute to exercise its enforcement discretion and may either decline to enforce the nondiscrimination notices, or deem entities in compliance based on compliance with other, existing requirements. In addition, OCR also has considerable flexibility to reinterpret its definition of “significant” using subregulatory guidance (for example, adopting the suggestions provided in our draft FAQ). In a “listening session” over a year ago with interested stakeholders, there appeared to be broad agreement among the diverse attendants that subregulatory reform on this issue would be appropriate.

We believe HHS has the flexibility, and indeed obligation, to implement the notice and tagline requirements in a way that is workable and cost efficient for covered entities, and productive and meaningful for beneficiaries. PBMs continue to receive complaints from enrollees regarding the waste produced under the current interpretation of “significant.” A poorly thought out implementation continues to result not only in enormous costs to plans and PBMs and ultimately enrollees and the government, but a failure to faithfully implement the new protections against discrimination in a way that meaningfully informs members of their rights under the law.

PCMA Recommendation: In light of the need to minimize the regulatory burden as instructed by the Administration’s executive orders, and in line with the goals of the Blueprint RFI, we urge HHS to take appropriate action to reconstruct the scope of the nondiscrimination notice and tagline requirements in such a way that is financially and administratively feasible for all stakeholders in the marketplace, including PBMs. Further, we also ask HHS to continue to be mindful of overlapping meaningful access requirements that would place an undue burden on issuers and PBMs, and consider deferring to the least restrictive standard when determining compliance.

Exhibit I

Antitrust Considerations of Proposals to Limit Rebates

I. Introduction

In May 2018, the Department of Health and Human Services (HHS) introduced a policy Blueprint setting forth actions and proposed policies to help lower prescription drug costs. A major focus of the Blueprint is reform of the rebate system. Several proposed policies would result in elimination of rebates in favor of upfront discounts for brand drugs.

Policy reforms that incent brand drug manufacturers to lower prices are needed. Lower brand drug prices will make health insurance more affordable for employers and individuals, reduce consumer spending, and enhance patient access to needed medications. The Administration should be applauded for exploring a range of policies to address the problem of high brand drug pricing.

But some of the proposed changes to the rebate system may have the unintended consequence of higher brand drug prices – potentially much higher. Antitrust precedent is likely to impede a shift from rebates to upfront discounts. For years, brand drug manufacturers have refused to provide upfront discounts based on this antitrust precedent, and instead have required use of rebates. Barring or restricting rebates without addressing this antitrust precedent could lead to substantial consumer and patient harm. Brand drug manufacturers could be in the position of neither providing rebates off of list prices nor providing upfront discounts from list prices.

This danger is real. FDA Commissioner Gottlieb, before his appointment, testified to Congress that antitrust precedent led manufacturers to insist on use of rebates, that manufacturers have refused to provide upfront discounts based on the perceived legal risks, and that, before restricting rebates, legislative changes are needed to ensure that manufacturers provide upfront discounts. The proposed reform needs to account for the high risk of manufacturer inaction and higher prices.

II. The Policy Blueprint Proposes Restrictions on Drug Rebates

The Blueprint includes proposed changes to the rebate system that would impact price negotiations between brand drug manufacturers and managed care organizations.¹⁹⁹ HHS has requested public comments by July 16, 2018. The Blueprint identifies four “key strategies” for reform, with one strategy focusing on a reduction in list prices for pharmaceuticals.²⁰⁰

¹⁹⁹ See Department of Health and Human Services, “American Patients First” policy proposal (May 2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf>.

²⁰⁰ *Id.* at 9.

For each of the four “key strategies,” the Blueprint includes two phases of policy implementation: (1) actions that President Trump can direct HHS to “immediately implement” and (2) “further opportunities” that HHS is actively considering before implementing. The second phase includes opportunities to lower list pricing through changes to the rebate system.²⁰¹ These further opportunities include restricting the use of rebates by revisiting the safe harbor for drug manufacturers under the anti-kickback statute and additional reforms to the rebate system.²⁰²

As examples of further opportunities for rebate reform, the Blueprint also raises a series of questions for consideration.²⁰³ These questions include:

- “Do PBM rebates and fees based on the percentage of the list price create an incentive to favor higher list prices (and the potential for higher rebates) rather than lower prices?”
- “Do higher rebates encourage benefits consultants who represent payers to focus on high rebates instead of low net cost?”
- “Do payers manage formularies favoring benefit designs that yield higher rebates rather than lower net drug costs?”
- “Should PBMs be forbidden from receiving any payment or remuneration from manufacturers, and should PBM contracts be forbidden from including rebates or fees calculated as a percentage of list prices?”
- “What effect would imposing this fiduciary duty on PBMs on behalf of the ultimate payer (i.e., consumers) have on PBMs' ability to negotiate drug prices?”
- “What should CMS consider doing to restrict or reduce the use of rebates?”
- “Should Medicare Part D prohibit the use of rebates in contracts between Part D plan sponsors and drug manufacturers, and require these contracts to be based only on a fixed price for a drug over the contract term?”
- “What incentives or regulatory changes (e.g., removing the discount safe harbor) could restrict the use of rebates and reduce the effect of rebates on list prices?”

²⁰¹ *Id.* at 11.

²⁰² *Id.*

²⁰³ *Id.* at 33-34.

The Blueprint raised these questions without attempting to answer them. The questions suggest that HHS may take action to restrict rebates with the hope that brand drug manufacturers will lower list price or provide upfront discounts.

III. In the 1990s, Brand Drug Manufacturers Settled Antitrust Litigation Challenging Their Use of Upfront Discounts

Responses to these questions and later policy reforms must account for important antitrust conditions underlying the brand drug manufacturer behavior that led to this system. The rebate system that prevails today was largely shaped by a series of private antitrust lawsuits brought in the 1990s by pharmacies against brand drug manufacturers.²⁰⁴ These cases were consolidated in a federal antitrust class action, *In re Brand Name Prescription Drugs Antitrust Litigation*.²⁰⁵

In *Brand Name Prescription Drugs Antitrust Litigation*, pharmacies alleged that brand drug manufacturers provided more favorable prices to managed care payers through use of upfront discounts and that this amounted to illegal price discrimination under the Robinson-Patman Act.²⁰⁶ The pharmacies alleged that managed care payers, but not pharmacies, received upfront discounts from brand drug manufacturers.²⁰⁷ According to the pharmacies, the manufacturers refused to make the upfront discounts available to them.²⁰⁸ The pharmacy plaintiffs cited an internal memorandum from one manufacturer discussing the use of these “upfront deposit/credits” with managed care as evidence of anticompetitive conduct.²⁰⁹ Manufacturers allegedly agreed to these discounts only with “favored classes of customers,” who

²⁰⁴ See S. Gottlieb, *How Congress Can Make Drug Pricing More Rational*, FORBES (Sept. 12, 2016), <https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/2/#26155e936532>.

²⁰⁵ *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997 (N. D. Ill. 1994).

²⁰⁶ *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997, 1996 WL 167350, at *2 (N.D. Ill. Apr. 4, 1996).

²⁰⁷ *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997, 177 F.R.D. 414, 417 (N.D. Ill. 1997).

²⁰⁸ *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997, 1996 WL 167350, at *2 (N.D. Ill. Apr. 4, 1996).

²⁰⁹ *Id.* at *8.

were managed care payers.²¹⁰ Plaintiff pharmacies asserted that manufacturers refused to even discuss the issue of discounts with retail pharmacies.²¹¹

To end the class action litigation, the drug manufacturers settled the antitrust claims for over \$350 million.²¹² The federal court approved a settlement that included restrictions on future pricing.²¹³ In the settlement agreement, the drug manufacturers agreed that, with limited exceptions, they would offer retail pharmacies the same discounts offered to managed care payers.²¹⁴

While the litigation challenged the manufacturers' upfront discount practices, the use of rebates was not condemned by the court. Rather, the court viewed rebates as inherently pro-competitive. In one of the rulings in this litigation, Judge Posner of the Seventh Circuit Court of Appeals found that "the chargeback system [based on rebates paid from manufacturers to drug wholesalers] . . . is supported by commercial reasons independent of any desire to . . . facilitate collusive pricing" and that the rebate system has "innocent commercial virtues."²¹⁵

IV. Drug Manufacturers Responded to the Antitrust Precedent by Changing Their Pricing Practices to Offer Rebates

Brand Name Prescription Drugs Antitrust Litigation led drug manufacturers to change their approach to pricing. Manufacturers moved away from upfront, volume-based discounts. In their place, manufacturers shifted to the use of back-end rebates. To incent manufacturers to lower prices, payers acting on behalf of government and commercial plans needed to wait for price reductions after pharmacy dispensing and after the manufacturers verified that the payers met volume or share requirements.

Before his appointment to FDA Commissioner, Scott Gottlieb explained this change in testimony before the Senate. His testimony addressed the question: "Why, in other words, does the discounting in the drug space take the form of rebates paid to pharmacy benefit managers through a convoluted system on the back end of the transaction, rather than an up-front discount

²¹⁰ *In Re Brand Name Prescription Drugs Antitrust Litigation*, 123 F.3d 599, 603 (7th Cir. 1997).

²¹¹ *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997, 1996 WL 167350, at *1 (N.D. Ill. Apr. 4, 1996).

²¹² *See Judge Agrees to Settlement in Drug Case*, THE NEW YORK TIMES (June 22, 1996), <https://www.nytimes.com/1996/06/22/business/judge-agrees-to-settlement-in-drug-case.html>.

²¹³ *In Re Brand Name Prescription Drugs Antitrust Litigation*, 94 C 897, MDL 997, 1996 WL 351180 (N.D. Ill. June 24, 1996).

²¹⁴ *Id.*

²¹⁵ *In re Brand Name Prescription Drugs Antitrust Litigation*, 288 F.3d 1028, 1034-35 (7th Cir. 2002) (Posner).

on the drugs?”²¹⁶ Scott Gottlieb testified that “[i]t all stems from litigation in the late 1990s. . . . To get around this outcome, the drug makers moved away from offering discounts and toward today’s model of rebates.”²¹⁷

Based on their interpretation of the antitrust precedent, manufacturers concluded that they could make the rebate model available to all—both PBMs and smaller pharmacy purchasers—knowing that the smaller purchasers may be unable to meet the manufacturers’ requirements to qualify for the rebates. Scott Gottlieb testified: “These rebates are based on complex formulas tied to some measure of units of a drug that are sold. The idea was that these rebates could be offered to everyone, including pharmacies. But the pharmacies would never be able to satisfy the burden of evidence to qualify for the rebates.”²¹⁸ As Scott Gottlieb testified, the manufacturers believed that “[o]nly health plans could make the required representations related to how many units of a particular drug it sold.”²¹⁹

The same findings come from other studies of industry pricing. For example, *The Source on Healthcare Pricing and Competition*, a non-profit initiative by UC Hastings, published an analysis entitled: “A Drug Rebate’s Tale: How a Class Action Lawsuit in the 90s Shaped Drug Pricing.”²²⁰ This analysis explained that after the settlement, manufacturers wanted to make any

²¹⁶ S. Gottlieb, Resident Fellow at American Enterprise Institute, Statement before the Senate Comm. on Health, Education, Labor and Pensions, *EpiPen Price Increases, How Regulatory Barriers Inhibit Pharmaceutical Competition* (Oct. 7, 2016), at 11, <https://www.help.senate.gov/download/testimony/gottlieb-testimony>.

²¹⁷ S. Gottlieb, *How Congress Can Make Drug Pricing More Rational*, FORBES (Sept. 12, 2016), <https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/2/#26155e936532/>, (“It’s the outcome of a two-decade old dispute that forced drug makers to try and conceal just how much they discounted off the medicines that they were selling to health plans. . . . To work around the litigation, and the settlement they struck with the pharmacies, drug makers came up with a rebate scheme rather than offering discounts up front.”).

²¹⁸ S. Gottlieb, Resident Fellow at American Enterprise Institute, Statement before the Senate Comm. on Health, Education, Labor and Pensions, *EpiPen Price Increases, How Regulatory Barriers Inhibit Pharmaceutical Competition* (Oct. 7, 2016), at 11, <https://www.help.senate.gov/download/testimony/gottlieb-testimony>; *see also* S. Gottlieb, *How Congress Can Make Drug Pricing More Rational*, FORBES (Sept. 12, 2016), <https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/2/#26155e936532> (“But the drug makers knew that the retailers couldn’t possibly fulfill the burden of proof needed to qualify for the rebate. . . . For obvious reasons, the drug makers don’t want to write contracts with the insurers that the retailers could also demand.”).

²¹⁹ S. Gottlieb, Resident Fellow at American Enterprise Institute, Statement before the Senate Comm. on Health, Education, Labor and Pensions, *EpiPen Price Increases, How Regulatory Barriers Inhibit Pharmaceutical Competition* (Oct. 7, 2016), at 11, <https://www.help.senate.gov/download/testimony/gottlieb-testimony>.

²²⁰ K. Gudiksen, Senior Research Fellow, THE SOURCE ON HEALTHCARE PRICING AND COMPETITION (Feb. 23, 2018), <http://sourceonhealthcare.org/a-drug-rebates-tale-how-a-class-action-lawsuit-in-the-1990s-shaped-drug-pricing/>.

price cuts contingent on the payers or pharmacies demonstrating that specific drug sales exceeded a “market share” threshold for a therapeutic class or other category.²²¹ On the surface, the manufacturer’s rebate model would be offered to all and thus manufacturers believed this reduced antitrust risks. Under this approach, the price cuts or rebates would be “calculated retrospectively” and manufacturers “structured the agreements in a way that pharmacies were unable to provide the evidence to prove qualification for the rebates.”²²²

V. Legislative Change Is Needed to Prevent Large Drug Price Increases if Manufacturers Cannot Offer Rebates

The proposed policy changes would leave untouched the antitrust precedent and laws invoked by manufacturers to end upfront discounting. Moving forward on this basis is dangerous to consumers. Manufacturers would cease cutting prices through rebates. And they would refuse to provide upfront discounts because of antitrust precedent. Drug prices will be significantly higher as list prices remain the same, but no rebates are passed along to the health plan sponsors to reduce premiums or prices at the point of sale.

Congressional action would be needed to solve this problem. Scott Gottlieb and others have recognized the importance of legislative change to ensure manufacturers will provide upfront discounts.²²³ There is too much risk to consumers in the absence of legal change.

It will be important to ensure that payers for government and commercial plans retain the tools needed to incent manufacturers to lower price. In particular, the use of formularies that reward volume or share in exchange for price cuts must remain available as a check on manufacturer pricing.

²²¹ *Id.*

²²² *Id.*

²²³ S. Gottlieb, Resident Fellow at American Enterprise Institute, Statement before the Senate Comm. on Health, Education, Labor and Pensions, *EpiPen Price Increases, How Regulatory Barriers Inhibit Pharmaceutical Competition* (Oct. 7, 2016), at 11, <https://www.help.senate.gov/download/testimony/gottlieb-testimony> (“Could Congress legislate to make it legal for drug makers to engage in price discrimination based on purchaser, offering discounts to one channel and not to another, so long as the drug makers were not conspiring to offer similar discounts? The answer, probably, is yes.”); S. Gottlieb, *How Congress Can Make Drug Pricing More Rational*, FORBES (Sept. 12, 2016), <https://www.forbes.com/sites/scottgottlieb/2016/09/12/how-congress-can-make-drug-pricing-more-rational/2/#26155e936532>, (“Addressing the precedent set by that court ruling . . . could provide policy makers with a simple way to improve the transparency, competitiveness, and affordability of how drugs are priced and sold.”); K. Gudiksen, Senior Research Fellow, THE SOURCE ON HEALTHCARE PRICING AND COMPETITION (Feb. 23, 2018), <http://sourceonhealthcare.org/a-drug-rebates-tale-how-a-class-action-lawsuit-in-the-1990s-shaped-drug-pricing/> (“In addition, allowing pharmaceutical manufacturers to offer discounts rather than rebates to health plans and PBMs that create formularies could meaningfully increase the competition between drugs and alternative treatment options.”).



The necessary legal change could be accomplished by an amendment to the Robinson-Patman Act, the federal law governing price discrimination. At the front end, manufacturers could price differently based on differences in volume or share commitments. That pricing approach, when done at the front-end, can be exempt from the Robinson-Patman Act. This change is needed to ensure that any change barring rebates does not leave consumers vulnerable.