IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

The ERISA Industry Committee, National Labor Alliance of Health Care Coalitions, The Cigna Group, *and* Cigna Health and Life Insurance Company,

Plaintiffs,

v.

Minnesota Department of Commerce *and* Grace Arnold, *in her official capacity as Commissioner of the Minnesota Department of Commerce*,

Defendants.

Case No. 24-cv-_____

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

The ERISA Industry Committee (ERIC), National Labor Alliance of Health Care Coalitions (NLA), The Cigna Group, and Cigna Health and Life Insurance Company bring this complaint against the Minnesota Department of Commerce (the Department) and Grace Arnold, in her official capacity as Commissioner of the Department (the Commissioner), and allege as follows:

INTRODUCTION

1. This case concerns prescription-drug benefit plans established and maintained by employers and other plan sponsors for the benefit of countless millions of Americans. More specifically, it concerns Minnesota's regulation of the design and implementation of prescription-drug benefit plans' provider networks.

2. A benefit plan's network is the collection of pharmacies where participants can receive "in-network" prescription-drug benefits. Variation in network design is a principal means by which plan sponsors tailor benefits to the needs of their workforces.

Some plans use broader and more inclusive networks, which are more costly and entail higher premiums. Others use narrower networks through which they can obtain better prices and in turn offer lower premiums or enhanced benefits. Still other plans use tiered networks, which include "preferred" in-network providers where plans incentivize enrollees to obtain drugs from lower-cost providers with lower copays or co-insurance.

3. Designing and constructing pharmacy networks that meet employees' needs is an extraordinarily complex and time-consuming task requiring substantial resources; it is one far beyond the ability of a typical plan sponsor acting on its own. Plan sponsors thus ordinarily retain one or more pharmacy benefits managers, or PBMs, to provide recommendations concerning the design of the plan and to administer their networks, in addition to other administrative aspects of a prescription-drug benefit plan.

4. The State of Minnesota adopted the Minnesota Pharmacy Benefit Manager Licensure and Regulation Act of 2019 (the Act), asserting the authority to regulate prescription-drug benefit plan design. The Act dictates the kinds of pharmacies that plan sponsors must allow into their mail-order and specialty pharmacy networks, and it micromanages the terms of coverage for certain drug purchases.

5. While laws like the Act are characterized as regulations of PBMs, their practical effect is often to regulate plan sponsors and the benefits that plan sponsors choose to offer through networks maintained by PBMs.

6. Plan sponsors, not PBMs, exercise ultimate control over pharmacy network design, which is a core element of any prescription drug benefit plan that a plan sponsor may choose to offer employees. While PBMs may assist plan sponsors by, among other things, providing them with standard network options, nearly all plan sponsors adapt those initial templates to meet their unique needs. Thus, state laws like the Act, which constrain

how PBMs are permitted to construct pharmacy networks, necessarily dictate how plan sponsors are permitted to design the benefit plans that they offer employees.

7. Section 62W.07 of the Minnesota Statutes, as amended by the Act, regulates network design. It prohibits sponsors of prescription-drug benefit plans that retain PBMs from adopting common network structures. In particular, Section 62W.07(b) prevents plans from designing their mail-order networks or specialty pharmacy networks so that they include only pharmacies affiliated with the plan's PBM. Section 62W.07(d) specifies that plans may not select networks that require enrollees to obtain covered maintenance drugs from a PBM-owned mail-order pharmacy and must instead permit enrollees to fill these drugs at independent retail pharmacies. The only way to avoid these prohibitions is for a plan sponsor to open its mail-order network and specialty pharmacy network to additional non-PBM affiliated pharmacies. *See* Minn. Stat. § 62W.07(c), (e). This kind of open-network law makes a number of commonly used quality control and cost containment measures impossible, thus effectively prohibiting employers and labor union health trust funds from using them.

8. This kind of intrusive regulation of substantive benefit plan design is plainly preempted by the Employee Retirement Income Security Act of 1974 (ERISA). ERISA's express preemption clause makes regulations of the design and administration of employee benefit plans a matter of exclusively federal law. It thus protects the right of employers and labor unions to make plan design decisions for themselves.

9. By the Department's own admission, Section 62W.07 dictates the design and structure of the pharmacy networks that plan sponsors are permitted to use. As applied to self-funded ERISA benefit plans, the Act is therefore preempted. But the Department has

refused to limit its enforcement of Section 62W.07, insisting in effect that it may ignore ERISA's preemption clause.

10. In addition, the Department has asserted the power to apply the Act not only to benefit plans offered and insurance policies sold within the state, but also to plans and policies entirely outside of Minnesota and with no meaningful connection to the state. Extraterritorial regulation of this sort is forbidden by the Commerce Clause, Due Process Clause, and Full Faith and Credit Clause of the United States Constitution.

11. The Department is enforcing Section 62W.07 extraterritorially, in violation of these constitutional provisions. In the Department's view, Section 62W.07 applies to *any and every* prescription-drug benefit plan that uses a PBM licensed by Minnesota, even if the plan itself has no other connection with Minnesota. In this way, Minnesota is using a purported licensing law to regulate benefit plans that were created and operate entirely or mostly outside Minnesota's borders.

12. Paragraphs 62W.07(b) and (d) are therefore unlawful twice over. As applied to ERISA-covered prescription-drug benefit plans, they are preempted by 29 U.S.C. § 1144(a). And as applied to plans and policies offered and operating outside of Minnesota, they are barred by the Constitution.

13. In making these claims, plaintiffs ERIC and NLA understand the complaints that are sometimes brought against PBMs and the role they play in the market for prescription drugs. And to be sure, plan sponsors and PBMs do not agree on every issue. At the same time, almost none of ERIC's member companies or NLA's member funds could feasibly establish and maintain prescription-drug benefit plans without assistance from PBMs. Often the most affordable and reliable plan design options involve PBM-owned pharmacies. More generally, plan sponsors depend on PBMs' expertise to negotiate with

prescription drug manufacturers, contract with pharmacies to assemble networks, and manage the payments and supply chain that ensure prescriptions are accessible and affordable for employees and their families. They utilize PBMs to help ensure that employer-sponsored and employee-directed health benefits are equitable and uniform for all employees, no matter the state in which they may live, work, or receive medical care.

14. Ultimately, this case is not about regulating PBMs—it is about regulating benefit plan design and administration. Given "the centrality of pension and welfare plans in the national economy, and their importance to the financial security of the Nation's work force" (*Boggs v. Boggs*, 520 U.S. 833, 839 (1997)), protection of uniform plan design and administration for multistate employers and union trusts is critical to all Americans who depend on the benefits that plaintiffs and their members offer.

15. Despite assertions defendants may make to the contrary, granting the requested relief here would not mean that PBMs are free from regulation by Minnesota. The state has ample regulatory tools at its disposal—consumer protection laws, unfair trade practices laws, the antitrust laws, and others—that can be used effectively to challenge alleged misconduct by PBMs. Minnesota may also regulate PBM services in the fully insured market, with respect to policies sold within its own borders. But that, too, is not what this case is about—it is about Minnesota micromanaging relationships between plan sponsors, PBMs, and pharmacies as applied to ERISA-covered benefit plans and out-of-state plans.

16. The Department's enforcement of the Act against ERISA-covered plans and plans offered and operating outside of Minnesota is causing plaintiffs immediate and irreparable injuries. Plaintiffs accordingly seek a declaration that the Act is preempted by ERISA and that its extraterritorial enforcement is unconstitutional, and an injunction

against the Department's impermissible attempts to regulate prescription-drug benefit plan design as applied to ERISA-covered, self-funded benefit plans, and as applied to benefit plans and insurance policies offered and operating outside of Minnesota.

CAUSE OF ACTION, JURISDICTION, AND VENUE

17. Plaintiffs bring this case under 42 U.S.C. § 1983, the Supremacy Clause of the U.S. Constitution, and the Court's inherent equitable powers. *See Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 96 n.14 (1983) (recognizing cause of action to enforce ERISA preemption against state regulators).

18. This complaint arises under and presents questions of federal law. The Court's subject matter jurisdiction is thus invoked under 28 U.S.C. § 1331. *See Shaw*, 463 U.S. at 96 n.14 ("A plaintiff who seeks injunctive relief from state regulation, on the ground that such regulation is pre-empted by a federal statute . . . presents a federal question which the federal courts have jurisdiction under 28 U.S.C. § 1331 to resolve.").

19. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because defendants reside in the District.

PARTIES

20. ERIC is a nonprofit trade association with its principal place of business in Washinton, D.C. ERIC's member companies are large, multistate employers throughout the United States. Its member companies sponsor prescription-drug benefit plans that are governed by ERISA, are offered within and outside of Minnesota, and in all events are impacted by the Act. With member companies that are leaders in every sector of the economy, ERIC is the voice of large employer plan sponsors on federal, state, and local public policies impacting their ability to sponsor benefit plans for tens of millions of active and retired workers, as well as their families.

21. All of ERIC's member companies sponsor ERISA-covered prescription-drug benefit plans. Most of those plans include networks designed with recommendations from and administered by PBMs licensed in Minnesota. Many use cost-saving provisions relying upon PBM-owned or PBM-affiliated pharmacies. Many have participants residing in Minnesota, but in some instances no plan participants are resident in Minnesota.

22. Every year, ERIC's members make carefully considered decisions concerning the design of the provider networks in their benefit plans. In doing so, they depend on being able to make uniform decisions for all their employees, and not unique state-by-state judgments varying with local requirements.

23. One of ERIC's primary missions is to call attention to instances in which state laws are preempted by ERISA. As part of its institutional mission, ERIC frequently participates in litigation representing the interests of its member companies.

24. NLA is a national alliance of healthcare coalitions primarily representing labor union trust funds, mostly Taft-Hartley funds. Taft-Hartley plans, or multiemployer plans, are employee benefit plans created through collective bargaining agreements between a labor union and multiple employers in the same industry. Generally, multiemployer plans are governed by trusts directed by a board of trustees selected by the employers and the union. NLA's member funds offer a wide variety of health benefits and work together to increase the value of the benefits they offer. They serve more than six million covered individuals throughout the United States, including Minnesota, and in eastern Canada.

25. NLA's member companies sponsor ERISA-covered prescription-drug benefit plans. Most of those plans include networks designed with recommendations from and administered by PBMs licensed in Minnesota. Many use cost-saving provisions relying

upon PBM-owned or PBM-affiliated pharmacies. Some of those plans are offered to participants residing in Minnesota, but many are not.

26. As part of its institutional mission, NLA sometimes participates in litigation representing the interests of its members.

27. The Cigna Group (Cigna) is a multistate managed healthcare and insurance company based in Bloomfield, Connecticut. It employs more than 70,000 individuals in all 50 states and across the world, including in Minnesota. It is a member of ERIC.

28. Among Cigna's operating subsidiaries is Cigna Health and Life Insurance Company (CHLIC), also based in Bloomfield, Connecticut. CHLIC insures and administers group medical and dental plans, including self-funded ERISA-covered plans. Among other things, it provides third party administrator and PBM services. CHLIC is licensed as a health insurance provider and PBM by the Minnesota Department of Commerce.

29. The Minnesota Department of Commerce is the Minnesota executive department authorized to implement and enforce the Act.

30. Grace Arnold is Commissioner of the Department of Commerce. She is sued in her official capacity.

LEGAL BACKGROUND

ERISA preemption

31. In enacting ERISA, Congress recognized that "[a] patchwork scheme of regulation would introduce considerable inefficiencies in benefit program operation," leading to "reduce[d] benefits" for American workers. *Fort Halifax Packing Co. v. Coyne*, 482 U.S. 1, 11 (1987). Efficient administration of a multistate plan "is impossible . . . if plans are subject to different legal obligations in different states." *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 148 (2001).

32. To ensure against a patchwork of regulation, Congress included an express preemption provision in the statute. That provision specifies that ERISA and its implementing regulations "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan" covered by the statute. 29 U.S.C. § 1144(a).

33. With this language, Congress "intended to preempt the field for Federal regulations, thus eliminating the threat of conflicting or inconsistent State and local regulation of employee benefit plans." *Shaw*, 463 U.S. at 99. Congress intended to ensure that "the regulation of employee welfare benefit plans" would be "exclusively a federal concern" (*New York State Conference of BCBS Plans v. Travelers Insurance*, 514 U.S. 645, 656 (1995)) so that Congress could establish a "uniform regulatory regime over employee benefit plans" (*Aetna Health Inc. v. Davila*, 542 U.S. 200, 208 (2004)).

34. The driving concern behind ERISA's purely federal regulatory scheme was clear: "Requiring ERISA administrators to master the relevant laws of 50 States . . . would undermine the congressional goal of minimiz[ing] the administrative and financial burden[s] on plan administrators—burdens ultimately borne by the beneficiaries." *Gobeille v. Liberty Mutual Insurance Co.*, 577 U.S. 312, 321 (2016). ERISA's preemption provision is thus intended to "ensur[e] that plans [would] not have to tailor substantive benefits to the particularities of multiple jurisdictions." *Rutledge*, 592 U.S. at 86 (citations omitted).

35. Under ERISA's express preemption clause, state laws are therefore invalid as applied to ERISA-covered plans if they "bind ERISA plan administrators to a particular choice" concerning benefit plan design. *Egelhoff*, 532 U.S. at 147. ERISA "pre-empt[s] [state] laws that require providers to structure benefit plans in [statutorily-specified] ways, such as by requiring payment of specific benefits." *Id.*

36. Put another way, ERISA preempts state laws that "forc[e] plans to adopt [a] particular scheme of substantive coverage." *Rutledge*, 592 U.S. at 88. A state law that "require[s] providers to structure benefit plans in particular ways" (*id.* at 86-87) or "prohibits employers from structuring their employee benefit plans in a [certain] manner" (*Shaw*, 463 U.S. at 97) is preempted. *See also PCMA v. Mulready*, 78 F.4th 1183, 1198 (10th Cir. 2023) (state law requirements are preempted when a "provision either directs or forbids an element of plan structure or benefit design").

37. At the same time, Congress did not want ERISA's preemption clause to displace state insurance regulation of health insurance companies selling commercial policies to fully insured ERISA-covered benefit plans. *See* H.R. Rep. No. 94- 1785, at 48 (1977). Congress thus added a Saving Clause specifying that ERISA's preemption clause "shall [not] be construed to exempt or relieve any person from any law of any State which regulates insurance[.]" 29 U.S.C. § 1144(b)(2)(A). The Act goes beyond regulating insurance, and directly regulates the plan design of ERISA-covered group health plans.

38. Congress was also concerned that states might "deem" self-funded ERISA plans to be insurers, so that the statute's express preemption clause would not apply to them under the Saving Clause. Recognizing that the "deeming" gambit would gut ERISA's preemption clause of its meaning and expose ERISA-governed plans to a patchwork of differing state regulations, Congress added the Deemer Clause. That clause provides in relevant part that no self-funded ERISA-covered benefit plan "shall be deemed to be an insurance company or other insurer" for purposes of the Saving Clause. 29 U.S.C. § 1144(b)(2)(B). In other words, the Deemer Clause exempts "self-funded ERISA plans from state laws that 'regulate insurance' within the meaning of the saving clause." *FMC Corp. v. Holliday*, 498 U.S. 52, 61 (1990).

39. In sum, Minnesota may regulate the design of prescription-drug insurance policies sold in commercial markets, but it may *not* regulate the design of ERISA-covered prescription-drug benefit plans offered by self-insured employers or multiemployer union trusts.

Constitutional limits on states' extraterritorial regulation

40. The Constitution grants Congress the power to regulate commerce "among the several states." U.S. Constitution, art. I § 8, cl. 3. Though the clause does not expressly limit the regulatory power of individual states, the Supreme Court has long "recognized that this affirmative grant of authority to Congress also encompasses an implicit or 'dormant' limitation on the authority of the States to enact legislation affecting interstate commerce." *Healy v. Beer Institute*, 491 U.S. 324, 326 n.1 (1989). The federalist plan of government embodied in the Constitution would not be possible if one state could enact a law that is binding in another state.

41. One aspect of the dormant Commerce Clause doctrine is the extraterritoriality test. States may not enact statutes that "directly control[] commerce occurring wholly outside [their] boundaries" or that have the "practical effect of controlling conduct beyond the boundaries of the State." *Id*. at 336 (cleaned up).

42. The Supreme Court has long reiterated "the rule that a state may not directly regulate transactions that take place wholly outside the state and have no connection to it." *Association for Accessible Medicine v. Ellison*, 704 F. Supp. 3d 947, 953 (D. Minn. 2023) (citing *National Pork Producers Council v. Ross*, 598 U.S. 356, 371-376 (2020)). "A state statute has undue extraterritorial reach and 'is *per se* invalid' when it 'requires people or businesses to conduct their out-of-state commerce in a certain way.'" *North Dakota v.*

Heydinger, 825 F.3d 912, 919 (8th Cir. 2016) (invalidating Minnesota statute) (quoting *Cotto Waxo Co. v. Williams*, 46 F.3d 790, 793 (8th Cir. 1995)).

43. As the Supreme Court has explained, "one State's power to impose burdens on the interstate market[s]" is "not only subordinate to the federal power over interstate commerce, but is also constrained by the need to respect the interests of other States." *BMW of North America v. Gore*, 517 U.S. 559, 571 (1996). That is to say, "[t]he sovereignty of each State" implies "a limitation on the sovereignty of all of its sister States" under the Due Process Clause. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 293 (1980). "[I]t follows from these principles of state sovereignty and comity" "that a State may not impose economic sanctions" on persons or entities "with the intent of changing [their] lawful conduct in other States." *BMW*, 517 U.S. at 572.

44. Under the Due Process Clause, one State cannot "attempt[] to alter [a company's] nation-wide policy" by punishing or burdening out-of-state conduct; doing so would "infring[e] on the policy choices of other States" to regulate lawful conduct taking place within their own borders. *Id.*

45. The Full Faith and Credit Clause is "[a]nother traditional constitutional source of restriction on a state's power to apply its law beyond its borders." *Adventure Communications, Inc. v. Kentucky Registry of Election Finance*, 191 F.3d 429, 436 n.6 (4th Cir. 1999). Under that Clause, a state law that "in effect regulates throughout the United States" by regulating or punishing conduct outside its borders violates the principle of federalism that "prevents States from 'adopting any policy of hostility to the public Acts' of another State." *National Pork Producers*, 598 U.S. at 409 (Kavanaugh, J.) (quoting *Carroll v. Lanza*, 349 U.S. 408, 413 (1955)); *see id.* at 376 (Full Faith and Credit Clause embraces principles of sovereignty and comity). Like the Commerce Clause, the "purpose"

of the Full Faith and Credit Clause was "to prevent" the "parochial entrenchment on the interests of [the several] States" in relation to one another. *Thomas v. Washington Gas Light Co.*, 448 U.S. 261, 272 (1980).

46. In sum, Minnesota may regulate prescription-drug insurance policies sold in commercial markets within the state, but not outside the state.

FACTUAL ALLEGATIONS

Prescription-Drug Benefit Plans

47. Prescription drug transactions involve a range of market participants. First, wholesalers purchase drugs and drug ingredients from manufacturers. Wholesalers then supply drugs to pharmacies. Consumers obtain the prescription drugs they need from pharmacies. When covered by a pharmacy benefit plan, consumers have the advantage of negotiated prices with pharmacies, and reimbursement of some or all of the remaining drug cost after their out-of-pocket obligation.

48. Around 65% of employer-sponsored benefit plans and multiemployer plans choose to self-fund their employee benefits, reimbursing covered products and services with their own funds and employee contributions, rather than purchasing third-party health insurance for their employees. These are called self-funded benefit plans. *See* Kaiser Family Foundation, *2023 Employer Health Benefits Survey* (Oct. 18, 2023), https://perma.cc/-EXN7-ULKV.

49. Designing and administering health benefit plans is a complex and time-consuming undertaking that employers and multiemployer union trusts cannot realistically handle on their own. *See PCMA v. District of Columbia*, 613 F.3d 179, 183 (D.C. Cir. 2010). Virtually all sponsors of self-funded plans, including ERIC's member companies and NLA's member funds, therefore retain third-party administrators to provide recom-

mendations on the design of their benefit plans, to construct the networks of pharmacies to be used under the plan, to process claims, and to perform other benefit-administration functions. The third party administrators for prescription-drug benefit plans are called pharmacy benefit managers, or PBMs.

50. As a matter of benefit plan design, the sponsor of an employee prescription-drug benefit plan must determine "what drugs the plan covers (the formulary), how much the plan will pay for those drugs (the cost-sharing terms), and at which pharmacies beneficiaries can have prescriptions filled (the pharmacy network)." *PCMA v. Mulready*, 78 F.4th 1183, 1188 (10th Cir. 2023). As a matter of benefit plan design and administration, a plan must have contracts with hundreds or thousands of network pharmacies, and it must process reimbursement for the hundreds or thousands of prescriptions that plan participants fill every month.

51. Plan sponsors, including ERIC's member companies and NLA's member funds, almost always retain PBMs to do this work for them. "When a beneficiary of a prescription-drug plan goes to a pharmacy to fill a prescription, the pharmacy checks with a PBM to determine that person's coverage and copayment information. After the beneficiary leaves with his or her prescription, the PBM reimburses the pharmacy for the prescription, less the amount of the beneficiary's copayment. The prescription-drug plan, in turn, reimburses the PBM." *Rutledge v. PCMA*, 592 U.S. 80, 83 (2020).

52. One of the most important design functions on which PBMs make recommendations to plan sponsors is the composition of the networks of pharmacies from which plan participants can obtain covered drugs. Pharmacy networks are selected groups of contracted pharmacies where beneficiaries may purchase prescription drugs at negotiated prices and receive reimbursement. Pharmacies are either "in network" or not. This distinc-

tion is an essential element of the prescription-drug benefit plan's overall substantive design.

53. PBMs give advice to plan sponsors, including ERIC's member companies and NLA's member funds, with respect to the design of pharmacy networks, helping ensure that they best serve plan beneficiaries' needs and control costs. But plan sponsors are the final decisionmakers with respect to the structure of the benefit plans they offer—including prescription-drug network design.

54. Many different considerations factor into a plan sponsor's benefit-design decisions, depending on the plan's goals and beneficiaries' needs. For example, some plans may prioritize convenience, selecting a broad and flexible network, allowing beneficiaries to obtain covered drugs from a wide range of retail drug stores. Other plans may prioritize cost containment and focus on making prescription drugs more affordable for enrollees. Plan sponsors also set standards for pharmacies to participate in the network based on factors affecting quality of care. To meet any number of objectives—including improving access, improving quality of care, or achieving cost savings—health plans may employ one or more common pharmacy network features and designs, including (i) preferred pharmacy networks; (ii) mail-order incentives; and (iii) limited or preferred specialty pharmacy networks.

55. **Preferred pharmacy networks.** Among one of the most effective cost savings tools at a plan's disposal are tiered networks, which use preferred-pharmacy networks. A single-tier network allows beneficiaries to obtain coverage on the same cost-sharing terms regardless of which network pharmacy they use. In contrast, a preferred-pharmacy network offers greater cost savings to beneficiaries when they fill prescriptions at preferred pharmacies that have agreed to additional cost-containment conditions.

56. Preferred-pharmacy networks offer advantages to pharmacies, beneficiaries, and plans alike. Pharmacies accept discounted reimbursement rates from plans in exchange for higher volumes of business from the plan's beneficiaries. Plans benefit, in turn, from reduced costs, all or most of which are passed on to beneficiaries in the form of lower drug prices, lower cost-sharing obligations, and easier access to higher-quality, more reliable pharmacies within the preferred network.

57. The cost-savings offered by preferred networks typically cannot be realized if the plan cannot control and limit the pharmacies within the preferred network. If all pharmacies can participate in preferred networks, preferred pharmacies will not have the assurance of receiving higher volume and therefore have no reason to accept lower reimbursement amounts.

58. **Mail-order pharmacies.** Plan sponsors also typically include a mail-order pharmacy network as part of their prescription-drug benefit design. Mail-order pharmacies dispense and deliver drugs via common carrier, such as UPS or FedEx.

59. Plan sponsors include mail-order networks for a number of reasons. First, mail-order pharmacies have greater purchasing power and lower acquisition costs. They accordingly are able to deliver drugs at significantly lower cost (and thus with lower reimbursement rates) than independent brick-and-mortar pharmacies.

60. Second, in addition to direct cost savings, mail-order pharmacies help improve clinical outcomes. Mail service improves patient adherence to medical prescriptions because beneficiaries do not have to travel to the pharmacy or abide by retail hours. They also can benefit from automatic shipments and refills.

61. Because mail-order pharmacies operate differently and more efficiently than brick-and-mortar retail stores, they frequently agree to lower reimbursement amounts than

independent retail pharmacies. Plans design their benefits to allow beneficiaries to share in this cost savings, which in turn encourages mail-order pharmacy use. For example, beneficiaries on long-term maintenance medications are often able to obtain 90-day supplies of their drugs from mail-order pharmacies for the same copay or co-insurance that they would owe for a 30-day supply from a retail pharmacy.

62. In addition to saving money, mail-order pharmacies also improve patient adherence to medication protocols because beneficiaries do not have to travel to the pharmacy or abide by retail hours. Refills are sometimes automated. This improved adherence enhances clinical outcomes.

63. Given all the health and financial benefits of obtaining drugs by mail, plan sponsors (including ERIC's member companies and NLA's member funds) sometimes specify that after a set number of fills, certain long-term maintenance drugs will be reimbursed only when they are obtained from an in-network mail-order pharmacy. In addition, plans typically offer lower cost-sharing obligations for mail-order coverage, to encourage mail-order use.

64. Plan sponsors often limit their mail-order pharmacy networks to pharmacies affiliated with the plan's PBM. This is referred to as mail-order exclusivity, and it allows plans to realize additional cost savings. The close oversight relationship that PBMs have with their PBM-affiliated pharmacies makes possible a range of cost-saving plan features, including special manufacturer arrangements and savings, which are not available to plan sponsors when the network is opened to non-affiliated pharmacies.

65. **Specialty pharmacies.** Plan sponsors also typically require that purchases of certain "specialty" drugs will be reimbursed only when filled by in-network specialty pharmacies. Specialty drugs are characterized by their greater expense, potency, or sensitivity.

Some require special handling, like refrigeration. These drugs play a significant and expanding role in the treatment for complex diseases like cancer. Today, they account for more than half of overall pharmacy spending.

66. Specialty pharmacies are expert in dispensing specialty drugs, which require not only specialized handling (due to kinetic, light, or heat sensitivity), but also patient qualification and monitoring requirements. Indeed, many specialty drug manufacturers limit their distribution of specialty drugs to qualified specialty pharmacies only.

67. Specialty pharmacies have important benefits for cost, access, and quality of care. First, specialty pharmacies can buy specialty drugs in bulk, with better rates for the plan and its beneficiaries. Second, because specialty pharmacies have additional expertise handling, storing, and advising patients on specialty medications, they generally produce better patient outcomes. Such pharmacies are few in number and high in demand, and they dispense predominantly via mail or other common carrier.

68. It is an industry standard for benefit plans to require or at least encourage beneficiaries to utilize specific specialty pharmacies to access specialty drugs.

69. The specially-negotiated relationship that PBMs have with specialty pharmacies brings numerous benefits. To start, PBMs are able to ensure quality control and patient-compliance measures, which lead to better outcomes for beneficiaries.

70. PBMs are also able to offer a number of cost-saving plan features and services that would not otherwise be available to plan sponsors without the level of oversight available at a PBM-affiliated pharmacy. For example, when the PBM is able to assure that quality-control procedures are being followed and patient-compliance measures are being implemented, it typically can obtain favorable drug acquisition terms from manufacturers. These cost-saving terms are not available, or achieve less savings, when specialty phar-

macy networks are opened to non-affiliated pharmacies, as to which the PBM cannot provide the same assurances.

Minnesota's Pharmacy Benefit Manager Licensure and Regulation Act of 2019

71. The Minnesota legislature enacted the Pharmacy Benefit Manager Licensure and Regulation Act in 2019, imposing several new regulatory requirements on PBMs. *See* 2019 Minn. Sess. Law Serv. Ch. 39.

72. The Act applies to "pharmacy benefits managers," which are defined as "a person, business, or other entity that contracts with a plan sponsor to perform pharmacy benefits management." Minn. Stat. § 62W.02, subd. 15. A "plan sponsor" is defined as, among other things, "an employer in the case of an employee health benefit plan established or maintained by a single employer" or "an employee organization" or "association," such as a Taft-Hartley trust. *Id.* subd. 16. Thus, the term "plan sponsor" is explicitly defined to include a sponsor of any employee health benefit plan, including a self-funded plan governed by ERISA.

73. In two respects especially, the Act directly regulates the composition of prescription-drug benefit plans' pharmacy networks, restricting the network structures that plans may select for their ERISA-covered prescription-drug benefit plans.

74. **Incentive Restriction.** The Act first prohibits cost-sharing incentives used to encourage the use of PBM-affiliated pharmacies. It prohibits PBMs, on behalf of the plan sponsors to which they provide services, from:

> penalizing, requiring, or providing financial incentives, including variations in premiums, deductibles, co-payments, or coinsurance, to an enrollee as an incentive to use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other network pharmacy provider in which a [PBM] has an ownership interest . . .

Minn. Stat. § 62W.07(b). The Act includes an exception to this prohibition, specifying that it does not apply if the PBM, on behalf of the plan sponsors to which it provides pharmacy benefits management services,

> offers an enrollee the same financial incentives for using a network retail pharmacy, mail order pharmacy, specialty pharmacy, or other network pharmacy in which the [PBM] has no ownership interest and the network pharmacy has agreed to accept the same pricing terms, conditions, and requirements related to the cost of the prescription drug and the cost of dispensing the prescription drug that are in the agreement with a network pharmacy in which the [PBM] has an ownership interest.

Id. § 62W.07(c); *see also* Minn. R. 2737.1100, subp. 2, 4.

75. The net effect is that plan sponsors that design a network (preferred, mail-order, or specialty) to include only PBM-affiliated pharmacies may not provide beneficiaries with financial incentives to use those networks. For such incentives to be permissible, paragraph (c) requires a plan to open its mail-order network and specialty pharmacy network to other willing providers. S*ee* Minn. R. 2737.1100, subp. 4, subp. 2.

76. **Refill Restriction.** In addition to regulating network design and structure, the Act directly regulates the terms of reimbursement for covered drugs. It does so by requiring plans to cover unlimited refills of maintenance drugs at retail pharmacies if the plan utilizes a mail-order network comprising only PBM-affiliated pharmacies. In particular, the Act prohibits PBMs, on behalf of the plan sponsors to which they provide services, from "imposing limits, including quantity limits or refill frequency limits, on an enrollee's access to medication that differ based solely on whether the" PBM "has an ownership interest in a pharmacy or the pharmacy." Minn. Stat. § 62W.07(d).

77. The Act again includes an exception to this prohibition, specifying that the prohibition does not apply if the PBM, on behalf of the plan sponsors to which they provide

services, ensures that beneficiaries have "the option to use a mail order pharmacy or retail pharmacy with the same limits imposed in which the [PBM] . . . does not have an ownership interest." *Id.* § 62W.07(e).

78. The Department's implementing regulations explain that a PBM, which acts only on behalf of the plan sponsors to which it provides services, "may only impose quantity limits or refill frequency limits at a non-owned retail pharmacy" if the PBM also "has imposed the same limits at the [PBM-]owned retail pharmacies." Minn. R. 2737.1100, subp. 3(A). If the plan's PBM does not own a retail pharmacy, then any restriction on refills at retail pharmacies is prohibited. *See id.* 2737.1100, subp. 4.

79. Moreover, according to Department regulations, "[i]f a pharmacy benefit manager administers a network with only mail order pharmacies that are [PBM-]owned pharmacies, the pharmacy benefit manager is prohibited from (1) offering financial incentives to use the mail order pharmacies, or (2) imposing limits on an enrollee's access to medication." Minn. R. 2737.1100, subp. 4.

The Commissioner's Enforcement of the Act

80. The Department recently has been aggressively enforcing Section 62W.07 against PBMs licensed in the state.

81. The Department initiated a 2023 enforcement proceeding against the PBM CaremarkPCS (Caremark) for alleged violations of Section 62W.07(b) and (d). The Department alleged that Caremark had violated those provisions by (1) requiring participants in its Maintenance Choice program, in order to receive coverage, to refill maintenance-category medications only at affiliated retail or mail-order pharmacies; and (2) limiting covered refills of maintenance medications based solely on whether Caremark has an ownership interest in the pharmacy. *See In the Matter of the Pharmacy-Benefit-Manager*

License of CaremarkPCS Health, LLC, OAH No. 82-1002-38306, 2023 WL 3574951, at *1 (Minn. Dep't of Commerce Apr. 28, 2023).

82. Caremark did not admit liability or the truth of the Department's allegations but agreed to pay a civil penalty and cease and desist from the complained-of conduct. *Id.*

83. The judgment further required that "[i]n accordance with Minnesota law," Caremark would "open its Maintenance Choice program, or any successor or similar program, to any pharmacy that wishes to enroll and accepts the network's standard terms, conditions, and pricing." *Id.*

84. The order provided expressly that this condition would "apply to all plans enrolled in the program, regardless of the nature of the plan, including but not limited to any ERISA plans that are enrolled in it." The order contains no geographic limit.

85. Following its consent order with Caremark, the Department commenced a regulatory inquiry of Express Scripts Administrators LLC (Express Scripts). In correspondence with Express Scripts, the Department acknowledged that Section 62W.07 regulates "the composition of PBM pharmacy networks" and that under Section 62W.07 "pharmacy networks . . . are prohibited from being structured in [particular] ways." *See* May 15, 2023 Letter (Exhibit A). The Department further recognized that the law may therefore be preempted as applied to self-funded ERISA-covered benefit plans. But the Department refused to take a position on ERISA preemption, calling the issue of ERISA preemption "highly contentious" (*id.*) and refusing to issue an "advisory opinion" on the matter (Oct. 15, 2024 Letter (Exhibit B)). Instead, the Department insisted, it would simply apply Section 62W.07 without regard for ERISA preemption.

86. The Department clarified further that any PBM that "does business in Minnesota" must comply with Minn. Stat. § 62W.07 *categorically*, with respect to any and

every prescription-drug benefit plan it helps design or administer, no matter where the plan sponsor or the plan beneficiaries reside or purchase covered drugs. *See* Exhibit B.

GROUNDS FOR RELIEF

Section 62W.07 is preempted as applied to ERISA-covered benefit plans

87. Section 62W.07 is preempted as applied to self-funded ERISA-covered benefit plans. Both elements of Section 62W.07 restrict a plan's ability to design its pharmacy network—a fundamental component of plan design—by forbidding or limiting common design tools that as a practical matter plan sponsors must use to encourage beneficiaries to obtain covered drugs in the most cost-effective ways.

88. The **Incentive Restriction** prohibits a plan from designing its prescription drug benefit in a particular way. If the plan's PBM has an ownership interest in the in-network mail-order or specialty pharmacy, plan documents may not specify that drug purchases are covered only if the beneficiary uses that mail-order or specialty pharmacy. Plan documents also may not provide cost-sharing inducements for using the mail-order or specialty pharmacy. The only way to avoid these limitations is for the plan to open the mail-order pharmacy network or specialty pharmacy network to pharmacies that are not affiliated with the plan's PBM—pharmacies that the plan otherwise would exclude from its networks. *See* Minn. Stat. § 62W.07(b), (c). This provision will require plans sponsored by ERIC's member companies and NLA's member funds to change the terms of their ERISA-governed group health plans.

89. In these ways, the Incentive Restriction "forc[es] plans to adopt [a] particular scheme of substantive coverage" and "require[s] providers to structure benefit plans in particular ways." *Rutledge*, 592 U.S. at 86-88.

90. The **Refill Restriction** also prohibits a plan from designing prescription drug benefits in a particular way. If the plan's PBM has an ownership interest in the in-network mail-order pharmacy, plan documents may not impose limits, including quantity limits or refill frequency limits, on coverage under the plan of drugs obtained at in-network retail pharmacies. In other words, drugs obtained from in-network retail pharmacies must be covered without limit—without requiring as a condition of coverage that the drugs be obtained instead from the mail-order pharmacy—if the mail-order pharmacy is PBM-owned. The only way to avoid these limitations is for the plan to open the mail-order pharmacy network to pharmacies that are not affiliated with the plan's PBM—pharmacies that the plan otherwise would exclude from its networks. *See* Minn. Stat. § 62W.07(d), (e).

91. In these ways, the Refill Restriction "forc[es] plans to adopt [a] particular scheme of substantive coverage" and "require[s] providers to structure benefit plans in particular ways." *Rutledge*, 592 U.S. at 86-88.

92. Plans sponsored by ERIC's member companies and NLA's member funds use, or wish to use, provisions that the Act forbids. Without relief from this Court, enforcement of these provisions will require them to use different network structures at higher cost. Yet these two provisions of Section 62W.07 "do more than increase costs." *Mulready*, 78 F.4th at 1200. Instead, "[t]hey home in on PBM pharmacy networks—the structures through which plan beneficiaries access their drug benefits." *Id.* "And they impede PBMs from offering plans some of the most fundamental network designs," like closed mail-order and specialty pharmacy networks. *Id.*

93. Section 62W.07 increases the burden of designing and managing multistate drug benefit plans in more than a *de minimis* way. Considering financial impact alone, the network design tools forbidden by Section 62W.07 may drive up costs, according to one

estimate, by as much as $150 per participant per year. The benefit plans offered by ERIC's member companies have tens of thousands, and sometimes millions, of plan participants, meaning that such an impact would be highly significant.

94. Moreover, network structure and cost-sharing terms are core elements of overall benefit design, which is a central matter of plan administration. Multistate plan sponsors using PBMs licensed in Minnesota (which is every major PBM) will not be able to use a plan design of their choosing, nor will they be able to achieve nationally uniform plan design or administration. Other states have adopted laws similar to but different from Section 62W.07, and plan sponsors therefore will confront inconsistent and conflicting regulatory obligations.

95. It is no answer to say that Section 62W.07 regulates PBMs and not the plan sponsors whose benefits they manage. A state law does not "escape [ERISA] preemption" by "regulat[ing] PBMs rather than plans" directly. *PCMA v. Wehbi*, 18 F.4th 956, 966 (8th Cir. 2021). "Because PBMs manage benefits on behalf of plans, a regulation of PBMs 'function[s] as a regulation of an ERISA plan itself.'" *Id.* (quoting *District of Columbia*, 613 F.3d at 188).

Section 62W.07 is being enforced extraterritorially in violation of the Commerce Clause, Due Process Clause, and Full Faith and Credit Clause

96. The Incentive and Refill Restrictions are not only preempted by ERISA, but they also violate the dormant Commerce Clause, Due Process Clause, and Full Faith and Credit Clause to the extent defendants are enforcing them extraterritorially.

97. Under the Constitution's restrictions on extraterritorial regulations, "a state may not directly regulate transactions that take place wholly outside the state and have no

connection to it." *Association for Accessible Medicine*, 704 F. Supp. 3d at 953 (citing *National Pork Producers Council*, 598 U.S. at 371-376).

98. The Department is enforcing Section 62W.07 extraterritorially. It has taken the position that Section 62W.07 is a condition for a PBM that is "doing business in Minnesota" to obtain a license. *See* Exhibit B. And it has therefore explained that "the composition of the pharmacy networks that PBMs offer to *all* plans with which they contract to provide PBM services must meet the standards outlined," no matter where those plans or their enrollees are located. *See* Exhibit A at 1.

99. A PBM does business in Minnesota within the meaning of Section 62W.03 when it "is in contract to perform pharmacy benefits services with a plan sponsor that . . . makes a contract or engages in a terms-of-service agreement with a Minnesota resident," and the contract "is performed in whole or in part by either party in Minnesota." Minn. R. 2737.0100, subp. 3.

100. Section 62W.07 is not by its terms limited to plans with Minnesota residents or performed in whole or in part in Minnesota. Nothing in the Act's text limits its application to PBMs administering benefits for Minnesota plans, Minnesota employers, or Minnesota beneficiaries. Instead, defendants assert that it reaches all agreements between a licensed PBM and any and every benefit plan to which it provides PBM services. *See generally* Minn. Stat. § 62W.07; *see also id.* § 62W.02 Subds. 5, 15-16 (defining "enrollee," "pharmacy benefit manager," and "plan sponsor" without reference to geographic boundaries or Minnesota contacts).

101. The Department is thus applying Section 62W.07 extraterritorially in practice. In the Caremark matter, the consent judgment provided that, "[i]n accordance with Minnesota law . . . Caremark shall open its Maintenance Choice program . . . to any

pharmacy that wishes to enroll and accepts the network's standard terms, conditions and pricing." *CaremarkPCS,* 2023 WL 3574951, at *2. The judgment further clarified that it "will apply to *all plans enrolled in the program*, regardless of the nature of the plan, including but not limited to *any ERISA plans* that are enrolled in it." *Id.* (emphasis added). The order imposes no geographic limit.

102. Other states regulate prescription-drug benefit plans in ways that differ from Minnesota's regulations. Many have made the policy choice *not* to regulate network design for prescription-drug benefits in the same manner as Minnesota. These states include Alaska, Arizona, California, Connecticut, Florida, Hawaii, Idaho, Illinois, Kansas, Kentucky, Maine, Massachusetts, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, Utah, Vermont, Wisconsin, and Wyoming. Although these states regulate PBMs in various other ways, they have made a policy judgment not to regulate PBM-affiliated mail-order or specialty pharmacy networks.

103. Still other states regulate on the same general topic as Section 62W.07, but using conflicting standards. For example, Oregon law specifies that a PBM "[m]ay not require a prescription to be filled or refilled by a mail order pharmacy as a condition for reimbursing the cost of the drug" but allows preferential cost sharing to encourage mail-order use and expressly carves out mail-order specialty pharmacies from the prohibition. *See* Oregon Rev. Stat. § 735.536. Other states take a similar approach. *See, e.g.*, Md. Insurance Code Ann. § 15-1611.1; S.C. Code Ann. § 38-71-2230, 2245. Virginia, meanwhile, applies a limitation similar to Minnesota's, but only to HMOs and not self-insured employer plans. *See* Va. Code Ann. § 38.2-4312.1.

104. By enforcing Section 62W.07 against any contract that a Minnesota-licensed PBM may enter with a plan sponsor anywhere located, Minnesota is projecting its contrary law and policy judgments into these other states, overriding their different policy choices. Under the Commerce Clause, Due Process Clause, and Full Faith and Credit Clause, these states (and their residents) are free to regulate (and be regulated) in the manner that local state legislatures determine is most appropriate, as long as it is consistent with federal law. Minnesota's projection of its differing policy standards into these other statues thus violates the Constitution.

105. In both text and practice, Section 62W.07 extends its regulatory reach into other states. In doing so, it "infring[es] on the policy choices of other States" to permit what Minnesota forbids. *BMW*, 517 U.S. at 572. The Constitution three times over bars one state from "adopting any policy of hostility to the public Acts" of another state like this. *Carroll*, 349 U.S. at 413.

CLAIMS FOR RELIEF

Count I
ERISA Preemption

106. Plaintiffs reallege the foregoing allegations as if fully set forth herein.

107. ERISA contains an express-preemption provision stating that ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a). The Act covers many such plans, including plans sponsored or maintained by ERIC's member companies and NLA's member funds, and including CHLIC's customers.

108. Section 62W.07 has a "connection to" those plans and thus "relates to" those plans. Applied in this manner, Section 62W.07 is thus preempted by ERISA.

109. Enforcement of Section 62W.07 against ERIC's member companies and NLA's member funds, and CHLIC's customers, is causing them injury. In particular, it is forbidding certain benefit-plan design choices, depriving them of their federally protected right to control plan design. It is furthermore increasing the cost of providing prescription drug benefits and increasing the costs of covered drugs for plan participants. Enforcement of Section 62W.07 against CHLIC is furthermore limiting the range of services and benefit designs it is permitted to offer its customers.

110. Because plaintiffs have no adequate remedy at law to protect against unlawful enforcement of the Act, the Court should declare the Act preempted as applied to self-funded ERISA benefit plans and enjoin defendants from enforcing Section 62W.07 as applied to self-funded ERISA benefit plans.

Count II
Unlawful Extraterritorial Regulation

111. Plaintiffs reallege the foregoing allegations as if fully set forth herein.

112. The Commerce Clause, Due Process Clause, and Full Faith and Credit Clause prohibit Minnesota from regulating contractual arrangements consummated and performed outside of Minnesota; and from regulating prescription-drug transactions that take place outside the state and have no direct connection to it.

113. The Department is enforcing Section 62W.07 in a manner that regulates out-of-state commerce by regulating contracts and arrangements between any PBM licensed in Minnesota and any plan or insurer, even when the plan or insurer is not a Minnesota resident and operates entirely or mostly outside of the state.

114. Many plans, including some offered by ERIC's member companies and NLA's member funds, operate wholly or predominantly outside of Minnesota. Extraterritorial

enforcement of Section 62W.07 is causing those members injury. In particular, it is forbidding certain benefit-plan design choices, depriving them of their federally protected right to control plan design. It is furthermore increasing the cost of providing prescription drug benefits and increasing the costs of covered drugs for plan participants. Enforcement of Section 62W.07 against CHLIC is furthermore limiting the range of services and benefit designs it is permitted to offer its out-of-state customers.

115. Because plaintiffs have no adequate remedy at law to protect against unlawful enforcement of the Act, the Court should declare the Act unconstitutional as applied extraterritorially and enjoin defendants from enforcing Section 62W.07 extraterritorially.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs ask the Court to enter judgment in their favor and:

(a.) declare that Section 62W.07 is preempted by ERISA as applied to self-funded ERISA-covered benefit plans;

(b.) declare that extraterritorial enforcement of Section 62W.07 violates the Commerce Clause, Due Process Clause, and Full Faith and Credit Clause;

(c.) permanently enjoin defendants and their agents from taking any action to enforce Section 62W.07 against self-funded ERISA-covered benefit plans or their pharmacy benefits managers;

(d.) permanently enjoin defendants and their agents from enforcing Section 62W.07 extraterritorially;

(e.) order defendants to pay plaintiffs' reasonable attorneys fees to the extent permitted by law; and

(f.) grant plaintiffs such additional or different relief as it deems just and proper.

Dated: December 27, 2024

Respectfully submitted,

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