IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF IOWA
CENTRAL DIVISION

IOWA ASSOCIATION OF BUSINESS AND INDUSTRY, IOWA BANKERS BENEFIT PLAN, IOWA LABORERS DISTRICT COUNCIL HEALTH AND WELFARE FUND, DES MOINES ORTHOPAEDIC SURGEONS P.C., and IOWA SPRING MANUFACTURING & SALES COMPANY, Plaintiffs, v. DOUG OMMEN, in his official capacity as Iowa Insurance Commissioner, Defendant.	)	Case No. 4:25-cv-00211-SMR-WPK ORDER ON MOTION FOR PRELIMINARY INJUNCTION

This case presents fundamental questions about the boundaries of federal preemption amid growing state efforts to address rising healthcare costs and preserve healthcare access through legislation. Plaintiffs—a coalition of Iowa employers and employee benefit plans governed by ERISA—challenge Iowa Senate File 383 ("SF 383"), a comprehensive statute that regulates pharmacy benefit managers ("PBMs") while simultaneously constraining health plan operations. The dispute highlights the practical reality that modern prescription drug benefits require PBM intermediary services. This creates functional interdependence between state-regulated entities and federally-governed employee benefit plans.

Iowa[1] defends SF 383 as necessary consumer protection legislation designed to preserve rural pharmacy access and prevent anticompetitive practices, while Plaintiffs contend the statute

[1] For ease of reference, Defendant Doug Ommen, in his official capacity as Iowa Insurance Commissioner, will be referred to throughout this Order as "Defendant," "the State," "Iowa," or "the Commissioner."

exceeds state authority by dictating central aspects of plan design and administration that Congress reserved to exclusive federal oversight under ERISA. The legal issues encompass both ERISA's express preemption doctrine and First Amendment protections for commercial speech. The Court must determine whether state regulation of PBM conduct impermissibly interferes with the structure and administration of employee benefit plans, and whether statutory restrictions on truthful communications between PBMs, plans, and participants violate constitutional protections for commercial speech.

I. BACKGROUND

A. The Iowa Regulatory Framework

1. The Prescription Drug Benefit Industry

PBMs serve as intermediaries in the prescription drug market, operating between pharmaceutical manufacturers, retail pharmacies, health insurers, and employer-sponsored health plans. These entities perform critical functions including negotiating manufacturer discounts and rebates, creating preferred pharmacy networks, managing drug formularies, and administering prescription benefits for health plans. The industry has consolidated significantly over recent decades: three major PBMs now control approximately 80% of the national market and serve roughly 270 million Americans.

Modern ERISA plans have become functionally dependent on PBM services to administer prescription drug benefits. As the United States Court of Appeals for the Eighth Circuit has explained, PBMs "manage benefits on behalf of plans" and serve as agents "who undertake and perform administrative duties for and on behalf of ERISA plans." *Pharm. Care Mgmt. Ass'n v. Wehbi*, 18 F.4th 956, 966–67 (8th Cir. 2021) (citations omitted). This practical interdependence means that ERISA plans cannot feasibly operate their pharmacy benefit programs without contracting for PBM services.

PBMs generate revenue through various mechanisms, including "spread pricing"—retaining the difference between what health plans pay them and what they reimburse pharmacies—and keeping portions of manufacturer rebates. The parties offer sharply different characterizations of these practices and their effects on healthcare markets.

2. SF 383's Regulatory Structure

SF 383 substantially restructures Iowa's regulation of PBMs while extending new restrictions to health benefit plans, health carriers, and third-party payors. The statute operates through four principal mechanisms that collectively govern both PBM conduct and health plan operations.

First, the law establishes comprehensive network and provider access requirements. It prohibits discrimination against pharmacies by PBMs, health carriers, health benefit plans, and third-party payors, requiring identical treatment regarding "participation, referral, reimbursement of a covered service, or indemnification." Iowa Code § 510B.1(4). The statute creates "any willing provider" standards for pharmacy network participation by mandating that qualifying pharmacies be permitted to join PBM networks. *Id.* § 510B.4B(1)(b). Additionally, SF 383 restricts PBMs' ability to steer patients toward preferred pharmacies, bars requirements for exclusive use of mail-order pharmacies, and mandates equal cost-sharing between retail and mail-order options.

Second, SF 383 establishes mandatory reimbursement standards. PBMs must reimburse retail pharmacies at no less than the published national average drug acquisition cost and must pay a minimum dispensing fee of $10.68 per prescription. *Id.* § 510B.8B(3). The law further prohibits PBMs from reimbursing unaffiliated pharmacies at rates below those paid to their own affiliated entities. *Id.* § 510B.8B(1).

Third, the statute imposes extensive transparency and contractual requirements. It mandates "pass-through pricing" under which PBMs must transfer 100% of manufacturer rebates

to health plans. *Id*. § 510B.8(4). The law also requires quarterly reporting by PBMs to state regulators and prescribes specific contractual terms for PBM agreements with health plans. *Id*. § 510B.8B(4).

Fourth, SF 383 restricts communications between plans and their participants. It prohibits PBMs from "promotion of one participating pharmacy over another" and bars disclosure "comparing the reimbursement rates" between pharmacies and mail-order options that might "affect a covered person's choice" of pharmacy provider. *Id*. § 510B.4B(1)(a).

3. Plaintiffs and Their ERISA Plans

Plaintiffs in this action represent a diverse coalition of Iowa business interests united by their common reliance on employer-sponsored health benefit plans governed by ERISA. Plaintiff Iowa Association of Business and Industry ("IABI") serves as an advocacy organization for more than 600 member businesses that collectively employ over 300,000 individuals. [ECF No. 1 ¶ 8]. These members, nearly universally, sponsor ERISA-covered health benefit plans for their employees—both self-funded and fully insured arrangements—and many contract with PBMs to assist in plan administration. *Id*. IABI actively opposed SF 383 during the legislative process and brings this challenge on behalf of its substantial membership base. *Id*.

Plaintiff Iowa Bankers Benefit Plan operates as a tax-exempt Voluntary Employee Beneficiary Association under Internal Revenue Code section 501(c)(9) and provides health benefits to more than 9,300 bank employees and approximately 20,000 total covered lives. *Id*. ¶ 9. Plaintiff Iowa Laborers District Council Health and Welfare Fund functions as a self-funded Taft-Hartley welfare benefit plan covering over 2,200 active participants and 505 retirees, with dependents totaling 5,700 lives, the majority residing in Iowa. *Id*. ¶ 10. The two remaining Plaintiffs—Des Moines Orthopaedic Surgeons PC and Iowa Spring Manufacturing & Sales Company—represent private employers who provide health benefits through ERISA plans

covering approximately 150 and 175 employees respectively, along with their dependents. *Id.* ¶¶ 11, 12. Together, these Plaintiffs cover tens of thousands of Iowans and possess both the requisite standing and the practical expertise necessary to challenge SF 383's interference with established methods of healthcare plan administration.

4. Plaintiffs' Challenge and Projected Impact

Plaintiffs contest both the law's characterization and its projected effects as articulated by Defendant. Acknowledging that SF 383 is nominally directed at regulating PBMs, they contend the statute actually governs employer-sponsored health plans—a domain they argue falls exclusively within federal jurisdiction under ERISA. Plaintiffs project substantial compliance costs, supported by detailed actuarial analysis and concrete declarations from affected entities.

Bradley W. Bartle, Chief Actuary and Vice President for Wellmark Inc., provides comprehensive actuarial analysis based on 2024 pharmacy claims data from approximately 800,000 covered lives in Iowa. [ECF No. 6-1 ¶¶ 10, 12] (Bartle Decl.). Bartle's analysis estimates that SF 383 will impose substantial financial burdens through multiple mechanisms. The mandatory dispensing fee alone will increase benefit plan costs between $17.9 million and $20.1 million annually, resulting in an average per-enrollee cost increase of $22.08 to $25.02. *Id.* ¶ 16. The prohibition on copay accumulator and maximizer programs represents an even more significant cost driver, with estimated increases of $39.5 million to $50.7 million annually for benefit plans, translating to $49.18 to $63.12 per enrollee annually. *Id.* ¶ 18.

Bartle's analysis concludes that SF 383 will increase total costs for Wellmark-administered benefit plans by as much as $96.8 million annually, with an average per-enrollee increase of up to $120.51, while separately imposing up to $38.7 million in additional annual costs directly on covered persons, averaging up to an additional $48.18 per enrollee. *Id.* ¶ 22.

Kirk Veenstra, Senior Benefits Manager at Pella Corporation, provides a concrete illustration of SF 383's impact on individual employers. [ECF No. 6-2] (Veenstra Decl.). Pella Corporation, which spent $63.4 million on its health plan in 2024 covering approximately 14,837 lives, estimates that SF 383 will add at least $1.2 million annually to plan costs. *Id*. ¶¶ 17, 19, 30. This reflects the statute's interference with fundamental plan design elements, including the inability to favor in-network pharmacies and mandatory $10.68 dispensing fees. *Id*. ¶ 31.

Particularly significant is SF 383's elimination of beneficial programs that provide direct cost savings to plan participants. Paul Karow, Vice President and Chief Pharmacy Officer at Wellmark, details how the statute will terminate the PrudentRx specialty drug program, which currently allows covered persons to obtain high-cost specialty medications at no out-of-pocket cost. [ECF No. 6-3 ¶¶ 11–13] (Karow Decl.). Karow provides specific examples demonstrating immediate cost impacts: enrollees currently receiving Enbrel[2] at no cost will face $2,310 per prescription, while other specialty medications will impose costs ranging from $100 to $4,380 per prescription. *Id*. ¶ 13.

Plaintiffs further argue that SF 383's primary beneficiary will be Hy-Vee, a large retail pharmacy chain, rather than the rural independent pharmacies Iowa seeks to protect. They contend the statute will eliminate beneficial programs that provide cost savings to plan participants, including specialty drug programs that waive copayments for patients with serious medical conditions.

5. The State's Justification and Supporting Evidence

SF 383 represents a necessary response to anticompetitive practices in the PBM industry under Defendant's characterization. According to the state, PBMs have exploited their market

[2] Enbrel is a prescription medication used to treat autoimmune conditions such as rheumatoid arthritis, psoriasis, and ankylosing spondylitis.

dominance to impose below-cost reimbursement rates on independent pharmacies while favoring their own affiliated entities through preferential pricing and network placement. Iowa contends these practices constitute harmful self-dealing that has contributed to widespread pharmacy closures, with 34 rural pharmacies closing in Iowa in 2024 alone and over 150 closures in the past decade. The state argues that such closures create "pharmacy deserts" that compromise patient access to healthcare, particularly in rural communities where the local pharmacy may be the only readily accessible healthcare provider. Iowa frames SF 383 as a consumer protection measure designed to ensure fair reimbursement to pharmacies, increase transparency in PBM operations, and preserve healthcare access for Iowa residents.

In support of its position, Iowa presents the declaration of Aaron Wiese, President of Hy-Vee, Inc., who provides a comprehensive perspective from an entity that operates simultaneously as a retail pharmacy, an ERISA plan sponsor, and owner of a transparent PBM. *See* [ECF No. 24-2] (Wiese Decl.). Wiese details how Hy-Vee operates 270 pharmacies, including 132 in Iowa, and has experienced firsthand the effects of what he characterizes as "increasingly aggressive and opaque PBM practices: unsustainable reimbursement rates, hidden fees, and patient steering to PBM-owned mail-order pharmacies." *Id.* ¶ 9. He reports that these practices have forced Hy-Vee to close 25 pharmacies since 2019, demonstrating that even large retail chains with diversified revenue streams are not immune to PBM-related pressures. *Id.* ¶ 20.

Wiese provides concrete evidence of below-cost reimbursement, stating that since January 1, 2025, of 500 prescriptions filled, Hy-Vee's pharmacies have dispensed 115 different drugs for which the reimbursement rate was less than national average drug acquisition cost. *Id.* ¶ 18. He characterizes PBM practices as exploiting market concentration, noting that the three largest PBMs control over 80% of the market and process prescription claims for approximately 180 million Americans. *Id.* ¶¶ 11, 25.

From his perspective as an ERISA plan sponsor covering more than 15,759 members, Wiese argues that PBM practices actually increase rather than decrease costs for employers and plan participants. *Id*. ¶ 24. He contends that vertical integration between PBMs and health insurers has created conflicts of interest, citing Federal Trade Commission findings that PBMs have profited $7.3 billion over five years at the expense of plans and patients through practices such as steering patients to affiliated specialty pharmacies that charge plans 20–40 times what unaffiliated pharmacies might charge. *Id*. ¶¶ 28–29.

Particularly significant is Wiese's description of Hy-Vee's operation of Vivid Clear Rx, a transparent PBM founded on principles of accountability and pass-through pricing. *Id*. ¶ 35. He provides specific examples of cost savings achieved through transparent practices: one employer covering 250 individuals saved approximately $35,000 per month on a specialty cancer medication compared to pricing from a large traditional PBM, while another plan sponsor covering 150 individuals would have received $110,000 in annual rebates compared to only $35,000 under traditional PBM arrangements. *Id*. ¶¶ 41–42. Wiese argues that these examples demonstrate that substantial cost reductions are achievable when PBMs operate transparently, but that traditional PBMs use their market power to undercut competitive threats through various exclusionary practices. *Id*. ¶ 43.

In further support of its defense, Iowa presents the declaration of Charles S. Hartig, Owner and Chief Executive Officer of Hartig Drug Company, who provides additional testimony regarding the effects of PBM practices on Iowa's pharmacy landscape. [ECF No. 24-5] (Hartig Decl.). Hartig brings unique expertise to these proceedings, having served as both a licensed pharmacist for 16 years and a licensed attorney in Iowa for 13 years, with previous employment at Express Scripts as a pharmacist and at CVS Health as Senior Legal Counsel specializing in pharmacy compliance and regulatory matters. *Id*. ¶¶ 4–5.

Hartig provides concrete financial data demonstrating the unsustainable nature of current PBM reimbursement practices. Over the five calendar quarters from January 1, 2024 to March 31, 2025, Hartig Drug Company averaged less than $5.75 in gross margin per commercially insured prescription, with brand drug medications generating an average gross margin loss of $26.37 per prescription. *Id.* ¶ 9(a). He contrasts these figures with state and national estimates that the average cost to dispense medication ranges from $10 to $15 per prescription, demonstrating that current PBM reimbursement rates fall far below the actual costs of pharmacy operations. *Id.* ¶ 9(b).

The scope of below-cost reimbursement practices receives detailed documentation in Hartig's declaration, which reports that PBMs underpaid his company, making payments below the cost to acquire drug products on just under 10,000 prescription drug claims in the first quarter of 2025 alone. *Id.* ¶ 9(c). He describes additional PBM tactics including unilateral "discount card" arrangements that reduce contractual reimbursement while adding administrative fees averaging $5.00 or more. *Id.* ¶ 10.

Specific examples of PBM practices that prioritize profit over patient care emerge from Hartig's declaration, including the forced transfer of a patient receiving PrEP (HIV prevention) medication from his pharmacy to CVS Health's mail-order pharmacy within three months of initiating treatment at Hartig Drug, noting that 'as a specialty medication, PrEP is profitable' and the patient was subsequently unable to continue receiving the medication from his local pharmacy. *Id.* ¶ 12. He also documents how PBMs regularly "claw back" patient payments, citing one day in June 2025 when over 230 prescription drug claims resulted in PBMs reclaiming approximately $1,000 from payments made by individual patients to his pharmacy. *Id.* ¶ 13(b).

Hartig provides practical evidence of SF 383's projected benefits, stating that financial modeling of the new reimbursement methodology shows an increase of less than one-half of a

percent to net profit as a percentage of sales, characterizing this not as a "financial windfall" but as ensuring "a fair operating margin to ensure its personnel and fixed costs can be paid." *Id.* ¶¶ 21–22. He warns that absent SF 383's protections, Hartig Drug Company, which already closed two of its fifteen Iowa pharmacies in 2024, expects to close additional locations, further contributing to the pharmacy access crisis in Iowa. *Id.* ¶ 23.

B. Procedural Background

Iowa Governor Kim Reynolds signed SF 383 into law on June 11, 2025, with an effective date of July 1, 2025. Plaintiffs filed suit on June 23, 2025, eight days before the statute's effective date, seeking declaratory and injunctive relief. On June 26, 2025, Plaintiffs moved for a temporary restraining order. After determining that the Commissioner opposed voluntary delay of enforcement, United States District Judge Rebecca Goodgame Ebinger granted *ex parte* emergency relief on June 30, 2025, enjoining enforcement of SF 383 against the named Plaintiffs pending a preliminary injunction hearing. [ECF No. 17].

The temporary restraining order reflected Judge Ebinger's preliminary determination that certain provisions of SF 383 likely violate ERISA's preemption doctrine by impermissibly interfering with central matters of plan administration, and that restrictions on truthful commercial speech likely violate the First Amendment under intermediate scrutiny analysis. She further concluded that Plaintiffs faced irreparable harm both from unrecoverable compliance costs and from interference with their ability to structure benefit plans and fulfill fiduciary obligations to plan participants.

Plaintiffs now seek a preliminary injunction against enforcement of the entire statute, arguing that individual provisions are either independently invalid or inseverable from the statutory scheme as a whole. The fundamental disagreement between the parties centers on SF 383's true regulatory target: Iowa maintains the law primarily regulates PBMs as intermediaries

in pharmaceutical markets, while Plaintiffs contend it actually governs the structure and administration of employer-sponsored health plans in ways that intrude upon exclusively federal regulatory authority.

II. DISCUSSION

A. Framework for Preliminary Injunctive Relief

Preliminary injunctive relief is an extraordinary remedy, not issued routinely or "as a matter of right." *Winter v. Nat'l Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008) (quoting *Munaf v. Green*, 553 U.S. 674, 689–90 (2008)). The primary purpose of a preliminary injunction is to preserve the status quo and prevent irreparable harm until the Court can render a final decision on the merits. *Cigna Corp. v. Bricker*, 103 F.4th 1336, 1342 (8th Cir. 2024). A plaintiff seeking this extraordinary relief bears the burden of demonstrating that such intervention is warranted. *H&R Block, Inc. v. Block, Inc.*, 58 F.4th 939, 946 (8th Cir. 2023).

Courts consider four factors when determining whether to issue a preliminary injunction: (1) the plaintiff's likelihood of success on the merits; (2) the threat of irreparable harm to the plaintiff absent preliminary relief; (3) the balance of equities between the parties; and (4) the public interest. *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981) (en banc).

Although all factors must be considered, the Eighth Circuit has determined that the likelihood of success on the merits is the "most significant" factor. *Sleep Number Corp. v. Young*, 33 F.4th 1012, 1016 (8th Cir. 2022). When a party seeks to enjoin the enforcement of a duly enacted statute or regulation, a heightened standard applies, requiring the moving party to show they are "likely to prevail on the merits" of their claims. *Firearms Regulatory Accountability Coalition, Inc. v. Garland*, 112 F.4th 507, 517 (8th Cir. 2024) (quoting *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 732 (8th Cir. 2008) (en banc)). This heightened standard applies because government action undertaken through "presumptively reasoned democratic

processes" is entitled to substantial deference and "should not be enjoined lightly." *D.M. by Bao Xiong v. Minn. State High Sch. League*, 917 F.3d 994, 1000 (8th Cir. 2019) (cleaned up). The Eighth Circuit has clarified that this "more-likely-than-not standard" applies when "a preliminary injunction is sought to enjoin the implementation of a duly enacted state statute." *Rounds*, 530 F.3d at 732.

With respect to irreparable harm, a plaintiff need not establish with absolute certainty that such harm will occur but must demonstrate that "irreparable injury is likely in absence of an injunction." *Winter*, 555 U.S. at 22. Failure to show irreparable harm constitutes an "independently sufficient basis upon which to deny a preliminary injunction." *Sessler v. City of Davenport*, 990 F.3d 1150, 1156 (8th Cir. 2021).

In balancing the equities, the Court weighs "the threat of irreparable harm shown by the movant against the injury that granting the injunction will inflict on [the] other part[y] litigant[s]." *MPAY Inc. v. Erie Custom Comp. Applications, Inc.*, 970 F.3d 1010, 1020 (8th Cir. 2020) (cleaned up).

B. Preliminary Injunction Analysis

The preliminary injunction analysis requires examining several interconnected factors to determine whether Plaintiffs may obtain relief against SF 383's enforcement. Standing doctrine requires an initial determination of whether each Plaintiff faces concrete injury sufficient to invoke federal jurisdiction. This inquiry proves particularly important here because many challenged provisions regulate PBMs rather than Plaintiffs directly. The Court must also examine whether established causes of action support Plaintiffs' claims for prospective relief under federal preemption and constitutional principles.

On the likelihood of success on the merits factor, the fundamental question is whether Iowa's regulation of PBMs crosses constitutional boundaries by intruding upon areas of exclusive

federal authority under ERISA or by restricting protected commercial speech. The heightened standard applicable to challenges against duly enacted legislation demands that Plaintiffs demonstrate not merely possible success, but likelihood of prevailing on claims that would invalidate the democratic will expressed through Iowa's legislative process. Each element of the preliminary injunction framework must be satisfied before the Court may grant the extraordinary remedy of enjoining state law enforcement. Should Plaintiffs prevail on the merits, the Court must further determine whether unconstitutional or preempted provisions may be severed from SF 383's broader regulatory scheme, and whether relief should extend to the statute's entirety or only to specific problematic provisions as applied to ERISA plans and their administration.

1. Threshold Issues

a. Article III Standing Requirements

Federal courts possess only limited jurisdiction, and they must therefore determine as a threshold matter whether a plaintiff has Article III standing to bring suit. *Murthy v. Missouri*, 603 U.S. 43, 56 (2024); *see also Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 133 (2011) (stating "a case or controversy under Article III" requires that "a plaintiff must establish standing"). Standing doctrine serves the essential constitutional function of ensuring that federal courts adjudicate only genuine cases and controversies, rather than abstract policy disputes or generalized grievances. *See FDA v. All. for Hippocratic Medicine*, 602 U.S. 367, 379 (2024) (explaining that federal courts do not "operate as an open forum for citizens 'to press general complaints about the way in which the government goes about its business'") (quoting *Allen v. Wright*, 468 U.S. 737, 760 (1984)). To establish standing, a plaintiff must demonstrate injury in fact, causation, and redressability. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). The injury-in-fact requirement demands that plaintiffs have "suffered 'an invasion of a legally

protected interest'" that is both "concrete and particularized" and "actual or imminent." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016) (quoting *Lujan*, 504 U.S. at 560).

Where plaintiffs challenge a statute's validity, they may satisfy the injury requirement by demonstrating either present harm from the law's operation or by pleading "facts that affirmatively and plausibly suggest that they are indeed subject to a credible threat of prosecution under the statute for engaging in the conduct for which they invoke constitutional protection." *Zanders v. Swanson*, 573 F.3d 591, 594 (8th Cir. 2009) (citation omitted); *see also Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 159 (2014). Organizations "can assert the standing of their members." *Summers v. Earth Island Inst.*, 555 U.S. 488, 494 (2009). To invoke representational standing, an organization must establish that its members possess individual standing to sue, that the interests at stake relate to the organization's purposes, and that neither the claims nor the requested relief requires individual member participation in the litigation. *Students for Fair Admissions, Inc. v. President & Fellows of Harvard Coll*., 600 U.S. 181, 199 (2023) (citing *Hunt v. Wash. State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977)).

Plaintiffs have Article III standing to challenge SF 383's provisions, including many of those primarily directed at PBMs. This conclusion rests on well-established precedent recognizing the functional interdependence between ERISA plans and the intermediaries essential to their operation.

Plaintiffs indisputably have standing to challenge SF 383's provisions that directly regulate health benefit plans and third-party payors. Multiple sections of SF 383 explicitly impose obligations on "health benefit plans," "third-party payors," and "health carriers," creating immediate regulatory burdens for entities like Plaintiffs. These provisions subject Plaintiffs to direct enforcement action and create concrete compliance obligations, satisfying the injury-in-fact requirement without difficulty.

More challenging is the question whether Plaintiffs may challenge SF 383's provisions directed primarily at PBMs. For Plaintiffs' preemption arguments, *Wehbi* provides dispositive guidance. In that case, the United States Court of Appeals for the Eighth Circuit held that "a regulation of PBMs 'function[s] as a regulation of an ERISA plan itself.'" 18 F.4th at 966. This principle reflects the practical reality that modern ERISA plans have become "functionally dependent on PBM services to administer prescription drug benefits," making it "practical[ly] impossib[le]" for plans to "manage [their] own pharmacy benefits and avoid using a PBM." *Pharm. Care Mgmt. Ass'n v. Mulready*, 78 F.4th 1183, 1195 (10th Cir. 2023). The ERISA preemption analysis further clarifies this issue because the pertinent question is whether the state law has an impermissible "connection with" or "reference to" ERISA plans, not whether it is directed at them. *Wehbi*, 18 F.4th at 967.

The Supreme Court's standing doctrine does not require that plaintiffs be the direct target of regulation when they suffer concrete injury from regulatory compliance. Here, Plaintiffs have demonstrated substantial financial harm flowing from SF 383's PBM provisions. The actuarial analysis projects compliance costs exceeding $120 per enrollee annually, with mandatory dispensing fees alone adding $17.9 to $20.1 million in annual costs. [ECF No. 6-1 ¶¶ 16–19] (Bartle Decl.). These are not speculative future harms but immediate consequences of regulatory implementation.

Plaintiffs' standing is further reinforced by standard indemnification provisions in their PBM contracts. Such clauses create direct financial exposure for ERISA plans when their service providers face regulatory penalties, as the Second Circuit has recognized. The ERISA plan sponsor in that case had standing because it would "indemnif[y] [the third-party administrator] for the ensuing civil penalties." *Liberty Mut. Ins. Co. v. Donegan*, 746 F.3d 497, 502 (2d Cir. 2014), *aff'd sub nom. Gobeille v. Liberty Mut. Ins. Co.*, 577 U.S. 312 (2016). Similarly here, Plaintiffs'

agreements require them to hold their PBMs harmless for regulatory compliance costs, converting indirect regulatory burdens into direct financial obligations.

ERISA plan sponsors possess standing to challenge state laws regulating their service providers, as established precedent demonstrates. In a previous case, the United States Court of Appeals for the Eighth Circuit allowed Tyson Foods to challenge an any-willing-provider law applicable only to insurance companies because Tyson maintained agreements with those companies for network access and administrative services. *See Prudential Ins. Co. of Am. v. Nat'l Park Med. Ctr.*, 413 F.3d 897, 901 (8th Cir. 2005). The functional relationship between plan sponsors and their intermediaries created sufficient injury for standing purposes.

The Commissioner's argument that Plaintiffs lack standing because they "are not PBMs" misapprehends both standing doctrine and ERISA's structure. Standing requires injury-in-fact, not identity with the regulated entity. When regulatory burdens imposed on essential service providers create concrete financial harm for plan sponsors—whether through increased costs, compliance obligations, or contractual indemnification—Article III's requirements are satisfied. Under ERISA preemption analysis, regulations on PBMs that govern central matters of ERISA plan administration or interfere with national uniformity in plan administration impermissibly injure plans and plan sponsors, establishing standing to challenge PBM provisions on preemption grounds. *See Rutledge v. Pharm. Care Mgmt. Ass'n*, 592 U.S. 80, 87 (2020).

Different considerations govern Plaintiffs' First Amendment challenges. Regulations restricting only PBMs' First Amendment rights do not create cognizable injury flowing to plan structure or plan sponsors in the manner that supports ERISA preemption claims. Plaintiffs must assert their own legal rights and interests rather than resting their claim to relief on the legal rights or interests of third parties. *Warth v. Seldin*, 422 U.S. 490, 499 (1975). Plaintiffs cannot demonstrate concrete injury from alleged violations of PBMs' First Amendment rights. They

therefore lack Article III standing for their First Amendment challenge to Iowa Code § 510B.4B(1)(a), which restricts only PBMs from sharing information or promoting different pharmacies to participants and beneficiaries. However, Plaintiffs do possess standing for their First Amendment challenges to provisions that apply directly to third-party payors and health benefit plans. Iowa Code §§ 510B.1(4), 510B.4B(2)(a).

For Plaintiff IABI, organizational standing is established through its members' individual standing. The Association represents over 600 businesses that collectively sponsor ERISA plans covering more than 300,000 individuals. The interests at stake—freedom from preempted state regulation and protection of fiduciary discretion—directly relate to the Association's purposes. Additionally, neither the claims nor requested relief requires individual member participation, satisfying the requirements for organizational standing. *See Hunt*, 432 U.S. at 343.

The Court therefore concludes that all Plaintiffs possess Article III standing to challenge SF 383's provisions as preempted under ERISA, both those directly applicable to health benefit plans and those primarily directed at PBMs. The modern structure of employee benefit administration creates a sufficient nexus between PBM regulation and plan sponsor injury to support federal jurisdiction over those claims. Plaintiffs likewise possess standing to challenge provisions that directly restrict their own First Amendment rights, though they cannot assert the constitutional rights of third-party PBMs.

b. Availability of Cause of Action

The parties present a fundamental dispute regarding Plaintiffs' authority to invoke federal jurisdiction. Plaintiffs' claims rest on SF 383's alleged violation of the Supremacy Clause through conflict with ERISA's preemptive scope, seeking equitable relief under *Ex parte Young* alongside constitutional remedies under 42 U.S.C. § 1983. Defendant responds that Plaintiffs lack any

cognizable cause of action because the challenged provisions do not directly regulate them and they face no credible enforcement threat.

The constitutional architecture governing such disputes establishes clear but limited avenues for relief. The Supremacy Clause operates as a "rule of decision" directing courts to give no effect to state laws that conflict with federal laws, but it does not itself create federal rights or causes of action. *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 324 (2015). Rather than providing an enforcement mechanism, the Clause instructs courts how to resolve conflicts between state and federal law while remaining silent on who may seek such resolution and under what circumstances. *Id*. at 325. This structural limitation reflects the Constitution's careful allocation of enforcement authority between federal and state sovereigns. *See id.*, 575 U.S. at 324–25.

The Supreme Court acknowledged in *Armstrong* that "federal courts may in some circumstances grant injunctive relief against state officers who are violating, or planning to violate, federal law." *Id.* at 326–27. When "an individual claims federal law immunizes him from state regulation, the court may issue an injunction upon finding the state regulatory actions preempted" through the federal judiciary's traditional equitable powers. *Id.* at 326 (citing *Ex parte Young*, 209 U.S. 123, 155–56 (1908)). This authority remains "subject to express and implied statutory limitations," reflecting the principle that equity cannot "disregard statutory and constitutional requirements" any more than courts of law. *Id*. at 329.

Established precedent confirms that parties may seek prospective relief to prevent enforcement of preempted state law. When a plaintiff challenges state regulation as preempted by federal statute, such claims present federal questions within the jurisdiction of federal courts under 28 U.S.C. § 1331, since the Supremacy Clause requires that conflicting federal law must prevail.

For constitutional violations, Section 1983 supplies an additional mechanism for relief against state officials acting under color of law. *Shaw v. Delta Air Lines*, 463 U.S. 85, 96 n.14 (1983).

Applying these principles, Plaintiffs have demonstrated credible enforcement threats sufficient to invoke federal jurisdiction under these established legal frameworks.

c. Scope of Constitutional Challenge

Defendant characterizes Plaintiffs' lawsuit as a facial challenge to SF 383, arguing this creates an "insurmountable burden" requiring Plaintiffs to demonstrate that "no set of circumstances" exists under which the law would be valid. [ECF No. 24-1 at 17]. Defendant contends that because SF 383 applies to both ERISA and non-ERISA plans, and ERISA governs only employee benefit plans subject to federal jurisdiction, ERISA cannot preempt SF 383's application to non-ERISA plans. Therefore, Defendant argues, the statute has valid applications that preclude facial relief as a matter of law.

Plaintiffs sharply contest this characterization, maintaining they have brought an as-applied challenge. They argue that certain SF 383 provisions are unlawful as applied to their ERISA plan circumstances, with the remainder invalid as to them due to inseverability. Plaintiffs emphasize that their complaint explicitly limits the challenge as "to Plaintiffs and particularly self-funded and insured ERISA plans only." [ECF No. 39-1 at 3]. They note the linguistic disparity between the parties' characterizations: while "facial" appears repeatedly in Defendant's brief, "Plaintiffs have never used it." *Id.*

Plaintiffs' position proves more persuasive for several reasons. First, the Complaint's language supports an as-applied interpretation. It alleges that SF 383's provisions are preempted and "null and void as applied to ERISA plans, their sponsors, their fiduciaries, their administrators, their PBMs, and their participants and beneficiaries." [ECF No. 1 ¶ 63]. The Complaint further contends that "as applied to ERISA plans and their sponsors, either directly to them or indirectly

through their PBMs," SF 383 violates federal preemption principles. *Id*. ¶ 55. This formulation tracks the established framework for as-applied challenges where plaintiffs contend specific applications violate their rights while potentially leaving other applications intact.

Second, Plaintiffs' briefing consistently frames their arguments in as-applied terms. Their preliminary injunction brief argues that "ERISA preempts some or all of [SF 383's provisions] as applied to self-funded ERISA plans" and similarly pursues preemption "as applied to insured ERISA plans." [ECF No. 39-1 at 3–4]. This language demonstrates Plaintiffs' focus on how SF 383 affects their particular circumstances rather than challenging the statute's validity in all possible applications.

Third, Plaintiffs' opposition to Defendant's motion for a briefing schedule explicitly clarified their position: "Plaintiffs do not seek to enjoin the statute as to non-ERISA entities, but only as applied to ERISA plans and those administering them." [ECF No. 9 at 2]. This statement directly refutes Defendant's facial challenge characterization and confirms Plaintiffs seek relief limited to their circumstances.

Fourth, the Supreme Court has cautioned that "the distinction between facial and as-applied challenges is not so well defined that it has some automatic effect or that it must always control the pleadings and disposition in every case." *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 331 (2010). Although the distinction can be "instructive and necessary" in certain cases, it goes "to the breadth of the remedy employed by the Court, not what must be pleaded in a complaint." *Id.*

Moreover, ERISA's own language supports as-applied relief. The statute preempts state laws only "insofar as they may now or hereafter relate to any employee benefit plan." 29 U.S.C. § 1144(a). This limiting language confirms that courts may—and routinely do—enjoin a law's enforcement as applied to ERISA-governed plans while leaving applications to non-ERISA plans

intact. Indeed, virtually every state law held preempted under ERISA also covers non-ERISA plans. *See, e.g.*, *Nat'l Park Med. Ctr.*, 413 F.3d at 913 n.10 (holding Arkansas law preempted as applied to ERISA, but not non-ERISA plans); *Mulready*, 78 F.4th at 1200–01 (limiting preemption of Oklahoma's law to ERISA plan applications).

Defendant's argument proves too much. If accepted, it would render as-applied ERISA preemption challenges virtually impossible whenever state laws apply broadly to both ERISA and non-ERISA entities—the common situation. This would undermine ERISA's preemptive scope and conflict with established precedent allowing targeted relief protecting ERISA plans while preserving state regulatory authority over non-ERISA entities.

The Court therefore concludes that Plaintiffs have brought an as-applied challenge to SF 383, seeking relief limited to its enforcement against their own ERISA plans and those who administer them. This characterization governs the analysis of their claims and the scope of any relief granted.

2. Federal Preemption Under ERISA

Congress enacted ERISA to protect the interests of participants in employee benefit plans and their beneficiaries by establishing substantive regulatory requirements for such plans and ensuring "appropriate remedies, sanctions, and ready access to the Federal courts." *Aetna Health Inc. v. Davila*, 542 U.S. 200, 208 (2004) (quoting 29 U.S.C. § 1001(b)). ERISA establishes uniform standards and requirements for employee benefit plans, extending its comprehensive regulatory framework to all employer-sponsored benefit plans except those maintained by governmental entities and churches. 29 U.S.C. §§ 1001(b), 1003(a)–(b). The statute's reach encompasses both pension arrangements and employee welfare benefit plans that provide medical, disability, or other specified benefits, including prescription-drug coverage, whether "through the purchase of insurance or otherwise." *Id.* § 1002(1).

ERISA broadly preempts "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan." *Id.* § 1144(a). A law "relates to" an employee benefit plan when "it has a connection with or reference to such a plan." *Shaw*, 463 U.S. at 96–97. The "connection with" inquiry centers on state laws that dictate the fundamental architecture of employee benefit plans. Such preempted regulation characteristically mandates that providers "structure benefit plans in particular ways, such as by requiring payment of specific benefits or by binding plan administrators to specific rules for determining beneficiary status." *Rutledge*, 592 U.S. at 87 (citations omitted). A state law also has a "connection with" ERISA plans if it "governs . . . a central matter of plan administration," such as reporting, recordkeeping, disclosures, or fiduciary obligations, all of which are specifically addressed within ERISA. *Gobeille*, 577 U.S. at 320 (quoting *Egelhoff v. Egelhoff*, 532 U.S. 141, 148 (2001)). Adherence to ERISA's standards in these areas ensures "nationally uniform plan administration." *Id.*

A state law crosses the threshold for an impermissible "reference to" ERISA plans under one of two circumstances: the law must either "act immediately and exclusively upon ERISA plans," or "the existence of ERISA plans is essential to the law's operation." *Rutledge*, 592 U.S. at 88 (quoting *Gobeille*, 577 U.S. at 319–20). ERISA plans become essential to a statute's operation only where the law cannot reach non-ERISA plans. *Id.* at 88–89.

Not every state law that touches upon employee benefit plans triggers preemption. The fact that a state regulation "affects an ERISA plan or causes some disuniformity in plan administration" falls short of the requisite showing, particularly where the challenged law does no more than influence plan costs. *Id.* at 87.

Additionally, ERISA's express preemption provision contains important exceptions. The savings clause provides that preemption does not "exempt or relieve any person from any law of any State which regulates insurance." 29 U.S.C. § 1144(b)(2)(A). This generally "returns to the

States the power to enforce those state laws that 'regulate insurance,'" as when a plan or plan sponsor engages an insurer to provide benefits under an ERISA plan. *FMC Corp. v. Holliday*, 498 U.S. 52, 58 (1990). However, the deemer clause constrains this authority by providing that no ERISA-covered plan "shall be deemed to be an insurance company" for purposes of state insurance regulation, thus preventing States from treating self-funded plans as insurance entities subject to state regulation. 29 U.S.C. § 1144(b)(2)(B); *see FMC Corp.*, 498 U.S. at 61–62.

3. Likelihood of Success Analysis

The Court now turns to the central question in this litigation: whether SF 383's comprehensive regulation of PBMs and related entities crosses the constitutional boundary into federal preemption under ERISA. This analysis requires careful application of the Supreme Court's guidance in *Rutledge* and the Eighth Circuit's decision in *Wehbi* to determine which state regulatory measures constitute permissible cost regulations and which impermissibly dictate the structure and administration of employee benefit plans. The parties' fundamental disagreement extends beyond SF 383's characterization to encompass the proper scope of ERISA preemption in an industry where state-regulated intermediaries have become essential to federally-governed employee benefit plans.

Although Iowa correctly observes that not every state law affecting ERISA plans triggers preemption, the Court finds that several of SF 383's provisions cross the line from permissible cost regulation into impermissible structural mandates that govern central matters of plan administration. The analysis nevertheless reveals that certain provisions operate as traditional rate regulations that fall within the state's regulatory authority and do not bear the requisite connection with ERISA plans to warrant preemption. Plaintiffs challenge more than twenty distinct provisions within SF 383 on preemption grounds. The Court addresses each category of challenged provisions in turn, applying the established framework to distinguish between permissible state

regulation and federal preemption. The analysis below is grouped according to the topic and substance of the particular provisions.

a. Anti-Discrimination and Network Access

The Court begins its ERISA preemption analysis with SF 383's most direct intrusions into plan design authority. SF 383's anti-discrimination and network access provisions directly regulate fundamental plan design decisions. The anti-discrimination provision prohibits discrimination against pharmacies in participation and reimbursement, while the any-willing-provider standards establish open-access requirements for specialty drugs. Plaintiffs argue these provisions impermissibly dictate plan structure by eliminating sponsors' discretion to configure networks based on cost and quality considerations. Iowa characterizes the provisions as consumer protection measures that regulate PBM conduct without mandating specific plan benefits.

i. Anti-Discrimination Provision (Iowa Code § 510B.1(4))

SF 383 establishes broad anti-discrimination requirements prohibiting PBMs, health carriers, health benefit plans, and third-party payors from discriminating against pharmacies or pharmacists "with respect to participation, referral, reimbursement of a covered service, or indemnification if a pharmacist is acting within the scope of the pharmacist's license, as permitted under state law, and the pharmacy is operating in compliance with all applicable laws and rules." Iowa Code § 510B.1(4).

This provision is preempted by ERISA because it impermissibly restricts ERISA plans and their sponsors from structuring benefit arrangements that favor particular providers based on legitimate considerations such as price, safety, or convenience. The Supreme Court's decision in *Shaw* establishes that ERISA preempts state anti-discrimination requirements that prohibit employers from structuring their employee benefit plans in certain ways. *Shaw*, 463 U.S. at 96–97. The Court recognized that state laws which prohibit "employers from structuring their

employee benefit plans in a manner that discriminates" against providers clearly "relate to" employee benefit plans and are therefore preempted by ERISA. *Id*. at 97. The plain text of SF 383 operates in precisely this manner by preventing ERISA plans from making "special arrangements with particular providers for access to prescription drugs" or from engaging in preferential "referral" practices that might benefit plan participants and the plan itself. [ECF No. 16 at 18].

The anti-discrimination provision interferes with central matters of plan administration by restricting fiduciary decision-making regarding provider networks and participant guidance. Under ERISA, plan fiduciaries have the obligation to act "for the exclusive purpose" of "providing benefits to participants and their beneficiaries" and "defraying reasonable expenses of administering the plan." 29 U.S.C. § 1104(a)(1)(A). When it may be in participants' and the plan's best financial interests to direct individuals to particular pharmacies with preferred terms or lower costs, Iowa's anti-discrimination provision prevents fiduciaries from fulfilling these duties by barring such guidance to avoid discrimination among pharmacies.

The prohibition on discrimination in "participation, referral, reimbursement of a covered service, or indemnification" directly regulates fundamental aspects of plan design and administration that ERISA reserves to plan sponsors and fiduciaries. *See Mulready*, 78 F.4th at 1201 (recognizing that pharmacy networks constitute "cornerstones in plans' prescription-drug benefit structures" and that "state efforts to undermine those pharmacy networks diminish plans' benefit options").

By preventing differential treatment of pharmacies regardless of the underlying business rationale, the provision "require[s] providers to structure benefit plans in particular ways" in violation of established preemption doctrine. *Rutledge*, 592 U.S. at 86–87. This broad prohibition prevents plan fiduciaries from making the very distinctions between providers that sound business judgment and fiduciary duty would dictate.

Iowa's attempt to distinguish this provision by arguing that it merely regulates PBM network curation fails to address the provision's direct application to health benefit plans and third-party payors. The provision applies explicitly to "health benefit plans" and "third-party payors," not merely to PBMs, placing it squarely within the category of state laws that courts have recognized as specifically designed to affect employee benefit plans. *Mackey v. Lanier Collection Agency & Serv.*, 486 U.S. 825, 829 (1988). By requiring that the plans extend the same requirements to all pharmacies, the provision restricts the incentives and deterrents that can be incorporated in plan design to achieve the most beneficial coverage and relationships within the network. This fundamentally alters plan structure in ways that exceed permissible state authority. *See Shaw*, 463 U.S. at 97.

The provision is materially different from the restriction upheld in *Wehbi*, which did not restrict plan structure but rather prohibited PBMs from having certain ownership interests in pharmacies within their networks. Here, by contrast, the statute constrains all participants in the benefit delivery system and affects the structure of the plans themselves by prohibiting discrimination in participation, referrals, reimbursement, and indemnification. The anti-discrimination provision mandates the same terms and requirements for all pharmacies seeking network participation, which constitutes a key benefit design element for ERISA plans analogous to the network scope and cost-sharing arrangements that courts have recognized as central to plan administration. *See Mulready*, 78 F.4th at 1198.

ERISA preempts the anti-discrimination provision of Iowa Code § 510B.1(4) because it impermissibly dictates plan structure, interferes with central matters of plan administration, and prevents fiduciaries from exercising their duty to act in the exclusive interests of plan participants and beneficiaries.

ii. Any-Willing-Provider Provisions (Iowa Code §§ 510B.4B(1)(b) and 510B.4B(2)(a))

Network composition represents a core element of plan sponsors' fundamental authority under ERISA to design benefit structures that best serve their participants' interests. When plan sponsors select which pharmacies to include in their networks, they make strategic decisions about cost, quality, geographic accessibility, and specialized services that directly affect both the benefits available to participants and the expenses incurred by the plan. The Supreme Court has distinguished between laws that "merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage" and those that "require providers to structure benefit plans in particular ways." *Rutledge*, 592 U.S. at 86, 88 (citations omitted). Iowa's any-willing-provider provisions fall squarely within the latter category of impermissible structural mandates.

The analysis of these two provisions is guided by the Tenth Circuit's decision in *Mulready*, which confronted Oklahoma's Patient's Right to Pharmacy Choice Act containing any-willing-provider provisions substantially similar to Iowa's requirements. The *Mulready* court concluded that any-willing-provider provisions are "quintessential state laws that mandate benefit structures" because they prevent plans from implementing "some of the most fundamental network designs, such as preferred pharmacies, mail-order pharmacies, and specialty pharmacies." 78 F.4th at 1199–1200. *Mulready* recognized that pharmacy network composition represents a core component of plan design because it directly affects both the benefits available to participants and the costs incurred by the plan. *Id*. at 1199.

This reasoning reflects a deeper understanding of how modern employee benefit plans operate. Plan sponsors do not select network pharmacies arbitrarily; they make strategic choices based on factors including cost-effectiveness, quality of service, geographic convenience, and specialized capabilities. By requiring plans to accept any pharmacy willing to meet basic terms,

Iowa's provisions eliminate the customizability and discretion that ERISA reserves to plan sponsors and fiduciaries.

Wehbi addressed materially different regulatory provisions and cannot be extended to validate Iowa's any-willing-provider requirements as Defendant argues. In that case, the court considered North Dakota statutes that merely limited the accreditation requirements that a PBM may impose on pharmacies as a condition for participation in its network. The court concluded that these provisions constituted "at most, regulation of a noncentral 'matter of plan administration' with *de minimis* economic effects." 18 F.4th at 968.

Critically, the North Dakota provisions did not mandate network inclusion or create any-willing-provider standards. Rather, they established boundaries on the types of qualifications PBMs could demand beyond basic state licensing requirements. The distinction between these regulatory approaches is dispositive. Where the North Dakota statutes merely constrained the criteria for network participation, Iowa's provisions mandate actual network inclusion for any-willing-pharmacy.

This distinction places Iowa's law within a fundamentally different category of regulations. The North Dakota provisions allowed plans to maintain discretion over which pharmacies to include in their networks, subject only to limited constraints on the qualification criteria. Iowa's provisions, by contrast, eliminate such discretion entirely by requiring inclusion of any-willing-provider. This mandatory approach represents precisely the type of state interference with plan design that ERISA preempts.

The consensus among courts that have addressed this issue supports preemption. Every court that has considered true any-willing-provider laws in the ERISA context has concluded that such provisions are preempted. These decisions span multiple circuits and have uniformly recognized that such laws impermissibly "strik[e] at the heart of network and benefit design" by

constraining fundamental plan structuring decisions. *Mulready*, 78 F.4th at 1209; *see also Ky. Ass'n of Health Plans v. Nichols*, 227 F.3d 352, 363 (6th Cir. 2000); *CIGNA Healthplan of La., Inc. v. Louisiana ex rel. Ieyoub*, 82 F.3d 642, 648 (5th Cir. 1996).

This judicial consensus reflects a recognition that any-willing-provider laws fundamentally alter the relationship between plan sponsors and service providers. Rather than allowing market forces and plan-specific objectives to guide network construction, these laws impose a regulatory framework that prioritizes provider access over plan flexibility. Such reordering of priorities conflicts with ERISA's fundamental premise that plan sponsors should retain authority to structure benefits in ways that best serve their participants' interests.

Iowa's attempt to distinguish its provisions by characterizing them as regulations of "pharmacy network curation" rather than benefit design fails to appreciate their actual operation. The statutes explicitly require that qualifying pharmacies be permitted to participate in networks, leaving no discretion to exclude willing providers regardless of strategic considerations. This represents a direct legal mandate affecting plan structure, not merely an indirect consequence of regulating third-party relationships.

The provisions effectively force ERISA plans to adopt a "take all comers" approach to network participation. This mandatory requirement eliminates the ability of plan sponsors to make strategic decisions about network composition based on factors such as cost-effectiveness, quality metrics, geographic optimization, or specialized service capabilities. When a plan sponsor determines that limiting network participation to certain high-performing or cost-effective pharmacies would benefit plan participants, Iowa's law prevents such strategic choices.

Similarly, a plan sponsor seeking to control costs by negotiating favorable terms with a limited number of high-volume pharmacies would be required to extend network participation to any-willing-provider, potentially undermining the volume-based pricing advantages that benefit

plan participants. These are not theoretical concerns but practical realities that demonstrate how Iowa's provisions dictate fundamental aspects of plan design.

Iowa's reliance on *Wehbi* to defend its any-willing-provider provisions is misplaced. Defendant reads *Wehbi* too broadly to create an irreconcilable conflict with established precedent. Although *Wehbi* acknowledges that the preemption standard addresses laws that require providers to structure benefit plans in particular ways, it specifically concerned provisions that merely limited accreditation requirements without mandating network inclusion. The Iowa law, by contrast, requires plan benefits to be structured and offered in a particular way by mandating indiscriminate network access. This impedes plan structure and benefit design even without directly dictating the specific terms and requirements that must be imposed.

The any-willing-provider provisions in Iowa Code §§ 510B.4B(1)(b) and 510B.4B(2)(a) are preempted by ERISA because they impermissibly dictate fundamental aspects of plan design by mandating network structures that eliminate plan sponsors' discretion to configure pharmacy networks in ways that best serve their participants' interests and control plan costs. The provisions cannot be distinguished from the regulatory mandates that courts have consistently held to exceed state authority under ERISA's preemptive scope.

The Tenth Circuit's analysis in *Mulready* provides the controlling framework for understanding why such mandates constitute impermissible benefit design requirements. The Eighth Circuit's different result in *Wehbi* addressed materially different regulatory provisions and cannot credibly be extended to validate Iowa's structural constraints on plan design. The consensus among courts that have addressed this issue supports preemption, recognizing that any-willing-provider laws fundamentally alter the relationship between plan sponsors and service providers in ways that conflict with ERISA's preservation of plan sponsor authority over benefit design decisions.

iii. Open-Access Standard for Specialty Drugs (Iowa Code § 510B.4B(1)(d))

Under Iowa Code § 510B.4B(1)(d), PBMs may not "designate a drug as a specialty drug in order to prevent participants and beneficiaries from obtaining the drug from any in-network provider." This provision restricts PBMs' ability to use specialty drug designations as a mechanism to limit where plan participants may obtain certain medications within an established network.

ERISA preempts this provision for substantially the same reasons as the anti-discrimination provision analyzed above. The arguments advanced by both parties regarding this provision largely mirror their positions on the broader anti-discrimination requirements, as both provisions operate to restrict differential treatment of pharmacies in ways that interfere with plan design and administration.

The open-access standard impermissibly constrains ERISA plans' ability to structure their pharmacy networks and benefit arrangements based on the specialized nature of certain medications. Specialty drugs, as defined by SF 383, are medications used to treat "chronic and complex, or rare medical conditions" that "require[] special handling or administration, provider care coordination, or patient education that cannot be provided by a nonspecialty pharmacy or pharmacist." Iowa Code § 510B.1(21B). The clinical complexity and specialized requirements associated with these medications distinguish them fundamentally from standard prescription medications and provide legitimate business and clinical reasons for plans to limit their dispensing to pharmacies with appropriate capabilities and expertise.

By preventing PBMs from using specialty drug designations to direct participants to pharmacies with specialized capabilities, the provision interferes with central matters of plan administration and fiduciary decision-making. *See Mulready*, 78 F.4th at 1189 (recognizing that plans design their benefits based partly on drug coverage and the locations where beneficiaries

may obtain covered medications). Plan fiduciaries have obligations under ERISA to ensure that participants receive appropriate care while managing plan costs effectively. *See* 29 U.S.C. § 1104(a). This may reasonably include directing participants to pharmacies with specialized expertise in handling complex medications, enhanced patient monitoring capabilities, or established protocols for managing specialty drug therapies.

SF 383 eliminates a tool that plans use to ensure quality care delivery and cost management for their most complex and expensive medications. The Tenth Circuit explained in *Mulready* that network restrictions crossing into impermissible structural mandates are those that "impede PBMs from offering plans some of the most fundamental network designs, such as preferred pharmacies, mail-order pharmacies, and specialty pharmacies." *Mulready*, 78 F.4th at 1200.

Like the anti-discrimination provision, this requirement prevents plan sponsors from making strategic decisions about provider networks based on legitimate considerations including clinical expertise, patient safety, care coordination capabilities, and cost-effectiveness. The provision essentially mandates that plans treat all network pharmacies equivalently for specialty drug dispensing purposes, regardless of their varying capabilities to provide appropriate specialized services.

Defendant's response to this provision follows the same reasoning advanced for the anti-discrimination provision—arguing that the provision merely regulates PBM conduct without dictating plan benefits and permits plan sponsors to establish participation terms of their choosing. This argument fails for the same reasons discussed above. The provision directly constrains fundamental plan design decisions about how to ensure appropriate care delivery for complex medications, thereby interfering with central matters of plan administration.

The provision also implicates the same fiduciary concerns as the anti-discrimination provision. When plan fiduciaries determine that certain medications require specialized handling

or enhanced patient monitoring that may not be available at all network pharmacies, their duty to act with "an eye single" towards the interest of the beneficiaries may require directing participants to pharmacies with appropriate capabilities. *See Pegram v. Herdrich*, 530 U.S. 211, 235 (2000) (citation omitted). The open-access standard prevents such fiduciary decision-making by prohibiting specialty drug designations that would accomplish this objective.

The open-access standard for specialty drugs in Iowa Code § 510B.4B(1)(d) exceeds permissible state regulatory authority under ERISA because it impermissibly restricts plan sponsors' ability to structure their networks and benefit arrangements based on the specialized nature of certain medications, interferes with fiduciary obligations to ensure appropriate care delivery, and mandates plan structures that may not serve participants' best interests for complex medication management.

b. Patient Choice and Access

The Court next examines provisions that restrict communications between PBMs and participants regarding pharmacy choices. The limitation on guidance to preferred pharmacies restricts promotional activities and cost comparisons. Plaintiffs contend this provision interferes with fiduciary obligations to provide cost-effective guidance. Iowa argues it prevents improper steering while preserving participant autonomy.

i. Limitation on Guidance to Preferred Pharmacies (Iowa Code § 510B.4B(1)(a))

Iowa Code § 510B.4B(1)(a) restricts PBMs from imposing "a monetary advantage or penalty that would affect a covered person's choice" and specifically prohibits PBMs from "promot[ing] one participating pharmacy over another" or "comparing the reimbursement rates of a [participating] pharmacy against mail order pharmacy reimbursement rates." This provision limits the ability of PBMs to steer plan participants toward particular pharmacies within an established network through promotional activities or cost comparisons.

Federal preemption does not reach this provision given its exclusive application to PBMs without direct regulation of ERISA plans or their sponsors. The statutory language specifically targets PBM conduct rather than imposing requirements on health benefit plans or third-party payors. Since PBMs are not ERISA fiduciaries and ERISA does not directly regulate their activities, state laws governing PBM conduct fall outside ERISA's core concerns.

The provision regulates the manner in which PBMs may communicate with plan participants about network pharmacy options, but it does not dictate the terms of plan benefits or require plans to provide specific coverage. Plan sponsors maintain complete authority over their network composition, participation requirements, and reimbursement structures. The restriction operates only after these fundamental plan design decisions have been made and affects solely how PBMs may present information about available network options to participants.

Moreover, the provision does not prevent PBMs from implementing legitimate cost-containment strategies or network preferences established by the plan sponsor. It simply requires that promotional activities and rate comparisons be conducted in a manner that does not unduly influence participant choice through PBM-directed steering mechanisms. Plans remain free to structure their networks and cost-sharing arrangements to incentivize use of preferred pharmacies; the provision merely limits the promotional methods PBMs may use to effectuate those preferences.

The regulation falls within the category of PBM conduct that courts have recognized as permissible under ERISA preemption analysis. *Wehbi* upheld similar restrictions on PBM activities, finding that regulations affecting PBM-pharmacy relationships without directly mandating plan structure or benefits do not trigger ERISA preemption. 18 F.4th at 968 (finding that such provisions constitute "regulation of a noncentral matter of plan administration with *de minimis* economic effects").

This provision allegedly interferes with central matters of plan administration by restricting fiduciary guidance to participants and beneficiaries about cost-effective pharmacy options. Plaintiffs argue that the provision prevents plan fiduciaries from fulfilling their obligations to act in participants' best interests by limiting communications about preferred network options that might reduce costs or improve service quality.

This argument mischaracterizes both the provision's scope and its relationship to ERISA fiduciary duties. The provision applies specifically to PBMs, not to plan fiduciaries or ERISA plans themselves. Plan sponsors and fiduciaries retain the authority to communicate directly with participants about network preferences and cost considerations. Plans remain free to structure benefits encouraging use of preferred pharmacies or to provide participants with information about cost-effective options; only specific promotional activities that PBMs may undertake face restriction.

Furthermore, while PBMs may function as service providers to ERISA plans, the provision does not interfere with the contractual relationship between plans and PBMs in ways that would implicate central plan administration functions. Plans can still direct PBMs to implement network strategies that serve participants' interests; the provision simply establishes parameters for how those strategies may be communicated to participants.

If this provision prohibited promotional activities, copayment variations, and incentives built into the plan terms themselves, it would impact plan structure and benefit design in ways that could trigger preemption concerns. By contrast, regulating PBM promotions, discounts, rebates, or incentives that operate independently after the fact for beneficiaries does not impermissibly reach into plan administration. By regulating post-plan-design promotional activities rather than dictating fundamental plan structure, this requirement remains within permissible constitutional boundaries.

The limitation on guidance to preferred pharmacies in Iowa Code § 510B.4B(1)(a) is therefore not preempted by ERISA because it regulates PBM conduct rather than plan structure or benefits, applies to entities that are not ERISA fiduciaries, and does not interfere with central matters of plan administration or dictate fundamental plan design decisions.

c. Cost-Sharing Provisions

The Court now examines provisions that establish mandatory parity requirements between different pharmacy delivery channels and restrict plans' ability to structure differential cost-sharing arrangements. Iowa contends these provisions constitute permissible cost regulations that prevent discriminatory reimbursement practices without dictating specific benefit designs, while Plaintiffs argue the requirements impermissibly eliminate fundamental plan design tools by mandating uniform cost-sharing structures that constrain fiduciary decision-making regarding optimal benefit arrangements.

i. Mail-Order Pharmacy Cost Provisions (Iowa Code §§ 510B.4B(1)(f) and 510B.8(3))

Iowa's cost-sharing provisions include two specific mechanisms: first, Iowa Code § 510B.4B(1)(f) prohibits PBMs from imposing payment requirements or purchasing conditions on retail pharmacies that prove "more costly or restrictive" than those applied to mail-order facilities; second, Iowa Code § 510B.8(3) bars PBMs from varying "cost-sharing" obligations based upon a covered person's choice of pharmacy provider. These provisions work in tandem to constrain how PBMs structure financial incentives within their networks, effectively mandating parity between retail and mail-order pharmacy arrangements.

These provisions are preempted by ERISA because they impermissibly dictate fundamental aspects of plan design by mandating specific cost-sharing arrangements that eliminate plans' discretion to structure benefits in ways that serve participants' interests and control costs.

Cost-sharing arrangements represent core elements of benefit plan design that ERISA reserves to plan sponsors and fiduciaries.

Mulready establishes that state laws regulating cost-sharing arrangements constitute impermissible interference with plan structure. The Tenth Circuit recognized that "cost-sharing arrangements" are "key benefit designs for an ERISA plan" that states cannot mandate without triggering preemption. 78 F.4th at 1198. Regulations dictating how plans must structure their cost-sharing obligations represent the type of plan design mandates that ERISA preempts.

The cost-sharing provisions in Iowa Code §§ 510B.4B(1)(f) and 510B.8(3) go far beyond permissible cost regulation by directly constraining fundamental plan design decisions. Unlike regulations that merely affect the amounts paid for particular services, these provisions eliminate entire categories of benefit design strategies that plans have traditionally used to manage costs and encourage efficient utilization. By prohibiting differential cost-sharing based on pharmacy type, the provisions prevent plans from using one of their most important tools for steering participants toward cost-effective providers.

The prohibition on differential cost-sharing between retail and mail-order pharmacies particularly illustrates the provisions' interference with plan design. Mail-order pharmacies typically offer significant cost advantages for maintenance medications through bulk purchasing, reduced overhead, and operational efficiencies. Plans have historically used cost-sharing incentives to encourage participants to utilize these cost-effective options for appropriate medications. Iowa's provision eliminates this fundamental cost-containment strategy by requiring identical cost-sharing regardless of the delivery mechanism chosen.

These provisions operate to mandate specific benefit structures rather than merely affecting the costs of plan administration. In *Rutledge*, the state law required PBMs to reimburse pharmacies at a price equal to or higher than the price it cost the pharmacy to obtain the drug. State regulations

that merely increase costs or alter incentives for ERISA plans fall outside ERISA's preemptive scope. *Rutledge*, 592 U.S. at 88. The Arkansas law was determined to simply establish a cost regulation, dictating how PBMs reimburse pharmacies. Although the Court recognized that this could have an effect on plans because PBMs may pass their increased costs onto the plans, the law did not require the plans to provide any particular benefit to any particular beneficiary in any particular way.

In contrast, Iowa Code §§ 510B.4B(1)(f) and 510B.8(3) constrain plan administrators' fundamental design choices by restricting how they structure cost-sharing arrangements and fee schedules across different pharmacy providers. Because PBMs face limitations in administering these benefits, the regulatory effect flows backward to circumscribe plan design itself. Cost-sharing terms constitute essential elements of ERISA plan benefit architecture. *Mulready*, 78 F.4th at 1189, 1201.

The practical consequence proves decisive: plans cannot customize benefit structures through differential incentives and agreements with various pharmacies because their PBMs would face potential state law compliance issues in administering such arrangements. These provisions mandate alterations to benefit design to ensure that cost-sharing obligations and fees remain constant regardless of pharmacy selection. By prohibiting differential cost-sharing between retail and mail-order facilities, the statutes do more than establish pricing floors—they require uniform benefit structures across pharmacy categories.

The cost-sharing provisions also interfere with fiduciary obligations by constraining fiduciaries' ability to structure benefits in ways that best serve participants' interests. When fiduciaries determine that certain cost-sharing arrangements would encourage more efficient utilization or better health outcomes, Iowa's provisions may prevent implementation of those

arrangements. This represents the type of interference with fiduciary decision-making that ERISA preempts.

The cost-sharing provisions in Iowa Code §§ 510B.4B(1)(f) and 510B.8(3) exceed permissible state regulatory authority because they impermissibly dictate plan structure by mandating specific cost-sharing arrangements, eliminate fundamental plan design tools, and extend far beyond the type of cost regulation that the Supreme Court approved in *Rutledge*.

d. Network Standards

The Court turns to provisions governing the qualifications PBMs may impose on pharmacy network participants. The pharmacy-accreditation standard limits PBMs to requiring only those credentials consistent with state licensing requirements, preventing the imposition of additional or more stringent qualifications. Plaintiffs argue this provision, while seemingly directed at PBMs, effectively constrains plan sponsors' ability to ensure specialized pharmacy capabilities for complex medications. Iowa defends the provision as protecting state regulatory authority over professional licensing while preventing PBMs from using excessive credentialing demands to inappropriately restrict network access.

i. Pharmacy-Accreditation Standard for Network Participation (Iowa Code § 510B.4B(1)(c))

Under Iowa Code § 510B.4B(1)(c), PBMs may not impose on pharmacies "any course of study, accreditation, certification, or credentialing that is inconsistent with, more stringent than, or in addition to state requirements for licensure or certification, and the administrative rules adopted by the board of pharmacy." This provision establishes limits on the accreditation criteria that PBMs may require as a condition for pharmacy participation in their networks.

The accreditation standard is not preempted by ERISA because it regulates PBM network curation practices without dictating plan structure or requiring specific benefits. The Eighth Circuit's decision in *Wehbi* directly addresses similar accreditation requirements and provides

controlling precedent for this analysis. In *Wehbi*, the court considered a North Dakota law that limited accreditation requirements PBMs could impose on pharmacies and concluded that such regulations do not warrant preemption. 18 F.4th at 968.

The *Wehbi* court recognized that while accreditation requirements might "cause some disuniformity in plan administration," they do not "requir[e] payment of specific benefits" or "bind[] plan administrators to specific rules for determining beneficiary status." *Id*. at 968 (quoting *Rutledge*, 592 U.S. at 86–87). Rather, these requirements constitute "regulation of a noncentral matter of plan administration with *de minimis* economic effects." *Id*.; *see also Gobeille*, 577 U.S. at 320. The provision here operates in substantially the same manner as the North Dakota law upheld in *Wehbi*.

The accreditation standard represents an exercise of traditional state regulatory authority over pharmacy licensing and qualification requirements. States have long possessed the power to determine who is qualified to dispense prescription drugs and to establish professional standards for pharmacy practice. The Iowa provision prevents PBMs from circumventing state licensing standards by imposing additional or more stringent requirements that would effectively override the state's determination of professional competency.

By limiting PBM accreditation requirements to those consistent with state licensing standards, the provision ensures that pharmacy network participation decisions are based on legitimate professional qualifications rather than arbitrary or excessive credentialing demands. This approach supports the state's interest in maintaining uniform professional standards while preventing PBMs from using accreditation requirements as a mechanism to inappropriately restrict network access.

Network inclusion decisions and coverage requirements remain within PBM and plan discretion. The provision merely establishes that accreditation requirements, when imposed, must

be reasonable and consistent with state professional standards. PBMs retain discretion to establish other network participation criteria, including geographic considerations, service quality metrics, contract terms, and reimbursement requirements.

The regulation falls within the category of "laws of general applicability" that "operate in an area traditionally left to state regulation" and therefore do not trigger ERISA preemption. *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 661 (1995) (citation omitted). These regulations address PBM conduct in areas beyond ERISA's scope rather than interfering with central plan administration functions.

The provision's impact on plan administration is minimal and indirect. Although it may affect the composition of available pharmacy networks by preventing PBMs from imposing excessive accreditation requirements, it does not mandate specific network structures or require plans to contract with particular providers. Any effects on plan design flow from pharmacies credentialed under the state standard, which restricts PBMs from establishing their own accreditation requirements for network participation.

The similarity between Iowa's accreditation provision and the North Dakota law upheld in *Wehbi* is particularly significant. Both provisions limit PBM accreditation requirements to standards consistent with state licensing rules, and both operate to prevent PBMs from using excessive credentialing demands to inappropriately restrict network access. The Eighth Circuit's analysis in *Wehbi* therefore applies directly to the Iowa provision.

Unlike other provisions in SF 383 that set specific restrictions on how PBMs may create and utilize their pharmacy networks in ways that affect the structure and design of the plans themselves, accreditation requirements for network participation do not create effects that cascade back to alter fundamental plan design. The provision regulates the professional qualifications that

may be required for network participation without dictating the substantive terms of benefit coverage or the structural arrangements through which benefits are delivered.

The accreditation standard in Iowa Code § 510B.4B(1)(c) is therefore not preempted by ERISA because it regulates PBM network curation practices within the state's traditional authority over professional licensing, imposes only *de minimis* effects on plan administration, and does not require specific benefits or dictate plan structure in ways that would trigger preemption under controlling Eighth Circuit precedent.

e. Financial and Reimbursement Rules

The Court now addresses provisions that regulate the financial arrangements between PBMs, plans, and pharmacies. The pass-through rebate requirement mandates that PBMs transfer all manufacturer rebates to health plans, while reimbursement rate provisions establish minimum payment standards and require equal treatment between affiliated and unaffiliated pharmacies. Plaintiffs characterize these provisions as impermissible interference with fiduciary contracting decisions and plan administration. Iowa contends they constitute permissible cost regulations that increase transparency and prevent self-dealing without dictating plan structure or benefit design.

i. Pass-Through Rebates (Iowa Code § 510B.8(4))

Iowa law now requires PBMs to "pass through pricing" under which PBMs must transfer 100% of manufacturer rebates to health plans. The provision mandates that all rebates received by PBMs from pharmaceutical manufacturers "be passed through to the health carrier or employee plan sponsor" which eliminates PBMs' ability to retain portions of these rebates as compensation. Iowa Code § 510B.8(4).

This requirement falls outside ERISA's preemptive scope as a permissible cost regulation that does not dictate plan structure or interfere with central matters of plan administration. Under Plaintiffs' theory, this provision regulates a central part of ERISA plan administration by intruding

on fiduciary duties through restrictions on PBM contracting methods and prohibitions on rebate-based or pricing-mechanism compensation. They argue that ERISA requires fiduciaries not enter into contracts for more than reasonable compensation, and that the law restricts fiduciary discretion by controlling compensation arrangements.

Plaintiffs fail to demonstrate how this provision actually intrudes on the fiduciary duty to avoid contracts for more than reasonable compensation. Although the provision clearly affects PBMs and the current system where they retain a significant portion of manufacturer rebates, it benefits ERISA plans and sponsors by ensuring that rebates flow to them rather than being retained by PBMs. This approach appears to further rather than hinder fiduciary duties by ensuring that financial benefits from manufacturer relationships reach the plans and their participants.

Fiduciary contracting with PBMs remains unrestricted; the provision simply requires PBMs to take specific action if they receive rebates from manufacturers. This operates more like a cost regulation, similar to requiring PBMs to pay pharmacies specific reimbursement rates, than an actual intrusion on plan sponsors' fiduciary duties. The provision establishes a procedural requirement for rebate handling without dictating the substantive terms of plan benefits or requiring specific coverage decisions.

Plaintiffs also argue that the provision's express mention of ERISA creates both impermissible "connection with" and "reference to" preemption because the statute specifically states that rebates must pass through to the health carrier or employee plan sponsor "as permitted by ERISA." They contend that ERISA is essential to this provision's operation because without it the provision would have no effect. [ECF No. 16 at 23].

This argument fails because the law does not make an impermissible reference to ERISA. The provision applies to all PBMs regardless of whether they contract with ERISA plans or non-ERISA plans. ERISA plans are not essential to the provision's operation because the law reaches

non-ERISA plans as well. The reference to ERISA serves merely to clarify that the pass-through requirement operates within existing federal regulatory constraints, not to single out ERISA plans for different treatment.

The provision functions as a transparency and cost regulation that establishes how PBMs must handle manufacturer rebates without mandating specific plan structures or benefit designs. Plans maintain complete authority over their formularies, network composition, and benefit arrangements. The requirement affects the financial flows between PBMs and plans but does not constrain plan design decisions or require particular coverage arrangements.

The pass-through rebate requirement in Iowa Code § 510B.8(4) is therefore not preempted by ERISA because it constitutes a permissible cost regulation that benefits ERISA plans and sponsors, does not restrict fiduciary discretion in plan design, and applies generally to all PBM arrangements regardless of their relationship to ERISA plans.

ii. Reimbursement Provisions (Iowa Code §§ 510B.8B(1) and 510B.8B(2))

SF 383 prohibits PBMs from setting reimbursement rates for non-affiliated pharmacies at levels lower than the rates paid to affiliated pharmacies for the same drugs. Iowa Code § 510B.8B(1). A related provision requires PBMs to reimburse retail pharmacies at the national average drug acquisition cost ("NADAC") or wholesale acquisition cost ("WAC") for prescription drugs when NADAC is unavailable. *Id.* § 510B.8B(2).

These provisions are not preempted by ERISA because they constitute permissible cost regulations under *Rutledge*. The Supreme Court in *Rutledge* specifically upheld an Arkansas law requiring PBMs to reimburse pharmacies at rates at least equal to the pharmacy's acquisition cost. 592 U.S. at 87–88. There is no principled distinction between Iowa's reimbursement rate requirements and the Arkansas law upheld in *Rutledge*.

The requirement that PBMs reimburse all pharmacies at least as much as they pay their own affiliated pharmacies represents a permissible cost regulation that addresses potential conflicts of interest in PBM reimbursement practices. This provision operates similarly to the cost floors established in *Rutledge* by ensuring that non-affiliated pharmacies receive fair reimbursement rates compared to PBM-owned entities.

Plan structure and specific benefit requirements remain outside this provision's scope. Plans retain complete discretion over their formularies, network composition, and benefit design. The regulation affects the business relationship between PBMs and pharmacies without constraining plan design decisions or mandating particular coverage arrangements. Plans may still customize reimbursements and negotiate agreements with pharmacies, subject only to the requirement that non-affiliated pharmacies receive rates no less favorable than those paid to affiliated entities.

This regulation falls within the state's traditional authority to prevent unfair business practices and ensure competitive markets. The provision addresses the potential for PBMs to favor their own affiliated pharmacies through preferential reimbursement, which could distort market competition and disadvantage independent pharmacies.

The requirement that PBMs reimburse retail pharmacies at NADAC or WAC rates is squarely permissible under *Rutledge*. The Supreme Court approved an Arkansas law that required pharmacy reimbursement at rates at least equal to acquisition costs, and there is no meaningful distinction between that requirement and Iowa's NADAC pricing mandate.

The NADAC reimbursement standard establishes a cost floor for prescription drug benefits obtained through retail channels without dictating plan choices about benefit structure. Like the Arkansas regulations in *Rutledge*, this provision represents cost regulation that affects the pricing

methodology for pharmacy benefits without mandating plan structure or requiring specific coverage decisions.

Plans need not "adopt any particular scheme of substantive coverage" under this provision, which merely establishes minimum reimbursement standards that may affect costs or alter incentives for ERISA plans. *Rutledge*, 592 U.S. at 88. They retain full discretion over their formularies, network composition, coverage levels, and benefit design; they simply face regulated pricing for benefits they choose to provide through retail pharmacies.

Plaintiffs appear to concede that the NADAC pricing provision would survive preemption analysis, arguing only that the NADAC pricing is tied to the rate scheme that involves preempted provisions, such as the dispensing fee for retail pharmacies, in ways that render the entire pricing structure inseverable and inappropriate to maintain as part of the statutory scheme. The severability issue will be addressed in the Court's analysis below, but the NADAC reimbursement standard represents a standalone cost regulation that survives the preemption challenge under established precedent.

These provisions regulate PBM-pharmacy relationships and pricing methodologies without dictating plan structure or requiring specific benefits. The regulations affect the operational costs of providing benefits but do not directly dictate how benefits are structured or delivered to participants.

Accordingly, the reimbursement rate parity and standardization requirements in Iowa Code §§ 510B.8B(1) and 510B.8B(2) are not preempted by ERISA because they constitute permissible cost regulations directly supported by *Rutledge* that address PBM-pharmacy relationships without dictating plan structure or requiring specific benefits.

iii. Dispensing Fee for All Prescriptions (Iowa Code § 510B.8B(3))

Iowa Code § 510B.8B(3) establishes a mandatory dispensing fee of $10.68 that PBMs must reimburse to retail pharmacies for each prescription filled. This fee applies universally to all prescriptions dispensed through retail pharmacies and represents a significant new cost obligation for PBMs and, indirectly, for the ERISA plans they serve.

Rutledge supports the validity of this requirement as a permissible cost regulation outside ERISA's preemptive reach. Plaintiffs acknowledge that dispensing fees generally fall within the category of cost regulations that ERISA permits, but argue that this particular fee should be preempted because its immediate effective date creates "acute" financial effects that effectively dictate plan choices.

The dispensing fee regulation operates similarly to the PBM reimbursement requirements that the Supreme Court upheld in *Rutledge*. The *Rutledge* court specifically recognized that States may "establish[] a floor for the cost of the benefits that plans choose to provide" without triggering ERISA preemption. 592 U.S. at 90. The dispensing fee functions in precisely this manner by establishing a minimum reimbursement amount that PBMs must pay to retail pharmacies, thereby setting a cost floor for prescription drug benefits obtained through retail channels.

Like the Arkansas regulations in *Rutledge*, the dispensing fee represents "nothing more than cost regulation" that affects the pricing methodology for pharmacy benefits without dictating plan structure or requiring specific coverage decisions. The fee does not mandate that plans provide particular benefits, cover specific medications, or structure their networks in particular ways. Plans retain full discretion over their formularies, network composition, coverage levels, and benefit design; they simply face higher costs for benefits they choose to provide through retail pharmacies.

The Supreme Court's analysis in *Rutledge* demonstrates that cost regulations may permissibly "merely increase costs or alter incentives for ERISA plans without forcing plans to adopt any particular scheme of substantive coverage." 592 U.S. at 88 (citing *Travelers*, 514 U.S. at 668). The dispensing fee operates exactly within these parameters by increasing the cost of retail pharmacy services while preserving plan discretion over whether and how to provide those services to participants.

Plaintiffs' argument that the dispensing fee creates impermissibly "acute" financial effects relies on an overly restrictive interpretation of this concept that is not supported by Supreme Court precedent. The Court in *Rutledge* and other decisions has used "acute" to describe economic effects that are so severe as to eliminate meaningful choice and effectively coerce particular plan structures. The standard requires economic pressure that rises to the level of "an exorbitant tax leaving consumers with a Hobson's choice" or effects "so acute that it will effectively dictate plan choices." *Travelers*, 514 U.S. at 664; *Rutledge*, 592 U.S. at 88.

The $10.68 dispensing fee, while representing a new cost obligation, does not approach the level of economic coercion that would trigger this exception to permissible cost regulation. Plaintiffs themselves acknowledge that the fee would not be preempted if it "took effect later," indicating that the fee amount itself is not inherently coercive. This concession undermines any argument that the fee creates acute effects within the meaning of Supreme Court precedent.

The comparison to the cost regulation upheld in *Travelers* further supports this conclusion. In *Travelers*, the Court found no acute effects from a hospital surcharge that could reach up to 13% of billing rates for certain patients. 514 U.S. at 650, 662. The dispensing fee here, at $10.68 per prescription, represents a far less substantial cost impact than the percentage-based surcharge in *Travelers* and therefore cannot be considered acute under established precedent.

Plaintiffs' focus on the immediate effective date of July 1, 2025, misconstrues the nature of the "acute" standard. The Court's use of "acute" in ERISA preemption analysis refers to the severity of economic impact rather than the timing of implementation. Although sudden implementation may create administrative challenges, it does not transform an otherwise permissible cost regulation into an impermissibly acute economic effect unless the underlying cost burden is itself coercive. Moreover, Iowa's new dispensing fee will not impose immediate economic impact on plans and their sponsors. The statute requires PBMs to pay the fee directly to retail pharmacies. Although PBMs may eventually renegotiate their contracts with plans and plan sponsors to account for this added cost, Plaintiffs have repeatedly emphasized that existing contracts cannot be immediately amended. They therefore have sufficient time to determine how they will modify their plans to accommodate this dispensing fee. Even if the cost regulation takes effect more quickly that Plaintiffs prefer, it does not alter its fundamental character as a permissible pricing methodology regulation into a mandate affecting plan structure.

The dispensing fee also falls within the state's traditional authority to regulate the business of pharmacy and establish professional fee standards. States have long possessed the power to determine appropriate compensation levels for professional services, and the dispensing fee represents an exercise of this authority rather than an attempt to regulate ERISA plan design.

Defendant correctly argues that the dispensing fee constitutes standard cost regulation that affects the pricing methodology for pharmacy services without dictating plan choices. The fee establishes a floor for professional dispensing compensation while preserving plan discretion over all fundamental benefit design decisions. This approach aligns with the Supreme Court's recognition in *Rutledge* that states may regulate PBM reimbursement practices as part of their traditional oversight of commercial relationships.

The dispensing fee for all prescriptions in Iowa Code § 510B.8B(3) is therefore not preempted by ERISA because it constitutes a permissible cost regulation that establishes a pricing floor for professional pharmacy services without dictating plan structure, requiring specific benefits, or creating economic effects sufficiently acute to eliminate meaningful plan choice.

f. Deductible Provisions (Iowa Code §§ 510B.8(6); 510B.8(5); and 510B.8(7))

The Court turns to provisions governing how patient payments toward prescription drugs must be credited against deductible obligations and coordinated with federal health savings account requirements. These provisions present distinct constitutional questions because they directly regulate the relationship between plans and participants rather than intermediary conduct. Plaintiffs maintain these requirements impermissibly dictate fundamental cost-sharing structures that constitute core elements of benefit plan design, while Iowa defends them as administrative requirements that ensure proper accounting of patient contributions without constraining underlying plan architecture.

Under Iowa Code § 510B.8(6), any amount a patient pays for prescription drugs must be applied to their deductible according to their plan documents. Iowa Code §§ 510B.8(5) and 510B.8(7) require PBMs to count payments by patients toward their contribution requirements and establish special rules to ensure patients do not lose health savings account eligibility due to third-party payments before meeting their minimum deductible. These provisions govern how cost-sharing contributions are credited toward deductible requirements and how such crediting interacts with health savings account regulations.

i. Credit Toward Deductible (Iowa Code § 510B.8(6))

Iowa Code § 510B.8(6) is preempted by ERISA because it goes too far in dictating cost-sharing requirements for beneficiaries in their benefit plans. Rather than explicitly restricting only PBMs, the provision uses passive voice stating that any amount paid shall be applied to the

deductible imposed by the benefit plan in accordance with the plan and its coverage documents. This provision seemingly applies to plan sponsors and the plans themselves, specifically referencing them and their cost-sharing arrangements with beneficiaries.

The provision tells ERISA plans which cost-sharing arrangements they must adopt, which constitutes an impermissible dictation of plan structure or benefit design because cost-sharing is delineated in the ERISA plan itself. Cost-sharing arrangements constitute key benefit designs for ERISA plans under established precedent. In *Mulready*, the Tenth Circuit explained that the "[c]ost sharing the plan member will be required to pay for the covered drug" is a factor in plan design of benefits. 78 F.4th at 1198.

Unlike other provisions that regulate PBM conduct, this provision directly affects the relationship between plan sponsors and beneficiaries by mandating how deductible contributions must be calculated and applied. The provision requires plans to structure their deductible arrangements in a particular manner, which represents exactly the type of plan design mandate that ERISA preempts.

This requirement exceeds permissible cost regulation by directly constraining how plans must handle participant payments toward deductible requirements. This goes to the heart of benefit plan design and administration, areas that ERISA reserves to plan sponsors and fiduciaries. The mandatory nature of the deductible crediting requirement eliminates plan discretion over fundamental aspects of benefit structure.

ii. PBM Requirement and Exception for High-Deductible Health Plans (Iowa Code §§ 510B.8(5) and 510B.8(7))

Iowa Code § 510B.8(5) mandates that contributions made on behalf of covered persons be credited toward deductibles and out-of-pocket maximums regardless of payment source, including manufacturer coupons and other third-party assistance. Unlike other cost-sharing provisions

within the statutory framework, this requirement addresses payment processing and crediting procedures rather than dictating the architecture of cost-sharing arrangements themselves.

The provision operates as an administrative mandate that governs PBM operations without constraining fundamental plan design authority. Although it directs how PBMs must account for payments made by or on behalf of covered persons, it neither mandates particular cost-sharing structures nor dictates how plans must configure their benefit arrangements. Plans retain complete discretion over formularies, network composition, cost-sharing levels, and underlying benefit designs. The requirement affects administrative processing of existing cost-sharing obligations without compelling plans to restructure their coverage schemes.

This provision functions analogously to the cost regulations sustained in *Rutledge*, which imposed procedural requirements on PBM operations without mandating specific plan structures or benefit designs. The mandate that PBMs credit third-party payments toward cost-sharing obligations affects the computational methodology for determining participant obligations under existing plan terms but does not compel plans to adopt particular substantive coverage arrangements.

Iowa Code § 510B.8(7) is not preempted by ERISA because it functions as an exception to the application of Iowa Code § 510B.8(5) rather than imposing independent mandates on plan structure. The provision states that PBMs are not compelled to consider payments for beneficiaries if doing so will make them ineligible for a health savings account until they have satisfied the minimum deductible set in the plan.

This provision represents an exception for PBM requirements governing how they consider the fulfillment of cost-sharing obligations that are set in the plan, rather than dictating the cost-sharing terms within the plan itself. Therefore, this requirement constitutes a cost regulation on

PBM administration that will ultimately affect the plan but does not dictate plan structure or coverage.

These provisions together require PBMs to count amounts paid by a covered person toward their cost-sharing contributions while preserving health savings account eligibility. Regardless of the cost-sharing arrangement established in the plan, this provision regulates how PBMs administer the benefits rather than the structure or design of the plan itself. This will almost undoubtedly have an impact on plan administration by altering incentives, but it does not mandate specific plan choices about benefit structure. *Rutledge*, 592 U.S. at 88.

The provision falls within the category of cost regulations that affect PBM administration without constraining fundamental plan design decisions. The requirement addresses the intersection between PBM cost-sharing administration and federal health savings account regulations without dictating how plans must structure their underlying benefit arrangements.

Iowa Code § 510B.8(6) falls within ERISA's preemptive scope because it impermissibly dictates the cost-sharing arrangements that plans must adopt and directly regulates plan-beneficiary relationships in ways that constrain fundamental benefit design authority. By contrast, Iowa Code §§ 510B.8(5) and 510B.8(7) constitute permissible cost regulations that govern PBM administration of existing plan cost-sharing structures without mandating specific plan architectures or benefit designs.

g. Reporting and Transparency Provisions

The Court will next evaluate the provisions requiring disclosure of pricing methodologies and network information to state regulators and the public. The quarterly reporting and internet publication requirements mandate that PBMs disclose drugs reimbursed significantly above or below national average costs, while notice requirements compel third-party payors to inform area pharmacies of network participation opportunities. Unlike the direct plan regulation examined in

previous sections, these provisions target disclosure obligations that may fall outside ERISA's core concerns. The State emphasizes its legitimate oversight interests, while Plaintiffs counter that reporting requirements applicable to ERISA plans necessarily intrude upon the federal regulatory framework governing plan administration.

i. Quarterly Reporting and Internet Publication (Iowa Code § 510B.8B(4)(a)–(d))

The quarterly reporting and internet publication requirements escape ERISA preemption because they target PBMs alone, not ERISA plans or their sponsors, which remain subject to distinct reporting obligations under the federal regulatory framework. This distinction proves decisive. In *Gobeille*, the Vermont statute imposed reporting and disclosure mandates directly upon ERISA plans and their insurers. The Court determined that such requirements necessarily intrude upon ERISA's comprehensive reporting, disclosure, and recordkeeping regime—obligations that constitute a central part of the uniform system of plan administration. 577 U.S. at 323. State regulations of this character must yield to federal authority, the Court explained, lest individual states impose "novel, inconsistent, and burdensome reporting requirements on plans" that would fragment the uniform administration Congress intended. *Id.*

PBMs, however, operate outside ERISA's governance structure entirely. State reporting requirements imposed upon these entities therefore encounter no preemption barrier. Equally important, such requirements neither dictate benefit structures nor constrain plan design—the very considerations that animate ERISA's preemptive force.

ii. Notice Requirement about In-Network Pharmacies (Iowa Code § 510B.4B(2)(b))

The notice requirement is not preempted by ERISA because it imposes only modest disclosure requirements with *de minimis* impact on plan administration. Iowa Code § 510B.4B(2)(b) requires third-party payors to inform beneficiaries of the names and locations of

all pharmacies participating in the plan. This represents basic information reported with minimal frequency. It does not require ongoing maintenance or public disclosure.

Although this provision governs third-party payors rather than PBMs, it does not trigger automatic preemption. The analysis in *Wehbi* proves instructive, where reporting requirements applicable to both PBMs and third-party payors survived a preemption challenge. Iowa's notice requirement demands disclosure of only fundamental information—the sort of "modest disclosure requirements" that impose but *de minimis* burdens on uniform plan administration and thus remain permissible under established precedent. *Wehbi*, 18 F.4th at 969.

The notice requirement does not compel disclosure of proprietary pricing information, reimbursement methodologies, or other competitively sensitive plan details. Rather, it requires straightforward notification of participating pharmacy locations, which serves a basic consumer information function without creating the type of burdensome reporting obligations that interfere with uniform plan administration.

Overall, the requirement resembles the permissible disclosures in *Wehbi* rather than the impermissible reporting requirements in *Gobeille*. It does not require ongoing record-keeping, regular reporting to government agencies, or public disclosure of sensitive business information. The basic nature of the required information to be reported to beneficiaries and the limited scope of the disclosure obligation distinguish it from the more intrusive reporting requirements that courts have found preempted.

The reporting and internet publication requirements in Iowa Code § 510B.8B(4)(a)–(d) are not preempted because they do not impose reporting requirements on ERISA plans or plan sponsors. Likewise, the notice requirement in Iowa Code § 510B.4B(2)(b) remains within permissible state regulatory authority because it requires only modest disclosure of basic network

information with *de minimis* impact on plan administration, falling within the permissible boundaries established in *Wehbi*.

h. Contract Terms and Enforcement

The Court next examines provisions that dictate the substantive terms of agreements between ERISA plans and their service providers. The contract terms provision mandates particular pass-through pricing specifications in third-party payor agreements, while the supersession requirement ensures these state-imposed terms override any conflicting negotiated provisions. Both the general enforcement provision permitting beneficiary lawsuits and the appeal process requirements for PBM-pharmacy disputes raise questions about state interference with ERISA's exclusive remedial scheme. These provisions present the most direct challenge to fiduciary autonomy in service provider relationships, with parties disputing whether such contractual mandates exceed permissible state authority over commercial arrangements.

i. Contract Terms Between Third-Party Payor and PBM (Iowa Code § 510B.8D(1))

Iowa Code § 510B.8D(1) mandates that all contracts executed after July 1, 2025, must include pass-through pricing specifications and prescribe how PBM payments must be distributed. This provision establishes mandatory contractual requirements that directly govern the terms of agreements between third-party payors and PBMs, including specific provisions regarding rebate handling and payment distribution mechanisms.

ERISA preempts this provision through its impermissible restriction of fiduciary discretion in contracting arrangements and interference with central matters of plan administration. Unlike the pass-through rebate requirement in Iowa Code § 510B.8(4), which merely requires PBMs to take specific action regarding rebates they receive, this provision directly restricts what plan sponsors may include in their contracts with PBMs.

ERISA fiduciaries have clear obligations to enter into contracts with reasonable costs for plan beneficiaries and to exercise prudent judgment in selecting and monitoring service providers. *See* 29 U.S.C. § 1108(b)(2)(A). By directly regulating how plan sponsors, who are fiduciaries, may construct their contracts, this provision limits fiduciary discretion in ways that interfere with their ability to negotiate arrangements they deem most reasonable or beneficial for plan administration and beneficiaries.

The provision goes beyond permissible cost regulations upheld in *Rutledge* by mandating specific contractual terms rather than merely establishing cost floors or pricing methodologies. Although cost regulations will typically affect the amounts paid for services without needing to constrain the structure of contractual relationships, this provision dictates the substantive terms that must be included in third-party payor agreements. This represents the type of direct interference with plan administration that ERISA reserves to federal oversight.

In practice, this provision will limit third-party payors' discretion in constructing their agreements in ways they may deem most reasonable or beneficial for plan administration and beneficiaries. When plan fiduciaries determine that alternative contractual arrangements might better serve participant interests or provide superior plan administration, the mandatory contract terms prevent implementation of those arrangements.

This requirement directly constrains fiduciary decision-making regarding service provider relationships, a central matter of plan administration under ERISA. The selection and oversight of service providers, including the negotiation of appropriate contractual terms, represents a core fiduciary responsibility that ERISA reserves to plan sponsors and administrators.

Plaintiffs note that Defendant does not meaningfully address their argument that pass-through pricing requirements for third-party payor/PBM contracts intrude upon central matters of plan administration by implicating service-provider compensation arrangements. The absence of

substantive response to this argument suggests acknowledgment that such contractual mandates exceed permissible state authority.

The provision cannot be justified under *Rutledge* because that case did not involve contract requirements between ERISA plans and PBMs. Rather, *Rutledge* addressed reimbursement rate regulations that affected PBM-pharmacy relationships without mandating specific contractual terms between plans and their service providers.

ERISA preempts Iowa Code § 510B.8D(1) because it impermissibly restricts fiduciary discretion in service provider contracting, interferes with central matters of plan administration, and mandates specific contractual terms that constrain plan sponsors' ability to negotiate arrangements they determine would best serve their participants' interests.

ii. Supersession Over Contrary Contract Terms (Iowa Code § 510B.8D(2))

Iowa Code § 510B.8D(2) provides that Iowa Code § 510B.8D(1)'s requirements override any conflicting contract terms. This provision establishes that the mandatory contractual requirements for pass-through pricing and PBM payment distribution supersede any contrary provisions that parties might have negotiated in their agreements.

ERISA preemption extends to this provision through its inseverability from Iowa § 510B.8D(1) and its compounding of the underlying contractual mandate's constitutional infirmities. The supersession clause makes no sense without the prior section establishing mandatory contract terms and cannot operate independently of those requirements. It cannot be given effect with the other provision enjoined. *See* Iowa Code § 4.12. As such, if Iowa Code § 510B.8D(1) is preempted, this provision must also be enjoined.

Additionally, this provision exacerbates the interference with fiduciary discretion identified in the analysis of Iowa Code § 510B.8D(1) by ensuring that plan sponsors cannot negotiate around the state-mandated contractual requirements. This eliminates any remaining

flexibility that fiduciaries might have to structure their service provider relationships in ways they determine would best serve plan participants' interests.

By mandating that state-imposed contract terms supersede negotiated agreements, the provision directly interferes with the contractual relationship between ERISA plans and their service providers. This represents an impermissible intrusion into central matters of plan administration by preventing fiduciaries from exercising their judgment regarding appropriate contractual arrangements with PBMs.

The supersession requirement also undermines the principles of contract law that ordinarily govern commercial relationships between sophisticated parties. When plan fiduciaries determine that particular contractual arrangements would better serve their participants' interests, the supersession clause prevents implementation of those arrangements regardless of their merit or appropriateness for the specific plan.

The provision operates as a direct constraint on fiduciary decision-making that goes beyond permissible cost regulation. Rather than merely affecting the pricing of services, the supersession clause ensures that state regulatory preferences override the professional judgment of plan fiduciaries regarding optimal contractual structures for their particular circumstances.

The mandatory nature of the supersession requirement eliminates the type of flexibility in service provider relationships that ERISA contemplates for plan administration. ERISA reserves to plan fiduciaries the authority to structure their relationships with service providers in ways that best serve plan participants, subject to their fiduciary obligations to act prudently and in participants' best interests.

ERISA preempts Iowa Code § 510B.8D(2) because it is inseverable from the preempted contractual mandate in § 510B.8D(1), compounds the interference with fiduciary discretion, and

eliminates plan sponsors' ability to negotiate service provider arrangements that they determine would best serve their participants' interests.

i. Enforcement Provisions

The Court concludes its ERISA analysis by examining provisions that establish alternative remedial mechanisms for statutory violations. The general enforcement provision permits covered persons and pharmacies to bring lawsuits for any SF 383 violation, while the appeal process requirements establish internal procedures for PBM-pharmacy disputes. The constitutional concern centers on whether these state enforcement mechanisms impermissibly supplement or duplicate ERISA's comprehensive remedial scheme. Iowa maintains that enforcement provisions targeting entities outside ERISA's regulatory framework remain permissible, but Plaintiffs assert that any alternative remedy affecting plan administration conflicts with federal exclusivity principles.

i. General Enforcement Provision (Iowa Code § 510B.4B(4))

Iowa Code § 510B.4B(4) is preempted by ERISA because it creates alternative enforcement mechanisms that conflict with ERISA's exclusive remedial scheme. This provision permits a covered person or a pharmacy to bring a cause of action for any violation of SF 383, and many of the statute's provisions apply directly to health benefit plans and third-party payors. As such, this provision permits beneficiaries to bring causes of action against their ERISA plans and the third-party payor fiduciaries who are governed by ERISA.

The Supreme Court has held that "any state-law cause of action that duplicates, supplements, or supplants the ERISA civil enforcement remedy conflicts with the clear congressional intent to make the ERISA remedy exclusive and is therefore pre-empted." *Davila*, 542 U.S. at 209. Complete ERISA preemption applies when an individual could have brought

their claim under ERISA enforcement mechanisms and "there is no other independent legal duty that is implicated by a defendant's actions." *Davila*, 542 U.S. at 210.

The broad language of this provision reaches well beyond PBM conduct to encompass the fundamental terms and relationships binding plans, beneficiaries, and fiduciaries. SF 383's various requirements apply directly to health benefit plans and third-party payors, thereby exposing ERISA-governed entities to potential liability under state law—entities already subject to the federal statute's comprehensive and exclusive enforcement regime. Such broad regulatory sweep transgresses the boundaries of permissible state action by intruding upon "the intricate web of relationships between the key ERISA players" that Congress reserved to federal oversight. *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 305 (1st Cir. 2005) (explaining that state enforcement mechanisms impermissibly intrude upon the complex network of relationships among ERISA's principal actors).

When beneficiaries seek to enforce violations of statutory provisions that apply to their ERISA plans, such enforcement necessarily implicates the plan's terms and the administration of ERISA-regulated benefit plans. The interpretation of plan benefits and the scope of coverage become essential elements of determining liability under the state enforcement provision. This represents exactly the type of alternative enforcement mechanism that conflicts with ERISA's comprehensive legislative scheme.

Defendant's assertion that this constitutes a separate state enforcement mechanism for legal duties independent of ERISA is unconvincing in light of *Davila*. The Supreme Court's analysis focuses on whether plan terms form an essential part of the state law claim and whether liability would exist only because of the administration of ERISA-regulated benefit plans. Here, many of SF 383's requirements that can be enforced through this provision directly regulate plan administration, fiduciary duties, and benefit structure.

Allowing beneficiaries to sue their plans and third-party payors for violations under SF 383, regardless of the specific nature of those violations, supplements ERISA's "comprehensive legislative scheme" which includes "an integrated system of procedures for enforcement." *Davila*, 542 U.S. at 208 (quoting *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 147 (1985)). This is not the type of state law that touches upon enforcement but has no real bearing on the web of relationships governed by ERISA. *See Rowe*, 429 F.3d at 305.

ii. Appeal Process Requirements (Iowa Code § 510B.8E)

Iowa Code § 510B.8E is not preempted by ERISA because it establishes appeal processes between PBMs and pharmacies that do not implicate ERISA's enforcement scheme. *Rutledge* held that internal appeal processes for pharmacies against PBMs do not require certain benefit plan structure or govern central matters of plan administration. 592 U.S. at 90. The state law at issue in *Rutledge* required PBMs to provide an administrative appeal procedure for pharmacies to challenge reimbursements, and the Court found this related specifically to the relationship and agreement between a pharmacy and the PBM.

Although the results of these appeals may cause plans to recalculate how much they and the beneficiary owe, that represents a mere incidental effect, and ERISA does not preempt all state laws which could have some effect on the price or provision of benefits. *Rutledge*, 592 U.S. at 90. The Court recognized that ERISA does not preempt state law mechanisms for enforcement of judgments against benefit plans even if they prevent receipt of benefits under the plan. *Id*. at 90–91.

The appeal process requirements limit appeals to matters between PBMs and pharmacies, a relationship not governed by ERISA. As the First Circuit noted in *Rowe*, when enforcement mechanisms target PBMs which fall outside "the intricate web of relationships among the principal players in the ERISA scenario," they are not preempted by ERISA's civil enforcement scheme.

Id. at 305 (quoting *Carpenters Local Union No. 26 v. U.S. Fid. & Guar. Co.*, 215 F.3d 136, 141 (1st Cir. 2000)).

The expansion in SF 383 to permit appeals of "any matter" does not change the fundamental reasoning in *Rutledge*. The appeal process required of PBMs for pharmacies is not an impermissible duplication, supplement, or supplanting of the ERISA enforcement mechanisms because it is contained to matters not governed by ERISA. The procedures address disputes arising from the business relationship between PBMs and pharmacies rather than plan administration or beneficiary rights under ERISA plans.

Iowa Code § 510B.4B(4) is therefore preempted by ERISA because it permits beneficiaries to bring causes of action against ERISA plans and fiduciaries in ways that supplement ERISA's exclusive enforcement scheme and implicate plan terms and administration. Iowa Code § 510B.8E is not preempted by ERISA because it establishes appeal procedures for PBM-pharmacy relationships that fall outside ERISA's regulatory scope and do not interfere with plan administration or beneficiary enforcement rights.

4. First Amendment Challenge

Having addressed Plaintiffs' federal preemption claims, the Court turns to their constitutional challenge under the First Amendment's protection of commercial speech. SF 383's anti-referral provision prohibits health benefit plans and third-party payors from making pharmacy referrals, while the notice requirement compels disclosure of network participation terms to unrelated pharmacies. The constitutional analysis differs fundamentally from ERISA preemption because it focuses on the suppression and compulsion of truthful commercial expression rather than the boundaries of federal regulatory authority. Plaintiffs maintain these provisions violate intermediate scrutiny by restricting factually accurate information that serves both speaker

interests and consumer welfare, while Iowa defends the restrictions as necessary to prevent misleading practices and promote transparency in pharmacy markets.

a. Commercial Speech Protection Under the First Amendment

The First Amendment, made applicable to the states through the Fourteenth Amendment, provides that government "shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I. Although the Constitution accords lesser protection to commercial speech than to other constitutionally guaranteed expression, commercial speech nonetheless remains protected from "unwarranted governmental regulation." *Cent. Hudson Gas & Electric Corp. v. Publ. Serv. Comm. of N.Y.*, 447 U.S. 557, 561 (1980); *1-800-411-PAIN Referral Serv., LLC v. Otto*, 744 F.3d 1045, 1054 (8th Cir. 2014).

Commercial speech encompasses a broad range of expression, including pricing information concerning lawful transactions. *Va. State Pharm. Bd. v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761–64 (1976). Laws restricting commercial speech are subject to intermediate scrutiny under the framework established by the Supreme Court. *Cent. Hudson*, 447 U.S. at 563.

b. The *Central Hudson* Test

The *Central Hudson* framework begins with a threshold determination of whether the commercial speech at issue qualifies for First Amendment protection. Government regulation of commercial speech is assessed in a four-part inquiry: First, the commercial speech at issue must concern lawful activity and not be misleading. *Otto*, 744 F.3d at 1055. If the speech concerns unlawful activity or is misleading, it receives no First Amendment protection.

Second, the government must demonstrate that its interest in regulation is substantial. *Id.*

Third, the challenged regulation must directly advance the government's asserted interest. This prong requires the government to show that the statute advances a substantial interest "in a

direct and material way." *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (quoting *Edenfeld v. Fane*, 507 U.S. 761, 767 (1993)). The burden is not satisfied by speculation or conjecture; rather, the government must demonstrate that the harms it identifies are real and that its restriction will in fact alleviate them to a material degree. *Id.* A statute will not be sustained if it provides only ineffective or remote support for the government's purpose. *Cent. Hudson*, 447 U.S. at 564.

Fourth, the regulation must be no more extensive than necessary to further the government's interest. In assessing this prong, courts consider whether numerous and obvious less-burdensome alternatives to the restriction exist, as this is certainly a relevant consideration in determining whether the fit between ends and means is reasonable. *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410, 417 n.13 (1993).

The material degree standard in the third prong is critical; otherwise, a state could easily restrict commercial speech in the service of other objectives that could not justify a burden on commercial expression themselves. *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 188 (1999).

This intermediate scrutiny framework balances the constitutional protection afforded to commercial speech with the government's legitimate regulatory authority. Although commercial expression enjoys First Amendment protection, the government may regulate such speech in furtherance of substantial interests, provided the regulation directly advances those interests and is no more extensive than necessary to achieve them.

c. Threshold Challenge Framework

As discussed above, Plaintiffs have brought an as-applied challenge seeking relief limited to SF 383's enforcement against ERISA plans and those who administer them. Defendant's attempt to recast this as a facial challenge requiring satisfaction of *NetChoice*'s demanding

standard proves no more persuasive in the First Amendment context than it did regarding ERISA preemption. *See Moody v. NetChoice, LLC*, 603 U.S. 707 (2024). The same reasoning that supports as-applied relief for preemption claims applies with equal force to constitutional violations: Plaintiffs seek protection from SF 383's application to their specific circumstances, not wholesale invalidation of the statute under every factual scenario.

Defendant's facial challenge characterization would require Plaintiffs to prove that "no set of circumstances" exists under which the challenged provisions would be constitutional—a standard that ignores the targeted nature of their complaint. The Supreme Court's admonition that the facial-versus-as-applied distinction "goes to the breadth of the remedy employed by the Court, not what must be pleaded in a complaint" reinforces that Plaintiffs' request for targeted relief does not transform their challenge into a facial attack on the statute's validity. *Citizens United*, 558 U.S. at 331.

d. *Central Hudson* Application

SF 383 contains three provisions that constrain commercial speech and mandate disclosure in ways that invoke First Amendment scrutiny. The first prohibits health benefit plans, third-party payors, health carriers, and PBMs from making pharmacy "referrals." Iowa Code § 510B.1(4). The second bars PBMs from "promotion of one participating pharmacy over another" that might "affect a covered person's choice." *Id.* § 510B.4B(1)(a). The third compels third-party payors to "notify, in writing, all pharmacies" of network participation requirements and available opportunities. *Id.* § 510B.4B(2)(a).

Although each provision either restricts truthful commercial speech or compels unwanted disclosure, only Iowa Code §§ 510B.1(4) and 510B.4B(2)(a) warrant First Amendment analysis here. The anti-promotion provision targeting PBMs falls outside this Court's consideration

because, as established above, it does not govern Plaintiffs' conduct. They cannot invoke the constitutional rights of third parties not before the Court.

The challenged provisions regulate commercial speech through both content-based and speaker-based restrictions, thereby invoking intermediate scrutiny under *Central Hudson*. The anti-referral provision discriminates based on content by targeting speech that favors particular pharmacies in referral communications—a form of content discrimination that parallels the constitutional violation the Supreme Court identified when Vermont prohibited certain uses of prescriber information while permitting others. *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 564 (2011). The provision also discriminates based on speaker identity by singling out health benefit plans, third-party payors, and PBMs for disfavored treatment.

The notice requirement presents distinct but related constitutional issues. By compelling disclosure of commercially sensitive information to unrelated third parties, the mandate "necessarily alters the content of the speech" and constitutes impermissible compelled expression. *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 795 (1988).

As noted earlier, the *Central Hudson* inquiry is whether the commercial speech is misleading. Speech that is "inherently misleading" is speech that "inevitably will be misleading" to consumers. *Bates v. State Bar of Ariz.*, 433 U.S. 350, 372 (1977). The "inherently misleading" character of speech may be inferred from the "particular content or method of the advertising" as well as from "experience [that] has proved that in fact such advertising is subject to abuse." *In re R.M.J.*, 455 U.S. 191, 203 (1982). Such misleading advertising may be prohibited entirely. *Id.* Whether speech is "inherently misleading" presents a question of law. *Peel v. Att'y Reg. & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 108 (1990) (plurality opinion).

Addressing this threshold inquiry, the regulated speech here concerns truthful information about lawful commercial transactions—specifically, communications regarding pharmacy

services. The State does not contend that such speech misleads consumers or promotes unlawful activity. The anti-referral provision prohibits health benefit plans and PBMs from directing beneficiaries toward particular pharmacies based on fees, cost-sharing arrangements, or other plan considerations—speech that serves both the economic interests of the speakers and the informational needs of consumers. *Cent. Hudson*, 447 U.S. at 561–62.

Defendant argues that the anti-referral provision differs meaningfully from the anti-promotion provision by permitting information sharing and cost-comparison communications. Yet the statutory language operates with similar restrictive effect in practice. The provision broadly prohibits plans and plan sponsors from "discriminating" against pharmacies "with respect to referrals"—language that constrains what plans may communicate to beneficiaries about available pharmacy options. Iowa Code § 510B.1(4). Given the expansive meaning of "referral," this prohibition could readily encompass information that identifies certain pharmacies as preferable choices. Having established that the regulated speech qualifies for First Amendment protection, the Court proceeds to examine the remaining *Central Hudson* factors.

Second, while Iowa may advance substantial interests in protecting rural pharmacies and ensuring healthcare access, these objectives cannot justify suppressing truthful commercial information. The Supreme Court has made clear that restrictions premised on the "fear that people would make bad decisions if given truthful information" constitute impermissible governmental paternalism. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 374 (2002).

SF 383's practical effect compounds this constitutional defect by preventing plan sponsors from discharging their fiduciary duties to inform participants about the most advantageous pharmacy options—a consequence that subverts rather than advances consumer protection. The State's legitimate interest in supporting rural pharmacies cannot overcome the First Amendment's protection of truthful speech that simultaneously serves consumer welfare and the economic

interests of plan sponsors. Where the government seeks to achieve policy objectives by restricting the flow of accurate commercial information, the constitutional calculus weighs against such suppression.

Third, the challenged provision fails to directly advance Iowa's asserted interests. The anti-referral provision suppresses factually accurate information regarding optimal pharmacy choices, leading Plaintiffs to characterize these restrictions as "an outright effort to make clear that the state is forcing employers and their employees to subsidize certain pharmacies over others" rather than addressing demonstrable harm. [ECF No. 16 at 31]. As Plaintiffs observe, while "[p]romoting rural pharmacies might be a legitimate government interest . . . muzzling employers from speaking the truth is not." *Id.*

Iowa maintains that the provisions advance substantial interests in "transparency, protecting consumer choice, and limiting PBMs' ability to self-deal" yet fails to articulate how suppressing truthful information that fulfills fiduciary obligations serves these objectives. [ECF No. 24-1 at 47]. Rather than protecting rural pharmacies through direct subsidies or ensuring equitable reimbursement structures, these provisions merely silence information that might inform consumer decisions. This approach represents, at best, an indirect strategy that sacrifices First Amendment principles without meaningfully furthering the State's proclaimed goals. The nexus between prohibiting truthful commercial speech and preserving rural pharmacy access remains entirely speculative—a constitutional failing that *Central Hudson* does not permit.

Fourth, the restrictions are more extensive than necessary. Iowa possessed alternatives to achieve its stated objectives without restricting truthful speech, including direct subsidies to rural pharmacies, minimum reimbursement standards (as established elsewhere in SF 383), or mandatory disclosure of PBM practices to regulators.

Iowa does not meaningfully address less restrictive alternatives, instead defending its chosen approach of speech suppression. The State's failure to consider or pursue these alternatives undermines any claim that SF 383's speech restrictions are narrowly tailored. Rather, Iowa chose the constitutionally problematic approach of suppressing speech when multiple less restrictive means were available. The principle that "regulating speech must be a last—not first—resort" governs constitutional analysis of speech restrictions. *Thompson*, 535 U.S. at 373. The availability of these alternatives demonstrates that SF 383's speech restrictions exceed constitutional bounds.

e. Notice Requirement Analysis

Defendant argues the notice requirement merits deferential review because it requires only disclosure of "purely factual and uncontroversial information." [ECF No. 24-1 at 46]; *see Zauderer v. Off. of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). Iowa contends that requiring third-party payors to notify all pharmacies in their coverage area of network participation requirements serves legitimate transparency interests and should receive the same deferential treatment accorded to routine commercial disclosures. The State analogizes to disclosure requirements upheld in other circuits, particularly the First Circuit's decision in *Rowe*, where disclosure requirements between PBMs and their existing customers survived constitutional scrutiny. This argument fails on multiple grounds.

First, *Zauderer* applies only to disclosures addressing "inherently misleading" commercial speech. *Otto*, 744 F.3d at 1062 (holding that *Zauderer* applies only to disclosures addressing "inherently misleading" commercial speech). The notice requirement in SF 383 does not remedy misleading conduct because it requires disclosures to pharmacies with whom third-party payors have no relationship. Defendant identifies no misleading practices that such notice would address.

Second, even under *Zauderer*'s deferential standard, the notice requirement proves constitutionally problematic. The provision is not "reasonably related to the State's interest in

preventing deception of consumers" because the State makes no argument that the requirement addresses consumer deception. *Zauderer*, 471 U.S. at 651. Rather, the State characterizes its purpose as allowing willing pharmacies fair opportunity to participate in a network—an objective unrelated to consumer deception.

Third, requiring indiscriminate disclosure of commercially sensitive plan terms constitutes an undue burden. Plaintiffs say that the notice requirement forces them to "reveal commercially sensitive information" they otherwise would not disclose to third parties with whom they have no preexisting relationship. [ECF No. 16 at 29]. They contend that requiring "uniform disclosure to all area pharmacies, regardless of whether any given pharmacy demonstrates interest in participating in a third-party payor's network" imposes significant implementation costs and competitive ramifications that render the requirement unduly burdensome under *Zauderer*. *Id*. at 31 n.15. Iowa responds that transparency is "a feature, not a bug" of its regulatory scheme, arguing that the State has substantial interests in "promoting consumer choice and transparency and protecting against misleading practices that disrupt care." [ECF No. 24-1 at 47].

The implementation costs and competitive ramifications of mandatory disclosure to all area pharmacies—regardless of their interest in participation—exceed constitutional boundaries. The requirement compels disclosure of competitively sensitive network terms and reimbursement information to entities that may be competitors or may have no legitimate interest in participation. This indiscriminate approach differs materially from traditional disclosure requirements that address ongoing commercial relationships or remedy specific misleading practices. As one court recently observed, *Zauderer* is inapposite when the regulated persons "are not already engaged in commercial speech to which the disclosures compelled . . . are appended." *Pharm. Rsch. & Mfrs. of Am. v. Stolfi*, 724 F. Supp. 3d 1174, 1200 (D. Or. 2024).

Defendant seeks to bolster its position by analogizing to disclosure requirements upheld in other Circuits. This reliance on *Rowe* proves misplaced. That decision upheld disclosure requirements between PBMs and their existing customers regarding ongoing transactions—a materially different situation from SF 383's requirement that third-party payors disclose sensitive information to unrelated pharmacies. The panel specifically noted that the challenged provisions involved "routine disclosure of economically significant information" in existing commercial relationships. *Rowe,* 429 F.3d at 316. SF 383's notice requirement lacks this crucial limitation.

Defendant advances a broader defense of the State's regulatory framework, arguing that the challenged provisions serve substantial interests in "transparency, protecting consumer choice, and limiting PBMs' ability to self-deal." [ECF No. 24-1 at 47]. Even accepting these as legitimate governmental objectives, the constitutional inquiry focuses on means rather than ends. The State's chosen approach—suppressing truthful commercial information—fails to directly advance these interests and employs unnecessarily sweeping restrictions on protected expression.

Prohibiting plan sponsors from communicating the comparative advantages of particular pharmacies does not enhance transparency but diminishes it by withholding relevant information that consumers need to make informed decisions. This restriction similarly undermines rather than promotes consumer choice by constraining the guidance available to plan participants. When governmental means prove not merely ineffective but actively counterproductive to stated ends, the constitutional balance tips decisively against such regulation. The State cannot satisfy *Central Hudson*'s demanding standard through measures that achieve the opposite of their purported purpose.

f. Conclusion

The challenged provisions of SF 383 impose content-based and speaker-based restrictions on truthful commercial speech without adequate constitutional justification. The anti-referral

provision prevents disclosure of factually accurate information and guidance that would assist consumer decision-making, while the notice requirement compels disclosure to unrelated parties without sufficient justification. Under either *Central Hudson*'s intermediate scrutiny or *Zauderer*'s more deferential framework, these provisions fail constitutional review. Plaintiffs have demonstrated a likelihood of success on their First Amendment claims sufficient to support preliminary injunctive relief.

5. Remaining Factors for Preliminary Injunction Analysis

The Court's determination that Plaintiffs demonstrate a likelihood of success on several of their claims requires analysis of the remaining preliminary injunction factors under the *Dataphase* analysis. The irreparable harm inquiry focuses on both the immediacy and recoverability of threatened injury, while the balance of equities weighs Plaintiffs' demonstrated harm against potential injury to the State from enjoining a duly enacted statute. Plaintiffs assert they face immediate and unrecoverable compliance costs alongside constitutional deprivations that cannot be remedied through subsequent monetary relief. Iowa responds that preliminary relief would frustrate the State's sovereign authority to protect its citizens' healthcare access and prevent the implementation of necessary consumer protections for rural pharmacy markets.

a. Irreparable Harm

Plaintiffs demonstrate a likelihood of irreparable harm sufficient to support preliminary injunctive relief. The inquiry encompasses both the immediacy and recoverability of the threatened injury, as well as the constitutional dimensions of the alleged violations.

Plaintiffs face substantial and immediate financial consequences from SF 383's implementation. As detailed above, actuarial analyses projects compliance costs of $121 per participant annually, with specific provisions adding over $10 per prescription filled at retail pharmacies. [ECF No. 6-1 ¶¶ 16–22] (Bartle Decl.). Pella Corporation's estimates, likewise

described earlier, project annual costs exceeding $1.1 million. [ECF No. 6-2 ¶ 30] (Veenstra Decl.). These expenditures commence immediately upon the statute's July 1 effective date and continue indefinitely during litigation.

The threat of unrecoverable economic loss constitutes irreparable harm where, as here, recovery through subsequent litigation remains highly improbable. *Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996). Defendant enjoys qualified immunity from damages claims unless his conduct violates clearly established statutory or constitutional rights of which a reasonable person would have known. *Z.J. by and through Jones v. Kansas City Bd. of Police Comm'rs*, 931 F.3d 672, 693 (8th Cir. 2019). Given the evolving nature of ERISA preemption doctrine and the absence of directly controlling precedent on SF 383's specific provisions, qualified immunity would likely shield Defendant from monetary liability. Additionally, the State's sovereign immunity under the Eleventh Amendment further insulates it from damages recovery. *See Baker Elec. Co-op., Inc. v. Chaske*, 28 F.3d 1466, 1473 (8th Cir. 1994) (finding irreparable harm where plaintiff "would be unable to recover any damages" due to sovereign immunity). SF 383 itself contains no reimbursement mechanism for compliance costs incurred during litigation. These immunity doctrines, combined with the statute's silence on cost recovery, render Plaintiffs' financial losses effectively irretrievable regardless of this litigation's ultimate outcome.

The loss of constitutional protections independently supports a finding of irreparable harm. It has long been established that First Amendment deprivations, even of brief duration, "unquestionably constitute[] irreparable injury." *Powell v. Noble*, 798 F.3d 690, 702 (8th Cir. 2015) (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976)); *see also Ohlensehlen v. Univ. of Iowa*, 509 F. Supp. 3d 1085, 1103 (S.D. Iowa 2020) (noting that "[t]he denial of a constitutional right is a cognizable injury and an irreparable harm.") (citation omitted).

SF 383's immediate effective date creates irreparable structural harm that cannot be easily remedied. Once the statute takes effect, Plaintiffs must modify ERISA plan designs, alter administrative procedures, and restructure PBM contracts to achieve compliance. These changes become embedded in plan documents and contractual arrangements that remain in force until the next amendment cycle, which for many plans extends well beyond the resolution of this litigation. The timing presents particular difficulty given ongoing 2026 plan year negotiations. As one declarant testifies, companies are currently already in their negotiation cycle contracting for PBM services for the 2026 plan year. [ECF No. 6-2 ¶¶ 42–44] (Veenstra Decl.). If relief is denied, Plaintiffs must incorporate SF 383's requirements into contracts that will remain binding regardless of this litigation's ultimate outcome. Such structural modifications render it "impossible to restore the status quo" even following favorable adjudication. *Brady v. Nat'l Football League*, 640 F.3d 785, 793 (8th Cir. 2011).

SF 383's immediate effect creates an additional form of irreparable harm by placing Plaintiffs in an untenable position between conflicting legal obligations. ERISA requires plan administrators to operate "in accordance with the [plan] documents and instruments governing the plan." 29 U.S.C. § 1104(a)(1)(D). Simultaneously, SF 383 mandates plan modifications that may conflict with existing plan terms, creating the risk of dual enforcement exposure. As the Supreme Court has recognized, state law requirements that "run[] counter to ERISA's commands" place administrators in an impossible position. *Egelhoff*, 532 U.S. at 147.

Defendant argues that Plaintiffs' litigation timing "vitiates much of the force" of their irreparable harm claims, noting they sought relief only two business days before SF 383's effective date despite monitoring the legislative process. [ECF No. 24-1 at 49]. This argument is unpersuasive. Plaintiffs filed suit within two weeks of the Governor's signature and more than a week before the effective date—a reasonable timeframe given the complexity of federal

preemption litigation and the need to coordinate among multiple parties. Any timing pressure stems from the legislature's decision to impose an effective date of merely sixteen days between enactment and implementation, not from dilatory conduct by Plaintiffs.

The record establishes that Plaintiffs face immediate, substantial, and largely irreparable harm from SF 383's enforcement. The combination of unrecoverable financial costs, constitutional deprivations, and structural disruption to ERISA plan administration satisfies the irreparable harm standard for preliminary injunctive relief.

b. Balance of Harms and Public Interest

When a plaintiff seeks to restrain governmental action, the balance of equities and public interest factors largely merge. *Eggers v. Evnen*, 48 F.4th 561, 564 (8th Cir. 2022) (collecting cases). The Court weighs the threat of irreparable harm demonstrated by the movant against the injury that granting the injunction will inflict on other parties to the litigation. *MPAY Inc.*, 970 F.3d at 1020 (quoting *Dataphase*, 640 F.2d at 113).

Federal preemption carries particular significance in the preliminary injunction analysis. Express preemption of a statute means that "a finding with regard to likelihood of success fulfills the remaining preliminary injunction requirements." *United States v. Texas*, 719 F. Supp. 3d 640, 695 (W.D. Tex. 2024) (cleaned up) (citation omitted); *see also GEO Grp. v. Inslee*, 720 F. Supp. 3d 1029, 1068 (W.D. Wash. 2024).

The balance of equities favors Plaintiffs, though the analysis is largely subsumed within the irreparable harm inquiry already addressed. The harm extends beyond Iowa's borders because many employers maintain uniform plans across multiple states, forcing nationwide termination of cost-saving programs to achieve compliance with Iowa-specific requirements. Such broad disruption to established benefit structures contradicts ERISA's objective of promoting nationally uniform plan administration.

Defendant argues that enjoining SF 383 inflicts irreparable harm on the State by preventing enforcement of a duly enacted statute and undermining Iowa's sovereign authority to protect its citizens' health. The State emphasizes its substantial interest in preserving rural pharmacy access, preventing anticompetitive practices, and ensuring fair reimbursement to independent pharmacies. Iowa contends that 34 rural pharmacies closed in 2024 alone, creating "pharmacy deserts" that compromise healthcare access in underserved communities.

However, the State "lack[s] a meaningful equity in attempting to enforce a patently preempted ordinance." *Couser v. Shelby Cnty.*, 681 F. Supp. 3d 920, 948 (S.D. Iowa 2023). Any interest the State has in enforcing its laws generally becomes obviated where the law appears "invalid." *Id.*; *accord Missouri v. Trump*, 128 F.4th 979, 997 (8th Cir. 2025) (describing governmental interest in enforcing a law as "minimal" given likelihood that the law exceeded agency authority).

The public interest likewise supports preliminary relief. There exists a "substantial public interest in ensuring that governmental agencies abide by federal laws." *Saxena v. Noem*, 5:25-CV-0505-KES, 2025 WL 1149498, at *3 (D. S.D. Apr. 18, 2025). It is "always in the public interest to protect constitutional rights." *Carson v. Simon*, 978 F.3d 1051, 1061 (8th Cir. 2020) (citation omitted).

Finally, the Court notes that preliminary relief preserves the status quo by preventing the implementation of a comprehensive regulatory scheme that fundamentally alters the relationship between ERISA plans, PBMs, and pharmacy networks. Preliminary injunctions serve the essential function of maintaining existing conditions and preventing irreparable injury while courts resolve the underlying dispute "on the merits." *Arc of Iowa v. Reynolds*, 566 F. Supp. 3d 921, 930 (S.D. Iowa 2021); *accord Nebraska v. Biden*, 52 F.4th 1044, 1048 (8th Cir. 2022). The balance of equities and public interest therefore support granting preliminary injunctive relief.

6. Severability

The Court's conclusion that some provisions of SF 383 are likely invalid while others are not requires a determination of whether the problematic provisions may be severed from the remainder of the statute. SF 383 contains an express severability provision directing the application of Iowa Code § 4.12, which codifies this principle:

> If any provision of an Act or statute or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the Act or statute which can be given effect without the invalid provision or application, and to this end the provisions of the Act or statute are severable.

Iowa Code § 4.12. The Iowa Supreme Court has established that "the cardinal principle of statutory construction is to save and not to destroy." *Breeden v. Iowa Dep't of Corrs.*, 887 N.W.2d 602, 609 (Iowa 2016) (citation omitted). Courts must endeavor "'to save as much of the statute as possible, eliminating only that which is necessary to make it constitutionally sound.'" *Clark v. Miller*, 503 N.W.2d 422, 425 (Iowa 1993) (quoting *Harryman v. Hayles*, 257 N.W. 2d 631, 635 (Iowa 1977)).

Severability analysis requires courts to determine "whether the valid and the invalid parts of a statute are independent and separable, or interdependent." *State v. Monroe*, 236 N.W.2d 24, 35 (Iowa 1975) (en banc). This inquiry focuses on "legislative intent, as indicated by the words employed and the considerations underlying the enactment of the statute." *Id.* Severance is appropriate "if it does not substantially impair legislative purpose, the enactment remains capable of fulfilling the apparent legislative intent, and the remaining portion of the enactment can be given effect without the invalid provision." *Westco Agronomy Co., LLC v. Wollesen*, 909 N.W.2d 212, 224 (Iowa 2017) (quoting *Breeden*, 887 N.W.2d at 608).

The severability inquiry asks whether the legislature's core objectives can survive the removal of invalid provisions. Courts preserve a statute's valid portions unless doing so would

destroy the legislature's "paramount intent or chief purpose" or if "the legislature probably would not have enacted the statute at all if the invalid part had been eliminated." *Monroe*, 236 N.W.2d at 35–36. The remaining provisions must be capable of independent operation—"complete in itself and capable of being executed in accordance with the apparent legislative intent . . . wholly independent of that which was rejected." *Id.* at 35.

This doctrine serves constitutional separation of powers principles by ensuring that courts "leave the valid parts in force on the assumption that the legislature would have intended those provisions to stand alone." *Breeden*, 887 N.W.2d at 608. Courts have applied this "rule of constitutional restraint for over 100 years," recognizing that the judicial role requires preserving rather than destroying legislative enactments wherever constitutionally permissible.

SF 383 encompasses multiple discrete regulatory provisions that can function independently. The statute addresses pharmacy network access, reimbursement standards, transparency requirements, and enforcement mechanisms through separate provisions that serve distinct but related purposes within Iowa's comprehensive approach to PBM regulation.

The anti-discrimination provisions, any-willing-provider requirements, and cost-sharing mandates all serve the legislative purpose of ensuring equitable treatment of pharmacies within PBM networks. These provisions nevertheless operate through different mechanisms and do not depend upon one another for their effectiveness. For example, the reimbursement rate requirements that prohibit PBMs from paying affiliated pharmacies more than unaffiliated entities would advance the legislative goal of preventing self-dealing even if network access provisions were preempted.

Similarly, the transparency and reporting requirements serve the independent purpose of regulatory oversight and can function effectively regardless of the validity of other provisions.

The pass-through pricing requirements address manufacturer rebate handling and operate independently of network composition or cost-sharing arrangements.

Several provisions present closer questions of interdependence. The mandatory dispensing fee in Iowa Code § 510B.8B(3) illustrates the potential for severability problems where preemption of related provisions could undermine or reverse legislative intent. If anti-discrimination and anti-steering provisions are preempted while the dispensing fee remains, the fee could incentivize plans and PBMs to avoid affected pharmacies entirely, producing an effect opposite to the legislature's protective intent. The dispensing fee cannot survive severance from the anti-discrimination framework given that the legislature would not have enacted a provision driving business away from the rural pharmacies the statute seeks to protect.

The Court identifies one additional provision that cannot survive independently: Iowa Code § 510B.8D(2), which provides that contractual requirements override conflicting terms but depends entirely on the underlying contractual mandates.

Some of SF 383's provisions remain severable from those found likely preempted or unconstitutional. The express severability clause demonstrates legislative intent to preserve all constitutionally permissible provisions. The remaining valid provisions—including accreditation standards, certain reimbursement requirements, notice provisions, and appeal procedures—can fulfill significant portions of the legislature's regulatory objectives without the invalid provisions.

The Court will therefore enjoin only those provisions found likely preempted or unconstitutional, along with the limited number of dependent provisions identified above that cannot properly function independently. This approach preserves the maximum constitutionally permissible scope of Iowa's regulatory scheme while protecting Plaintiffs from likely invalid state interference with federal ERISA authority and First Amendment rights.

7. The Proper Reach of Injunctive Relief

The proper scope of preliminary injunctive relief presents considerations fundamentally altered by the Supreme Court's recent decision in *Trump v. CASA, Inc.*, 606 U.S. ----, 2025 WL 1773631 (2025), which definitively resolved the longstanding question of federal courts' authority to issue universal injunctions.

Plaintiffs acknowledge that *CASA* precludes universal relief but argue that complete relief for each plaintiff requires extending the injunction beyond the named parties to encompass their "contractors and agents who assist in the administration of their health benefit plans, including their PBMs." [ECF No. 39-1 at 27]. They contend that without such extension, "the preliminary injunction would have little value, since it would permit the Commissioner to enforce SF 383 against the very entities that Plaintiffs utilize to administer the prescription drug benefits program in their plans." *Id*. Plaintiffs characterize this as merely implementing *CASA*'s directive to fashion its ruling to "award[] complete relief" to each plaintiff rather than seeking impermissible universal coverage. *Id*.

In *CASA*, the Supreme Court established clear boundaries for injunctive relief issued by federal courts under the Judiciary Act of 1789. *CASA* directs that federal courts may award only plaintiff-specific relief and that injunctions must be no "broader than necessary to provide complete relief to each plaintiff with standing to sue." *CASA*, 2025 WL 1773631, at *15. The Court emphasized that "'complete relief' is not synonymous with 'universal relief'" but rather constitutes "a narrower concept" rooted in equity's traditional authority to "administer complete relief between the parties." *Id.* at *11 (cleaned up) (quoting *Kinney-Coastal Oil Co. v. Kieffer*, 277 U.S. 488, 507 (1928)). Although party-specific injunctions sometimes may "incidentally" benefit nonparties, such benefits are permissible only when they flow naturally from relief that is itself limited to remedying the plaintiffs' particular injuries. *Id.*

The Supreme Court further clarified that the complete relief principle is a "ceiling" rather than a mandate, noting that "complete relief is not a guarantee—it is the maximum a court can provide." *Id.* at *12. Courts must ensure that any injunction falls within traditional limits on equitable power and comports with "principles of equity" that have historically governed the scope of judicial remedies. *Id.* at *15.

Under *CASA*'s framework, the Court finds that extending preliminary relief to Plaintiffs' contractors and agents is appropriate to afford Plaintiffs effective relief. The modern structure of employee benefit administration creates functional interdependence between ERISA plans and the intermediaries essential to their operation. The Eighth Circuit concluded in *Wehbi* that "a regulation of PBMs 'function[s] as a regulation of an ERISA plan itself.'" 18 F.4th at 966. This principle reflects the practical reality that modern ERISA plans have become "functionally dependent on PBM services to administer prescription drug benefits," making it "practical[ly] impossib[le]" for plans to "manage [their] own pharmacy benefits and avoid using a PBM." *Mulready*, 78 F.4th at 1195.

The Court does not embrace Plaintiffs' contention that extension of the injunction is necessary because they are entitled to complete relief. Under *CASA*, complete relief operates as a ceiling, not a floor. Courts cannot award relief merely because it might be more convenient or comprehensive for plaintiffs. The inquiry focuses on whether relief limited to the named plaintiffs would provide meaningful protection for their interests.

The practical realities of employee benefit administration nevertheless support extending preliminary relief to Plaintiffs' service providers. Modern prescription drug benefit programs operate through an integrated system where ERISA plans depend functionally on PBM intermediaries to deliver benefits to participants. The interconnected nature of this relationship means that enforcement against PBMs and other contractors would render any plaintiff-specific

injunction largely a pyrrhic victory. Plaintiffs cannot realistically administer their prescription drug benefits without PBM intermediaries, and those intermediaries cannot provide legally compliant services if they remain subject to provisions the Court has found likely preempted. Allowing the State to enforce the enjoined provisions against Plaintiffs' essential service providers would effectively recreate the same regulatory interference with ERISA plans that federal preemption prohibits.

This extension falls within *CASA*'s recognition that party-specific injunctions may sometimes benefit nonparties when such benefits flow naturally from relief tailored to remedy Plaintiffs' particular injuries. The extension here does not seek to protect the general public or nonparty interests for their own sake. Rather, it operates to ensure that relief granted to Plaintiffs can be meaningfully implemented given the realities of employee benefit plan administration.

The Court therefore concludes that preliminary relief should extend to Plaintiffs' contractors and agents who assist in the administration of their health benefit plans, including their PBMs, to the extent necessary to ensure effective relief for the named Plaintiffs. This extension is limited to preventing enforcement of those specific SF 383 provisions the Court has found likely invalid as applied to ERISA plans. The scope of this extended relief remains constrained by the underlying limitation that only certain provisions of SF 383 warrant preliminary injunctive relief, while others may proceed to implementation. The Commissioner retains full authority to implement all provisions of SF 383 against persons not covered by this injunction, and to enforce all non-enjoined provisions against all persons, including Plaintiffs and their contractors and agents. Additionally, the Commissioner may develop appropriate regulatory guidance concerning compliance with the entirety of SF 383's requirements.

Within 24 hours after the filing of this Order, Plaintiffs shall promptly provide to the Court a list of contractors and agents they currently utilize for plan administration, enabling the Commissioner to understand precisely which entities are covered by this preliminary relief.

8. Security Requirements Under Rule 65(c)

Federal Rule of Civil Procedure 65(c) ordinarily requires a movant to post "security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c). Although the text of the rule suggests that security is mandatory, the Eighth Circuit has recognized that district courts possess substantial discretion in determining the appropriate bond amount. *Richland/Wilkin Joint Powers Auth. v. U.S. Army Corps of Engr's*, 826 F.3d 1030, 1043 (8th Cir. 2016). The bond must "bear a rational relationship to the defendant's probable damages in the event it is later determined that the injunction should not have been entered." *In re President Casinos, Inc.*, 360 B.R. 262, 266 (B.A.P. 8th Cir. 2007). The party requesting the bond bears the burden of establishing a rational basis for the amount sought, and "[a] defendant's bond calculation should be supported by evidence as strong as the evidence supporting a damage calculation submitted at trial." *Luminara Worldwide, LLC v. Liown Elecs. Co.*, No. 14-CV-3103 SRN/FLN, 2015 WL 3559273, at *6 (D. Minn. May 27, 2015) (citation omitted).

Defendant seeks an $80,000 bond based on the maximum regulatory penalties that could be imposed under SF 383—$10,000 for each Plaintiff and $10,000 for their PBMs. This calculation fundamentally misconceives the purpose of Rule 65(c). This approach improperly conflates enforcement mechanisms with actual harm and rests entirely on speculation that Plaintiffs would violate the enjoined provisions. Moreover, where the Court grants preliminary relief to prevent likely constitutional violations, courts "may elect to require no security at all." *BellSouth Telecomms., Inc. v. MCIMetro Access Transmission Servs., LLC*, 425 F.3d 964, 971

(11th Cir. 2005) (citation omitted). Defendant has identified no concrete, non-speculative damages the State would suffer from the temporary enforcement of this injunction. Accordingly, the Court exercises its discretion to waive the bond requirement entirely.

III. CONCLUSION

This case presents the familiar tension between state regulatory authority and federal preemption, complicated by the modern realities of employee benefit administration. Iowa's comprehensive approach to PBM regulation reflects legitimate concerns about market concentration and rural healthcare access. Yet the Constitution's allocation of regulatory authority between state and federal governments requires careful adherence to established boundaries, particularly where Congress has included express preemption provisions through comprehensive legislation like ERISA.

The Court's analysis reveals that SF 383 crosses constitutional lines in multiple respects. Several provisions impermissibly dictate the structure and administration of employee benefit plans by mandating network compositions, cost-sharing arrangements, and contractual terms that ERISA reserves to plan sponsors and fiduciaries. Other provisions violate the First Amendment by suppressing truthful commercial speech without adequate constitutional justification. These constitutional defects cannot be remedied by Iowa's characterization of the statute as regulating only intermediary conduct, given the functional interdependence between ERISA plans and the service providers essential to their operation.

The remaining provisions of SF 383 that survive constitutional scrutiny reflect permissible exercises of state authority over professional licensing, cost regulation, and commercial relationships outside ERISA's scope. Iowa's express severability provision demonstrates legislative intent to preserve all constitutionally permissible aspects of its regulatory scheme.

Accordingly, IT IS ORDERED that Plaintiffs' Motion for Preliminary Injunction is GRANTED IN PART and DENIED IN PART. [ECF No. 6].

Defendant Iowa Insurance Commissioner Doug Ommen, his officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with him who receive actual notice of this injunction by personal service or otherwise, are enjoined from enforcing the following provisions of Iowa Senate File 383 against Plaintiffs and their contractors and agents who assist in the administration of their health benefit plans:

The following provisions are enjoined as preempted by ERISA:

1) **Iowa Code § 510B.1(4)** (anti-discrimination requirements);
2) **Iowa Code §§ 510B.4B(1)(b), 510B.4B(2)(a)** (any-willing-provider standards);
3) **Iowa Code § 510B.4B(1)(d)** (open-access standard for specialty drugs);
4) **Iowa Code §§ 510B.4B(1)(f) and 510B.8(3)** (mail-order pharmacy and cost-sharing provisions);
5) **Iowa Code § 510B.8(6)** (deductible credit requirements);
6) **Iowa Code §§ 510B.8D(1), 510B.8D(2)** (mandatory contract terms and supersession provisions); and
7) **Iowa Code § 510B.4B(4)** (general enforcement provision).

The following provisions are enjoined as violative of the First Amendment:

1) **Iowa Code § 510B.1(4)** (anti-referral provision) and
2) **Iowa Code § 510B.4B(2)(a)** (compelled disclosure requirements).

Finally, the following provisions are enjoined as inseverable from the foregoing invalid provisions:

1) **Iowa Code § 510B.8D(2)** (supersession over contrary contract terms) and
2) **Iowa Code § 510B.8B(3)** (dispensing fee provision that cannot survive without the anti-discrimination framework).

The preliminary injunction shall remain in effect pending final resolution of this matter or further order of the Court. Within 24 hours of this Order, Plaintiffs shall provide the Court with a list of contractors and agents currently utilized for plan administration. No injunction bond is required under Federal Rule of Civil Procedure 65(c).

IT IS SO ORDERED.

Dated this 21st day of July, 2025.

STEPHANIE M. ROSE, CHIEF JUDGE
UNITED STATES DISTRICT COURT