



January 16, 2018

Ms. Seema Verma
Administrator, Centers for Medicare & Medicaid Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard C1-13-07
Baltimore, MD 21244

Re: CMS-4182-P—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

Dear Administrator Verma:

On November 28, 2017, the Centers for Medicare & Medicaid Services (CMS or the Agency) published in the *Federal Register* 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.”¹ The Agency has indicated that the proposed rule would revise, among other things, the Medicare Prescription Drug Benefit program (Part D). The Food Marketing Institute (FMI) greatly appreciates the opportunity to comment on the proposed rule, and in particular to proposals relating to Medicare Part D Plan Sponsors.

By way of background, FMI proudly advocates on behalf of the food retail industry, which employs nearly 5 million workers and represents a combined annual sales volume of almost \$800 billion. FMI member companies operate nearly 33,000 retail food stores and 12,000 pharmacies. FMI membership includes the entire spectrum of food retail venues; single owner grocery stores, large multi-store supermarket chains, pharmacies, online and mixed retail stores. Through programs in public affairs, food safety, research, education, health and wellness and industry relations, FMI offers resources and provides valuable benefits to almost 1,000 food retail and wholesale member companies and serves 85 international retail member companies. In addition, FMI has almost 500 associate member companies that provide products and services to the food retail industry. For more information, visit www.fmi.org and for information regarding the FMI Foundation, visit www.fmifoundation.org.

Health and wellness is of the utmost importance to retailers and for years, FMI and its members have recognized the need to help consumers navigate these important aspects of the shopping experience. Retailers continuously strive to provide consumers with innovative ways to improve

¹ 82 Fed. Reg. 56,336 (Nov. 28, 2017).

and maintain their health by making it easier for them to identify nutritious foods, and by providing wellness-focused programs that help customers improve their overall well-being. Supermarket programs range from carrying more health and wellness specific products to in-store clinic and pharmacy offerings, such as medication counseling, blood pressure monitoring, other screening programs, prescription compounding and delivery, medical equipment training, immunizations and many more. Supermarket pharmacies remain an important factor in the ability of American consumers to purchase the drugs they need to remain healthy, and 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. It is important to our members and the communities they serve to maintain these pharmacies and the benefits they provide.

As part of the Proposed Rule, CMS has solicited information relating to a proposal that Medicare Part D Plan Sponsors (“Sponsors”) be required to include all pharmacy price concessions and a minimum percentage of manufacturers rebates in the drug’s “negotiated price” at the point of sale rather than accounting for retrospective pharmacy price concessions and manufacturer rebates as “Direct and Indirect Remuneration” (“DIR”) long after completion of the plan year. FMI supports an approach that would require Sponsors to recognize retrospective pharmacy concessions—so-called “DIR Fees”—as price concessions in the “negotiated price” used to adjudicate Part D claims at the point of sale, rather than as DIR after termination of the plan year. This approach would provide greater transparency, enhance the predictability of business operations, and, as CMS concluded, lead to significant beneficiary savings.

Currently, DIR fees are assessed retroactively, often weeks or even months after a prescription has been filled. This creates uncertainty for the supermarket pharmacy as to what its net reimbursement for dispensing a medication will be. Such a delay imposes an unnecessary burden on supermarket operators as they assess their ability to invest in and grow their business. Furthermore, the sheer magnitude of these fees, which can often amount in the tens of thousands of dollars annually, often forces supermarket pharmacies to make tough decisions, to reduce employee hours, or in some cases, lay off employees. While these fees 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 1.0 and 2.0%.² At such low profit margins, grocery retailers have virtually no ability to absorb unexpected costs and are ultimately forced to pass the cost on to consumers in the form of higher prices, or to reduce services such as those discussed above. With such low profit margins, supermarkets rely heavily on predictability when determining the number of pharmacists and health professionals to hire, and the additional services such as health screenings and immunizations they are able to provide each year. Increased transparency will help improve FMI members’ ability to calculate the cost of drugs and operating pharmacies. By building more predictable costs into their yearly operating calculations, supermarkets will be more able to maintain these important pharmacies and the benefits they offer to customers.

In addition to the benefits to supermarket pharmacies, CMS has indicated that, even when considering the potential for slight increases in monthly premiums that CMS predicts,

² FMI Report, Food Retailing Industry Speaks (2017).

beneficiaries would realize net savings of \$10.8 billion. This would also slow beneficiary progression through the phases of the Part D program. These conclusions align with CMS' previous findings that DIR affects beneficiary cost-sharing and CMS payments to plans while also pushing patients into, and through, the coverage gap sooner. Finally, CMS recognized that several research studies demonstrate that the higher patient cost-sharing that results from retroactively applying pharmacy DIR fees can impede beneficiary access to necessary medications. As has been well-noted, medications don't work in those who don't take them; thus, the result is often poorer health outcomes and higher costs to the health care system as patients seek costlier treatments. Requiring pharmacy DIR fees to be reported at point-of-sale could create greater savings to Medicare by promoting medication access and adherence.

Given the overall patient savings predicted by CMS and the enhanced transparency created by these provisions, we believe that CMS acted prudently by considering them in the proposed rule. We urge CMS to act swiftly in adopting a requirement to account for all pharmacy DIR at point-of-sale. Once again, FMI appreciates the opportunity to submit comments to CMS regarding the proposed rule.

If you have questions about these comments or would like additional information, please feel free to contact me at (202) 220-0637 or dgraber@fmi.org.

Sincerely,

A handwritten signature in cursive script, reading "Dana Mullen Graber".

Dana Mullen Graber
Regulatory Counsel