THE ERISA INDUSTRY COMMITTEE
Shaping benefit policies before they shape you.

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Director, State Advocacy and Litigation

Superintendent Adrienne E. Harris
New York Department of Financial Services
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Submitted Electronically

Re: Proposed Consolidated Rulemaking for Insurance Regulations 219, 224, and 226-229 – Public Comments from The ERISA Industry Committee

Dear Superintendent Harris:

The ERISA Industry Committee ("ERIC") appreciates the opportunity to comment on the regulations contained in "Proposed Consolidated Rulemaking for Insurance Regulations 219, 224, and 226-229" ("Proposed Rules") issued by the New York Department of Financial Services ("Department") covering pharmacy benefit managers ("PBMs") and their network practices. ERIC has deep concerns with aspects of the Proposed Rules as currently drafted that would overstep state authority to control self-insured employer health care plans governed by the federal Employee Retirement Income Security Act of 1974 ("ERISA").

ERIC is a national advocacy organization exclusively representing the largest employers in the United States in their capacity as sponsors of employee benefit plans for their nationwide workforces. With member companies that are leaders in every economic sector, ERIC is the voice of large employer plan sponsors on federal, state, and local public policies impacting their ability to sponsor benefit plans. ERIC member companies offer benefits to tens of millions of employees and their families, located in every state and city.. New Yorkers engage with ERIC member company many times a day, such as when they drive a car or fill it with gas, use a cell phone or a computer, watch TV, dine out or at home, enjoy a beverage or snack, use cosmetics, fly on an airplane, visit a bank or hotel, benefit from our national defense, receive or send a package, or go shopping.

Large employers have long been at the forefront of innovating health care benefit design and administration. By combining nationwide workforces into uniform benefit plans, employers are able to negotiate from a position of strength and secure valuable health care coverage at reduced rates, all to the benefit of plan participants. Use of this cost-saving advantage was the precise intention behind ERISA's creation by Congress, which provides a single set of standards for multistate employers to design and administer uniform health care and retirement benefits to their nationwide employees, regardless of where they live or work. Since ERISA's enactment, multistate employers have done just that, securing truly effective and efficient health care coverage enjoyed today by millions of Americans.

Unfortunately, a series of state laws proposed and enacted in recent years have begun to erode ERISA preemption, endangering valuable benefits that self-insured, large-employer plans have long provided. There is growing frustration among many about PBM practices and their role in the ever-rising costs of health care, such as how PBMs impact patient access to pharmacists or affordable drugs (such as generics and biosimilars). ERIC shares many of these concerns and has called upon Congress to increase PBM transparency and accountability through specific, meaningful federal reforms.

However, many of these state laws clearly violate, and are preempted by, ERISA because they infringe on the national uniformity of self-insured plans and overstep the limited authority that court interpretations have granted to states. Furthermore, many of these well-intentioned state laws have the ultimate effect of increasing health care costs across the state instead of reducing them for patients.

While ERIC understands the importance of competition between pharmacies and the desire to improve areas of health care coverage, the Proposed Rules would overstep state authority to regulate PBMs, establish more direct control of the design and administration of self-funded ERISA plans, and further increase the health care costs that New Yorkers already face. Furthermore, the impact of these regulatory provisions will likely be weighed heavily by employers with operations, employees, and health care benefit plans throughout New York, and could disadvantage the state's economic climate moving forward.

On behalf of our member companies, ERIC offers the following comments regarding the Proposed Rules and urges the Department to revise several key regulatory provisions that threaten the quality and affordability of prescription drug benefits across New York.

Comments

The Proposed Rules Explicitly Apply Regulatory Provisions to PBMs Administering Self-Insured Benefit Plans

First, and foremost, while the Proposed Rules and underlying New York statute are broadly focused on PBMs and the networks that they design and operate, they both explicitly include self-insured employee health plans in the list of administered plans to which new PBM regulations will be applied. Dictating the network practices available to a PBM that is administering a self-insured plan has the ultimate effect of stripping the design and administration options available to that self-insured plan.

Following ERISA preemption principles, states are prohibited from enacting controls that either refer directly to ERISA plans or "relate to" ERISA plans by affecting a central matter of plan administration, network design, or nationally plan uniformity. While the U.S. Supreme Court's opinion in *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474 (2020) found that

ERISA preemption does not necessarily prohibit *all* state regulation of PBMs, the way in which the Proposed Rules and underlying state statute prevent self-insured health care plans from designing and administering nationwide plans under ERISA clearly exceeds the limited flexibility provided by the U.S. Supreme Court decision. Most recently, ERISA's preemption of this sort of state overreach was reaffirmed by the Tenth Circuit in *Pharmaceutical Care Mgmt. Assoc. v. Mulready*, 78 F.4th 1183 (10th Cir. 2023). Several provisions of the Oklahoma PBM law at issue in that case, which are largely similar to the PBM practice controls in the Proposed Rules, were found to obstruct the design and administration of self-funded plans established under ERISA and were ultimately preempted.

Here, the Proposed Rules not only explicitly refer to self-insured plans administered by PBMs but also "relates to" ERISA plans via their attempt to indirectly dictate the design options available to those plans by controlling the practices of their PBM administrators. The ways in which the Proposed Rules "refer to" ERISA plans is laid out further in the comments below.

The Proposed Rules Would Control Self-Insured Plan Design by Applying Adequacy Standards, Limiting Use of Specialty Pharmacies, and Restricting Formulary Changes

As mentioned above, ERISA preemption prevents states from dictating the design and administration standards adopted by self-insured plans. Here, the Proposed Rules would establish a long list of pharmacy network standards that PBMs must follow, including those that administer self-insured ERISA plans, such as how many pharmacies must be available and their proximity to count toward coverage adequacy requirements. Under ERISA preemption, states have long been prohibited from placing these kinds of adequacy standards on self-insured plans, as doing so would clearly control the administration of plans' nationwide benefits.

Furthermore, the Proposed Rules seek to directly restrict PBM network use of specialty pharmacies, regardless of their long-established track record of providing reliable prescription services to patients and reducing overall prescription benefit costs. Not only does this limitation prevent access to critical specialty pharmacies and raise prescription drug costs, but it clearly impacts the ability of self-insured plans to make use of specialty pharmacies and design their own prescription benefits as they see fit.

Finally, the most concerning and flagrant impact that Proposed Rules would have on the design and administration of self-insured ERISA plans involve the attempted control of formulary changes. Essentially, the Proposed Rules prohibit PBMs from making any changes to a plan formulary unless such changes occur at the time of enrollment, issuance, or renewal of coverage. Importantly, no other state PBM policy in the country has attempted to so directly dictate the ways in which a plan or its administrator can make changes to its own formulary as this action is so inextricably linked to the design and administration of a health care plan. Aside from the ERISA preemption issues with "freezing" plan formularies, the Department does not have authority under the underlying state statute to regulate benefit design in this way. This

attempted control is not only impractical but preempted by federal law.

As reinforced by *Mulready*, affecting control of self-insured plan design by applying these kinds of standards to the PBMs administering those plans does not change the impact that they have and does not avoid ERISA preemption. If promulgated in their current form, the provisions contained in the Proposed Rules would overreach into the governance of health plan design and administration for self-insured plans and would likely spark a legal fight involving strong ERISA preemption arguments.

The Proposed Rules Establish Dispensing Fees Not Directed by Law and Would Drastically Increase Statewide Health Care Costs

The law being implemented by the Proposed Rules does not provide the Department with authority or direction to impose the sharp increase in minimum dispensing fees, or any changes to dispensing fees. While Section 280-a(2)(b) of the New York Public Health law provides authority to control "administrative fees," these are defined as payments meant to compensate PBMs for their services and do not extend to a general mandate for universal dispensing fees. The intent of law underlying the Proposed Rules was to cover the licensure of PBMs and key PBM practices, not control the entirety of contractual terms between PBMs and those they serve. Not only would the imposition of a universal minimum dispensing fee have a counterproductive impact on statewide health care costs, it also reaches beyond the intent of the law and the authority of the Department to dictate.

Moreover, when additional costs to PBMs such as dispensing fees are mandated by states, they are ultimately absorbed by employer plans and their workers. The Proposed Rules apply a minimum dispensing fee of $10.18 per filled prescription, representing more than a doubling of existing dispensing fees that have been negotiated and established in the commercial market. This will likely cost New Yorkers hundreds of millions of dollars.

Conclusion

ERIC appreciates the opportunity to provide regulatory comments on the Proposed Rules addressing statewide PBM network practices. As discussed above, several concerning provisions attempt to overstep state authority in this space and directly impact the design and administration of employer plans established under and governed by ERISA. If adopted without substantial revision, the Proposed Rules would threaten to erode the ability of large-employer plan sponsors to effectively operate national benefits plans, likely lead to litigation involving ERISA preemption issues, and undermine the ability of many employers to do business in the state of New York. **ERIC therefore strongly encourages the Department to remove all reference and application to self-insured ERISA plans from the Proposed Rules, or alternatively include an explicit exemption from regulatory provisions for PBMs administering self-insured ERISA plans.**

If you have any questions concerning our regulatory comments, the impact the Proposed Rules would have on self-insured health care plans across New York, or changes that could be made to avoid ERISA preemption, please contact us at (202) 789-1400 or dclair@eric.org.

Sincerely,

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