

January 25, 2019

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

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, CMS 4180-P*

Dear Secretary Azar and Administrator Verma,

We write to voice our strong support and appreciation for the administration's recent proposal regarding pharmacy direct and indirect remuneration (DIR) fees, also known as "pharmacy price concessions," in CMS' *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, CMS 4180-P* (the "proposed rule").¹ We are a group of multi-disciplined stakeholders who represent pharmacies and pharmacists. Together, we share the administration's goal to lower beneficiary out-of-pocket costs in the Medicare program, stabilize the operating environment for pharmacies, and standardize the way in which plan sponsors and PBMs report pharmacy price concessions. To meaningfully accomplish these goals, we write this letter to urge the administration to finalize through formal regulations the proposals regarding the application of pharmacy price concessions in the following ways.

First, we urge the administration to finalize the proposed changes to the "negotiated price" definition in 42 C.F.R § 423.100 that seeks to include all pharmacy price concessions at the point of sale, while excluding additional positive contingent amounts. This change would effectively eliminate retroactive pharmacy price concessions, which have a demonstrably negative impact on patients and pharmacies, and ensure all fees are charged at point of sale. As you noted in the proposed rule, post-point-of-sale pharmacy price concessions, net of all pharmacy incentive payments, grew an extraordinary 45,000 percent between 2010 and 2017.

¹ 83 Fed. Reg. 62152 (Nov. 30, 2018).

Requiring all pharmacy price concessions to be included at the point of sale would accomplish our shared goal to lower beneficiary out-of-pocket costs in the Medicare program. Beneficiaries win when pharmacy price concessions are included in the negotiated price and applied at the point of sale. When a beneficiary's cost-sharing is calculated based on the negotiated price at the point of sale, the beneficiary will benefit from that lower negotiated price. In fact, CMS estimates that beneficiaries would save \$7.1 to \$9.2 billion over ten years from the reduced cost-sharing, offset by slightly higher premiums.² The savings could be considerably higher for those beneficiaries who are prescribed some of the most expensive drugs.

In addition to positively impacting beneficiaries, the proposed change would improve the ability of pharmacies to participate in the Medicare program. For years, pharmacists and pharmacies have experienced the increasing consequences of DIR fees. The unpredictable, inconsistent, retroactive nature of these fees, usually assessed months after beneficiaries' prescriptions are filled, provide very little transparency into the pricing of prescription medications in the Part D program. Requiring all pharmacy price concessions to be applied at the point of sale would provide much-needed predictability, accountability, and transparency for all parties, including the Part D program and Medicare beneficiaries.

Second, in finalizing changes to the definition of negotiated price, we urge the administration to exclude those contingent amounts that are positive incentive payments made to pharmacies. Pharmacies should be incentivized to achieve certain standardized performance program metrics via payments by Part D plan sponsors and their PBMs. Additionally, as CMS noted in the proposed rule, if CMS were to include incentive payments in the negotiated price this would increase the basis used to determine beneficiary cost-sharing and would therefore create a perverse disincentive for beneficiaries to use higher performing pharmacies as they would have higher cost-sharing.

We also urge the administration to simultaneously formalize its proposal to develop or approve a standard set of metrics with achievable goals tailored to pharmacy type, drug dispensed, and disease state being managed, from which plans and pharmacies would base their contractual agreements. We support this standardization of metrics as part of a pharmacy quality incentive program in Part D.

Finally, in addition to addressing our comments to the proposed rule, we also urge the administration to implement safeguards that would provide for the reasonable reimbursement to pharmacies participating in Medicare Part D, even when all pharmacy price concessions are applied at point of sale.

² *Id.* at 62154. In the proposed rule, CMS states that this proposal would raise premiums by \$10.16 a month but reduce patient cost-sharing by \$26.69 a month.

Today's pharmacies often find that the reimbursement they receive is less than the pharmacy's costs (drug acquisition plus cost to dispense).³ Under-reimbursement can force pharmacies out of networks or even out of business, limiting beneficiary access to the pharmacy of their choice. Therefore, the negotiated price should be a product-specific reimbursement rate to network pharmacies that at a minimum covers the pharmacy's costs of purchasing and dispensing covered items and providing covered services. We urge the administration to require that contracts between Part D sponsors and CMS contain this protection to ensure patient access and choice in Medicare Part D plans.

In conclusion, we urge the administration to act swiftly in finalizing the proposed language to amend the definition of negotiated price, to ensure that all pharmacy price concessions are accounted for at the point of sale beginning in 2020. We also urge the administration to develop or approve a standard set of metrics with achievable goals from which plans and pharmacies base contractual agreements, which would serve as a first step toward a pharmacy quality incentive program in Part D. A move of this stature would demonstrate the administration's dedication to providing immediate savings for seniors at the pharmacy counter and needed support to pharmacies and the patients we serve.

Thank you,

Academy of Independent Pharmacy/Georgia Pharmacy Association (AIP)
AIDS Healthcare Foundation
Alabama Pharmacy Association
Alaska Pharmacists Association
Albertsons Companies
Alliance of Independent Pharmacists of Texas
American Associated Pharmacies
American Pharmacies
American Pharmacists Association
American Pharmacy Cooperative, Inc.
American Pharmacy Services Corporation
American Society of Consultant Pharmacists
Arete Pharmacy Network
Arizona Pharmacy Association
Arkansas Pharmacists Association
Brookshire Brothers, Inc.
Brookshire Grocery Company
Burlington Drug Company
California Pharmacists Association
CARE Pharmacies Cooperative Inc.
Cleveland Clinic

³ NCPA, *Report for Survey of DIR Fees Imposed on Pharmacies*, Dec. 2017, available at <http://phrma-docs.phrma.org/files/dmfile/Report---Part-D-Beneficiary-Cost-Relief---FINAL.pdf>.

Coborn's Inc.
College of Psychiatric and Neurologic Pharmacists
Colorado Pharmacists Association
Community Oncology Alliance (COA)
Compliant Pharmacy Alliance Cooperative
Connecticut Pharmacists Association
Costco
Currus Inc.
Dakota Drug, Inc.
Delaware Supermarkets
Discount Drug Mart
EPIC Pharmacies Inc.
Federation of Pharmacy Networks
Florida Pharmacy Association
Food Lion Pharmacy
Food Marketing Institute
Fruth Pharmacy
Garden State Pharmacy Owners
Gary & Leo's Health Mart
Georgia Pharmacy Association
Gerimed
Giant / Martin's Pharmacy
Good Neighbor Pharmacy
Hannaford Pharmacy
Harps Food Stores
Hartig Drug
Health Mart
HealthWise Pharmacy
Hematology/Oncology Pharmacy Association
Hercules Pharmaceuticals
Hi-School Pharmacy
Homeland Stores
Hometown Pharmacies of Wisconsin
Hy-Vee, Inc.
Idaho State Pharmacy Association
Illinois Pharmacists Association
Independent Pharmacy Alliance
Independent Pharmacy Buying Group, Inc.
Independent Pharmacy Cooperative
Indiana Pharmacists Alliance
International Academy of Compounding Pharmacists
Iowa Pharmacy Association
Kansas Pharmacists Association

Kentucky Pharmacists Association
Keystone Pharmacy Purchasing Alliance
Kinney Drugs
KTA Super Stores
KVAT Food Stores Inc.
LeaderNET
Lewis Drug
Louisiana Independent Pharmacies Association
Louisiana Pharmacists Association
Louisiana Wholesale Drug Company, Inc.
Mackenthun's Fine Foods
Maine Pharmacy Association
Maryland Pharmacists Association
Massachusetts General Hospital
Massachusetts Independent Pharmacists Association
Massachusetts Pharmacists Association
McKesson
Medicine Shoppe and Medicap
Michigan Pharmacists Association
Minnesota Pharmacists Association
Mississippi Independent Pharmacies Association
Missouri Pharmacy Association
Montana Pharmacy Association
Mutual Drug
National Alliance of State Pharmacy Associations
National Association of Chain Drug Stores
National Association of Specialty Pharmacy
National Community Pharmacists Association
National Grocers Association
ND Pharmacists Association
ND Pharmacy Service Corporation
Nebraska Pharmacists Association
New Hampshire Pharmacists Association
New Jersey Pharmacists Association
New Mexico Pharmacists Association
New Mexico Pharmacy Business Council
Niemann Foods INC
North Carolina Association of Pharmacists
Northeast Pharmacy Service Corporation
Ohio Pharmacists Association
Oklahoma Pharmacists Association
Oregon State Pharmacy Association
Osborn Drugs

PARD, an Association of Community Pharmacies
PBA Health
PCCA
Pennsylvania Pharmacists Association
Pharmacists Society of the State of New York
Pharmacy Alternatives
Pharmacy First
Pharmacy Franchisees and Owners Association
Pharmacy Providers of Oklahoma
Pharmacy Society of Wisconsin
PPSC
Puckett's Food Stores
QualityCare Pharmacies
Reasor's LLC
Restore Rx Inc.
Rite Aid
Rochester Drug Cooperative
Rodhe's Market, Inc.
Rosauers Supermarkets
RxPlus Pharmacies Inc.
Sav-Mor Drug Stores, Inc
ShopRite
Smith Drug Company
South Carolina Pharmacists Association
South Dakota Pharmacists Association
Southern Pharmacy Cooperative
SUPERVALU
Tennessee Grocers & Convenience Store Association
Tennessee Pharmacists Association
Texas Pharmacy Association
Texas Pharmacy Business Council
Texas Retailers Association
The Bartell Drug Company
Thrifty White Pharmacies
University of Wisconsin Health
US Oncology Network
Utah Pharmacy Association
Value Drug Company
Value Specialty Pharmacy LLC
Vermont Pharmacists Association
Virginia Pharmacists Association
Walgreens
Washington DC Pharmacy Association

Washington State Pharmacy Association
West Virginia Pharmacists Association
West Virginia University Health Systems
Western States Pharmacy Coalition
Wyoming Pharmacy Association

Cc: Mick Mulvaney, Acting White House Chief of Staff and Director, the Office of Management and Budget
Russell Vought, Acting Director, the Office of Management and Budget