ERIC
The ERISA Industry Committee
Driven By and For Large Employers
701 8th St., NW, Suite 610, Washington, DC 20001 • (202) 789-1400 • www.eric.org
James Gelfand, Senior Vice President of Health Policy

January 25, 2019

Submitted Electronically via: ***www.regulations.gov***

Attention: CMS-4180-P
Center for Medicare and Medicaid Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Comments on Proposed Rule on Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Costs

To Whom It May Concern:

The ERISA Industry Committee ("ERIC") is pleased to submit the following comments in response to the Proposed Rule ("the rule") on "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses." While we largely support the proposals contained therein, ERIC wishes to reiterate that government mandates to require point-of-sale rebates for branded prescription drugs will increase costs for plan beneficiaries, incentivize the use of branded prescriptions instead of generic or biosimilar options, serve to enshrine the rebate system, and reinforce the current high list cost crisis that the Administration otherwise seems focused on proactively addressing.

ERIC'S INTEREST IN THE PROPOSED RULE

ERIC is the only national trade association that advocates exclusively on behalf of large employer plan sponsors on health, retirement, and compensation public policies on the federal, state, and local levels. ERIC's member companies employ millions of workers and offer comprehensive group health benefits to their employees in compliance with the myriad federal laws including the Internal Revenue Code ("Code"), the Employee Retirement Income Security Act ("ERISA"), and the Public Health Service ("PHSA"). ERIC supports the ability of its large employer members to tailor retirement, health, and compensation benefits to meet the unique needs of their workforce, providing benefits to millions of workers, retirees, and their families across the country.

Many ERIC member companies still offer significant health benefits to their retirees, with some sponsoring Part D prescription drug plans, and others Medicare Advantage options such as Employer Group Waiver Plans (EGWPs). As such, we have a keen interest in improving these Medicare programs for the benefit of our employee and retiree populations. Further, ERIC is deeply committed to working towards making the cost of prescription drugs more affordable. While 181 million Americans currently get job-based health insurance coverage through employers such as ERIC members, we fully understand the important role the Medicare program

plays, insuring more than 50 million Americans. We support changes to Medicare that will enhance the program, incorporate more of the value-driven advances that employers include in our own coverage, and improve the overall health care system by driving value, affordability, and quality.

COMMENTS

I. Providing Plan Flexibility to Manage Protected Classes

In this section, CMS proposes to give Medicare plans more discretion in designing formularies as they relate to the six protected classes of drugs, in which current policy requires every available drug in that class to be covered under the plan. This proposal is likely to save significant money for both Medicare beneficiaries and the taxpayers, while fully maintaining access to treatments for all disease states.

More specifically, the proposal would allow Medicare plans to implement step-therapy measures for protected class drugs, exclude certain protected class drugs that might otherwise contribute to reducing competition, and exclude drugs that demonstrate egregious price increases.

The changes are warranted and necessary, and directly mirror medical management strategies that private sector employer plan sponsors have been successfully implementing for decades in our active employee plans. Without sufficient medical management, the costs of health insurance would continue to skyrocket, without improving care for beneficiaries. Step-therapy (sometimes referred to as "try first") policies are a critical part of medical management – often times, they fill gaps in knowledge among beneficiaries and providers, helping to steer patients first to more affordable medications that are appropriate for their indications. Step-therapy and substitution will be absolutely critical to the establishment and advancement of a functional and sustainable market for biosimilar drugs, which will significantly benefit all patients as well as plan sponsors and taxpayers.

Likewise, efforts to control high prescription drug costs are unlikely to be successful so long as coverage of all products within a class is mandatory, even if those products do not bring significant new benefit, or if they unjustifiably spike in cost. In private sector employer-sponsored plans, so long as patients will still have access to sufficient treatments, these drugs are often excluded – unless or until they can be shown to produce sufficient value, or their prices come back into alignment with market realities.

As such, these proposed provisions should be adopted to the fullest extent possible.

II. E-Prescribing and the Part D Prescription Drug Program; Updating Part D E-Prescribing Standards

The second proposed provision would expand the use of point-of-prescribing tools to help Medicare beneficiaries ensure that they are getting the most affordable treatments for a

given indication. These tools help providers to optimize patient care, empowering them to furnish patients with all the information.

Many ERIC member companies, their third-party administrators (TPAs), and the pharmacy benefit management (PMB) companies they contract with encourage providers to use point-of-prescribing tools. If providers increased utilization of these tools under the Medicare program, not only would there be significant savings for Medicare beneficiaries, but the providers would also be more likely to use these tools for enrollees in other coverage, including employer-sponsored plans. This would be a win for the whole health care system, reducing out-of-pocket costs, increasing price competition in the prescription drug space, and improving patient choice.

As such, CMS should fully implement requirements to advance point-of-prescribing tools used throughout the Medicare program.

III. Medicare Advantage and Step Therapy for Part B Drugs

The third provision would clarify that medical management tools like step-therapy and prior authorization requirements may be used by Medicare Advantage plans pertaining to Part B drugs. CMS – as well as the Administration in their American Patients First blueprint – has rightly identified that there are many problems with Part B that contribute to unnecessarily high drug costs both in Medicare and in the private market, and the lack of clarity about medical management is one. As stated earlier, ERIC member companies for decades have made use of these and other tools to help ensure maximum utilization of the most affordable medically-appropriate treatments.

As such, CMS should implement this provision and ensure that every part of the Medicare program is empowered to drive value by using critical medical management tools.

IV. Pharmacy Price Concessions to Drug Prices at the Point of Sale

The fourth provision in the rule constitutes at least the third iteration of a proposal to divert prescription drug rebate payments, which under the current model are directed toward lowering premiums for all plan enrollees. Instead, the proposal would direct that these rebates (to some extent) be paid to the specific beneficiaries who fill those branded prescriptions that give rise to rebates. When the Administration proposed this idea in the American Patients First blueprint, ERIC's response was the following (emphasis partly added):

"***Requiring that plans pay rebates directly to consumers will not lower drug costs****. It will reduce spending for a small subset of patients who fill certain branded prescriptions. However, **it will raise costs for all plan participants** (including the patients who receive the rebate), by causing premiums to increase. It will also increase the likelihood of individuals choosing to fill a branded prescription instead of a lower-cost or generic alternative, which will have the net effect, again, of raising premiums for all plan enrollees. And perhaps worst of all, this change would perpetuate the current system of rebates, thus taking the wind out of the sails of efforts to make drug purchasing more transparent and straightforward. This "solution" is*

strongly supported by branded manufacturers, but payers are aware of the adverse effects it presents. Not to mention, point-of-sale rebates create fiduciary issues for plan sponsors, as ERISA has very strict rules about the treatment of "plan assets." ***The Administration should eschew efforts to mandate point-of-sale rebates***."

We stand by these comments and would directly apply them to the new proposal. We will note that CMS' cost-estimate for this proposal is striking – the government would lose $13.6 to $16.6 billion over ten years, branded pharma companies would receive $4.9 to $5.8 billion in new profits, and the specific beneficiaries who fill these prescriptions would save money, but this savings may be illusory due to higher premiums. This is in stark, abrupt contrast to the other proposals contained in the proposed rule, as the rest seem to be designed to save money for beneficiaries, taxpayers, and Medicare.

When the Administration sought comments on a previous point-of-sale rebate requirement proposal (CMS-4182-P), ERIC provided extensive comments. Below are some excerpts, which still apply in their entirety (emphasis added):

"*The impact on Part D beneficiary premiums deserves particularly close scrutiny. Manufacturer rebates are used by Part D sponsors (just as they are used by employers in the commercial market) to reduce costs for everyone. The CMS proposal would lower drug costs for Part D beneficiaries who utilize rebate-generating brand drugs, while providing no benefit for Part D beneficiaries who do not. But saving money for the few would have far greater consequences -* ***to compensate for the financial loss of manufacturer rebates, Part D sponsors would be required to raise premiums and out-of-pocket costs for all Part D beneficiaries****.*

More broadly, we are concerned that the CMS proposal is a band-aid solution to a complex set of problems. Most of the challenges CMS outlines are not new, are not simple, and will not be solved by a minor price reduction at the point-of-sale. We note that some studies have found that point-of-sale rebates could produce savings for beneficiaries using branded medications who are paying toward their deductibles or have coinsurance. However, ultimately plan design changes must be balanced between offering relief to limited sets of beneficiaries, and holding down costs for all enrollees.[…]

Indeed, MedPAC recently issued a report recommending strategies to minimize some of the challenges identified in the RFI. The MedPAC recommendations included shifting greater financial responsibility to Part D sponsors when Part D beneficiaries reach the catastrophic coverage level and, at the same time, eliminating cost-sharing for those beneficiaries. But MedPAC assumed that its recommendations could only be implemented by Congress. In other words, MedPAC's assessment was that many of the problems require statutory changes and do not lend themselves to administrative fixes through federal rulemaking.

It is compelling to note that even MedPAC disagrees with the current CMS proposal. In recently-filed comments on the RFI, MedPAC noted:

"However, we are concerned that CMS's proposed approach would be complex to implement, administratively burdensome and, for drug classes with few competing therapies,

would risk disclosure of confidential rebate information. Further, the policy would not help beneficiaries who take expensive drugs with no post-sale rebates or discounts. We strongly encourage CMS to search for alternative policies that are less complex but could help to achieve similar aims."

We share MedPAC's concerns. In our view, the CMS proposal represents a serious threat to the Part D program – higher premiums for Part D beneficiaries and increased government costs for taxpayers. Adding to this maelstrom are the disruptive effects for ERIC members and their covered retirees. Forcing rebates down to the point-of-sale would fundamentally alter the economics, and the premiums, for employers who offer retiree health benefits. The long-term financial impacts of this change are unknown."

As such, ERIC urges CMS to abandon this and any other similar proposal.

CONCLUSION

In addition, ERIC commends CMS for taking action as directed by Congress to eliminate gag clauses in Medicare. ERIC supported congressional efforts to fully eliminate gag clauses throughout the health care system, and is encouraged to see the "*Know the Lowest Price Act*" carried out to completion.

Thank you in advance for considering these comments. Please do not hesitate to contact me with any questions, or if I can serve as a resource on these very important issues.

Sincerely,

James P Gelfand

James P. Gelfand
Senior Vice President, Health Policy