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THE VOICE OF FOOD RETAIL

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January 25, 2019

Submitted Electronically via *www.regulations.gov*

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:

On May 11, 2018, the U.S. Department of Health and Human Services (HHS) released *American Patients First*, a comprehensive blueprint to bring down prescription drug prices and out-of-pocket costs. Since then, HHS has moved swiftly and taken several actions to meaningfully advance the plan, including the recent Centers for Medicare & Medicaid Services (CMS) proposal titled *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, CMS 4180-P* (the "proposed rule"), which CMS announced on November 30, 2018.[1] Food Marketing Institute (FMI)[2], on behalf of the food retail industry and the many thousands of supermarket pharmacies operated by our member companies, strongly supports the goals laid out in *American Patients First*.

FMI greatly appreciates this opportunity to provide input on the CMS proposed rule. Our comments focus on the proposed reforms to pharmacy direct and indirect remuneration (DIR) fees (also known as pharmacy price concessions), as well as the need for increased oversight of and transparency around pharmaceutical supply chain intermediaries – especially pharmacy benefit managers (PBMs). FMI

[1] 83 Fed. Reg. 62152 (Nov. 30, 2018).

[2] FMI proudly represents the food retail industry, including supermarket pharmacies, which employs nearly 5 million workers and represents a combined annual sales volume of almost $800 billion. In total, FMI member companies operate nearly 33,000 retail food stores and 12,000 pharmacies. FMI membership includes the entire spectrum of food retail venues – from single owner grocery stores and large multi-store supermarket chains, as well as their pharmacies, to online and mixed retail stores. Supermarket pharmacies provide a positive competitive market force in delivering affordable and accessible prescription medicines to consumers and patients. For more information, visit www.fmi.org.

thanks the Administration for its attention to this important topic and offers our support for the provisions specific to DIR fees. However, we also include cautionary points for your consideration. In particular, we ask that CMS both clarify and codify a requirement for standard and fair reimbursement provisions in agreements between pharmacies and pharmaceutical supply chain intermediaries.

Health and wellness, including pharmacy-specific programs, is of the utmost importance to our industry. From an in-store clinic and pharmacy perspective, supermarket pharmacies can offer a vast array of services, including medication counseling, blood pressure monitoring and other screening programs, prescription compounding and delivery, medical equipment training, immunizations and more. Moreover, supermarket pharmacies are among the most efficient and lowest cost competitors in the pharmacy market. Many supermarket pharmacies offer reduced price or free generic drug programs, free vaccinations, and other benefits that are important to low-income areas they serve. These efforts by the supermarket industry are recognized by many cities, states, and even by the U.S. Departments of Agriculture, Health and Human Services, and Treasury, as demonstrated by their attempts to incentivize grocery stores to enter communities to improve the health and wellness profile of certain areas, such as so-called "food deserts."

Over the years, however, many FMI members' retail pharmacies have experienced a lack of price transparency, as well as lack of certainty in reimbursements from intermediaries, particularly PBMs via clawback fees weeks or months after prescriptions were filled. As CMS noted in the proposed rule, DIR fees on pharmacies participating in Medicare Part D networks have grown by more than 45,000 percent between 2010 and 2017. The retroactive nature of pharmacy DIR fees means beneficiaries face higher cost-sharing for drugs and are accelerated into the coverage gap or "donut hole" phase of their benefit. Moreover, all retroactive pharmacy DIR fees are taken back from pharmacies months later rather than deducted from claims on a real-time basis with no transparency to the process. Additionally, our members have reported that some PBMs may use reimbursement data, without prior-approval from pharmacies, to directly contact pharmacy customers and steer them to competing mail-order or retail pharmacies in which the PBM has a financial interest. The combination of increased fees and lowered reimbursement rates – with no transparency – as well as lost access to pharmacy patients, is severely harming the ability of supermarkets to maintain pharmacies.

While the increased fees and lower reimbursement rates are concerning in and of themselves, they are even more significant in the supermarket industry where retailers operate on extremely thin profit margins, generally between 1-2%.[3] In the case of one FMI member company – a mid-sized, grocery chain located in New England – DIR fees account for 2.1% of sales, and have more than doubled in the last year alone. At such low profit margins, grocery retailers have virtually no ability to absorb these unexpected costs (especially weeks or months later). Therefore, they are forced to either pass those costs on to consumers in the form of higher prices, or worse, discontinue offering pharmacy services altogether at certain locations. Another result of having such low profit margins is that supermarkets rely heavily on predictability when determining the number of pharmacists, technicians and health professionals to hire, as well as their daily schedules. Increased oversight and transparency on the intermediaries – in addition to the proposed elimination of retroactive DIR fees – would greatly improve FMI members' abilities to calculate the costs of drugs as well as price them, both of which are integral to operating pharmacies.

[3] FMI Report, Food Retailing Industry Speaks (2018).

Again, FMI shares the Administration's goals 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 treat pharmacy price concessions. To accomplish these objectives, we urge the Administration to finalize through formal regulations the proposals regarding the application of DIR fees while considering the following points.

<u>Defining "Price Concession"</u>

Currently, the term "price concession" is not defined in statute or regulation. FMI strongly supports the proposed definition, which would be broad enough to include "all forms of discounts and DIR" that serve to reduce the costs incurred under Part D plans. The proposed language regarding the definition of "price concession" follows:

> *Price concession* means any form of discount, direct or indirect subsidy, or rebate received by the Part D sponsor or its intermediary contracting organization from any source that serves to decrease the costs incurred under the Part D plan by the Part D sponsor. Examples of price concessions include but are not limited to: discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, coupons, free or reduced-price services, and goods in kind.

Establishing a definition for "price concession" and redefining "negotiated price" – as outlined by the proposed rule and discussed more below – would effectively eliminate retroactive DIR fees, which have a demonstrably negative impact on patients and pharmacies, by ensuring all fees are charged at point of sale. FMI strongly supports the Administration's proposal to require all pharmacy price concessions for Medicare Part D prescription drugs at the point of sale. This would help to accomplish our shared goal of lowering Medicare beneficiaries' out of pocket costs, while also improving the ability of pharmacies to participate and thus enhancing the competitive balance in the program.

<u>Redefining "Negotiated Price" to Include All Pharmacy Price Concessions</u>

FMI supports and commends CMS' proposal to redefine "negotiated price" in 42 C.F.R § 423.100 to include all pharmacy price concessions at the point of sale, which would effectively eliminate retroactive pharmacy price concessions – including any dispensing fees – that could potentially flow from network pharmacies. To begin with, beneficiaries would benefit from lower negotiated prices if pharmacy price concessions are included in the negotiated price and applied at the point of sale. 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. Moreover, the savings could be considerably higher for beneficiaries who are prescribed to 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, pharmacies have experienced the increasing consequences of DIR fees. The unpredictable, inconsistent, retroactive nature of these fees – often 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.

Having said that, to properly effectuate the change and avoid unintended consequences of the change, FMI respectfully requests that the Administration consider the following: CMS proposes to redefine negotiated price to "reflect the lowest possible reimbursement that a network pharmacy could receive from a particular Part D sponsor for a covered Part D drug."[4] FMI is concerned that sponsors and PBMs may create a workaround for the new definition by moving all pharmacy price concessions to the point of sale, resulting in a net reimbursement rate below the pharmacy's acquisition cost. This would effectually hinder pharmacies from being able to participate in the Medicare program – not because of the unpredictable fees, but rather based on the lower and more aggressive reimbursement rates.

Accordingly, as discussed in greater length below, FMI respectfully requests that the Administration codify requirements for reasonable pharmacy reimbursements which cover, at the very least, pharmacies' drug acquisition costs, drug specific dispensing costs and other applicable costs associated with the dispensing of each specific drug.

Redefining "Negotiated Price" to Exclude Contingent Price Concessions That Could Flow to a Pharmacy

FMI supports CMS' proposal to exclude from the definition "any additional contingent amounts that could flow to network pharmacies and thus increase prices over the lowest reimbursement level, such as incentive fees." Pharmacies should be financially incentivized to support positive outcomes and meet applicable performance metrics. Therefore, we agree with the Administration's proposal to exclude contingent positive amounts from the definition, which would help to standardize the process of how Part D sponsors implement performance-based payment arrangements, while also providing an effective mechanism for network pharmacies to participate and be reimbursed accordingly. Importantly, these performance adjustments should continue to occur after the point of sale. All parties involved would benefit from such an arrangement: the sponsors would see positive results; beneficiaries would receive the benefit of high-level pharmacy services without taking on higher out of pocket costs; and pharmacies would receive reimbursements for their services.

Furthermore, we agree with CMS' assertion in the proposed rule that including incentive payments in the "negotiated price" definition would increase the basis used to determine beneficiary cost-sharing, thus creating a perverse disincentive for beneficiaries to use higher performing pharmacies as they would have higher cost-sharing.

Developing a Standard Set of Metrics for Contingent Amounts

FMI respectfully requests that the Administration adopt and codify a standard set of performance metrics with achievable goals tailored to pharmacy type, drug dispensed, and disease state being managed, from which all plans and pharmacies would base their contractual agreements. Currently, each plan has adopted its own unique set of metrics that may or may not equally apply to all network pharmacies. As a result, in certain situations, a pharmacy may not dispense drugs of a certain category, yet it will still be put into a pool of pharmacies which do dispense those drugs, and therefore, suffer negative points or metrics when it has no dispensing activity.

Often, pharmacies do not even know what the standards are, how they are applied, who they are being compared against, how performance is measured, and/or how performance translates into incentive payments. Therefore, FMI respectfully submits that a standard set of metrics – with realistic goals based

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[4] 83 Fed. Reg. 62152 (Nov. 30, 2018).

on pharmacy type, drug dispensed, and disease state being managed – must be formalized to enable pharmacies to both understand the expectations and gauge their own performances.

Request for CMS to Clarify and Codify Reasonable Pharmacy Reimbursement Requirements

FMI urges CMS to adopt language requiring fair and reasonable reimbursement terms, especially as it is foreseeable that Part D Sponsors and PBMs will impose upon pharmacies even more aggressive rates and less favorable reimbursement terms if they are no longer able to levy DIR fees beyond the point of sale. At a minimum, reimbursement rates should cover pharmacies' costs of purchasing and dispensing covered items and providing covered services. To that end, FMI urges the Administration to require that contracts between Part D sponsors and CMS contain this protection.

Most pharmacies do not have the ability to negotiate reimbursement rates, including guaranteed rates in the aggregate, which are offered by PBMs. Consequently, pharmacies are often forced to accept aggressive reimbursement terms based on arbitrary pricing mechanisms, such as maximum allowable cost ("MAC"). As a result, today's pharmacies often find that the reimbursement they receive is less than the pharmacy's costs (drug acquisition plus cost to dispense). Under-reimbursement can force pharmacies out of networks or even out of business, limiting beneficiary access to the pharmacy of their choice.

Therefore, in addition to clarifying and adopting regulations based on the foregoing points, FMI also requests that CMS affirmatively require intermediaries to offer reasonable and appropriate reimbursement terms for all Part D drugs, which at a minimum, cover the cost of procuring drugs and providing other services related to their dispensing. Furthermore, we also urge the Administration to implement safeguards to prevent Part D Sponsors and PBMs from creating workarounds to avoid reimbursing pharmacies reasonable amounts for such purposes. Adopting these requirements would help to ensure patient access and choice in Medicare Part D plans, while allowing pharmacies a true opportunity to participate in networks without netting negative reimbursements, or reimbursements so low they are forced to drop out of such networks.

In conclusion, CMS' proposed rule demonstrates the Administration's dedication to providing immediate savings for seniors at the pharmacy counter, as well as needed support to pharmacies and their patients; it is a first, but important, step in the right direction. We urge the Administration to consider our input while finalizing the proposal for plan year 2020. On behalf of the retail grocery sector and supermarket pharmacies, FMI appreciates the opportunity to provide these comments.

If you have questions about these comments or would like additional information, please feel free to contact me at pmatz@fmi.org or 202-452-8444.

Sincerely,

Peter Matz
Director, Food and Health Policy