ERIC The ERISA Industry Committee
Driven By and For Large Employers
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Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: CMS-4182-P

To Whom It May Concern:

The ERISA Industry Committee (ERIC) is pleased to submit these comments in response to the Centers for Medicare & Medicaid Services (CMS) notice of proposed rulemaking entitled "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," published in the Federal Register on November 28, 2017 (82 FR 56336).

ERIC'S INTEREST IN THE MEDICARE PRESCRIPTION DRUG PROGRAM

ERIC is the only national trade association that advocates exclusively on behalf of large employers on health, retirement and compensation public policies on the federal, state, and local levels. 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.

ERIC's member companies offer comprehensive group health benefits to their employees in compliance with the myriad federal requirements placed upon group health plans subject to the Employee Retirement Income Security Act (ERISA), and other federal laws including Medicare. As such, ERIC members are keenly interested in the ongoing promulgation and enforcement of rules relating to these laws, in order to maximize compliance, minimize unnecessary costs and burdens, and ensure optimal health outcomes for the millions of beneficiaries ERIC companies insure.

BACKGROUND

Many ERIC member companies voluntarily offer medical coverage to their Medicare-eligible retirees. These arrangements frequently involve employer group waiver plans (EGWPs) – established through direct contracts with CMS or, more commonly, through contracts with sponsors of Medicare Advantage (MA) and/or Medicare Part D plans. Other member companies provide retirees with stand-alone health reimbursement arrangements (HRAs) linked to Medicare exchanges, where beneficiaries get to pick their own Medicare plans with an employer subsidy. Contracting with MA and/or Part D plan sponsors allows employers to shift administrative responsibilities and insurance risk, thereby reducing long-term financial liabilities and lowering costs for retirees, while simultaneously saving significant amounts of money for CMS and taxpayers. In many cases, ERIC member companies offer retiree medical coverage that exceeds coverage provided under more traditional retiree medical plans or basic Medicare plans. As a result, employer-sponsored retiree health benefits produce high levels of beneficiary satisfaction.

EGWP enrollment is robust and has increased steadily in recent years. The Medicare Payment Advisory

Commission (MedPAC) estimates that 3.7 million Medicare beneficiaries were enrolled in Medicare Advantage EGWPs during 2017.[1] The 2017 Annual Report of the Board of Trustees estimates that 6.7 million Medicare beneficiaries were enrolled in Medicare Part D EGWPs during 2017.[2]

Unfortunately, continued utilization of EGWPs is not guaranteed, and cost increases could cause employers to further reduce their involvement in sponsoring the various retiree health arrangements they offer today. The 2010 Patient Protection and Affordable Care Act significantly reduced the financial incentive for employers to sponsor retiree prescription drug benefits. The looming 2020 deadline of the so-called Cadillac tax will force employers to re-evaluate, and possibly curtail, medical coverage for both active employees and retirees. In addition, program changes to the Medicare Advantage and Medicare Part D programs, such as those described in the notice of proposed rulemaking, may affect the availability and attractiveness of employer-sponsored retiree health benefits for both MA and/or Part D plan sponsors and the employers with which they contract, or make plans unaffordable for beneficiaries with stand-alone HRAs. We have reviewed the notice of proposed rulemaking and offer our general comments on two provisions.

COMMENTS

I. REQUEST FOR INFORMATION – APPLICATION OF MANUFACTURER REBATES AT THE POINT-OF-SALE

The notice of proposed rulemaking includes a request for information (RFI) discussing the application of manufacturer rebates at the point-of-sale. More specifically, the RFI indicates that CMS is considering future rulemaking that would *require* Part D plan sponsors to reflect a portion of drug manufacturer rebates at the point-of-sale.[3] Various rationales are offered in support of this proposal, including assertions that Part D sponsors and their pharmacy benefit managers (PBMs): (1) have incentives to under-forecast direct and indirect remuneration (DIR) in their Part D bids; and (2) prefer to negotiate higher list prices for drugs to increase DIR and push Part D beneficiaries more quickly to catastrophic coverage where Medicare liability is highest. Another stated rationale is that drug rebates should be reflected at the point-of-sale so that Part D beneficiaries can find the lowest-cost drugs or the lowest cost drug and pharmacy combination.

To combat these alleged problems, CMS outlines an elaborate methodology that would require Part D sponsors to reduce list prices at the point of sale by some percentage of the "average rebate amount" (amounts expected to be received during the current plan year based on a good faith estimate) focusing on 11-digit national drug codes for each rebated drug, with separate calculations required for each plan-benefit-package level. The average rebate amount to be applied to the point-of-sale price of a particular drug would be determined based on the average rebate amount for all rebated drugs in the same therapeutic category or class, weighted for each individual drug in that category. To add further complexity, Part D sponsors would be required to *recalculate* the applicable average rebate amount as frequently as every month.[4]

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[1] *The MedPAC June 2017 Data Book, Health Care Spending and the Medicare Program*, Chart 9-7 (Enrollment in employer group MA plans, 2006-2017 available at: http://www.medpac.gov/docs/default-source/data-book/jun17_databookentirereport_sec.pdf?sfvrsn=0

[2] *The 2017 Annual Report Of The Boards Of Trustees Of The Federal Hospital Insurance And Federal Supplementary Medical Insurance Trust Funds*, Table IV.B7 (Part D Enrollment) available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf

[3] To put it mildly, this would be a radical change. CMS regulations in effect from 2005 through 2015 excluded manufacturer rebates from the definition of "negotiated prices" unless the Part D sponsor *elected* to pass rebates through to Part D enrollees at the point-of-sale. Even now, the regulation only addresses point-of-sale price concessions from network pharmacies (not manufacturers). See 42 C.F.R. 423.100; 79 Fed. Reg. 29844, 29876 (May 23, 2014).

[4] The proposal would also require a Part D sponsor's CEO, CFO or COO to attest to the "accuracy, completeness and truthfulness" of the average rebate amount (despite the fact that amount will be based on a "good faith estimate"). This requirement raises the specter that Part D sponsors may face possible liability and triple damages under the federal False

While there is no question that Part D sponsors and their PBMs have the technical ability to comply with the CMS proposal (some PBMs already apply drug manufacturer rebates at the point-of-sale in the commercial market), the potential disruption of this proposal is significant. The financial impact tables included in the RFI are staggering – even passing a modest 33% of rebates through to the point-of-sale would increase Part D beneficiary premiums by $9.2 billion and would increase CMS costs by $27.3 billion (over a 10 year period). Even if the financial impact on Part D sponsors and their PBMs is neutral (that impact is not illustrated) it leads ERIC members to wonder – will the CMS proposal have the counterproductive effect of incenting Part D sponsors to drop out of the Part D program? In the very least, CMS needs to reconsider the complicated nature of this mandate, and consider simpler ways to achieve the goals of sharing savings between plan sponsors and beneficiaries. It is critical that the PBMs who would be responsible for managing delivery of new savings models are consulted in this process.

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.[5] However, ultimately plan design changes must be balanced between offering relief to limited sets of beneficiaries, and holding down costs for all enrollees. Over the years, various stakeholders have flagged the variety of challenges facing the Part D program – the growing disparity in the gross-to-net "bubble," the myriad distortions in the Part D reimbursement process, and the open-ended financial exposure for Part D beneficiaries reaching the catastrophic coverage level.[6]

Indeed, MedPAC recently issued a report recommending strategies to minimize some of the challenges identified in the RFI.[7] 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:

Claims Act if and when CMS later questions the accuracy of an average rebate amount.

[5] *See* Milliman, *Point of Sale Rebate Analysis in the Commercial Market* (Oct. 2017). Available at: http://phrma-docs.phrma.org/download.cfm?objectid=5F5FD190-AEDD-11E7-833F0050569A4B6C ("Patients whose pharmacy cost sharing is in the deductible or coinsurance phase of a "Coinsurance HDHP" could see POS cost reductions averaging over $200 a month per script.")

[6] *See*, e.g., Dusetzina, Conti, Yu and Bach, *Association of Prescription Drug Price Rebates in Medicare Part D with Patient Out-of-Pocket and Federal Spending,* JAMA Internal Medicine (August 2017).

[7] *MedPAC Report to the Congress: Medicare and the Health Care Delivery System, Chapter 6, Improving Medicare Part D (June 2016)*, available at: http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf

> "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."[8]

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 impact of this change are unknown. Employers and Part D plans need sufficient lead time to understand, evaluate, and plan for changes of this magnitude, and it does not appear that any of those issues have been taken into consideration. For all these reasons, we recommend that CMS reconsider its proposal to require Part D sponsors to reflect a portion of drug manufacturer rebates at the point-of-sale.

II. ANY WILLING PHARMACY STANDARDS, TERMS AND CONDITIONS, AND DEFINITIONS

The notice of proposed rulemaking also includes a series of changes related to the requirement that Part D sponsors contract with "any pharmacy" that meets the sponsor's standard terms and conditions. ERIC members are concerned that CMS now appears willing to re-interpret the any willing pharmacy requirement in ways that could undermine the existence and future development of preferred pharmacy networks.

Employer-sponsored Part D plans are already under significant stress; providers, including hospital and doctor groups, are increasingly opening up their own captive pharmacies, that offer drugs on site but at steeply higher costs than preferred pharmacies. The problem is especially significant in the specialty drug space, with costs significantly higher to both patients and plan sponsors.

Preferred pharmacy networks have become an integral part of Part D plans. These networks help Part D sponsors negotiate deeper discounts with selected pharmacies in exchange for providing those pharmacies with the opportunity to expand prescription volume. In addition, plan sponsors use preferred pharmacy networks as a key element of their plans' health management strategies, such as engaging with diabetics and COPD patients. Despite the anecdotal evidence of "abuses" mentioned by CMS, the reality is that preferred pharmacy networks developed by Part D sponsors have saved significant taxpayer dollars without any sacrifice of quality or member satisfaction.[9] Our members believe that preferred pharmacy networks enable Part D sponsors to recognize and reward high-performing pharmacies, and that this practice improves the quality of pharmacy services provided to our Medicare-eligible retirees. If changes are made in this space, it is critical that plans are able to offer discounts to beneficiaries who do use preferred pharmacy partners.

There has always been tension between the statutory dictate that Part D sponsors contract with any willing pharmacy and the practical reality that Part D sponsors must carefully manage the cost, clinical oversight and delivery of prescription drugs. CMS recognized this tension when writing the original 2005 Part D regulations, and expressly endorsed the principle that Part D sponsors have substantial discretion in developing contractual terms and conditions. Indeed, the preamble to the 2005 Part D regulations includes the following statement:

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[8] Available at: http://www.medpac.gov/docs/default-source/comment-letters/01032018_partc_d_comment_v2_sec.pdf?sfvrsn=0

[9] *See* Milliman, *The Impact of Preferred Pharmacy Networks on Federal Medicare Part D Costs, 2014-2013* (Oct. 2013). Available at: http://www.pcmanet.org/images/stories/uploads/2013/milliman%20preferred%20pharmacy%20networks.pdf ("Preferred pharmacy network plans are estimated to reduce federal Medicare spending by approximately $870 million in 2014. Over the next ten years, preferred pharmacy network plans are estimated to reduce federal Medicare spending by $7.9 to $9.3 billion").

> "Ultimately…it is at Part D plans' discretion how they will establish pharmacy networks—including the offering of contracting terms and conditions that are different than standard contracting terms and conditions and the establishment of preferred pharmacies provided they meet our pharmacy access standards, non-discrimination provisions, and other applicable requirements under Part D."[10]

We urge CMS not to forego this exquisitely balanced principle. If preferred pharmacy networks are completely open to any pharmacy whatsoever, then no pharmacy will have an incentive to change. There will be no way for Plan D sponsors to reward pharmacies for offering deeper discounts, improving the quality of services, or adopting value-based performance practices. As plan sponsors continue to introduce new quality improvement efforts, pharmacists may play a key role in advancing coordinated care and improving patient safety – but this will be greatly hampered if a plan cannot create and effectively maintain a pharmacy network. Part D beneficiaries deserve the most that pharmacies can offer, not the least.

We have similar concerns with respect to the CMS proposals regarding accreditation terms and conditions. We do not believe that CMS is within bounds prohibiting Part D sponsors from establishing accreditation standards that are in addition to, or different from, accreditation standards developed by recognized accrediting organizations. There is no statutory authority for this proposition, and it is completely at odds with the view that CMS takes with respect to Medicare Advantage organizations.[11] It also makes no sense from a practical perspective. Part D sponsors and PBMs operate in the forefront of prescription drug delivery, and are closely attuned to the quality measures that define optimal pharmacy practices. In contrast, recognized accrediting organizations may take longer to develop consensus measures, and are not as close to rapidly-changing market developments. Finally, we have concerns that this level of CMS oversight could violate the statutory prohibition against interference. As you are well aware, the law prohibits CMS from interfering in negotiations between Part D sponsors and pharmacies.[12]

With respect to the CMS proposals revising the definition of "retail pharmacy" and adding a new definition of "mail-order pharmacy" we have few comments. Others with greater expertise can opine whether the proposed definitions are more or less accurate. Our concern, further to our comments above, is that the revised definitions not be construed in a manner that would deny or restrict the ability of Part D sponsors to develop preferred pharmacy networks.

To conclude, we believe that CMS must remain flexible when interpreting the any willing pharmacy requirement. The standard terms and conditions of pharmacy contracts are constantly evolving – what may have been "standard" ten years ago is no longer standard today. Pharmacy contracts are constantly evolving, and Part D sponsors have a responsibility to their Part D enrollees to ensure that preferred pharmacies adopt best practices. These practices may be reflected in process improvements related to drug counseling, medication management, e-prescriptions and other tools that optimize drug therapy and improve therapeutic outcomes for Part D beneficiaries. If and when CMS identifies abusive contracting practices by some Part D sponsors, then it is certainly appropriate to use existing enforcement tools against the wrongdoers. But degrading pharmacy contracting standards for all Part D sponsors weakens their collective ability to provide the 42 million Part D beneficiaries with prescription drug cost and quality improvements.

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[10] 70 Fed. Reg. 4194, at 4249-4250 (January 28, 2005).

[11] See 42 C.F.R. §422.204(b) (permitting Medicare Advantage organizations to require providers to meet "standards established by the organization itself").

[12] *See* §1860D-11(i) of the Social Security Act.

ERIC appreciates the opportunity to provide feedback at this time. We believe the comments laid out above will assist CMS in improving the administration of the Part C and D programs, while protecting the ability of employers to continue offering quality retiree health benefits to millions of Americans. If you have questions concerning our comments, or if we can be of further assistance, please contact us at (202) 789-1400.

Sincerely,

James P. Gelfand
Senior Vice President, Health Policy