



April 8, 2018

Submitted Electronically Via Federal Rulemaking Portal: www.regulations.gov

Aaron Zajic
Office of Inspector General
Department of Health and Human Services
Cohen Building
Room 5527
330 Independence Avenue, SW
Washington, DC 20201

RE: Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protections for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

To Whom It May Concern:

The U.S. Chamber of Commerce (the “Chamber”) submits these comments to the Department of Health and Human Services’ Office of Inspector General (the “Department”) in response to the proposed rule to amend the safe harbor regulation concerning discounts, which are defined as certain conduct that is protected from liability under the Federal anti-kickback statute, section 1128B(b) of the Social Security Act (“Proposed Rule”).¹ The Proposed Rule was published in the Federal Register on February 6, 2019.

This Proposed Rule would significantly revise the discount safe harbor to explicitly exclude certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D, Medicaid managed care organizations, or pharmacy benefit managers (“PBM”) under contract with them. In addition, the Department is proposing to protect certain point of sale reductions in price on prescription pharmaceutical products and protect certain PBM service fees.

OVERVIEW

The Chamber appreciates the opportunity to comment on this Proposed Rule. In particular, we share and support the Department’s interest in: addressing potential barriers to lowering drug costs; re-evaluating potential perverse incentives that may impact the way manufacturers set list prices, and; correcting distortions in the distribution chain. Employers are committed to improving access to treatment which includes exploring opportunities to lower costs associated with obtaining treatment as well as preserving the investments necessary for businesses to

¹ Proposed Rule, 84 Fed. Reg. 2340-2363. (February 6, 2019) (to be codified at 42 C.F.R. pt. 1001) [hereinafter referred to as the “Proposed Rule”] <https://www.govinfo.gov/content/pkg/FR-2019-02-06/pdf/2019-01026.pdf>

develop, innovate, and bring new therapies to market. These comments have been developed with the input of the Chamber's member companies with an interest in improving the health care system.

The Chamber strongly supports the employer-sponsored health care system through which 181 million individuals have health care coverage. Part of the employer-sponsored system includes coverage provided by employers to retirees through Medicare Advantage ("MA"), integrated Medicare Advantage – Part D plans ("MA-PD") and Medicare Part D ("PDP") Employer Group Waiver Plans ("EGWP"). Created by the Medicare Modernization Act of 2003, EGWPs are a type of MA and/or Part D plan that provide health coverage benefits to retirees who receive retiree health coverage through their former employer. There are 4.3 million Medicare beneficiaries currently enrolled coverage through EGWPs, which constitutes 21 percent of MA enrollees. On behalf of employers who provide and subsidize retiree coverage, the Chamber urges the Department to preserve the current rebate flexibility allowing plan sponsors to determine where rebates are applied and whether beneficiaries receive them directly (at point of sale) or indirectly.

PRESERVE FLEXIBILITY FOR PLAN SPONSORS

In addition to offering and subsidizing health care coverage for employees and their families through fully insured and self-insured group health plans, many employers contribute significantly to retirees' premiums for coverage under these EGWPs. For both populations, employers currently enjoy the ability to determine whether beneficiaries receive rebates at the point of sale or whether the rebates flow back to the plan sponsor to be used to offset costs or finance benefits elsewhere. This choice must be preserved for plan sponsors.

The Chamber is concerned the proposal to remove this long-standing safe harbor protection would eliminate the current flexibility afforded to plan sponsors. By mandating rebate dollars only flow to beneficiaries at point of sale, the proposed rule will remove an important lever employers currently use when designing and pricing benefits to best reflect the needs of their employees, retirees, and companies. Instead, we urge the Department to continue to allow plan sponsors to determine how to structure their retiree plans and not impose a one-size fits all approach on where and to whom rebates are issued.

CONCLUSION

The Chamber shares the goals of the Department to improve access, reduce barriers and incentives increasing costs, and promote transparency, but urge the Department to preserve the current benefit design flexibility for plan sponsors. We look forward to continuing to work together in the future.

Sincerely,



Katie Mahoney
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U.S. Chamber of Commerce