No *Shepard’s*  Signal™As of: August 13, 2018 2:59 PM Z

# [***Pharm. Care Mgmt. Ass'n v. Tufte***](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5RRG-V7K1-F27X-60J5-00000-00&context=)

United States District Court for the District of North Dakota

November 7, 2017, Decided; November 7, 2017, Filed

Case No.: 1:17-cv-141

**Reporter**

297 F. Supp. 3d 964 \*; 2017 U.S. Dist. LEXIS 218517 \*\*

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff, vs. MYLYNN TUFTE, in her official capacity as the State Health Officer of North Dakota, MARK J. HARDY, in his official capacity as the Executive Director of the North Dakota Board of Pharmacy, FRAN GRONBERG, in her official capacity as the President of the North Dakota Board of Pharmacy, and WAYNE STENEHJEM, in his official capacity as the Attorney General of North Dakota, Defendants.

**Core Terms**

pharmacy, sponsor, ***regulation***, plans, state law, bills, health plan, preemption, preliminary injunction, employee benefit plan, prescription drug, requirements, third party, preempted, entities, insured, third-party, pharmacists, benefits, weighs, public interest, argues, consumers, preemption clause, irreparable harm, potential harm, services, participants, provisions, specialty

**Counsel:** **[\*\*1]**For Pharmaceutical Care Management Association, Plaintiff: M. Miller Baker, LEAD ATTORNEY, PRO HAC VICE, McDermott Will & Emery LLP, Washington, DC; M. Daniel Vogel, LEAD ATTORNEY, VOGEL LAW FIRM, FARGO, ND; Alexander J. Kritikos, PRO HAC VICE, McDermott Will & Emery LLP (Boston), Boston, MA; Charles Quigg, PRO HAC VICE, McDermott Will & Emery LLP, Washington, DC; Neil Roesler, Robert B. Stock, VOGEL LAW FIRM (Fargo), FARGO, ND; Sarah P. Hogarth, PRO HAC VICE, McDermott Will & Emery LLP, Washington, DC.

For Mylynn Tufte, in her official capacity as the State Health Officer of North Dakota, Wayne Stenehjem, in his official capacity as the Attorney General of North Dakota, Defendants: Matthew A. Sagsveen, ATTORNEY GENERAL'S OFFICE NATURAL RESOURCES DIV., BISMARCK, ND; Robert Thomas Smith, Katten Muchin Rosenman LLP, Washington, DC.

For Mark J. Hardy, in his official capacity as the Executive Director of the North Dakota Board of Pharmacy, Fran Gronberg, in her official capacity as the President of the North Dakota Board of Pharmacy, Defendants: Daniel E. Lipton, Howard Robert Rubin, Robert Thomas Smith, Katten Muchin Rosenman LLP, Washington, DC.

**Judges:** Daniel L. Hovland, Chief United States District**[\*\*2]** Judge.

**Opinion by:** Daniel L. Hovland

**Opinion**

**[\*969]** **ORDER DENYING PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION**

Before the Court is the Plaintiff's "Emergency Motion for a Temporary Restraining Order and Preliminary Injunction" filed on July 20, 2017. See Docket No. 10. In its motion, the Plaintiff requested the Court temporarily restrain and preliminarily enjoin Defendants from enforcing North Dakota Senate Bills 2258 and 2301. On July 27, 2017, the parties submitted a joint stipulation in which the Plaintiff withdrew its request for a temporary restraining **[\*970]** order, in order to give the Court additional time to address the merits of the request for preliminary injunctive relief. See Docket No. 18. On July 28, 2017, the Court found as moot the Plaintiff's motion for a temporary restraining order. See Docket No. 19. On August 22, 2017, a hearing was held regarding the preliminary injunction. See Docket No. 24. For the reasons set forth below, the Court denies the Plaintiff's motion for a preliminary injunction.

**I. BACKGROUND**

The Plaintiff, Pharmaceutical Care Management Association (PCMA), is a national trade association representing pharmacy benefit managers (PBMs), with its principal place of business in Washington,**[\*\*3]** D.C. See Docket No. 1. PBMs are third-party health plan administrators which manage and administer prescription drug benefits on behalf of health insurance plans. Retail pharmacies purchase prescription drugs from wholesalers or manufacturers to fill health plan participants' prescriptions. When a plan participant (a patient or consumer) fills a prescription, the pharmacy contacts the PBM to obtain the participant's coverage and copayment information. After the prescription is filled, the PBM reimburses the pharmacy at a contractually-agreed upon rate. The PBM then bills the health plan, which provides the participant's insurance, at a rate negotiated between the PBM and the health plan. This role renders the PBM a third-party health plan administrator.

In April 2017, North Dakota State Governor Doug Burgum signed into law S.B. 2258 and S.B. 2301, which were to become effective August 1, 2017.[[1]](#footnote-0)1See S.B. 2258, 2017 Leg., 65th Sess. (ND 2017); S.B. 2301, 2017 Leg., 65th Sess. (ND 2017). Among other things, these laws will ***regulate*** how PBMs categorize prescription drugs and also require PBMs to make certain cost disclosures to network pharmacies and plan participants. PCMA highlights the**[\*\*4]** following provisions[[2]](#footnote-1)2 as concerning:

• S.B. 2258 § 1(2) prohibits PBMs and third-party payers from charging pharmacies certain fees, including fees that are imposed after the point of sale, not reported on the remittance advice for a claim, or are not apparent at the time of claim processing.

• S.B. 2258 § 1(3) limits the fees PBMs and third-party payers may impose based on pharmacy performance standards.

• S.B. 2258 § 1(4) bars PBMs and third-party payers from "redacting] the adjudicated cost," or the amount the PBM or third-party payer reimburses a pharmacy for a prescription.

• S.B. 2258 § 1(6) allows pharmacists or pharmacies belonging to a pharmacy service administration organization to receive a copy of contracts the pharmacy service administration organization entered into with a **[\*971]** pharmacy benefits manager or third-party payer on their behalf.

• S.B. 2258 § 1(7) allows pharmacies to disclose "relevant" information to patients, including reimbursement information, and prohibits contracts between PBMs and pharmacies that prevent such disclosure.

• S.B. 2258 § 1(8) authorizes pharmacies to "mail or deliver drugs to a patient as an ancillary service of a pharmacy."

• S.B. 2258 § 1(9) prohibits contracts which provide that a pharmacy**[\*\*5]** may not charge a shipping and handling fee to a patient.

• S.B. 2258 § 1(10) prohibits PBM or third-party payers from imposing accreditation and recertification standards beyond preexisting federal and state licensing requirements.

• S.B. 2301 § 1(2) obligates PBMs and third-party payers having ownership interest in a pharmacy to disclose the difference between the amount paid to the pharmacy and the amount charged to the plan sponsor on request.

• S.B. 2301 § 1(3) prohibits PBMs from having an ownership interest in patient assistance programs or mail-order specialty pharmacy unless the PBM agrees "not to participate in a transaction that benefits the PBM instead of another person owed a fiduciary duty."

• S .B. 2301 § 1(5) authorizes pharmacies to dispense "any and all drugs allowed" under its license.

• S .B. 2301 § 1(11) prohibits a PBM or third-party payer from imposing accreditation standards beyond preexisting federal and state licensing requirements.

See Docket No. 1, pp. 6-8; see also S.B. 2258 and 2301.

On July 11, 2017, PCMA filed a complaint against State Health Officer Mylynn Tufte; Executive Director of the North Dakota Board of Pharmacy, Mark J. Hardy; President of the North Dakota Board of Pharmacy,**[\*\*6]** Fran Gronberg; and Attorney General Wayne Stenehjem. See Docket No. 1. PCMA argues the new laws, which were scheduled to go into effect on August 1, 2017, place restrictions and requirements on PBMs that impermissibly reference or are connected with health plans under the [*Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq.*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GJT1-NRF4-4454-00000-00&context=), and [*Medicare Prescription Drug Improvement and Modernization Act of 2003 ("Medicare Part D"), 42 U.S.C. § 1395w-101 et seq.*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GP71-NRF4-41G1-00000-00&context=) As a result, PCMA seeks this Court's declaration that the North Dakota state laws are expressly preempted by federal legislation. The parties stipulated not to effectuate S.B. 2258 and S.B. 2301 as to ERISA and Medicare Part D plans, pending the resolution of this matter. See Docket No. 19.

**II. STANDARD OF REVIEW**

PCMA seeks to obtain a preliminary injunction pursuant to [*Rule 65(b) of the Federal Rules of Civil Procedure*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-2421-6N19-F16Y-00000-00&context=). [*Rule 65(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5GYC-2421-6N19-F16Y-00000-00&context=) directs the court to look to the specific facts shown by an affidavit to determine whether immediate and irreparable injury, loss, or damage will result to the applicant. It is well-established in the Eighth Circuit Court of Appeals that a court is required to consider the factors set forth in [*Dataphase Systems, Inc. v. C L Systems, Inc., 640 F.2d 109, 114 (8th Cir. 1981)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6690-0039-W2XH-00000-00&context=), in determining whether a preliminary injunction should be granted. The *Dataphase* factors include: "(1)**[\*\*7]** the threat of irreparable harm to the movant; (2) the state of balance between this harm and injury that granting the injunction will inflict on other parties; (3) the probability the movant will succeed on the merits; and (4) the public interest." Id.

**[\*972]** Preliminary injunctive relief is an "extraordinary and drastic remedy." [*Munaf v. Geren, 553 U.S. 674, 689-90, 128 S. Ct. 2207, 171 L. Ed. 2d 1 (2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4SRD-SPN0-TXFX-1387-00000-00&context=). Accordingly, the party seeking such relief bears the burden of establishing its propriety with "clear proof." [*Frejlach v. Butler, 573 F.2d 1026, 1027 (8th Cir. 1978)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-YNM0-0039-M264-00000-00&context=). It is well-established that the movant has the burden of establishing the necessity of a preliminary injunction. [*Baker Elec. Coop., Inc. v. Chaske, 28 F.3d 1466, 1472 (8th Cir. 1994)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4RT0-003B-P2XF-00000-00&context=). "No single factor in itself is dispositive; in each case all of the factors must be considered to determine whether on balance they weigh towards granting the injunction." [*Id. at 1472*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4RT0-003B-P2XF-00000-00&context=).

**III. LEGAL DISCUSSION**

PCMA argues S.B. 2258 and S.B. 2301 are preempted by ERISA and Medicare Part D, as those federal laws each contain provisions providing that any state laws relating to them will be superseded by each of them respectively. PCMA argues S.B. 2258 and S.B. 2301 impermissibly ***regulate*** ERISA and Medicare Part D health plans by ***regulating*** third-party payers and PBMs. According to PCMA, North Dakota's statutory definitions of third-party payers and PBMs are**[\*\*8]** broad enough to encompass ERISA and Medicare Part D health plans. Therefore, PCMA argues, any laws ***regulating*** third-party payers and PBMs, as they are statutorily defined, necessarily include ERISA and Medicare Part D health plans, and are therefore preempted by federal law.

**A. ERISA PREEMPTION**

ERISA comprehensively ***regulates***, among other things, employee welfare benefit plans that "though the purchase of insurance or otherwise," provide medical, surgical, or hospital care, or benefits in the event of sickness, accident, disability, or death. [*29 U.S.C. § 1001(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GJT1-NRF4-4454-00000-00&context=). ERISA was intended to:

protect . . . participants in employee benefit plans and their beneficiaries, by requiring the disclosure and reporting to participants and beneficiaries of financial and other information with respect thereto, by establishing standards of conduct, responsibility, and obligation for fiduciaries of employee benefit plans, and by providing for appropriate remedies, sanctions, and ready access to the Federal courts.

[*29 U.S.C. § 1001(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GJT1-NRF4-4454-00000-00&context=).

"To meet the goals of a comprehensive and pervasive Federal interest and the interests of uniformity with respect to interstate [health] plans, Congress included an express preemption clause in ERISA for the displacement**[\*\*9]** of State action in the field of private employee benefit programs." [*Minn. Chapter of Associated Builders & Contractors, Inc. v. Minn. Dep't of Pub. Safety, 267 F.3d 807, 810 (8th Cir. 2011)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:444W-9370-0038-X355-00000-00&context=). The scope of ERISA's preemption has left courts "deeply troubled." [*Prudential Ins. Co. v. Nat'l Park Medical Ctr., 154 F.3d 812, 815 (8th Cir. 1998)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3THY-9SS0-0038-X3YK-00000-00&context=). The Supreme Court has described the preemption clause as having "a broad scope, and an expansive sweep," and being "conspicuous for its breadth." [*California Division of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 324, 117 S. Ct. 832, 136 L. Ed. 2d 791 (1997)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S65-J1X0-003B-R37C-00000-00&context=).

Courts have struggled to reconcile the sweeping language of ERISA's preemption clause with the assumption that Congress does not intend to bar state action in fields of traditional state ***regulation*** or historic police powers. See [*New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654-55, 115 S. Ct. 1671, 131 L. Ed. 2d 695 (1995)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S42-78P0-003B-R3NX-00000-00&context=) ("we have never assumed lightly that Congress has derogated state ***regulation***, but instead have addressed claims of pre-emption with the starting presumption that **[\*973]** Congress does not intend to supplant state law."). The Supreme Court has cautioned courts interpreting ERISA's preemption clause that it must not be read to "extend to the furthest stretch of its indeterminacy.'" [*De Buono v. NYSA-ILA Medical and Clinical Services Fund, 520 U.S. 806, 813, 117 S. Ct. 1747, 138 L. Ed. 2d 21 (1997)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RVK-BC90-003B-R1F7-00000-00&context=).

The preemption clause specifically provides that ERISA "shall supersede any and all State laws insofar as they may now or hereafter *relate to* any employee benefit plan[.]" [*29 U.S.C. § 1144(a)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GV61-NRF4-44J6-00000-00&context=) (emphasis added). "Yet, Congress did not define what it meant by state laws that 'relate to' an ERISA benefit plan anywhere in the statute."**[\*\*10]** [*Prudential, 154 F.3d 812, 819 (8th Cir. 1998)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3THY-9SS0-0038-X3YK-00000-00&context=). The Supreme Court has offered some guidance on the scope of ERISA's preemption, by formulating a two-part test to determine whether a state law "relates to" an employee benefit plan covered by ERISA. It is now generally understood and accepted that "[a state] law relates to a covered employee benefit plan for purposes of [*§ 514(a)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GV61-NRF4-44J6-00000-00&context=) if it [1] has a connection with or [2] reference to such a plan." [*Shaw v. Delta Air Lines, Inc., 463 U.S. 85, 97, 103 S. Ct. 2890, 77 L. Ed. 2d 490 (1983)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4MP0-003B-S3TK-00000-00&context=).

*1. Likelihood of Success on the Merits*

The Eighth Circuit Court of Appeals has held that the likelihood of success on the merits is the "most significant" of the four factors to be considered by the district court in considering preliminary injunctive relief. [*S & M Constructors, Inc. v. Foley Co., 959 F.2d 97, 98 (8th Cir. 1992)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-54H0-008H-V3MS-00000-00&context=). When evaluating a movant's likelihood of success on the merits, the court should "flexibly weigh the case's particular circumstances to determine 'whether the balance of equities so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined.'" [*Calvin Klein Cosmetics Corp. v. Lenox Labs., Inc., 815 F.2d 500, 503 (8th Cir. 1987)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BT60-001B-K2X5-00000-00&context=). At this preliminary stage, the Court need not decide whether the party seeking the preliminary injunction will ultimately prevail. [*PCTV Gold, Inc. v. SpeedNet, LLC, 508 F.3d 1137, 1143 (8th Cir. 2007)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4R7S-0B00-TXFX-B1WR-00000-00&context=).

PCMA asserts it is likely to prevail on its claim against the Defendants because controlling precedent in**[\*\*11]** the Eighth Circuit requires finding S.B. 2258 and 2301 are expressly preempted by ERISA. See Docket No. 10-1, p. 7. PCMA points specifically to [*Pharm. Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722 (8th Cir. 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MKY-BGT1-F04K-S0FP-00000-00&context=). In *Gerhart*, PCMA sued the state of Iowa, seeking a declaration that an Iowa state law ***regulating*** how PBMs established generic drug pricing was preempted by ERISA. [*Id. at 726*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MKY-BGT1-F04K-S0FP-00000-00&context=). The district court in *Gerhart* found the statute did not have an impermissible connection with ERISA because the PBMs retained "sufficient choice and control." [*Id. at 727*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MKY-BGT1-F04K-S0FP-00000-00&context=). The Eighth Circuit Court of Appeals disagreed, holding that the Iowa statute contained both an impermissible "reference to" and "connection with" ERISA. [*Id. at 729-30*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MKY-BGT1-F04K-S0FP-00000-00&context=). The case was remanded, directing the district court to enter judgment in favor of PCMA on the issue of express preemption. [*Id. at 732*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MKY-BGT1-F04K-S0FP-00000-00&context=). In response the defendants argue that *Gerhart* is of no help in this case because the Iowa and North Dakota statutes are vastly different and the portions of *Gerhart* that PCMA relies on amount to mere commentary with no legal significance.[[3]](#footnote-2)3

Preemption claims turn on congressional intent. [*Cipollone v. Liggett* ***[\*974]*** *Group, Inc., 505 U.S. 504, 515-19, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S65-KDT0-003B-R20J-00000-00&context=). "To discern Congress' intent we examine the explicit statutory language and the structure and purpose of the statute." [*Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 138, 111 S. Ct. 478, 112 L. Ed. 2d 474 (1990)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4B80-003B-409J-00000-00&context=).

**[When] Congress has expressly [\*\*12]  included a broadly worded pre-emption provision in a comprehensive statute such as ERISA, our task of discerning congressional intent is considerably simplified**. In [*§ 514(a) of ERISA*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GV61-NRF4-44J6-00000-00&context=), as set forth in [*29 U.S.C. § 1144(a)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GV61-NRF4-44J6-00000-00&context=), **Congress provided**:

Except as provided in [*subsection (b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GV61-NRF4-44J6-00000-00&context=) of this section, the provisions of this subchapter and subchapter III of this chapter **shall supersede any and all State laws insofar as they may now or hereafter relate to any employee benefit plan** described in [*section 1003(a)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GT91-NRF4-40DK-00000-00&context=) of this title and not exempt under [*section 1003(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GT91-NRF4-40DK-00000-00&context=) of this title.

[*Ingersoll-Rand, 498 U.S. at 138*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4B80-003B-409J-00000-00&context=) (emphasis added). Courts have determined ERISA's preemption clause is "deliberately expansive," and "designed to establish pension plan ***regulation*** as exclusively a federal concern." Id. With the presumption that Congress intended preemption to be applied broadly, the Court turns to whether S.B. 2258 and S.B. 2301 relate to ERISA. The laws will be found to relate to ERISA if they have either a *reference to* or *connection with* ERISA.

a. Whether there is a "reference to" ERISA in S.B. 2258 and S.B. 2301

Under the "reference to" inquiry, the Supreme Court has preempted state laws that (1) imposed requirements by reference to ERISA covered programs[[4]](#footnote-3)4; (2) specifically exempted ERISA plans from an otherwise generally**[\*\*13]** applicable statute; and (3) premise a cause of action on the existence of an ERISA plan. [*Prudential, 154 F.3d 812, 822 (8th Cir. 1998)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3THY-9SS0-0038-X3YK-00000-00&context=) (internal citations and quotations omitted). An impermissible "reference to" ERISA plans will be found when a state law "acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation[.]" [*Gobeille v. Liberty Mut. Ins. Co., 136 S.Ct. 936, 943, 194 L. Ed. 2d 20 (2016)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J6J-DNP1-F04K-F31S-00000-00&context=) (internal citation and quotation marks omitted).

The parties seem to agree and the Court finds that neither S.B. 2258 nor S.B. 2301 contain an explicit reference to ERISA. Nowhere in either bill's language is ERISA explicitly mentioned, discussed, defined, or excluded. Therefore, the Court finds no explicit "reference to" ERISA. PCMA argues, however, that both S.B. 2258 and S.B. 2301 contain *implicit* references to ERISA because, within each bill, PBMs, third party payers, and plan sponsors are defined broadly enough to implicate ERISA health plans.

Both S.B. 2258 and S.B. 2301 explicitly provide that "pharmacy benefit manager," as used within each bill, has the same definition as in [*N.D.C.C. § 19-03.6-01*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P150-00000-00&context=). See S.B. 2258 § 1 (1)(a) and S.B. 2301 § 1 (1)(a); see also [*N.D.C.C. §§ 19-02.1-14.2(1)(d)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P0VX-00000-00&context=) and [*19-02.1-16.1(1)(a)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:8N2V-D9S2-D6RV-H54Y-00000-00&context=). "Pharmacy benefits manager" is defined as:

"Pharmacy benefits manger" means a person that performs pharmacy benefits**[\*\*14]** management and includes any other person **[\*975]** acting for such person under a contractual or employment relationship in the performance of pharmacy benefits management **for a managed care company, nonprofit hospital or medical service organization, insurance company, third-party payer, or health program administered by a state agency**.

See [*N.D.C.C. § 19-03.6-01(4)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P150-00000-00&context=) (emphasis added).

PCMA argues S.B. 2258 and S.B. 2301 attempt to ***regulate*** PBMs, and some of these PBMs provide services for ERISA health plans. Therefore, PCMA argues, the bills both implicitly reference ERISA. However, the legislation defines PBMs as a "person" who has a contractual relationship with a "managed care company, nonprofit hospital or medical service organization, insurance company, third-party payer, or health program administered by a state agency." [*N.D.C.C. § 19-03.6-01(4)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P150-00000-00&context=). For purposes of S.B. 2258 and S.B. 2301, it appears that a PBM is a distinct "person," entering a contractual relationship with one of the listed entities. The PBM is a separate entity distinguishable from any health benefit plan, let alone an ERISA-covered employee health benefit plan.

It is certainly conceivable that a "pharmacy benefits manager" could enter into a contractual relationship with**[\*\*15]** an employer sponsored health benefit plan, and that such an employer sponsored health benefit plan would be subject to ERISA. However, that is merely one outcome of many and not one that is clearly expressed in the statutory language.[[5]](#footnote-4)5 The standard set by the Supreme Court does not require preempting any laws that *could be read* to include ERISA health plans. Rather, the standard set by the Supreme Court requires finding an impermissible "reference to" ERISA plans when a state law "acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation[.]" [*Gobeille, 136 S.Ct. at 943*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J6J-DNP1-F04K-F31S-00000-00&context=).

Through S.B. 2258 and S.B. 2301, North Dakota seeks to ***regulate*** persons or entities who independently serve as third parties in a relationship between insurance plans and plan participants. The insurance plans that they contract with may or may not be ERISA plans. North Dakota's ***regulation*** of these third party entities has little or nothing to do with who is the insurance plan carrier. ERISA ***regulates*** employer sponsored health benefit plans. It does not preempt a state from ***regulating*** independent entities entering contractual**[\*\*16]** relationships with insurance plans, whether they be employer sponsored or not. An independent entity choosing to do business with an employee health benefit plan is not given a shield from state and local ***regulations***; to find that ERISA's preemption clause did as much would be to "extend to the furthest stretch of its indeterminacy." [*De Buono, 520 U.S. at 813*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RVK-BC90-003B-R1F7-00000-00&context=). Therefore, in this case the Court finds no implicit reference to ERISA plans by way of ***regulating*** pharmacy benefit managers.

Similarly, S.B. 2258 and S.B. 2301 explicitly provide that "third party payer," as used within each bill, has the same definition as in [*N.D.C.C. § 19-03.6-01*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P150-00000-00&context=). See S.B. 2258 § 1 (1)(c) and S.B. 2301 §1 (1)(d); see also [*N.D.C.C. § 19-02.1-16.1(1)(c)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:8N2V-D9S2-D6RV-H54Y-00000-00&context=). "Third party payer" is defined as "an organization other than the patient or health **[\*976]** care provider involved in the financing of personal health services." [*N.D.C.C. § 19-03.6-01(6)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P150-00000-00&context=). PCMA argues this is another impermissible, implicit reference to ERISA. The Court is unconvinced. While the statutory language *could* be read to include the employer sponsored health benefit plans subject to ERISA, nowhere in either bill does it say as much. The definition clearly applies to a broad range of entities that have no relation to ERISA or employer sponsored health plans. As described above,**[\*\*17]** to apply the preemption clause under this circumstance would result in "uncritical literalism," for if "'relate to' were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes pre-emption would never run its course, for really, universally, relations stop nowhere." [*Travelers, 514 U.S. at 655*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S42-78P0-003B-R3NX-00000-00&context=).

S.B. 2258 and S.B. 2301 also explicitly provide that "plan sponsors," as used within each bill, have the same definition as in [*N.D.C.C. § 19-03.6-01*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P150-00000-00&context=). See S.B. 2258 § 1(1)(b) and S.B. 2301 § 1(1)(b); see also [*N.D.C.C. § 19-02.1-16.1(1)(b)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:8N2V-D9S2-D6RV-H54Y-00000-00&context=). PCMA points to the definition of a "plan sponsor" as the mirror image of ERISA's definition of "plan sponsor," and argues this constitutes an implicit and impermissible reference to health care benefit plans covered by ERISA. "Plan sponsors" are defined as "the employer in the case of an employee benefit plan established or maintained by a single employer, or the employee organization in the case of a plan established or maintained by an employee organization." See [*N.D.C.C. § 19-03.6-01(5)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P150-00000-00&context=).

Like the definitions of "pharmacy benefits manager" and "third party payer," the definition of "plan sponsors" is referring to a person or entity separate and removed from the health plan itself. Unlike the definitions of "pharmacy benefits manager" and**[\*\*18]** "third party payer," however, the definition of "plan sponsor," explicitly references an employer who provides an employee benefit plan and makes mention of an employee benefit plan. The Court finds PCMA's argument that the statutory definition of "plan sponsor" makes "reference to" ERISA to be its most convincing argument. In order to fully explore the effect of "plan sponsor," the Court will review the relevant analysis.

"A state law has a prohibited "reference to" ERISA or ERISA plans when that law (1) impos[es] requirements by reference to [ERISA] covered programs, (2) specifically exempt[s] ERISA plans from an otherwise generally applicable [statute], or (3) premises a cause of action on the existence of an ERISA plan." [*Prudential, 154 F.3d at 822*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3THY-9SS0-0038-X3YK-00000-00&context=) (internal citations and quotations omitted). "[W]here a State's law acts immediately and exclusively upon ERISA plans . . . or where the existence of ERISA plans is essential to the law's operation . . . that 'reference' will result in pre-emption." [*Gobeille, 136 S.Ct. at 943*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J6J-DNP1-F04K-F31S-00000-00&context=).

Applying those three factors to this case, the Court finds that S.B. 2258 and S.B. 2301's definition of "plan sponsor," which includes an employer who provides an employee benefit plan, is not an implicit reference**[\*\*19]** to ERISA. First, neither S.B. 2258 and 2301 "impose requirements by reference to ERISA covered programs." See [*Dillingham, 519 U.S. at 324*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S65-J1X0-003B-R37C-00000-00&context=). S.B. 2258 and S.B. 2301 undoubtedly "impose requirements," but not "by reference to ERISA covered programs." Id. Both S.B. 2258 and 2301 make reference to a "plan sponsor." A "plan sponsor," by definition, is "*the employer* in the case of an employee benefit plan . . . *or the employee organization* in the case of a plan established . . . by an employee organization . . . ." See [*N.D.C.C. § 19-03.6-01(5)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P150-00000-00&context=) (emphasis added). The employer and the employee organization are both distinct **[\*977]** and separate entities, distinguishable from an employee benefit plan, itself.

"Plan sponsors" are referenced in one section of each bill:

S.B. 2258: "A pharmacy benefits manager or third-party payer may not prohibit a pharmacist or pharmacy from participating in a class action lawsuit. **A pharmacy or pharmacist may disclose to the plan sponsor** or to the patient **information regarding the adjudicated reimbursement paid to the pharmacy** which is compliant under the federal Health Insurance Portability and Accountability Act of 1996 . . . ."

S.B. 2301: "**If requested by a plan sponsor** contracted payer, **a pharmacy benefits manager or [\*\*20]  third-party payer** that has an ownership interest, either directly or through an affiliate or subsidiary, in a pharmacy **shall disclose to the plan sponsor contracted payer any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor** contracted payer."

See S.B. 2258(1)(5) and S.B. 2301(1)(2) (emphasis added).

The Court finds that S.B. 2258 does not impose requirements by making reference to ERISA covered programs. Looking to the statutory language, which is clear and unambiguous on its face, S.B. 2258 *permits* pharmacies and pharmacists to disclose information to a plan sponsor. See S.B. 2258 § 1(5). While, S.B. 2258 allows pharmacies and pharmacists to disclose information, it does not require them to, so it cannot be said that S.B. 2258 imposes requirements by making reference to an ERISA program. Even if the statutory language *required*, rather than permitted, pharmacies and pharmacists to disclose information to a plan sponsor, it would not change the outcome. In that instance, S.B. 2258 would impose a requirement on pharmacies and pharmacists, but not an ERISA covered program.

In contrast, S.B. 2301 *requires*, rather than permits, PBMs and third party payers**[\*\*21]** to disclose information to plan sponsors. While S.B. 2301 imposes a requirement, the Court finds it does not do so by reference to an ERISA-covered program. Instead, S.B. 2301 imposes a requirement on PBMs and third party payers by reference to plan sponsors. Plan sponsors, by definition, refer to *an employer* or *an employee organization*,[[6]](#footnote-5)6 both of which are separate and distinct entities and distinguishable from an employee benefit plan. [*Section 514(a)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GV61-NRF4-44J6-00000-00&context=) of [*29 U.S.C. § 1144(a)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GV61-NRF4-44J6-00000-00&context=) contains the preemption clause which states that ERISA "shall supersede any and all State laws insofar as they may now or hereafter relate to any *employee benefit plan* . . . ." but not insofar as they relate to an employer.

The second consideration for a court deciding whether a state law has a "reference to" ERISA is whether the laws specifically exempt ERISA plans from an otherwise generally applicable statute. See [*Mackey v. Lanier Collection Agency & Service, Inc., 486 U.S. 825, 830, 108 S. Ct. 2182, 100 L. Ed. 2d 836 (1988)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-F1F0-003B-43DD-00000-00&context=). The Court finds that neither S.B. 2258 nor S.B. 2301 specifically exempt ERISA plans, as no such provision exists in either bill. The third consideration, whether the law "premises a cause of action on the existence of an ERISA plan," is similarly irrelevant. **[\*978]** See [*Ingersoll-Rand, 498 U.S. at 140*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4B80-003B-409J-00000-00&context=). The Court finds that neither**[\*\*22]** S.B. 2258 nor S.B. 2301 premises a cause of action on the existence of an ERISA plan, as no such provision exists in either bill.

Accordingly, the Court finds that neither S.B. 2258 nor S.B. 2301 contain an implicit reference to ERISA. Significantly, neither of the bills act "immediately and exclusively upon ERISA plans." [*Dillingham, 519 U.S. at 325*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S65-J1X0-003B-R37C-00000-00&context=). Neither of the bills were "specifically designed to affect employee benefit plans," nor can it be said that "the existence of ERISA plans is essential to the law's operation." See [*Ingersoll-Rand, 498 U.S. at 139*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4B80-003B-409J-00000-00&context=); [*Dillingham, 519 U.S. at 325*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S65-J1X0-003B-R37C-00000-00&context=); see also [*Travelers, 514 U.S. at 656*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S42-78P0-003B-R3NX-00000-00&context=) (finding no preemption involving state-mandated surcharges imposed on parties and HMOs because the charges applied "regardless of whether the commercial coverage or membership, respectively, [was] ultimately secured by an ERISA plan.). Instead, both of the bills "function[ ] irrespective of . . . the existence of an ERISA plan." [*Ingersoll-Rand, 498 U.S. 133, 139, 111 S. Ct. 478, 112 L. Ed. 2d 474 (1990)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-4B80-003B-409J-00000-00&context=).

"In the end, what saves the [state law] from ERISA preemption is that it does not have anything to do with employee benefit plans in particular. It is merely one of many state laws that ***regulates*** one of many products that an employee benefit plan might choose to buy. The [state law] ***regulates*** health insurance in a broad and neutral way . . . The mere**[\*\*23]** fact that many ERISA plans choose to buy health insurance for their plan members does not cause a ***regulation*** of health insurance automatically to 'relate to' an employee benefit plan . . . ." [*Washington Physicians Service Ass'n v. Gregoire, 147 F.3d 1039,1046-47 (9th Cir. 1998)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3SYX-CV30-0038-X388-00000-00&context=). In conclusion, the Court finds that neither S.B. 2258 nor S.B. 2301 contain either an explicit or implicit "reference to" ERISA.

b. Whether S.B. 2258 and S.B. 2301 have a "connection with" ERISA

Because the Court finds that neither bill makes a "reference to" ERISA, the Court continues its preemption analysis, under the "connection with" prong. A state law has an impermissible "connection with" ERISA plans when it "governs . . . a central matter of plan administration" or "interferes with nationally uniform plan administration." [*Gobeille, 136 S.Ct. at 943*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J6J-DNP1-F04K-F31S-00000-00&context=). The Court finds that neither S.B. 2258 nor S.B. 2301 have such a connection with ERISA.

First, neither S.B. 2258 nor S.B. 2301 govern "a central matter of plan administration." [*Gobeille, 136 S.Ct. at 943*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5J6J-DNP1-F04K-F31S-00000-00&context=). "Obligations undertaken with plan administration include 'determining the eligibility of claimants, calculating benefit levels, making disbursements, monitoring the availability of funds for benefit payments, and keeping appropriate records in order to comply with applicable reporting requirements.'"**[\*\*24]** [*Gerhart, 852 F.3d at 730*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MKY-BGT1-F04K-S0FP-00000-00&context=) (quoting [*Fort Halifax Packing Co. Inc., v. Coyne, 482 U.S. 1, 9, 107 S. Ct. 2211, 96 L. Ed. 2d 1 (1987))*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-H8B0-003B-4557-00000-00&context=). None of these obligations are at issue here with either S.B. 2258 or S.B. 2301.

Neither S.B. 2258 nor S.B. 2301 contain any provisions discussing or addressing claimant eligibility determinations, the monitoring of funds for benefit payments, or the keeping of appropriate records for reporting requirements. If either bill is disguising some serious consequence in any of these matters, PCMA has not demonstrated it. PCMA does argue that the bills' provisions relate to calculations of benefit levels and making of disbursements. Some of the provisions in the bills which PCMA points to for support include **[\*979]** those preventing PBMs from charging pharmacies fees imposed after the point of sale; authorizing pharmacies to mail or deliver drugs to patients; requiring that PBMs allow pharmacies to charge shipping and handling fees; authorizing pharmacies to dispense any drugs allowed by their licensure; and barring PBMs from providing specialty drug benefits through mail-order specialty pharmacies in which the PBM owns an interest. See Docket No. 10-1, pp. 11-12.

The Defendants respond that not all state laws related to health care can constitute laws governing central matters of plan administration.**[\*\*25]** If that were the case, the roles the state plays in which physicians to license or which controlled substances to restrict could be said to affect how a health plan is administered because they ultimately impact the plan participants' benefit levels, prescription drug disbursements, and overall care. The Defendants point to cases in which the Supreme Court held that when a plan (or its agent) enters the marketplace for goods or services, the state may ***regulate*** those transactions without running afoul of ERISA. See [*De Buono, 520 U.S. at 816*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RVK-BC90-003B-R1F7-00000-00&context=)[[7]](#footnote-6)7; [*Dillingham, 519 U.S. 316, 329, 117 S. Ct. 832, 136 L. Ed. 2d 791 (1997)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S65-J1X0-003B-R37C-00000-00&context=)[[8]](#footnote-7)8; [*Travelers, 514 U.S. 645, 649, 115 S. Ct. 1671, 131 L. Ed. 2d 695 (1995)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S42-78P0-003B-R3NX-00000-00&context=)[[9]](#footnote-8)9. Otherwise, ERISA would preempt everything from general medical practice standards to state wage laws, because all ***regulations*** at the state level would "invariably affect the cost and price of services" ultimately paid for by ERISA plans.

The Court finds no provisions in either S.B. 2258 or S.B. 2301 governing central matters of plan administration. The bills at issue permit pharmacies to dispense prescription drugs the State has already licensed them to dispense.[[10]](#footnote-9)10 The bills provide for greater disclosure of third party payer's and PBMs' prescription drug pricing. The bills also limit the requirements and fees a third party payer or PBM can place on a pharmacy.**[\*\*26]** The majority of provisions in both S.B. 2258 and S.B. 2301 relate to communication issues between pharmacies and PBMs and, as such, do not govern central matters of any health plan's plan administration.

Because neither S.B. 2258 nor S.B. 2301 "govern . . . a central matter of plan administration," the Court finds they do not "interfere[] with nationally uniform plan administration." PCMA argues that these bills will impose a variety of burdens and expenses upon its members that will interfere with the "benefit structures" selected by ERISA benefit plans and administered by them. But, in the same breath, PCMA admits S.B. 2258 and S.B. 2301 can go into effect as to non-ERISA and non-Medicare Part D health plans. PCMA, is a national trade association representing multiple **[\*980]** PBMs, some of whom provide services for health plans covered by ERISA and some of whom provide services for non-ERISA health plans. PCMA cannot claim in good faith that S.B. 2258 or S.B. 2301 interferes with nationally uniform plan administration, while conceding the bills may ultimately take effect as to other health plans.

PCMA's argument is too abstract. "If ERISA were concerned with any state action — such as medical-care**[\*\*27]** quality standards or hospital workplace ***regulations*** — that increased costs of providing certain benefits, and thereby potentially affected the choices made by ERISA plans, [the Court] could scarcely see the end of ERISA's preemptive reach, and the words 'relate to' would limit nothing." [*Dillingham, 519 U.S. at 329*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S65-J1X0-003B-R37C-00000-00&context=). PCMA fails to explain in any detail how these bills, which essentially (1) require third party payers and PBMs to answer questions about payment determination, when asked; and (2) permit pharmacies to offer the same services as third party payers and PBMs, really affects nationally uniform plan administration. Accordingly, the Court finds S.B. 2258 and S.B. 2301 do not interfere with nationally uniform plan administration, the bills have no "connection with" ERISA, and the bills are not preempted by ERISA.

c. [*ERISA*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GJT1-NRF4-4454-00000-00&context=)'s Savings Clause

Neither party in this case argues the applicability of ERISA's so-called "savings" clause. "While [*§ 514(a) of ERISA*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GV61-NRF4-44J6-00000-00&context=) broadly pre-empts state laws that relate to an employee benefit plan, that pre-emption is substantially qualified by an 'insurance savings clause.'" [*Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, 733, 105 S. Ct. 2380, 85 L. Ed. 2d 728 (1985)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BDM0-0039-N50G-00000-00&context=). "The insurance saving clause preserves any state law 'which ***regulates*** insurance, banking, or securities.'" [*Id. at 739-40*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BDM0-0039-N50G-00000-00&context=). While neither party has raised this argument,**[\*\*28]** the Court makes the alternative finding that, even if S.B. 2258 and S.B. 2301 were preempted by ERISA, they would escape the effects of that preemption by falling within ERISA's saving clause.

In determining the scope of the savings clause, the Court begins by taking a "common-sense" view of the question of whether the state laws in question "***regulate*** insurance." [*Metropolitan Life, 471 U.S. at 739-40*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BDM0-0039-N50G-00000-00&context=). To determine whether a particular practice falls within the "business of insurance," the Supreme Court used three criteria from the McCarran Ferguson Act:

[F]irst, whether the practice has the effect of transferring or spreading a policyholder's risk; second, whether the practice is an integral part of the policy relationship between the insurer and the insured; and third, whether the practice is limited to entities within the insurance industry."

[*Id. at 743*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BDM0-0039-N50G-00000-00&context=).

The Supreme Court noted that the focus of the statutory term under the [*McCarran-Ferguson Act*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSB1-NRF4-4163-00000-00&context=) was "the relationship between the insurance company and the policyholder." [*Metropolitan Life, 471 U.S. at 744*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BDM0-0039-N50G-00000-00&context=). "A common-sense view of the word '***regulates***' would lead to the conclusion that in order to ***regulate*** insurance, a law must not just have an impact on the insurance industry, but must be specifically directed toward**[\*\*29]** that industry." [*Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 50-51, 107 S. Ct. 1549, 95 L. Ed. 2d 39 (1987)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HMG0-003B-415F-00000-00&context=) (Although the state common law did concern "the policy relationship between the insurer and the insured," the Court found that "[t]he connection to the insurer-insured relationship is attenuated at best," because it did not "define the terms of the relationship between the insurer and the insured.").

**[\*981]** Therefore, the North Dakota state laws will be found to "***regulate*** insurance" if (1) they are directed specifically toward the insurance industry, and (2) they apply to the "business of insurance" within the meaning of the McCarran-Ferguson Act. See [*15 U.S.C. §§ 1011-1015*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GSB1-NRF4-4163-00000-00&context=). [*Pilot Life Ins., 481 U.S. at 48*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HMG0-003B-415F-00000-00&context=). The laws apply to the business of insurance under the McCarran-Ferguson Act if they (1) have the effect of transferring or spreading the policyholder's risk; (2) are an integral part of the policy relationship between the insurer and the insured; and (3) are limited to entities within the insurance industry. [*Metropolitan Life, 471 U.S. at 743*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BDM0-0039-N50G-00000-00&context=).

The Court concludes that even if S.B. 2258 and S.B. 2301 were found to "relate to" ERISA, they would be saved from preemption by the ERISA savings clause. First, both bills "***regulate*** insurance" under a common-sense approach," because they are laws "specifically directly toward that industry." [*Pilot Life Ins. Co., 481 U.S. at 50*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HMG0-003B-415F-00000-00&context=). Both S.B. 2258 and S.B.**[\*\*30]** 2301 seek to ***regulate*** PBMs and third party payers, entities that are engaged in the business of health insurance. PBMs in North Dakota are ***regulated*** by the State's insurance department. See *Hearing on S.B. 2258 Before the H. Indus. Bus. & Labor Comm.*, 65th Leg. Assemb., Reg. Sess. (N.D. 2017) (statement of Mark Hardy, PharmD Executive-Director of the ND State Board of Pharmacy). It was the intent of the North Dakota Legislature to impose ***regulations*** on PBMs and third party payers that prevent them from restricting local North Dakota pharmacies from dispensing the drugs they are licensed to dispense, by placing these drugs on "specialty drug" lists.[[11]](#footnote-10)11

Further, the North Dakota laws satisfy the McCarran-Ferguson factors. First, they have the effect of transferring or spreading the policyholder's risk. See [*Gregoire, 147 F.3d at 1046-47*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3SYX-CV30-0038-X388-00000-00&context=) (concluding the Washington act did transfer or spread the policyholder's risk by mandating coverage of additional treatments or conditions). It is clear the bills confer a benefit on insureds. By allowing pharmacists and pharmacies to resume a greater role in the dispensing of prescription drugs, including the mailing and shipping of prescription drugs, S.B. 2258 and S.B. 2301 essentially**[\*\*31]** mandate greater coverage and treatment of conditions for the policyholder, which has the effect of spreading the policyholder's risk. See [*Gregoire, 147 F.3d at 1046*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3SYX-CV30-0038-X388-00000-00&context=) ("It is irrelevant that the Act accomplishes its risk-spreading function in an unusual way. Risk-spreading is a concept that involves more than the mere selection of certain medical conditions for coverage. The degree of risk-spreading between the insured and the carrier also depends on what kinds of treatments the policy agrees to pay for, what kinds of deductibles it will charge, and whether there will be a cap on overall expenses.")

Second, the North Dakota bills are an integral part of the policy relationship between the insurer and the insured. [*Metropolitan Life, 471 U.S. at 743*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BDM0-0039-N50G-00000-00&context=). The North Dakota laws have a "connection to the insurer-insured relationship" because they "define the terms of the relationship between the insurer and the insured," [*Pilot Life, 481 U.S. at 50-51*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-HMG0-003B-415F-00000-00&context=). In *Gregoire*, the Eighth Circuit rejected the argument that the Washington act ***regulated*** only the relationship between the carrier and the provider, rather than the relationship between the carrier **[\*982]** and the insured, because the Washington act "confers a benefit on insureds by expanding the treatments that their health carriers must provide**[\*\*32]** or pay for." [*Gregoire, 147 F.3d at 1046-47*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3SYX-CV30-0038-X388-00000-00&context=). Similarly, in this case, S.B. 2258 and S.B. 2301 confer a benefit on insureds by expanding the treatments available to them through their local pharmacies, and by mail, as opposed to ordering directly through PBMs.

Finally, the North Dakota laws are limited to entities within the insurance industry. S.B. 2258 and S.B. 2301 impose requirements on PBMs and third party payers, which are entities engaged in the business of health insurance, as discussed above. Neither S.B. 2258 nor S.B. 2301 contain ***regulations*** on entities outside the business of health insurance. Accordingly, the Court alternatively finds that even if S.B. 2258 and S.B. 2301 "relate to" ERISA, both bills "***regulate*** insurance" within the common-sense meaning and are thus saved by ERISA's preemption clause.

In evaluating PCMA's likelihood of success on the merits, the Court considered its responsibility to "flexibly weigh the case's particular circumstances to determine 'whether the balance of equities so favors the movant that justice requires the court to intervene . . . ." [*Calvin Klein Cosmetics, 815 F.2d 500, 503 (8th Cir. 1987)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-BT60-001B-K2X5-00000-00&context=). PCMA has not shown that such intervention is warranted under the circumstances. Preliminary injunctive relief is an "extraordinary and**[\*\*33]** drastic remedy." [*Munaf, 553 U.S. 674, 689-90, 128 S. Ct. 2207, 171 L. Ed. 2d 1 (2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4SRD-SPN0-TXFX-1387-00000-00&context=). Accordingly, the party seeking such relief bears the burden of establishing its propriety with "clear proof." [*Frejlach, 573 F.2d 1026, 1027 (8th Cir. 1978)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-YNM0-0039-M264-00000-00&context=). PCMA has not provided clear proof it is likely to succeed on the merits of its claim for a preliminary injunction. The Court finds that this factor weighs in favor of the Defendants.

*2. Irreparable Harm*

PCMA alleges it will experience irreparable harm if injunctive relief is not granted and that such harm will not be compensable by an award of money damages because the United States Constitution grants states immunity from such damage claims. See Docket No. 10-1, p. 19. PCMA alleges the State's bills impose "significant administrative, operational, and financial burdens on PBMs and health plans," and that the enforcement of these laws "may cause a loss of goodwill and injury to that PBM's reputation." See Docket No. 10-1, p. 24-25. The Defendants argue PCMA's alleged harm is overstated because PCMA will still have to comply with S.B. 2258 and S.B. 2301 as to non-ERISA and non-Medicare Part D plans, regardless of the outcome of this case. See Docket No. 22, pp. 7-8. Because PCMA will ultimately be forced to comply with the State's bills in some respects, the**[\*\*34]** State argues, any harm is not as perilous as PCMA would lead the Court to believe. Both parties agree that ERISA and Medicare Part D preemption applies only as to ERISA and Medicare Part D plans, and that PCMA's members will be forced to comply with the laws in some capacity, however the Court must still make an independent finding regarding the potential for irreparable harm.

"Irreparable harm occurs when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages." [*General Motors Corp. v. Harry Brown's, LLC, 563 F.3d 312, 319 (8th Cir. 2009)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4W34-FJ50-TXFX-B2TJ-00000-00&context=). When the potential economic loss is so great as to threaten the existence of the moving party's business, a preliminary injunction may be warranted. Loss of consumer goodwill can be irreparable harm, however, "[e]conomic loss, on its own, is not an irreparable injury so long as the **[\*983]** losses can be recovered." See id.; [*DISH Network Service L.L.C. v. Laducer, 725 F.3d 877, 882 (8th Cir. 2013)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5929-SFW1-F04K-S005-00000-00&context=). "[T]he absence of irreparable injury is by itself sufficient to defeat a motion for a preliminary injunction." [*DISH, 725 F.3d at 882*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5929-SFW1-F04K-S005-00000-00&context=).

Here, PCMA asserts its members will experience significant financial burdens and may experience a loss of reputation. PCMA does not offer any predictions or figures to demonstrate what its view of what a "significant" financial burden**[\*\*35]** might mean. Neither does PCMA address how complying with the State's bills as they relate to non-ERISA and non-Medicare Part D plans might mitigate any financial burdens. PCMA also fails to explain the theory that enforcement of the State bills may result in a loss of reputation. It is not immediately clear why complying with state law would be viewed so negatively as to result in a loss of reputation. PCMA does not allege S.B. 2258 or S.B. 2301 threaten the existence of its members' business and PCMA admits its members will comply with the State's laws as to non-ERSA and non-Medicare Part D health plans. The Court is not willing to find that this factor weighs in favor of the Plaintiff, where Plaintiff has failed to provide any evidence supporting its bare assertions that its members will experience a financial loss and may experience a loss of reputation. Accordingly, the Court finds this [*Dataphase*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6690-0039-W2XH-00000-00&context=) factor weighs in favor of the Defendants.

*3. Balance of Harms*

"Failure to show irreparable harm is an independently sufficient ground upon which to deny a preliminary injunction." [*Watkins, Inc. v. Lewis, 346 F.3d 841, 844 (8th Cir. 2003)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:49TY-GRC0-0038-X4P4-00000-00&context=). However, in the interest of a thorough and meaningful review, the Court next factors the balance between the**[\*\*36]** movant's potential harm and any injury an injunction may inflict on other interested parties. See [*Pottgen v. Mo. State High Sch. Activities Ass'n, 40 F.3d 926, 929 (8th Cir. 1994)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-1300-003B-P0V6-00000-00&context=). While the "irreparable harm" factor focused on the potential harm to the plaintiff, the Court balances the weight of plaintiff's potential harm against the potential harm to each party of the dispute, as well as the potential harm to the public. See [*Dataphase, 640 F.2d at 114*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6690-0039-W2XH-00000-00&context=); [*Glenwood Bridge, Inc. v. City of Minneapolis, 940 F.2d 367, 372 (8th Cir. 1991)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-9PJ0-008H-V545-00000-00&context=).

The Court finds that any harm PCMA's members may experience resulting from S.B. 2258 and S.B. 2301 is outweighed by the potential harm and injury a preliminary injunction may inflict on other interested parties. Testimony before the North Dakota Senate Industry, Business and Labor Committee indicated PBMs increasingly engage in anticompetitive or deceptive conduct that harms consumers, health plans, and local pharmacies. *Testimony Before the S. Indus. Bus. & Labor Comm.*, 65th Leg. Assemb., Reg. Sess. (N.D. 2017) (statement of Mike Schwab, Executive Vice President of the North Dakota Pharmacists Association).

For example, PBMs have the ability to prevent local pharmacies from dispensing any prescription drugs the PBM determines to be a "specialty drug," irrespective of what federal, state, and local authorities have already determined. The**[\*\*37]** PBM then directs consumers to purchase the specialty drug through PBM's own mail-order pharmacies. In addition to being anticompetitive, legislative history indicates this practice can be wasteful as patients have found their "specialty drugs" frozen on their doorstep or baking in their mailbox. In those instances, the PBM can provide an override code permitting the local pharmacists to provide an emergency refill or short-day supply of the medication. *Testimony Before the S. Indus. Bus. & Labor Comm.*, 65th Leg. Assemb., Reg. Sess. (N.D. 2017) (statement of Mike Schwab, **[\*984]** Executive Vice President of the North Dakota Pharmacists Association). Such testimony is evidence of the harms faced by other interested parties, including consumers, who are limited by where they may obtain their prescription drugs and how they obtain them, and local pharmacies who are limited by what prescription drugs they may provide and how and when they provide them.

The Court has reviewed the legislative history of both bills, including testimony from Howard Anderson Jr. of the North Dakota Pharmacists Association; Dr. Erik Christenson, Chief Professional Officer at Heart of America Medical Center; representatives**[\*\*38]** from Workforce Safety; representatives from CVS health; local pharmacists; and a public interest ***antitrust*** attorney. The overwhelming majority of testimony to the Committees indicated that consumers, pharmacies, and plan sponsors all suffer when PBMs exercise their power to restrict consumers to the PBM's own captive mail order and specialty pharmacy operations by reducing the available choices for accessing prescription drugs.[[12]](#footnote-11)12 Both S.B. 2258 and S.B. 2301 seek to address these and the other issues presented to the North Dakota State Legislature. After completing its review, the Court finds that the potential harm other interested parties would experience by preempting these bills, outweighs any potential harm PCMA may experience due to their implementation. Accordingly, the Court finds that the third [*Dataphase*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6690-0039-W2XH-00000-00&context=) factor weighs in favor of the Defendants.

4. *Public Interest*

The final *Dataphase* factor for the Court to consider is the public's interest in the outcome. For the same reasons enumerated in the Court's analysis of the third *Dataphase* factor, the public's interest in the outcome of this case requires a finding that this factor weighs in favor of the Defendants. The**[\*\*39]** public interests served by the implementation of S.B. 2258 and S.B. 2301 are those of transparency, accessibility, and free and open markets for prescription drugs. More specifically, the public has an interest in a plan sponsor's ability to obtain information regarding the rate at which a PBM reimburses a pharmacy and the rate at which the PBM then bills the plan sponsor because this type of transparency allows pharmacies and plan sponsors, as well as PBMs, to **[\*985]** evaluate, compare, and determine fair values of the products and services for which they are contracting.

The public also has an interest in encouraging as many prescription drug providers to enter the marketplace as federal, state, and local governments will allow because the public values increasing competition for products and services as a way to lower costs. Additionally, increasing the number of market participants serves the public interest by allowing consumers the choice to obtain their prescription drugs either over-the-phone, by mail, or in-person at their local pharmacy. The choice of how to obtain prescription drugs serves the public interest of accessibility and safety because consumers have more control of when**[\*\*40]** and how to get their medications, as well as the method by which they will be taught to use them (either over the phone or in person).

There is some evidence in the record that the public interest in keeping health care costs low might be injured by implementation of S.B. 2258 and S.B. 2301. *Testimony Before the S. Indus. Bus. & Labor Comm.*, 65th Leg. Assemb., Reg. Sess. (N.D. 2017) ("They may tell you this bill is going to raise costs. To be honest, that might be true in some circumstances. However, if costs go up, overall there is a high probability that it is because of the PBM not the pharmacy." Statement of Mike Schwab, Executive Vice President of the North Dakota Pharmacists Association). However, in the aggregate, the Court finds that the potential injury to public interests caused by implementation of S.B. 2258 and S.B. 2301 pales in comparison to the actual injuries the legislation seeks to remedy. Therefore, the Court finds this *Dataphase* factor weighs in favor of the Defendants.

Because the Court finds that all four *Dataphase* factors weigh in the Defendants' favor, PCMA's motion to preliminarily enjoin the State's enforcement of S.B. 2258 and S.B. 2301 as to ERISA health care**[\*\*41]** plans is denied.

**B. MEDICARE PART D PREEMPTION**

PCMA also requests this Court preliminarily enjoin the State from enforcing S.B. 2258 and S.B. 2301 as they relate to Medicare Part D health plans because PCMA believes a provision contained in Medicare Part D preempts the State's bills. The Court will apply the same *Dataphase* factors to PCMA's Medicare Part D claim to determine whether PCMA is entitled to a preliminary injunction on this basis.

1. *Likelihood of Success on the Merits*

In regards to Medicare, Congress has proclaimed that "*[t]he standards established* under this part shall *supersede any State law or* ***regulation*** . . . *with respect to [Part D] plans* which are offered by [Part D] organizations under this part." [*42 U.S.C. § 1395w-26(b)(3)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GN51-NRF4-418P-00000-00&context=) (incorporating Part C's preemption provision, [*42 U.S.C. § 1395w-112(g)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GN91-NRF4-42XM-00000-00&context=)) (emphasis added). A "standard within the meaning of this preemption provision means a statutory provision or a ***regulation*** promulgated under Medicare and published in the Code of Federal ***Regulations***. [*Do Sung Uhm v. Humana, Inc., 620 F.3d 1134, 1148 n. 20 (9th Cir. 2010)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:50WY-DJJ1-652R-80BN-00000-00&context=). The meaning of the phrase "with respect to" is broad. For a law to act "with respect to" a Medicare standard, it need not exclusively impact a Medicare standard, and it need not be inconsistent with a Medicare standard. [*Id. at 1149, 1150 n. 25*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:50WY-DJJ1-652R-80BN-00000-00&context=). But ultimately,**[\*\*42]** preemption is found "only where it is the 'clear and manifest purpose of Congress,'" and the plain language of the preemption clause offers the best evidence of Congress's preemptive intent. [*Id. at 1148*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:50WY-DJJ1-652R-80BN-00000-00&context=) (quoting [*Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230, 67 S. Ct.* ***[\*986]*** *1146, 91 L. Ed. 1447 (1947)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-JVD0-003B-S0M9-00000-00&context=). "A clear demonstration of conflict . . . must exist before the mere existence of a federal law may be said to pre-empt state law operating in the same field." [*New York City Health and Hospitals Corp. v. WellCare of New York, Inc., 801 F.Supp.2d 126, 136 (S.D.N.Y. 2011)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:52VG-BK01-F04F-017F-00000-00&context=).

PCMA first argues it is not obligated to show that S.B. 2258 and S.B. 2301 ***regulate*** areas also ***regulated*** by Medicare D, but this is plainly untrue. See Docket No. 23, p. 2-4. Medicare Part D preemption "operates only when CMS[[13]](#footnote-12)13 actually creates standards in the area ***regulated***." Medicare Program; [*Medicare Prescription Drug Benefit, 2005 WL 176041, p. 3, 70 Fed. Reg. 4194-01, 4320 (Jan. 28, 2005)*](https://advance.lexis.com/api/document?collection=administrative-codes&id=urn:contentItem:4FBW-M530-014W-D166-00000-00&context=). CMS has instructed that "[t]o the extent [it] do[es] not create any standards whatsoever in a particular area, [it] do[es] not believe preemption would be warranted." Id. To overcome the presumption *against* preemption, PCMA must show S.B. 2258 and S.B. 2301 ***regulate*** "with respect to" a "standard established under" Medicare Part D. PCMA waited until its reply brief to attempt such a showing and, even then, offered it only as an alternative argument. See Docket No. 23, p. 4.

PCMA alternatively argues that if it is required to show**[\*\*43]** that there are provisions in S.B. 2258 and S.B. 2301 that act with respect to Medicare Part D standards that the State laws are still preempted. PCMA offered a list of C.F.R. ***regulations***, each paired with a one-sentence legal conclusion supporting its position and nothing more. See Docket No. 23, pp. 4-6. PCMA left for the Court with the task of finding and then analyzing any relevant provisions within each cited C.F.R. ***regulation***. This Court is unwilling to do this, particularly when the remedy sought by PCMA is one as "extraordinary" and "drastic" as a preliminary injunction. [*Munaf v. Geren, 553 U.S. 674, 689-90, 128 S. Ct. 2207, 171 L. Ed. 2d 1 (2008)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4SRD-SPN0-TXFX-1387-00000-00&context=). The burden of proof, i.e., the burden of establishing the need for a preliminary injunction, rests on the shoulders of the Plaintiff.

The Court has reviewed the nine C.F.R. ***regulations*** listed by PCMA. Each ***regulation*** contains numerous pages of text. Some portions of text refer to additional ***regulations***. Other portions of text are merely definitions. The Court cannot and will not guess at which portions PCMA finds relevant or problematic in this matter. To do so would require the Court to analyze an issue not properly presented and rule on an argument not sufficiently made. Constructing a party's argument for**[\*\*44]** them is not within a court's purview. See [*Hopper v. Berryhill, 2017 U.S. Dist. LEXIS 155886, 2017 WL 4236974 \*15 (D.E.D. Mo. Sept. 25, 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5PJS-1B41-F04D-K16F-00000-00&context=) ("Plaintiff offers no argument or citation to the record to specify or support this argument. It is not [the] reviewing court's function to construct an argument for a party."); [*Laborers' Intern. Union of North America, AFL-CIO v. Foster Wheeler Energy Corp., 26 F.3d 375, 398 (3rd Cir. 1994)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-5VH0-003B-P37S-00000-00&context=) ("An issue is waived unless a party raises it in its opening brief, and for those purposes 'a passing reference to an issue . . . will not suffice to bring that issue before this court.'"); [*Rotskoff v. Cooley, 438 F.3d 852, 854-55 (8th Cir. 2006)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4J92-HH60-0038-X4DN-00000-00&context=) (observing that an issue is deemed abandoned when it is not developed in brief); [*McPherson v. Kelsey, 125 F.3d 989, 995-96 (6th Cir. 1997)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RPY-57T0-0038-X39W-00000-00&context=) ("[I]ssues adverted to in a perfunctory manner, unaccompanied by some effort at developed argumentation, are deemed waived. It is not sufficient for a party to mention a possible argument in **[\*987]** the most skeletal way, leaving the court to . . . put flesh on its bones.").

In a preliminary injunction, the party seeking relief bears the burden of establishing its propriety with "clear proof." [*Frejlach, 573 F.2d 1026, 1027 (8th Cir. 1978)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-YNM0-0039-M264-00000-00&context=). In analyzing the first *Dataphase* factor, the Court cannot say there is clear proof PCMA is likely to succeed on the merits. PCMA failed to point to any specific text within its cited C.F.R. ***regulations***, either in its briefing or in its oral arguments, that creates a preemption conflict with the State's bills. Pointing**[\*\*45]** to a list of C.F.R. ***regulations***, without any explanation of their relevance, is not enough. Plaintiff's conclusory statements are not adequate for the relief sought. Even if the Court was willing to guess which portions of the text Plaintiff finds relevant, Plaintiff offered no analysis for the Court to consider regarding what the text means, how the text is similar, its practical effects, or why preemption would exist in each scenario. Without more from the party seeking such "extraordinary" relief, the Court cannot find that PCMA is likely to succeed on the merits. Accordingly, the Court finds that this *Dataphase* factor weighs in favor of the Defendants.

2. *Irreparable Harm*

As with its argument regarding ERISA preemption, PCMA alleges it will experience irreparable harm if injunctive relief is not granted. PCMA alleges the state legislation ultimately imposes "significant administrative, operational, and financial burdens on PBMs and health plans," and that the enforcement of these laws "may cause a loss of goodwill and injury to that PBM's reputation." See Docket No. 10-1, p. 24-25. As previously discussed, "[i]rreparable harm occurs when a party has no adequate remedy at law, typically**[\*\*46]** because its injuries cannot be fully compensated through an award of damages." [*General Motors Corp., 563 F.3d at 319*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4W34-FJ50-TXFX-B2TJ-00000-00&context=). When the potential economic loss is so great as to threaten the existence of the moving party's business, a preliminary injunction may be warranted. "[L]oss of consumer goodwill can be irreparable harm," however, "[e]conomic loss, on its own, is not an irreparable injury so long as the losses can be recovered." [*DISH Network Service L.L.C., 725 F.3d at 882*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5929-SFW1-F04K-S005-00000-00&context=).

For the reasons enumerated in the Court's previous analysis of irreparable harm in considering the ERISA claim, the Court is not inclined to find that this factor weighs in favor of the Plaintiff when the Plaintiff has failed to provide any evidence supporting its bare assertions that it will experience a financial loss and may experience a loss of reputation. Such vague and unsubstantiated claims will not suffice for an "extraordinary" and "drastic" remedy. Accordingly, the Court finds that this *Dataphase* factor weighs in favor of the Defendants.

3. *Balance of Harms*

While "the absence of irreparable injury is by itself sufficient to defeat a motion for a preliminary injunction," the Court notes that it finds the third *Dataphase* factor weighs in favor of the Defendants as well. See [*DISH Network Service L.L.C., 725 F.3d at 882*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5929-SFW1-F04K-S005-00000-00&context=). The Court balances**[\*\*47]** the weight of plaintiff's potential harm against the potential harm to each party of the dispute, as well as the potential harm to the public. See [*Dataphase, 640 F.2d at 114*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6690-0039-W2XH-00000-00&context=); [*Glenwood Bridge, Inc., 940 F.2d at 372*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-9PJ0-008H-V545-00000-00&context=).

For the reasons enumerated in its above analysis, the Court finds that any harm PCMA's members may experience resulting from S.B. 2258 and S.B. 2301 is outweighed by the potential harm and injury a preliminary injunction may inflict on other interested parties. PCMA's bare assertions of harm, without any supporting **[\*988]** evidence, are outweighed by testimony before the North Dakota State Legislature detailing the harms that North Dakota consumers, health plans, and local pharmacies experience when PBMs engage in anticompetitive or deceptive conduct. *Testimony Before the S. Indus. Bus. & Labor Comm.*, 65th Leg. Assemb., Reg. Sess. (N.D. 2017) (statement of Mike Schwab, Executive Vice President of the North Dakota Pharmacists Association). Accordingly, the Court finds that this *Dataphase* factor weighs in favor of the Defendants.

4. *Public Interest*

The final *Dataphase* factor for the Court to consider is the public's interest in the outcome. For the same reasons enumerated in the Court's above analysis of this *Dataphase* factor, and for the reasons**[\*\*48]** enumerated in the Court's analysis of the third *Dataphase* factor relating to the balance of harms, the Court finds that the public's interest in the outcome of this case does not support preliminary injunctive relief. The public interests served by the implementation of S.B. 2258 and S.B. 2301 are those of transparency, accessibility, and free and open markets for prescription drugs. These and other public interests listed previously require finding that this *Dataphase* factor weighs in favor of the Defendants.

Preliminary injunctive relief is an "extraordinary and drastic remedy." [*Munaf, 553 U.S. at 689-90*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:4SRD-SPN0-TXFX-1387-00000-00&context=). As a result, the party seeking relief bears the burden of establishing its propriety with "clear proof." [*Frejlach, 573 F.2d at 1027*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4W-YNM0-0039-M264-00000-00&context=). PCMA has failed to meet that burden. As a result, PCMA's motion to preliminarily enjoin the State's enforcement of S.B. 2258 and S.B. 2301 as to ERISA health care plans is denied.

**IV. CONCLUSION**

The Court has carefully reviewed the parties' briefs, the Court's notes from the preliminary injunction hearing, the entire record in this case, and the relevant case law, including the [*Dataphase*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S4X-6690-0039-W2XH-00000-00&context=) factors, and finds that the Plaintiff has not met its burden for establishing the necessity of a preliminary injunction.**[\*\*49]** Accordingly, the Court **DENIES** the motion for a preliminary injunction (Docket No. 10).

**IT IS SO ORDERED**.

Dated this 7th day of November, 2017.

*/s/ Daniel L. Hovland*

Daniel L. Hovland, Chief Judge

United States District Court

**End of Document**

1. 1On August 1, 2017, S.B. 2258 and S.B. 2301 became law as applied to non-ERISA and non-Medicare Part D health plans. See [*N.D.C.C. §§ 19-02.1-14.2*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P0VX-00000-00&context=) and [*19-02.1-16.1*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:8N2V-D9S2-D6RV-H54Y-00000-00&context=). Prior to August 1, 2017, the parties stipulated the law would only go into effect as to non-ERISA and non-Medicare Part D plans, pending the resolution of this matter. See Docket No. 18. For the sake of clarity, the Court will continue to refer to the legislation at issue in this case as S.B. 2258 and S.B. 2301, as opposed to what are now [*N.D.C.C. §§ 19-02.1-14.2*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P0VX-00000-00&context=) and [*19-02.1-16.1*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:8N2V-D9S2-D6RV-H54Y-00000-00&context=), respectively. [↑](#footnote-ref-0)
2. 2These provisions are excerpted from Plaintiff's brief and are not direct quotes of either bill's language, unless indicated. They are Plaintiff's own summaries of the State bills' effects. [↑](#footnote-ref-1)
3. 3The Eighth Circuit Court of Appeals held that the Iowa law at issue in *Gerhart* was preempted by ERISA because it contained an explicit reference to [*ERISA*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:4YF7-GJT1-NRF4-4454-00000-00&context=). [*852 F.3d at 729 (8th Cir. 2017)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MKY-BGT1-F04K-S0FP-00000-00&context=). The Eighth Circuit went on to discuss possible implicit references. Defendants argue that S.B. 2258 and 2301 differ from the Iowa law because they contain no explicit references to ERISA and they further argue that any discussion in *Gerhart* regarding implicit references is only legal *dicta* and not binding precedent. [↑](#footnote-ref-2)
4. 4The obvious irony here is that in order to determine if there is a "reference to" ERISA, the reviewing court first considers whether the state law imposes requirements by "reference to" ERISA . . . . [↑](#footnote-ref-3)
5. 5In contrast, the Eighth Circuit Court of Appeals in *Gerhart* found that the Iowa law at issue made implicit reference to ERISA through the ***regulation*** of PBMs who administer benefits for "covered entities," which, by definition, included "health benefit *plans* and *employers*, labor unions, or other groups "*that provide health care coverage*." See [*Gerhart 852 F.3d 722, 729-30*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:5MKY-BGT1-F04K-S0FP-00000-00&context=). (emphasis added). [↑](#footnote-ref-4)
6. 6See [*N.D.C.C. 19-03.6-01(5)*](https://advance.lexis.com/api/document?collection=statutes-legislation&id=urn:contentItem:5CP7-WVC1-66WP-P150-00000-00&context=) ("'Plan sponsor' means *the employer* in the case of an employee benefit plan . . . *or the employee organization* in the case of a plan established . . . by an employee organization . . . ." ). To be sure, the plan sponsor (i.e., employer or employee organization) is associated with an employee benefit plan; plan sponsors are not, however, synonymous with the plan itself. [↑](#footnote-ref-5)
7. 7ERISA's preemption clause did not preclude New York from imposing a gross receipts tax on ERISA funded medical centers. See [*De Buono, 520 U.S. 806, 117 S. Ct. 1747, 138 L. Ed. 2d 21 (1997)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3RVK-BC90-003B-R1F7-00000-00&context=). [↑](#footnote-ref-6)
8. 8California wage law did not "relate to" employee benefit plans and thus is not preempted by ERISA. See [*Dillingham, 519 U.S. 316, 117 S. Ct. 832, 136 L. Ed. 2d 791 (1997)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S65-J1X0-003B-R37C-00000-00&context=). [↑](#footnote-ref-7)
9. 9New York law requiring hospitals to collect surcharges from patients covered by a commercial insurer but not by Blue Cross/Blue Shield plan did not "relate to" employee benefit plans and are not preempted by ERISA. See [*Travelers, 514 U.S. 645, 115 S. Ct. 1671, 131 L. Ed. 2d 695 (1995)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:3S42-78P0-003B-R3NX-00000-00&context=). [↑](#footnote-ref-8)
10. 10Currently, third party payers and PBMs create a list of what they have determined to be "specialty drugs". Third party payers and PBMs then restrict pharmacies from dispensing any prescription drugs on their "specialty drug" list. Plan participants are then directed to buy the "specialty drug" directly from the third party payer or PBM. [↑](#footnote-ref-9)
11. 11See N.D. Leg. Assemb., Bill Videos for S.B. 2301, http://www.legisl.nd.gov/assembly,65-2017/bill-video/bv2301.html . [↑](#footnote-ref-10)
12. 12Most of the testimony provided at the North Dakota State Legislature was given by pharmacists, pharmacy representatives, and consumers. It does not appear to be uncommon for plan sponsors to be absent from such a discussion. For example, in 2011, Express Scripts Inc. (ESI) and Medco Health Solutions Inc. (Medco) announced a merger agreement. See [*Louisiana Mun. Police Employees' Retirement System v. Medco Health Solutions, Inc., 2011 U.S. Dist. LEXIS 106661, 2011 WL 4386774, No. 2:11-cv-4211 (D.N.J. Sept. 19, 2011)*](https://advance.lexis.com/api/document?collection=cases&id=urn:contentItem:837D-VG51-652J-92PH-00000-00&context=). At the time, ESI was "the nation's leading PBM provider with 90 million covered lives, followed by CVS Caremark with 85 million, and Medco with 65 million covered lives." See [*Dissenting Statement of Commissioner Julie Brill Concerning the Proposed Acquisition of Medco Health Solutions Inc. by Express Scripts, Inc., 2012 FTC LEXIS 69, 2012 WL 1141093 (April 2, 2012)*](https://advance.lexis.com/api/document?collection=administrative-materials&id=urn:contentItem:55CR-1WK0-01KP-4019-00000-00&context=). The Federal Trade Commission (FTC) began an investigation into the proposed merger. The FTC ultimately determined the merger would not unduly increase the merged entity's bargaining power or harm the consumer and accordingly ended its investigation. After the merger of ESI and Medco, the merged entity became more than five times larger than the third largest firm. Id. In response to criticism during the merger that plan sponsors had not expressed concern over the merger, Senator Herb Kohl stated that "it is notable that no large employer who privately expressed concerns to us wished to testify at today's hearing, often telling us that they feared retaliation from the large PBMs with whom they must do business." Statement of U.S. Senator Herb Kohl on the Express Scripts/Medco merger (12.6.2011). Id. [↑](#footnote-ref-11)
13. 13The Centers for Medicare & Medicare Services (CMS) is part of the national Department of Health and Human Services. [↑](#footnote-ref-12)