United States Court of Appeals
for the Eighth Circuit

No. 18-2926

Pharmaceutical Care Management Association

Plaintiff – Appellant

v.

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; Steven P. Irsfeld, in his official capacity as President of the North Dakota Board of Pharmacy; Wayne Stenehjem, in his official capacity as the Attorney General of North Dakota

Defendants – Appellees

Appeal from United States District Court
for the District of North Dakota – Bismarck

Submitted: October 15, 2019
Filed: August 7, 2020

Before SMITH, Chief Judge, GRUENDER and BENTON, Circuit Judges.

GRUENDER, Circuit Judge.

This case concerns Pharmaceutical Care Management Association's ("PCMA") claim that the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq.*, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Part D"), 42 U.S.C. § 1395w-101 *et seq.,* preempt two sections of the North Dakota Century Code (the "legislation") regulating the relationship between pharmacies, pharmacy benefits managers ("PBMs"), and other third parties that finance personal health services. After PCMA and the State of North Dakota[1] cross-moved for summary judgment, the district court determined that only one provision in the legislation was preempted by Medicare Part D and entered judgment in favor of North Dakota on the remainder of PCMA's claims. We affirm in part, reverse in part, and remand with directions that judgment be entered in favor of PCMA.

PCMA is a national trade association that represents PBMs. PBMs are third-party health plan administrators that manage prescription drug benefits on behalf of health insurance plans. In this role, PBMs negotiate prescription drug prices with drug manufacturers and pharmacies, create networks of pharmacies to fill prescriptions for

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[1] PCMA sued Mylynn Tufte, State Health Officer of North Dakota, Mark Hardy, Executive Director of the North Dakota Board of Pharmacy, Fran Gronberg, President of the North Dakota Board of Pharmacy, and Wayne Stenehjem, Attorney General of North Dakota, in their official capacities. Because of the nature of PCMA's claims, we refer to the defendants collectively as "North Dakota."

insured individuals, and process insurance claims when prescriptions are filled.

In 2017, North Dakota passed N.D. Century Code sections 19-02.1-16.1 and 19.02.1-16.2, which, according to North Dakota, "sought to define the rights of pharmacist[s] in relation to [PBMs], and to regulate certain practices by PBMs." The legislation regulates the fees PBMs and "third-party payer[s]" may charge pharmacies, N.D. Cent. Code § 19-02.1-16.1(2); limits what copayments PBMs or third-party payers may charge, *id.* § 19-02.1-16.1(4); dictates the quality metrics PBMs and third-party payers may use to evaluate pharmacies and structures how they may reward performance, *id.* §§ 19-02.1-16.1(3), (11), -16.2(4); prohibits, subject to certain exceptions, PBMs from having "an ownership interest in a patient assistance program and a mail order specialty pharmacy," *id.* § 19.02.1-16.2(3); regulates benefits provisions and plan structures, *id.* §§ 19-02.1-16.1(3), (4), (5) (8), (9), (11), -16.2(5); and requires certain disclosures on the part of PBMs and prohibits PBMs from setting limits on information pharmacists may provide patients, *id.* §§ 19-02.1-16.1(6), (7), (10), -16.2(2). A PBM or third-party payer that violates any section of the legislation is guilty of a class B misdemeanor. *Id.* §§ 19-02.1-16.1(12), -16.2(6).

Shortly after the legislation's enactment in 2017, PCMA filed a complaint seeking a declaration of preemption and an injunction prohibiting the enforcement of the legislation. At summary judgment, the district court determined that none of the statutory provisions were preempted by ERISA and that only one of the provisions was preempted by

Medicare Part D. PCMA appeals, renewing its argument that both ERISA and Medicare Part D preempt the entire legislation.

We review *de novo* the district court's preemption and statutory interpretation rulings. *Pharm. Care Mgmt. Ass'n v. Rutledge,* 891 F.3d 1109, 1112 (8th Cir. 2018). With certain limited exceptions, ERISA preempts "any and all State laws insofar as they may now or hereafter *relate to* any employee benefit plan." 29 U.S.C. § 1144(a) (emphasis added). "The breadth of this section is well known," *Rutledge,* 891 F.3d at 1112, and courts have struggled for decades to cabin its reach in order to prevent the clause from becoming "limitless," *Gobeille v. Liberty Mut. Ins.,* 577 U.S. ---, 136 S. Ct. 936, 943 (2016); *N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins.,* 514 U.S. 645, 655-56 (1995) (rejecting an "uncritical literalism" that extends ERISA's preemption clause to the "furthest stretch of its indeterminacy"); *see also Cal. Div. of Labor Standards Enf't v. Dillingham Constr., N.A., Inc.,* 519 U.S. 316, 335 (1997) (Scalia, J., concurring) (counseling courts to avoid reading the clause too broadly because, "as many a curbstone philosopher has observed, everything is related to everything else").

Endeavoring to clarify ERISA's "unhelpful text," *Travelers Ins.,* 514 U.S. at 656, the Supreme Court has determined the clause preempts a state law that "relates to" an ERISA plan by having an impermissible "reference to" or "connection with" an ERISA plan, *id.* Here, we need not address the "connection with" element of the analysis because we conclude the legislation is preempted due to its

impermissible "reference to" ERISA plans. *See Pharm. Care Mgmt. Ass'n v. Gerhart,* 852 F.3d 722, 730 (8th Cir. 2017) ("Where a State law is preempted because it has a prohibited 'reference to' ERISA or ERISA plans, we need not reach the question of whether it is also preempted under the 'connection with' prong of the analysis.").

A state law has an impermissible "reference to" ERISA plans where it (1) "acts immediately and exclusively upon ERISA plans" or (2) "where the existence of ERISA plans is essential to the law's operation." *Gobeille,* 136 S. Ct. at 943. PCMA asserts that the legislation is preempted because it imposes requirements by reference to ERISA plans through its definitions of "third-party payers" and "plan sponsors." According to PCMA, these references "ensure[] that the existence of an ERISA plan triggers application" of the legislation's provisions. The district court disagreed, determining that, because the legislation also covers entities that are not ERISA plans, it neither acts immediately and exclusively upon ERISA plans nor does it make the existence of an ERISA plan essential to the operation of the regulatory scheme. We agree with PCMA that the legislation is preempted because its references to "third-party payers" and "plan sponsors" impermissibly relate to ERISA benefit plans.

Sections 19-02.1-16.1 and -16.2 regulate "[p]harmacy benefits manger[s]" and "[t]hird-party payer[s]." N.D. Cent. Code §§ 19-02.1-16.1(1), -16.2(1). They then define a "[p]harmacy benefits manager" as "a person that performs pharmacy benefits management . . . *for a . . . third-party payer.*" *Id.* § 19-03.6-01(4) (emphasis added). "Third-party

payer" is defined as "an organization other than the patient or health care provider involved in the financing of personal health services." *Id.* § 19-03.6-01(6). This definition includes ERISA plans, which are necessarily "involved in the financing of personal health services" and are distinct from "the patient or health care provider." *See id.;* 29 U.S.C. § 1002(1) (explaining that, for the purposes of ERISA, an employee benefit plan is one that is established "for the purpose of providing" "medical, surgical, or hospital care or benefits"). The legislation also regulates "[p]lan sponsor[s]," which it defines 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." N.D. Cent. Code § 19-03.6-01(5) (emphasis added). This definition is taken verbatim from ERISA, *see* 29 U.S.C. § 1002(16)(B), and these "plan sponsors," depending on their functions, may qualify as ERISA fiduciaries, *see id.* § 1002(21)(A).

Two of our prior cases dictate that regulating by implicit reference to ERISA plans results in preemption. First, in *Gerhart,* we determined that an Iowa statute was preempted because it had a prohibited "reference to" ERISA. 852 F.3d at 729-30. Although we found that the Iowa act at issue contained an "express reference" to ERISA, *see id.* at 729, we also noted that "the Iowa law . . . makes *implicit reference* to ERISA through regulation of PBMs who administer benefits for 'covered entities,' which, by definition, *include* health benefit plans and employers, labor unions, or other groups 'that provide[] health coverage,'" *id.* (emphasis added). We explained that because "[t]hese entities are

necessarily subject to ERISA regulation," the requirements "necessarily affect[] ERISA plans," and, as a result, the Iowa law contained an "impermissible reference to" ERISA. *Id.* at 729-30.

One year later, in *Rutledge,* we followed this reasoning in evaluating an Arkansas statute that was "similar in purpose and effect" to the Iowa law at issue in *Gerhart. See Rutledge,* 891 F.3d at 1112. There, we determined the Arkansas law contained an impermissible "reference to" ERISA plans, *see id.* at 1112-13, because the challenged law regulated PBMs that administered a "pharmacy benefits plan or program," *see* Ark. Code. Ann. § 17-92-507(a)(7) (2017), which in turn was defined as any plan or program that "pays for . . . pharmacist services," *id.* § 17-92-507(a)(9). We concluded the Arkansas law "implicitly referred to ERISA by regulating the conduct of PBMs administering or managing pharmacy benefits" on behalf of ERISA plans. *See Rutledge,* 891 F.3d at 1112.

As in *Gerhart* and *Rutledge,* so too here. The North Dakota legislation's definitions of and references to "pharmacy benefits manager," "third-party payer," and "plan sponsor" mean the legislation's provisions apply to plans "subject to ERISA regulation." *Id.* "Because benefits affected by [the statute] are provided by ERISA-covered programs, the requirements imposed for the management and administration of these benefits necessarily affects ERISA plans." *Gerhart,* 852 F.3d at 729. Thus, the existence of an ERISA plan is essential to the law's operation because "it cannot be said that the . . . law functions irrespective of the

existence of an ERISA plan." *Id.* at 729-30 (internal quotation marks, ellipses, and brackets omitted).

As the State of Arkansas did in *Rutledge,* North Dakota argues that *Gerhart* should be limited to its consideration of the Iowa law's "express reference" to ERISA plans and that *Gerhart's* "implicit reference" analysis is dicta inconsistent with Supreme Court precedent.[2] But we have already rejected this argument. Rutledge, 891 F.3d at 1112 ("The state argues that Gerhart should be limited to its consideration of the Iowa Act's 'express reference' to ERISA, and that Gerhart's 'implicit reference' analysis is dicta inconsistent with Supreme Court precedent. We disagree."). Instead, Gerhart and Rutledge control, and a statute that implicitly regulates ERISA plans as part of its regulatory scheme is preempted by ERISA and cannot be saved

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[2] Citing *Dillingham Construction,* 519 U.S. at 325, North Dakota argues that our cases construing the scope of ERISA's preemption clause conflict with Supreme Court precedent. The State suggests that if a law regulates a class of third-party administrators or claim processors whose customers merely include but are not limited to ERISA plans, it logically follows that the law does not act immediately and exclusively upon ERISA plans and that the existence of ERISA plans is not essential to the law's operation. *See also Pharm. Care Mgmt. Ass'n v. District of Columbia,* 613 F.3d 179, 189-90 (D.C. Cir. 2010) (reasoning similarly); *Pharm. Care Mgmt. Ass'n v. Rowe,* 429 F.3d 294, 304 (1st Cir. 2005) (same). The Supreme Court recently granted a writ of certiorari in *Rutledge,* 589 U.S. ---, 140 S. Ct. 812 (2020) (mem.), to resolve this question. But regardless of whether *Gerhart* and *Rutledge* were rightly decided, we are bound by those panel decisions unless they are abrogated by the Supreme Court or overruled by this circuit sitting *en banc. See Mader v. United States,* 654 F.3d 794, 800 (8th Cir. 2011) (en banc).

merely because the reference also includes entities not covered by ERISA. *See id.* (rejecting Arkansas's argument that "we are not completely bound by" the *Gerhart* panel's reasoning).

Accordingly, the North Dakota legislation is preempted because it "relates to" ERISA plans "by regulating the conduct of PBMs administering or managing pharmacy benefits." *See Rutledge,* 891 F.3d at 1112; *see also Metro. Life Ins. v Massachusetts,* 471 U.S. 724, 739 (1985) ("Even indirect state action bearing on private pensions may encroach upon the area of exclusive federal concern." (brackets omitted)); *Express Scripts, Inc. v. Wenzel,* 262 F.3d 829, 833 (8th Cir. 2001) ("State laws that are not targeted at ERISA plans, but which indirectly force a plan administrator to make a particular decision or take a particular action may be held to 'relate to' employee benefit plans.").

Next, North Dakota urges in a footnote at the end of its argument regarding ERISA preemption that, if we find the legislation to be preempted, we should "remand for a determination of which provisions are saved from preemption under ERISA's Savings Clause." The district court did not address this issue and North Dakota provides no argument as to which provisions might be saved by the savings clause. *See* 29 U.S.C. § 1144(b)(2)(A). We therefore conclude that North Dakota has waived this issue. *See Mahler v. First Dakota Title Ltd. P'ship*, 931 F.3d 799, 807 (8th Cir. 2019) (finding an issue waived where plaintiff mentioned it only in passing and did not include the issue in the statement of issues); *Hamilton v. Southland Christian Sch., Inc.,* 680 F.3d 1316, 1318-19 (11th Cir. 2012) (holding that appellee's failure to

raise an affirmative defense on appeal waives any right to claim such a defense on appeal).

For the reasons above, we affirm in part, reverse in part, and remand with directions to enter judgment in favor of PCMA.[3]

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[3] North Dakota does not cross-appeal the district court's determination that Medicare Part D preempts North Dakota Century Code section 19-02.1-16.2(2). And because *Gerhart* and *Rutledge* dictate that ERISA preempts the North Dakota legislation in its entirety, we need not address that determination. *See Duffner v. City of St. Peters,* 930 F.3d 973, 976 (8th Cir. 2019) (noting that "[w]e may affirm on any ground supported by the record").

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA

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.	**ORDER GRANTING IN PART AND DENYING IN PART THE PARTIES' CROSS MOTIONS FOR SUMMARY JUDGMENT** Case No.: 1:17-cv-141

Before the Court are cross motions for summary judgment. The Plaintiff, Pharmaceutical Care Management Association ("PCMA") filed its motion for summary judgment on January 19, 2018. See Docket No. 33. The Defendants, Mylynn Tufte, Mark

Hardy, Fran Gronberg, and Wayne Stenehjem, in their official capacities (collectively "North Dakota"), filed a response in opposition and a cross-motion for summary judgment on March 9, 2018. See Docket Nos. 38 and 39. PCMA filed a response on April 9, 2018. See Docket No. 40. North Dakota filed a reply onApril 23, 2018. See Docket No. 42. With the Court's permission, PCMA filed supplemental authority on July 9, 2018. See Docket No. 44. North Dakota filed a response to PCMA's supplemental authority on July 20, 2018. See Docket No. 50. In light of recent case law, both parties also filed supplemental briefing on July 20, 2018. See Docket Nos. 48 and 49. For the reasons set forth below, the Court grants, in part, each motion for summary judgment and denies, in part, each motion for summary judgment.

I. BACKGROUND

PCMA is a national trade association representing pharmacy benefit managers ("PBMs"), with its principal place of business in Washington, D.C. See Docket No. 1. PBMs are third-party health plan administrators that manage and administer prescription drug benefits on behalf of health insurance plans. See Docket No. 10-3, p. 3. PBMs negotiate prescription drug prices with drug manufacturers and pharmacies, create networks of pharmacies to fill prescriptions, and process and pay insurance claims. See Docket No. 1, p. 4. When an insured patient fills a prescription, the pharmacy generally contacts a PBM to obtain insurance coverage and copayment information. See Docket No. 39-2, p. 6. After the pharmacy fills the prescription,

the PBM reimburses the pharmacy based on a rate set out in a contract between the PBM and the pharmacy. See Docket No. 1, p. 6. The PBM then bills the health insurance plan at a rate negotiated between the PBM and the health insurance plan. See Docket No. 39-2, p. 6. In sum, PBMs are intermediaries between patients' and health insurance plans' demand for prescription drugs and manufacturers' and pharmacies' supply of prescription drugs.

In April 2017, North Dakota's governor, Doug Burgum, signed Senate Bills 2258 and 2301 into law. See S.B. 2258, 2017 Leg., 65th Sess. (ND 2017); S.B. 2301, 2017 Leg., 65th Sess. (ND 2017). The laws regulate PBMs and pharmacies. According to North Dakota, the legislation "sought to define the rights of pharmacist in relation to [PBMs], and to regulate certain practices by PBMs." See Docket No. 39-1, p. 2. The legislation contains provisions concerning (1) the practice of pharmacy; (2) pharmacy accreditation and credentialing; and (3) perceived self-dealing and abusive practices on the part of PBMs. The parties contest the validity of various provisions, all of which are summarized below.

A. PROVISIONS CONCERNING THE PRACTICE OF PHARMACY

The legislation contains the following provisions concerning the practice of pharmacy:

- S.B. 2258 §1(7) allows pharmacies to disclose "relevant" information to patients, including "the cost and clinical efficacy of a more affordable alternative drug if one is

available," and it prohibits gag orders on such disclosure.

- S.B. 2258 §1(5) allows pharmacies to disclose to patients or plan sponsors information regarding the amount of reimbursement the pharmacy receives after a prescription drug is dispensed.
- 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) bars contracts that prohibit pharmacies from charging patients shipping and handling fees.
- S.B. 2301 § 1(5) authorizes pharmacies to dispense "any and all drugs allowed" under their license.

B. PROVISIONS CONCERNING PHARMACY ACCREDITATION AND CREDENTIALING

The legislation contains the following provisions concerning pharmacy accreditation and credentialing:

- S.B. 2258 §1(11) prohibits PBMs from requiring "pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state."
- S.B. 2301 §1(4) similarly prohibits PBMs from requiring, for participation in a PBM's

pharmacy network, "accreditation standards or recertification requirements . . . which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state."

- S.B. 2258 § 1(3) requires PBMS to utilize pharmacy performance standards set by unbiased, nationally recognize entities, and it regulates the fees PBMs may impose based on pharmacy performance standards.

C. PROVISIONS CONCERNING PERCEIVED SELF-DEALING AND ABUSIVE PRACTICES ON THE PART OF PBMS

The legislation contains the following provisions concerning perceived self-dealing and abusive practices on the part of PBMs:

- 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(4) prohibits copayments that exceed the cost of the medication being purchased, and it bars PBMs from "redact[ing] the adjudicated cost," i.e., the amount the PBM or third-party payer reimburses a pharmacy for a prescription.
- S.B. 2258 §1(10) requires PBMs to disclose certain information about their pharmacy

networks "to enable the pharmacy to make an informed contracting decision."

- S.B. 2301 § 1(2) obligates PBMs and third-party payers having ownership interest in a pharmacy to disclose, to plan sponsors, on request, the difference between the amount paid to the pharmacy and the amount charged to the plan sponsor.
- 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 "to not participate in a transaction that benefits the [PBM] . . . instead of another person owed a fiduciary duty."

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, Fran Gronberg; and North Dakota's Attorney General, Wayne Stenehjem. See Docket No. 1. PCMA then filed a motion for a preliminary injunction on July 20, 2017. See Docket No. 10. The Court held a hearing regarding PCMA's motion for preliminary injunction on August 22, 2017. See Docket No. 24. On November 7, 2017, the Court denied PCMA's motion for a preliminary injunction. See Docket No. 27. Now the Court considers the parties' cross-motions for summary judgment. See Docket Nos. 33 and 38.

II. LEGAL DISCUSSION

PCMA argues the legislation places restrictions and requirements on PBMs that are preempted by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq.*, and Medicare Prescription Drug Improvement and Modernization Act of 2003 ("Medicare Part D"), 42 U.S.C. § 1395w-101 *et seq.* PCMA seeks this Court's declaration that the legislation is expressly preempted by federal law. In opposition, North Dakota contends the legislation regulates areas of concern that have been excepted from federal regulation. As detailed below, the Court concludes the legislation is not preempted by federal law, save one provision requiring PBMs to disclose certain information to health insurance plans, which the Court finds preempted by an overlapping Medicare Part D standard.

A. STANDARD OF REVIEW

Summary judgment is appropriate when the evidence, viewed in a light most favorable to the non-moving party, indicates no genuine issues of material fact exist and the moving party is entitled to judgment as a matter of law. Davison v. City of Minneapolis, 490 F.3d 648, 654 (8th Cir. 2007); see also Fed. R. Civ. P. 56(a). Summary judgment is not appropriate if there are factual disputes that may affect the outcome of the case under the applicable substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A genuine issue of material fact is not the "mere existence of some alleged factual dispute between the parties." State Auto Ins. Co. v.

Lawrence, 358 F.3d 982, 985 (8th Cir. 2004). Rather, an issue of material fact is genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson, 477 U.S. at 248. The moving party always bears the burden of demonstrating the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). The non-moving party may not rely merely on allegations or denials; it must set out specific facts showing a genuine issue for trial. Forrest v. Kraft Foods, Inc., 285 F.3d 688, 691 (8th Cir. 2002). The court must view the facts in the light most favorable to the non-moving party. Adickes v. S.H. Kress & Co., 398 U.S. 144, 157 (1970).

B. THE PREEMPTION DOCTRINE

The preemption doctrine is rooted in the Supremacy Clause, which states federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. Because of the Supremacy Clause's mandate, a state law that conflicts with federal law is without effect. Maryland v. Louisiana, 451 U.S. 725, 746 (1981). Courts have delineated two types of preemption: express and implied. See Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992). Express preemption occurs when Congress has "unmistakably ordained" that its enactments alone are to regulate a subject. Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977). Implied preemption occurs when congressional command is implicitly contained in a statute's structure and purpose. Gade, at 98.

Congressional intent is at the base of all preemption analysis. Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 516 (1992). Courts must start their inquiry with the assumption that the historic police powers of the States were not meant to be superseded by federal law unless that was the "clear and manifest" intent of Congress. Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947); see also Cipollone, at 516. This assumption assures the "federal-state balance will not be disturbed unintentionally by Congress or unnecessarily by the courts." Jones, 430 U.S. at 525. "[A] high threshold must be met if a state law is to be preempted for conflicting with the purposes of a federal Act." Chamber of Commerce of the U.S. v. Whiting, 563 U.S. 582, 607 (2011) (quoting Gade, 505 U.S. at 110).

C. ERISA PREEMPTION

ERISA comprehensively regulates employee welfare benefit plans that "through 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. § 1002(1). ERISA was intended to:

> protect interstate commerce and the interests of 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).

"To meet the goals of a comprehensive and pervasive Federal interest and the interests of uniformity with respect to interstate plans, Congress included an express preemption clause in ERISA for the displacement 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. 2001). The Supreme Court has described the preemption clause as having "a broad scope, and an expansive sweep," and being "conspicuous for its breadth." California Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 324 (1997) (internal citation omitted).

The scope of ERISA preemption has left courts "deeply troubled." Prudential Ins. Co. of America v. Nat'l Park Med. Ctr. Inc., 154 F.3d 812, 815 (8th Cir. 1998). 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 (1995) ("we have never assumed lightly that Congress has derogated state regulation, but instead have addressed claims of pre-emption with the starting presumption that Congress does not intend to supplant state law."). The Supreme Court has warned that ERISA's preemption clause must not be read to "extend to the furthest stretch of its indeterminacy." De Buono v. NYSA-ILA Med. and Clinical Services Fund, 520 U.S. 806, 813 (1997).

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) (emphasis added). "Yet, Congress did not define what it meant by state laws that 'relate to' an ERISA benefit plan anywhere in the statute." Prudential, 154 F.3d at 819. The Supreme Court has "endeavored with some regularity to interpret and apply the 'unhelpful text' of ERISA's pre-emption provision." Dillingham, 519 U.S. at 324 (quoting Travelers Ins. Co., 514 US at 656). The Court's endeavor has resulted in a two-part test. ERISA preempts state laws that (1) include a reference to ERISA plans, or (2) have an impermissible connection with ERISA plans. Gobeille v. Liberty Mut. Ins. Co., 136 S.Ct. 936, 943 (2016).

1. WHETHER S.B. 2258 AND S.B. 2301 INCLUDE A REFERENCE TO ERISA PLANS

Neither S.B. 2258 nor S.B. 2301 contain an explicit reference to ERISA or ERISA plans. ERISA is not mentioned, discussed, defined, or excluded in either bill. However, PCMA argues that both S.B. 2258 and S.B. 2301 contain "implicit" references to ERISA because, within each bill, the terms *pharmacy benefit manager, third-party payer,* and *plan sponsor* are defined broadly enough to implicate ERISA health plans. See Docket No. 33-1, pp. 16-18.

Under the "reference to" inquiry, the Supreme Court has preempted state laws that (1) imposed requirements by reference to ERISA covered programs; (2) specifically exempted ERISA plans

from an otherwise generally applicable statute; and (3) premise a cause of action on the existence of an ERISA plan. Prudential, 154 F.3d at 822. An impermissible reference to ERISA occurs 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 (internal citation and quotation omitted).

PCMA cites the Eighth Circuit Court of Appeals decision in *Pharmaceutical Care Management Association v. Gerhart* for the proposition that a general state-law reference broad enough to encompass ERISA plans must result in preemption. 852 F.3d 722 (8th Cir. 2017). In PCMA's words: "A statute that implicitly refers to ERISA plans, such as by including 'health benefit plans' within its scope, has a prohibited reference to ERISA plans." See Docket No. 33-1, p. 16. 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. The Eighth Circuit held the Iowa statute contained an impermissible reference to ERISA. Id. at 729-30. The court noted that, by its "express terms," the Iowa law "specifically exempts certain ERISA plans from its otherwise general application." Id. at 729. The court held that "[b]ecause of this impermissible reference to ERISA or ERISA plans, [the Iowa law] is preempted under 29 U.S.C. § 1144(a)." Id. at 730. The court also noted the law contained an "implicit reference" to ERISA because it regulated PBMs that administer benefits for plans subject to ERISA. Id. at 729.

The Eighth Circuit recently commented on the *Gerhart* holding in *Pharmaceutical Care Management Association. v. Rutledge,* 891 F.3d 1109 (8th Cir. 2018). The court stated:

> The state argues that Gerhart should be limited to its consideration of the Iowa Act's "express reference" to ERISA, and that Gerhart's "implicit reference" analysis is dicta inconsistent with Supreme Court precedent. We disagree. In addition to finding that Iowa Code § 510B.8 had a prohibited express reference to ERISA, the Gerhart court found that the "Iowa law also makes implicit reference to ERISA through regulation of PBMs who administer benefits for 'covered entities,' which, by definition, include health benefit plans and employers, labor unions, or other groups 'that provide[ ] health coverage.' These entities are necessarily subject to ERISA regulation." 852 F.3d at 729.

Id. at 1112 (alteration in original).

PCMA argues the decisions in *Gerhart* and *Rutledge* establish a new rule regarding the "reference to" inquiry. See Docket No. 48, p. 8 ("Rutledge confirmed that an implicit reference to ERISA exists even where the law does not *only* regulate entities necessarily subject to ERISA regulation.") (emphasis in original). However, the rule PCMA attempts to distill from *Gerhart*—that a general state-law provision broad enough to encompass ERISA plans within its scope constitutes an implicit reference to an ERISA plan—would vastly expand the scope of the ERISA preemption doctrine. The Court finds nothing in the Eight

Circuit's analysis to indicate such an intent. The *Rutledge* court explained *Gerhart* is not "inconsistent with the Supreme Court's precedent in Travelers or De Buono . . . ." 891 F.3d at 1112. Those cases require preemption under the "reference to" inquiry when a state law (1) acts "immediately and exclusively" on ERISA plans, or (2) when the existence of an ERISA plan is "essential to the law's operation." Gobeille, 136 S.Ct. at 943 (alteration in original) (quoting Dillingham, 519 U.S. at 325).

Reading any state-law definition broad enough to include ERISA plans within its scope to constitute an impermissible "implicit" reference to ERISA would extend the preemption clause "to the furthest stretch of its indeterminacy." De Buono, 520 U.S. at 813. For example, North Dakota's definition of "organization" includes, among others, "any legal or commercial entity," N.D.C.C. § 1-01-49(5), and would "by definition" include "entities [that] are necessarily subject to ERISA regulation." Gerhart, 852 F.3d at 729. The United States Supreme Court has rejected this type of "uncritical literalism" in applying the ERISA preemption clause. See Gobeille, 136 S.Ct. at 943 (quoting Travelers, 514 U.S. at 656). As such, regarding the "reference to" analysis the Court must conduct, it will apply the test set out in *Dillingham* and refined by its progeny: "[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, at 943 (alteration in original) (quoting Dillingham, 519 U.S. at 325).

i. NORTH DAKOTA'S DEFINITION OF "PHARMACY BENEFITS MANAGER"

PCMA argues North Dakota's definition of "pharmacy benefits manager" includes entities that provide services to ERISA plans, and thus the definition constitutes an impermissible reference to ERISA. See Docket No. 33-1, pp. 16-17. The legislation provides that "pharmacy benefit manager," as used within each bill, has the same definition as set out in N.D.C.C. § 19-03.6-01 (dealing with pharmacy records audits). 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) and 19-02.1-16.1(1)(a). "Pharmacy benefits manager" is defined as:

> [A] person that performs pharmacy benefits management and includes any other person 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).

It is conceivable that a "pharmacy benefits manager" could provide services to an insurance plan, and that the insurance plan could be subject to ERISA. But that is one outcome of many, and more importantly, one not expressed in the legislation's language. A state law impermissibly references ERISA when it "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. North Dakota's definition of "pharmacy benefits manager" includes entities that contract with a broad range of parties. Although insurance plans may be one of these parties, the definition makes no distinction as to whether an insurance plan is subject to ERISA. The Court finds the legislation does not impermissibly reference ERISA plans by way of North Dakota's definition of pharmacy benefits manager.

ii. NORTH DAKOTA'S DEFINITION OF "THIRD-PARTY PAYER"

PCMA argues North Dakota's definition of "third-party payer" impermissibly includes ERISA plans within its scope. See Docket No. 33-1, pp. 16-17. The legislation provides that the term "third-party payer," as used within each bill, has the same definition as in N.D.C.C. § 19-03.6-01. 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). "Third-party payer" is defined as "an organization other than the patient or health care provider involved in the financing of personal health services." N.D.C.C. § 19-03.6-01(6). The definition clearly applies to a broad range of entities that have no relation to ERISA. The legislation, by way of North Dakota's definition of third-payer, neither "acts immediately and exclusively upon ERISA plans" nor is the "existence of ERISA plans essential to the law's operation." Gobeille, 136 S.Ct. at 943. The Court finds no impermissible reference to ERISA in North Dakota's definition of third-party payer.

iii. NORTH DAKOTA'S DEFINITION OF "PLAN SPONSOR"

PCMA argues North Dakota's definition of "plan sponsor" impermissibly references ERISA plans. PCMA specifically cites the definition's inclusion of the term "employee benefit plan," which includes ERISA plans within its scope. See Docket No. 33-1, p. 18. The legislation provides that "plan sponsor," as that term is used within each bill, has the same definition as in N.D.C.C. § 19-03.6-01. 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). That provision defines "plan sponsor" 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 . . . or other similar group that establishes or maintains the plan." See N.D.C.C. § 19-03.6-01(5) (emphasis added). PCMA contends that because the reference to "employee benefit plan" encompasses ERISA covered plans, it constitutes an impermissible implicit reference to an ERISA plan. See Docket No. 33-1, p. 18.

PCMA's argument is without merit. The legislation uses the term "plan sponsor" to either allow pharmacies, or require PBMs, to disclose certain information to, among others, the sponsors of plans. See S.B. 2258 § 1(5) (allowing pharmacies to disclose information to plan sponsors and patients regarding drug reimbursement amounts); S.B. 2301 § 1(2) (requiring PBMs to disclose the difference between amounts paid to pharmacies and amounts charged to plan sponsors for prescription drugs). However, the plans referenced in the definition of

"plan sponsors" may or may not be subject to ERISA, and thus the law still has purpose absent ERISA applicability. See e.g. 29 U.S.C. §§ 1003(b) and 1144(a) (exempting government-sponsored plans, church-sponsored plans, workmen's compensation plans, and other types of plans from ERISA regulation and preemption). In other words, the legislation makes no distinction between ERISA and non-ERISA plans, and it applies equally to both. Thus, it does not constitute an impermissible reference to ERISA or ERISA plans.

In sum, PCMA's arguments regarding the scope of certain terms and definitions oversimplifies the issue. The "reference to" inquiry concerns the law's implications on ERISA plans—i.e., whether the 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 (internal citation and quotation omitted). North Dakota's law does neither, and thus the Court finds no impermissible reference to ERISA.

2. WHETHER THE LEGISLATION HAS AN IMPERMISSIBLE CONNECTION WITH ERISA PLANS

Because the Court finds that neither bill includes 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. PCMA's arguments largely focus on PBMs' relationships with ERISA plans. PCMA

asserts the legislation's imposition of requirements on PBMs necessarily affects PBMs' ability to provide services to ERISA plans. Thus, PCMA's logic continues, the legislation's limitations on PBMs have impermissible downstream effects on ERISA plans and plan administration. See Docket No. 33-1, pp. 20-21. In response, North Dakota emphasizes the legislation's relationship to the practice of pharmacy—an area normally left to state regulation. See Docket No. 49, p. 10.

Both parties also disagree as to how the Eighth Circuit Court of Appeals' recent decisions in *Gerhart* and *Rutledge* bear on the "connection with" analysis this Court must conduct. *Gerhart* involved an Iowa law that regulated how PBMs establish generic drug pricing and also mandated disclosure of PBMs' maximum allowable cost ("MAC") methodology.[1] 852 F.3d at 726. The Eighth Circuit found the establishment of MAC lists and generic drug reimbursement rates to be matters central to plan administration, and it concluded Iowa's regulation of MAC calculations interfered with nationally uniform plan administration. Id. at 731. Similarly, in *Rutledge,* PCMA challenged an Arkansas law mandating PBMs follow certain practices with regard to MAC methodology. 891 F.3d at 1111. The Eighth Circuit affirmed the district court's conclusion that the Arkansas law interferes with uniform plan administration because it "regulates PBMs in ways

[1] Maximum allowable cost lists detail the amount a PBM is willing to reimburse a pharmacy for the purchase of a generic prescription drug. Each PBM uses its own methodology to determine these reimbursement rates and to create maximum allowable cost lists. Gerhart, at 726.

fundamentally similar to the Iowa statute in *Gerhart* . . . ." 240 F. Supp. 3d. 951, 958 (E.D. Ark. 2017); 891 F.3d at 1112-1113;. While illustrative, the Court does not find either *Gerhart* or *Rutledge* necessarily dispositive of this case as the parties suggest. North Dakota's legislation does not mandate any specific practice regarding MAC methodology or reimbursement rates. Rather, the legislation contains provisions regulating the practice of pharmacy and pharmacy accreditation standards, provisions addressing disclosure obligations, and prohibitions on certain post point-of-sale fees that may be levied on pharmacies. Thus, the Court will examine the specifics of North Dakota's law to determine whether it (1) governs matters central to plan administration, or (2) interferes with nationally uniform plan administration. See Gobeille, 136 S.Ct. at 943.

i. WHETHER THE LEGISLATION GOVERNS MATTERS CENTRAL TO PLAN ADMINISTRATION

A state law that governs matters central to ERISA plan administration is preempted by ERISA. Gobeille, 136 S.Ct. at 943. "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.'" Gerhart, 852 F.3d at 730 (quoting Fort Halifax Packing Co. Inc., v. Coyne, 482 U.S. 1, 9 (1987)). Neither bill contains any provisions concerning claimant eligibility determinations, the

monitoring of funds for benefit payments, or the keeping of appropriate records for reporting requirements. Rather, the legislation limits the supplanting of state pharmacy licensing requirements, see e.g. S.B. 2258 § 1(11); S.B. 2301 § 1(4), addresses conflicts occurring in the provision of pharmacy services in North Dakota, see e.g. S.B. 2301 § 1(3), authorizes North Dakota pharmacies to engage in certain practices, see e.g. S.B. 2258 §§ 1(7), (8), and (9); S.B. 2301 § 1(5), and imposes disclosure obligations and post point-of-sale fee limitations, see e.g. S.B. 2258 §§ 1(2) and (4). In short, the legislation largely regulates pharmacy services, certain fees, and communication between pharmacies, their customers, and PBMs. The Court finds neither bill governs a matter central to ERISA plan administration.

ii. WHETHER THE LEGISLATION INTERFERES WITH NATIONALLY UNIFORM PLAN ADMINISTRATION

A state law that interferes with nationally uniform plan administration is preempted by ERISA. Gobeille, 136 S.Ct. at 943. PCMA argues the legislation will impose a variety of burdens and expenses upon PBMs, the imposition of which will have a downstream effect on ERISA plans. The legislation's incidental effect on plans, PCMA asserts, will result in interference with nationally uniform plan administration. See Docket No. 33-1, pp. 20-21. The Court does not doubt that, like other state healthcare regulation, the legislation will have some effect on healthcare plans. For example, the

legislation places various requirements on PBMs that may result in PBMs losing certain revenues or incurring expenses. See, e.g., S.B. 2258 §§ 1(2) and (9) (prohibiting PBMs from levying post point-of-sale fees on pharmacies and requiring disclosure of pharmacy network information to enable pharmacies to make informed contracting decisions). PBMs may attempt to recoup these lost revenues and expenses by passing costs on to plans. These increased costs could potentially affect plans' decision-making. But this effect is too tenuous to constitute interference with nationally uniform plan administration. "[I]f ERISA were concerned with any state action—such as medical-care 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 pre-emptive reach, and the words 'relate to' would limit nothing." Dillingham, 519 U.S. at 329.

PCMA's arguments fail to bridge the gap between the legislation and interference with plan administration—let alone nationally uniform plan administration. Put another way, PCMA has not explained how the alleged effects of the legislation will change how ERISA plans are administered. To be sure, PCMA has explained, in detail, how the legislation will force PBMs to modify their business practices. See, e.g., Docket Nos. 33-3, 33-4, and 33-5. But it has not articulated a change in custom or practice that the legislation requires ERISA plans to make. A state law interferes with nationally uniform plan administration when it subjects plans to different requirements in different states. See Egelhoff, 532 U.S. at 148. North Dakota's law does

not impose any requirements on ERISA plans. Consequently, the Court finds the legislation does not interfere with nationally uniform plan administration.

D. MEDICARE PART D PREEMPTION

Having determined the legislation is not preempted by ERISA, the Court turns to the parties' arguments concerning Medicare Part D preemption. In regards to Medicare, Congress has proclaimed: "The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to [Part D] plans which are offered by [Part D] organizations under this part." 42 U.S.C. § 1395w-26(b)(3); see also 42 U.S.C. § 1395w-112(g) (applying Part C's preemption provision to Part D). "The federal scheme preempts a state law when (1) Congress or the Centers for Medicare and Medicaid Services (CMS) has established 'standards' in the area regulated by the state law; and (2) the state law acts 'with respect to' those standards." Rutledge, 891 F.3d at 1113 (citing § 1395w-26(b)(3)). "For purposes of the preemption provision, a standard is a statutory provision or a regulation promulgated under [Medicare] and published in the Code of Federal Regulations." New York City Health and Hospitals Corp. v. WellCare of New York, Inc., 801 F. Supp. 2d 126, 140 (S.D.N.Y. 2011) (quoting Med. Card Sys., Inc., v. Equipo Pro Convalecencia, 587 F. Supp. 2d 384, 387 (D.P.R. 2008)); see also Uhm v. Humana, Inc., 620 F.3d 1134, 1148 n. 20 (9th Cir. 2010).

According to CMS, the agency responsible for regulating Medicare Part D plans, Part D preemption occurs "only when CMS actually creates standards in the area regulated. To the extent we do not create any standards whatsoever in a particular area, we do not believe preemption would be warranted." Federal Regulations for Medicare Program; Medicare Prescription Drug Benefit, 70 Fed. Reg. 4,320 (January 28, 2005). For preemption to occur, "[c]onflict between the state law and the federal standard is unnecessary." Rutledge, 891 F.3d at 1113.

Medicare's preemption provision contains a savings clause that expressly prohibits federal interference with state regulation of the practice of medicine: "Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided . . . ." 42 U.S.C. § 1395. In addition, the Medicare preemption provision expressly exempts "State licensing laws or State laws relating to plan solvency" from its scope. 42 U.S.C. § 1395w-26(b)(3).

PCMA argues nearly every provision of the legislation is preempted by Medicare Part D. North Dakota asserts none are preempted. The Court will address each contested provision in the following order: (1) provisions concerning the practice of pharmacy; (2) provisions regarding accreditation and credentialing requirements; and (3) provisions directed at perceived abusive practices and PBM self-dealing. But first the Court turns to PCMA's preliminary argument that three specific Medicare

provisions generally preempt any state regulation of contracts between PBMs and pharmacies.

1. PCMA'S GENERAL PREEMPTION ARGUMENT

PCMA first argues 42 U.S.C. § 1395w-104, which provides beneficiary protections for prescription drug coverage, preempts any state regulation of contracts between pharmacies and Part D plans. See Docket Nos. 33-1, p. 36 and 40, p. 46. PCMA specifically points to Section 1395w-104(b)(1)(A), requiring Part D plans to "permit the participation of any pharmacy that meets the terms and conditions under the plan." PCMA argues that because of this standard "a Part D Sponsor need not contract with a pharmacy that does not meet those terms and conditions; if a pharmacy wishes to participate in a plan sponsor's network, it has no choice but to accept the plan's 'terms and conditions.'" See Docket No. 33-1, p. 36. Thus, PCMA contends the legislation "interfere[s] with that standard by preventing North Dakota's pharmacies from accepting the plan's 'terms and conditions.'" See Docket No. 33-1, p. 36. First, the Court disagrees with PCMA's characterization of this standard, i.e. that it was meant to give pharmacies "no choice but to accept the plan's 'terms and conditions.'" See Docket No. 33-1, p. 36. The standard ensures patients have ready access to pharmaceutical services—hence its title: "Access to covered part D drugs—assuring pharmacy access—Participation of any willing pharmacy." 42 U.S.C. § 1395w-104(b)(1)(A); see also Rutledge, 891 F.3d at 1114 (characterizing the standard as setting "forth requirements with regard to Medicare recipients'

access to pharmacies"). Moreover, this standard has no bearing on the negotiation and contracting process between pharmacies and PBMs. The Court finds Section 1395w-104(b)(1)(A) does not overlap with North Dakota's regulation of contracts between pharmacies and PBMs, and thus it does not preempt the legislation.

PCMA similarly argues 42 C.F.R. § 423.505, which provides certain requirements for contracts between CMS and Part D plan sponsors, preempts any state regulation of contracts between pharmacies and PBMs. See Docket Nos. 33-1, p. 37 and 40, p. 46. PCMA specifically cites Section 423.505(b)(18) requiring Part D plans to agree "to have a standard contract with reasonable and relevant terms and conditions of participation whereby any willing pharmacy may access the standard contract and participate as a network pharmacy . . . ." This standard parallels 42 U.S.C. § 1395w-104, discussed directly above, to ensure Part D beneficiaries have access to pharmaceutical services. Moreover, it only applies to contracts "between the Part D plan sponsor and CMS." Section 423.505(a). The Court concludes this provision does not preempt the legislation's regulation of contracts between PBMs and pharmacies.

Last, PCMA argues the Medicare Part D "non-interference clause" preempts all state regulation of contracts between PBMs and pharmacies. See Docket Nos. 33-1, p. 38; 40, pp. 26-27; and 48, p. 11. The clause provides:

> In order to promote competition under this part and in carrying out this part, the Secretary –

> (1) may not interfere with negotiations between drug manufacturers and pharmacies and PDP sponsors; and
>
> (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

42 U.S.C. § 1395w-111(i). By its plain terms, the clause prohibits the Secretary of the United States Department of Health and Human Services from interfering in certain areas. However, the Eighth Circuit Court of Appeals has interpreted the clause to prohibit "both federal *and state* interference in negotiations between Part D sponsors and pharmacies . . . ." Rutledge, 891 F.3d at 1113 (emphasis added). PCMA argues "every challenged provision of [the legislation] interferes in contract negotiations between plan sponsors/PBMs and pharmacies by mandating or proscribing outcomes on issues that would otherwise be bargained for." See Docket No. 33-1, p. 38.

PCMA's argument—that the non-interference clause creates a type of general field preemption of state regulation on PBM contracts—is unpersuasive. First, *Rutledge* did not decide the preliminary issue of whether the non-interference clause even applies to PBM-related regulation. By its plain terms, the clause prohibits interference between "drug manufactures and pharmacies and PDP sponsors." 42 U.S.C. § 1395w111(i)(1). And thus *Rutledge* did not hold, as PCMA suggests, that any and all state regulation of contract negotiations between pharmacies and PBMs is preempted by Medicare Part D. Rather than finding the non-interference clause creates a type of field preemption, *Rutledge*

explained: "The federal scheme preempts a state law when (1) Congress or [CMS] has established 'standards' in the area regulated by the state law; and (2) the state law acts 'with respect to' those standards." Rutledge, at 1113. *Rutledge* then went on to examine specific Medicare Part D standards and concluded the state laws at issue were preempted because they acted "with respect to" the Part D Standard. See Rutledge, at 1113-1114 (finding Arkansas laws regulating the price of retail drugs and allowing pharmacies to decline to dispense drugs were preempted by the Medicare Negotiated Price Standard and the Medicare Pharmacy Access Standard). Given the Eighth Circuit's recent analysis in *Rutledge,* the Court concludes Section 1395w111(i) does not bar states from all regulation of PBM contracts. Accordingly, as instructed by *Rutledge,* the Court will examine each provision of the legislation to determine (1) if Congress or CMS has established a standard in the area regulated; and (2) whether the state regulation acts with respect to those standards. Id. at 1113. The Court concludes all but one provision survive Medicare Part D analysis.

2. PROVISIONS CONCERNING THE PRACTICE OF PHARMACY

The legislation contains various provisions regulating the practice of pharmacy. It contains provisions: (1) allowing pharmacies to dispense any drug they are licensed to dispense; (2) allowing pharmacies to disclose pricing information to patients; and (3) allowing pharmacies to mail or deliver drugs to patients. As detailed below, the Court finds these provisions, which regulate the

practice of pharmacy in North Dakota, are not preempted by Medicare Part D. They do not act with respect to a Medicare standard, and even if they did, they regulate the practice of medicine and thus fall within the scope of the Medicare savings clause. See 42 U.S.C. § 1395 ("Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided").

i. PHARMACIES MAY DISPENSE ANY DRUG ALLOWED BY THEIR LICENSE

The legislation provides: "A licensed pharmacy or pharmacist may dispense any and all drugs allowed under that license." S.B. 2301 § 1(5). PCMA suggests this provision acts with respect to CMS's standards concerning formularies. PCMA argues: "[T]his provision would bar the use of formularies. A formulary is a list of drugs that a Part D plan covers. CMS extensively regulates the development and use of formularies. . . . Allowing North Dakota to ban formularies deliberately undermines CMS's contemplation, regulation, and approval of them." See Docket No. 33-1, p. 47. The Court disagrees. This provision allows pharmacies to dispense drugs in a manner consistent with their licenses. It has no bearing on whether a drug may be listed on a formulary, and it contains no language banning formularies or compelling Part D plans to cover any drugs. The Court finds PCMA's arguments unavailing.

ii. PHARMACY DISCLOSURE OBLIGATIONS

The legislation contains two provisions regarding pharmacy disclosure obligations. It first contains a provision concerning the disclosure of information regarding drug efficiency and cost:

> A pharmacy or pharmacist may provide relevant information to a patient if the patient is acquiring prescription drugs. This information may include the cost and clinical efficacy of a more affordable alternative drug if one is available. Gag orders of such a nature placed on a pharmacy or pharmacist are prohibited.

S.B. 2258 § 1(7). The legislation also contains a provision allowing pharmacies to disclose reimbursement amounts they receive:

> 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. 2258 § 1(5). In support of preemption, PCMA asserts CMS has developed standards concerning what information must be disclosed to plan beneficiaries. PCMA cites to various provisions identifying plan sponsors' disclosure obligations to beneficiaries. See Docket No. 40, p. 53; see also 42 U.S.C. § 1395w-104(a)(1) and (a)(2) (setting forth annual disclosure obligations plan sponsors must provide to plan enrollees); 42 U.S.C. § 1395w-104(k)

(plan sponsors must ensure pharmacies inform plan enrollees of "any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered part D drug under the plan"). However, North Dakota's law does not speak to *plan sponsor* disclosure obligations. Rather, it sets forth disclosure obligations for *pharmacies*. Thus, it does not overlap with the standards PCMA cites. Moreover, it falls squarely within the savings clause for regulations concerning the manner in which medical services are provided. See 42 U.S.C. § 1395.

iii. DRUG DELIVERY SERVICES

The legislation also authorizes pharmacies to mail or deliver drugs to patients: "A pharmacy or pharmacist may mail or deliver drugs to a patient as an ancillary service of a pharmacy." S.B. 2258 § 1(8). A related provision allows pharmacies to charge shipping and handling fees: "A pharmacy benefits manager or third-party payer may not prohibit a pharmacist or pharmacy from charging a shipping and handling fee to a patient requesting a prescription be mailed or delivered." S.B. 2258 § 1(9). In support of preemption, PCMA cites standards that "contemplate the existence of mail-order pharmacies that are distinct from retail pharmacies." See Docket No. 33-1, p. 44; see also 42 C.F.R. § 423.120(a)(1) (authorizing Part D sponsors to charge beneficiaries higher cost-sharing amounts for using retail pharmacies instead of mail-order pharmacies). PCMA also cites the definition of "dispensing fees," which includes "pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee." 42

C.F.R. § 423.100. Although the standards PCMA relies on might "contemplate the existence" of mail order pharmacies, they do not regulate mail order pharmacy services like North Dakota's law. Thus, there is no overlap between the legislation and the federal standards. And even if there was, the Court finds the legislation's provisions regarding drug delivery services constitutes a regulation concerning the manner in which medical services are provided under the Medicare savings clause. See 42 U.S.C. § 1395.

3. PROVISIONS REGARDING PHARMACY ACCREDITATION AND CREDENTIALING REQUIREMENTS

The legislation contains provisions concerning two areas of pharmacy accreditation and credentialing. First, it contains provisions prohibiting PBMs from imposing accreditation requirements that are stricter than state and federal law. Second, the legislation requires PBMs to utilize benchmarks set by an unbiased, nationally-recognized entity when evaluating pharmacy performance, and it regulates the fees PBMs may levy on pharmacies due to deficient performance. As detailed below, the Court finds none of these provisions overlap with a CMS standard. Further, to the extent any did, they would fall under the Medicare preemption provision's exception for state laws concerning licensing. See 42 U.S.C. § 1395w-26(b)(3) (Medicare standards supersede any state law or regulation "other than State licensing laws"); see also 42 U.S.C. § 1395w-112(g) (applying Part C's preemption provision to Part D).

i. IMPOSITION OF ACCREDITATION REQUIREMENTS

With respect to PBMs' imposition of accreditation requirements on pharmacies, the legislation provides:

> A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state.

S.B. 2258 § 1(11). The legislation also regulates the accreditation requirements pharmacies must satisfy to participate in PBM networks:

> A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or certification requirements to participate in a network which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state.

S.B. 2301 § 1(4).

In support of preemption, PCMA points to federal standards requiring Part D sponsors to have quality assurance arrangements that ensure cost-efficiency, avoid adverse drug interactions, and mitigate medication errors. See Docket No. 33-1, p. 40; see also 42 U.S.C. § 1395w-104(c); 42 C.F.R. § 423.153(c). PCMA asserts these standards go "above and beyond state pharmacy licensing" and that CMS has "reserved for itself the role of partnering with private industry to identify the optimum performance

measures." See Docket No. 33-1, p. 40. However, as explained below, the regulation of pharmacy practice standards has been left to the states, and CMS has not imposed any pharmacy accreditation standards. In fact, the same standard PCMA cites requires Part D sponsors to ensure pharmacies "comply with minimum standards for pharmacy practice as established by the States." 42 C.F.R. § 423.153(c)(1). CMS has explained in its commentary:

> It has been our longstanding policy to leave the establishment of pharmacy practice standards to the states, and we do not intend to change that now. We continue to believe pharmacy practice standards established by the states provide applicable minimum standards for all pharmacy practice standards, and § 423.153(c)(1) requires representation that network providers are required to comply with minimum standards for pharmacy practice as established by the states.

Medicare Policy and Technical Changes; Contract Year 2019, 82 Fed. Reg. 56,336-01, 56,411 (Nov. 28, 2017) (to be codified at 42 C.F.R. pts. 405, 417, 422, 423 and 498).

After seeking public comment on various proposed rules, CMS indicated it does not intend to regulate pharmacy accreditation standards:

> Several commenters provided that accreditation is best performed by an independent, third-party actor . . . . Several commenters believed that CMS should establish accreditation standards, and that CMS approval should be the only requirement

> for acceptance of accreditation . . . . Many commenters contended.
>
> [. . . .]
>
> While we did not propose specific accreditation standards, we will consider it in the future if we find that our current requirements are no longer sufficient . . . . While CMS appreciates the commenters' concerns that accreditation is best performed by an independent, third-party actor, we did not consider such a policy change in the proposed rule and would need to consider the issue further.

Medicare Policy and Technical Changes; Contract Year 2019, 83 Fed. Reg. 16,440-01, 16,597-598 (Apr. 16, 2018) (to be codified at 42 C.F.R. pts. 405, 417, 422, 423 and 498). In this same commentary, CMS specifically addressed a comment concerning North Dakota's accreditation provision:

> Comment: A commenter provided that North Dakota and New Hampshire have enacted laws prohibiting PBMs from requiring additional accreditation other than the requirement of the applicable state board of pharmacy. Another commenter offered that they have seen situations where state standards are insufficient, unenforced, or unmonitored.
>
> Response: CMS thanks the stakeholder for this information, and encourages commenters to keep us apprised of such examples. However, at present, we continue to believe state pharmacy practice acts represent a

> reasonably consistent minimum standard of practice.

Id. at 16,598. Although the Court owes no deference to CMS, the agency does have a unique understanding of the Medicare statutes, and the Court may consider its commentary. See Wyeth v. Levine, 555 U.S. 555, 576-77 (2009) (although agencies generally have no authority to pronounce on preemption, their unique understanding of the statutes they administer gives them an ability to make determinations about how state requirements may impact the federal regulatory scheme); see also Uhm, 620 F.3d at 1155. As CMS has explained, accreditation and licensing are areas of regulation that have been left to the states. Because CMS has not promulgated standards in this area, the Court finds North Dakota's legislation concerning pharmacy accreditation requirements is not preempted by Medicare Part D.

ii. PHARMACY PERFORMANCE BENCHMARKS

The legislation also requires PBMs to utilize benchmarks set by an unbiased, nationally-recognized entity when evaluating pharmacy performance, and it regulates the fees PBMs may levy on pharmacies due to their deficient performance. Section 1(3) of S.B. 2258 provides as follows:

> 3. Pharmacy performance measures or pay for performance pharmacy networks shall utilize the electronic quality improvement platform for plans and pharmacies or other

unbiased nationally recognized entity aiding in improving pharmacy performance measures.

a. A pharmacy benefits manager or third-party payer may not collect a fee from a pharmacy if the pharmacy's performance scores or metrics fall within the criteria identified by the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.

b. If a pharmacy benefits manager or third-party payer imposes a fee upon a pharmacy for scores or metrics or both scores and metrics that do not meet those established by the electronic quality improvement platform for plans and pharmacies or other nationally recognized entity aiding in improving pharmacy performance measures, a pharmacy benefits manager or third-party payer is limited to applying the fee to the professional dispensing fee outlined in the pharmacy contract.

c. A pharmacy benefits manager or third-party payer may not impose a fee relating to performance metrics on the cost of goods sold by a pharmacy.

S.B. 2258 § 1(3). PCMA argues this provision is preempted by the same federal standards cited above, which require Part D plan sponsors to have

quality assurance arrangements that ensure cost-efficiency, avoid adverse drug interactions, and mitigate medication errors. See Docket No. 33-1, pp. 39-41; see also 42 U.S.C. § 1395w-104(c); 42 C.F.R. § 423.153(c). The Court rejects this argument for the same reasons articulated above. CMS has not articulated pharmacy practice standards. Rather, Part D sponsors must take measures to ensure pharmacies "comply with minimum standards for pharmacy practice as established by the States." 42 C.F.R. § 423.153(c)(1). North Dakota's legislation sets a standard for pharmacy performance by articulating the benchmarks that may be used to measure pharmacy performance—i.e., the "electronic quality improvement platform for plans and pharmacies" or "other unbiased nationally recognized entity aiding in improving pharmacy performance measures." S.B. 2258 § 1(3). The Court concludes S.B. 2258 § 1(3) is not preempted.

4. PROVISIONS CONCERNING SELF-DEALING AND ABUSIVE PRACTICES

North Dakota's law contains various provision directed at perceived self-dealing and abusive practices on the part of PBMs. The legislation (1) prohibits PBMs from levying certain fees and charges on pharmacies and patients; (2) imposes disclosure obligations on PBMs; and (3) prohibits PBMs that own mail-order or specialty pharmacies from engaging in self-dealing. As articulated below, the Court finds the bulk of the law not preempted, save one provision requiring PBMs to disclose certain information to plans, which the Court finds

preempted by an overlapping Medicare Part D standard.

i. REGULATION OF FEES AND CHARGES

The legislation provides the following prohibitions on post point-of-sale fees:

> 2. A pharmacy benefits manager or third-party payer may not directly or indirectly charge or hold a pharmacy responsible for a fee related to a claim:
>
> a. That is not apparent at the time of claim processing;
>
> b. That is not reported on the remittance advice of an adjudicated claim; or
>
> c. After the initial claim is adjudicated at the point of sale.

S.B. 2258 § 1(2). PCMA argues CMS has enacted "intricate standards" concerning post point-of-sale fees. See Docket No. 40, p. 56. PCMA points to standards that contemplate post point-of-sale fees in reconciliation calculations used to determine the amounts Part D sponsors "actually pay" for prescription drugs.[2] See Docket No. 40, pp. 56-57; see

[2] PCMA explains the reconciliation process: "CMS requires sponsors and PBMs to report post point-of-sale fees to CMS by requiring them to report amounts 'actually paid' for the drugs and the [remuneration] a plan has received. . . . The amounts reported by plans and PBMs factor into payments by CMS. At the end of a contract year, through a reconciliation process, CMS makes final reinsurance and risk corridor payments to Part D sponsors based on the amounts 'actually paid' by the

e.g. 42 C.F.R. § 423.308 (defining "direct and indirect remuneration" to include retroactive fees). PCMA suggests North Dakota's law alters the Part D reconciliation scheme by "banning retroactive fees." See Docket No. 40, p. 57. PCMA argues the legislation "would nullify part of the standard concerning what makes up a negotiated price and would change the calculation of payments made by CMS to plans during the reconciliation process by removing retroactive fees from the equation." See Docket No. 40, p. 57. The Court finds PCMA's argument unpersuasive. The legislation regulates the imposition of fees levied on pharmacies that are related to claims for prescription drugs. It does not overlap with, nor does it alter, the calculations used in the reconciliation process. PCMA has not pointed to any federal standard concerning PBMs' imposition of fees on pharmacies. The Court finds S.B. 2258's provision regulating post point-of-sale fees is not preempted by Medicare Part D.

PCMA also argues the legislation's regulation of copayments is preempted. The legislation provides the following concerning copayments:

> A pharmacy benefits manager or third-party payer may not charge a patient a copayment that exceeds the cost of the medication. If a patient pays a copayment, the dispensing provider or pharmacy shall retain the adjudicated cost and the pharmacy benefits manager or third-party payer may not redact the adjudicated cost.

Part D sponsor for the provision of the Part D benefit." See Docket No. 40, pp. 56-57.

S.B. 2258 § 1(4). PCMA argues this provision overlaps with federal standards that set copayment amounts for certain drugs. See Docket No. 33-1, pp. 41-42; see also 42 C.F.R. § 423.104(d)(5)(i). PCMA suggests that retainment of copayments is "an entitlement that CMS has granted to plans." See Docket No. 33-1, p. 42. The Court disagrees. The standards PCMA cites may set copayment amounts, but they do not specify which entity is entitled to retain copayments as does North Dakota's law. PCMA also argues there are federal standards accounting for "direct and indirect remuneration" to plans after a prescription drug has been sold, which may include copayment amounts. See Docket No. 33-1, p. 42; see also 42 C.F.R. § 423.308. However, these standards, which account for various fees and payments, also do not mandate the allocation of certain payments to certain parties. The Court finds North Dakota's regulation of copayments is not preempted by Medicare Part D.

ii. DISCLOSURE OBLIGATIONS

The legislation contains two provisions concerning PBM disclosure obligations. The first provision requires PBMs to disclose information about PBM pharmacy networks to pharmacies. According to North Dakota, this provision was intended to help pharmacies evaluate the profitability of PBM contracts by providing pharmacies with information detailing the number of patients that would be subject to a PBM contract's reimbursement policies. See Docket No. 39-1, p. 10. The provision states:

> Upon request, a pharmacy benefits manager or third-party payer shall provide a pharmacy or pharmacist with the processor control number, bank identification number, and group number for each pharmacy network established or administered by a pharmacy benefits manager to enable the pharmacy to make an informed contracting decision.

S.B. 2258 § 1(10). The second disclosure provision obligates PBMs with an ownership interest in a pharmacy to disclose, to plan sponsors, the difference between the amount paid to a pharmacy and the amount charged to the plan sponsor. It states:

> If requested by a plan sponsor contracted payer, a pharmacy benefits manager or 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.

S.B. 2301 § 1(2).

In support of preemption, PCMA cites various federal standards discussing PBMs' disclosure obligations to beneficiaries, CMS, and plan sponsors. See Docket No. 33-1, pp. 42-43; see also 42 U.S.C. §§1395w-104(a)(1)-(2) (setting forth annual disclosure obligations plan sponsors must provide to plan enrollees); 42 U.S.C. §§1395w-104(k) (plan sponsors must ensure pharmacies inform plan enrollees of "any differential between the price of the drug to the enrollee and the price of the lowest priced

generic covered part D drug under the plan"); 42 U.S.C. § 1320b-23 (requiring PBMs to disclose information regarding drug sales and pricing to CMS); 42 C.F.R. § 423.514(d) (detailing reporting requirements for pharmacy benefits manager data to plan sponsors and CMS).

PCMA does not cite any federal standard, and the Court is not aware of any, that concerns the disclosure of information by PBMs to pharmacies. Because CMS has not promulgated standards in this area, the Court finds S.B. 2258 § 1(10), which requires the disclosure of PBM pharmacy network information to pharmacies, is not preempted by Medicare Part D. However, the Court agrees with PCMA regarding S.B. 2301's PBM disclosure obligations to plan sponsors. Federal standards specifically require PBMs to provide information to plan sponsors, including the number of prescriptions dispensed, the amount of rebates, discounts, or price concessions the PBM negotiates and passes through to the plan sponsor, and the difference between the amount the PBM pays the pharmacy and the plan sponsor. See 42 C.F.R. § 423.514(d); 42 U.S.C. § 1320b-23. Senate Bill 2301 § 1(2), which requires certain PBMs to report to plan sponsors "any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor" overlaps with this standard, and thus the Court finds it is preempted as applied to Medicare Part D plans.[3]

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[3] The Court's holding does not invalidate the remainder of the legislation. North Dakota has enacted a broad severability clause. When a court finds any portion of a law invalid, "such judgment does not affect, impair, nor invalidate any other clause, sentence, paragraph, chapter, section or part . . . ."

iii. PBM SELF DEALING

The legislation also contains a provision aimed at potential self-dealing on the part of PBMs that own pharmacies. It states:

> A pharmacy benefits manager or a pharmacy benefits manager's affiliates or subsidiaries may not own or have an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the pharmacy benefit manager, affiliate, or subsidiary agrees to not participate in a transaction that benefits the pharmacy benefits manager, affiliate, or subsidiary instead of another person owed a fiduciary duty.

S.B. 2301 § 1(3). In support of preemption, PCMA cites 42 C.F.R. § 423.501, which defines "related entity" as any entity that is related to a PDP sponsor by common ownership or control and performs some of a plan's management functions, furnishes services to a plan enrollee, or leases or sells property to a plan. See Docket No. 33-1, p. 45. PCMA also points to a study and CMS manuals and publications that address potential conflicts of interest in the dispensing of prescription drugs. See Docket No. 33-1, pp. 46-48. PCMA argues: "CMS and North Dakota address the same problem but chose a different means to protect against it. As such, [S.B. 2301 § 1(3)] is preempted because CMS and North Dakota regulate the same conduct." See Docket No. 40, p. 60.

N.D.C.C. § 1-02-20. The parties do not dispute the validity or applicability of North Dakota's severability clause.

However, the manuals, publication, and study CMS cites are not standards. "[A] standard is a statutory provision or a regulation promulgated under [Medicare] and published in the Code of Federal Regulations." New York City Health and Hospitals Corp., 801 F. Supp. 2d at 140 (quoting Med Card Sys., Inc., 587 F. Supp. 2d at 387); see also Uhm, 620 F.3d 1148 n. 20. The one standard PCMA cites simply defines the term "related entity." See 42 C.F.R. § 423.501. This definitional provision does not regulate PBM conflicts of interest in any way. Because the legislation's provision concerning PBM self-dealing does not overlap with a Medicare Part D standard, the Court finds it is not preempted.

III. CONCLUSION

The Court has carefully reviewed the entire record, the parties' filings, and the relevant law. For the reasons set forth above, the Plaintiff's motion for summary judgment (Docket No. 33) is **GRANTED IN PART AND DENIED IN PART.** The Defendants' cross-motion for summary judgment (Docket No. 38) is also **GRANTED IN PART AND DENIED IN PART.**

IT IS SO ORDERED

Dated this 5th day of September, 2018.

/s/ Daniel L. Hovland
Daniel L. Hovland, Chief Judge
United States District Court

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTH DAKOTA

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.	**ORDER DENYING PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION** Case No.: 1:17-cv-141

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 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, 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] See 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 following provisions[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

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[1] On 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 and 19-02.1-16.1. 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 and 19-02.1-16.1, respectively.

[2] These 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.

based on pharmacy performance standards.

- S.B. 2258 § 1(4) bars PBMs and third-party payers from "redact[ing] 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 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 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, 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.,* and Medicare Prescription Drug Improvement and Modernization Act of 2003 ("Medicare Part D"), 42 U.S.C. § 1395w-101 *et seq*. 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. Rule 65(b) 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), in determining whether a preliminary injunction should be granted. The *Dataphase* factors include: "(1) 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.

Preliminary injunctive relief is an "extraordinary and drastic remedy." Munaf v. Geren, 553 U.S. 674, 689-90 (2008). 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). 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). "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.

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 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). 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).

"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 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). 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). 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 (1997).

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 (1995) ("we have never assumed lightly that Congress has derogated state regulation, but instead have addressed claims of pre-emption with the starting presumption that 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 (1997).

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) (emphasis added). "Yet, Congress did not define what it meant by state laws that 'relate to' an ERISA benefit plan anywhere in the statute." Prudential, 154 F.3d 812, 819 (8th Cir. 1998). 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) 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 (1983).

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). 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). 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).

PCMA asserts it is likely to prevail on its claim against the Defendants because controlling precedent in 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). 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. 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. 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. The case was remanded, directing the district court to enter judgment in favor of PCMA on the issue of express preemption. Id. at 732. 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]

Preemption claims turn on congressional intent. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 515-19 (1992). "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 (1990).

> **[When] Congress has expressly 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, as set forth in 29 U.S.C. § 1144(a), **Congress provided:**
>
> > Except as provided in subsection (b) of this section, the provisions

[3] The 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. 852 F.3d at 729 (8th Cir. 2017). 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.

> 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) of this title and not exempt under section 1003(b) of this title.

Ingersoll-Rand, 498 U.S. at 138 (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]; (2) specifically exempted ERISA plans from an otherwise generally 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) (internal citations and quotations omitted). An

[4] The 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 . . . .

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 (2016) (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. 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) and 19-02.1-16.1(1)(a). "Pharmacy benefits manager" is defined as:

> "Pharmacy benefits manger" means a person that performs pharmacy benefits management and includes any other person 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) (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). 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 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] The standard set by the Supreme Court

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[5] In 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. (emphasis added).

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.

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 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. 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. 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). "Third party

payer" is defined as "an organization other than the patient or health care provider involved in the financing of personal health services." N.D.C.C. § 19-03.6-01(6). 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, 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.

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. 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). 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).

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 "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 (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.

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 to ERISA. First, neither S.B. 2258 and 2301 "impose requirements by reference to ERISA covered programs." See Dillingham, 519 U.S. at 324.

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) (emphasis added). The employer and the employee organization are both distinct 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 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 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] both of which are separate and distinct entities and distinguishable from an employee benefit plan. Section 514(a) of 29 U.S.C. § 1144(a) 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 (1988). 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. See Ingersoll-Rand, 498 U.S. at 140. The Court finds that neither 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."

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[6] See N.D.C.C. 19-03.6-01(5) ("'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.

Dillingham, 519 U.S. at 325. 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; Dillingham, 519 U.S. at 325; see also Travelers, 514 U.S. at 656 (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 (1990).

"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 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). 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. 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. "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.'" Gerhart, 852 F.3d at 730 (quoting Fort Halifax Packing Co. Inc., v. Coyne, 482 U.S. 1, 9 (1987)). 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 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. 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[7]; Dillingham, 519 U.S. 316, 329 (1997)[8]; Travelers, 514 U.S. 645, 649 (1995)[9].

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[7] ERISA'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 (1997)

[8] California wage law did not "relate to" employee benefit plans and thus is not preempted by ERISA. See Dillingham, 519 U.S. 316 (1997).

[9] New York law requiring hospitals to collect surcharges from patients covered by a commercial insurer but not by Blue

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] 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. 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

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Cross/Blue Shield plan did not "relate to" employee benefit plans and are not preempted by ERISA. See Travelers, 514 U.S. 645 (1995).

[10] Currently, 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.

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 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 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. 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's Savings Clause

Neither party in this case argues the applicability of ERISA's so-called "savings" clause. "While § 514(a)

of ERISA 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 (1985). "The insurance saving clause preserves any state law 'which regulates insurance, banking, or securities.'" Id. at 739-40. While neither party has raised this argument, 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. 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.

The Supreme Court noted that the focus of the statutory term under the McCarran-Ferguson Act was "the relationship between the insurance company and the policyholder." Metropolitan Life, 471 U.S. at 744. "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 that industry." Pilot Life Ins. Co. v. Dedeaux, 481 U.S. 41, 50-51 (1987) (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.").

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. Pilot Life Ins., 481 U.S. at 48. 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.

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. Both S.B. 2258 and S.B. 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]

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 (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 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 ("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

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[11] See N.D. Leg. Assemb., Bill Videos for S.B. 2301, http://www.legisl.nd.gov/assembly,65-2017/billvideo/bv2301.html.

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. 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. 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 and the insured, because the Washington act "confers a benefit on insureds by expanding the treatments that their health carriers must provide or pay for." Gregorie, 147 F.3d at 1046-47. 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). PCMA has not shown that such intervention is warranted under the circumstances. Preliminary injunctive relief is an "extraordinary and drastic remedy." Munaf, 553 U.S. 674, 689-90 (2008). 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). 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 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). 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 losses can be recovered." See id.; DISH Network Service L.L.C. v. Laducer, 725 F.3d 877, 882 (8th Cir. 2013). "[T]he absence of irreparable injury is by itself sufficient to defeat a motion for a preliminary injunction." DISH, 725 F.3d at 882.

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 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* factor weighs in favor of the Defendants.

3. Balance of the 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). However, in the interest of a thorough and meaningful review, the Court next factors the balance between the 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). 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; Glenwood Bridge, Inc. v. City of Minneapolis, 940 F.2d 367, 372 (8th Cir. 1991).

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 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, 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 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] Both S.B. 2258 and

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[12] Most 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 WL 4386774, No. 2:11-cv-4211 (D.N.J. Sept. 19, 2011). 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

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* 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 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

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WL 1141093 (April 2, 2012). 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.

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 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 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 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) (incorporating Part C's preemption

provision, 42 U.S.C. § 1395w-112(g)) (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). 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. But ultimately, 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 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). "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).

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] 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). CMS has instructed that "[t]o the extent

[13] The Centers for Medicare & Medicare Services (CMS) is part of the national Department of Health and Human Services.

[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 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 (2008). 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 them is not within a court's purview. See Hopper v. Berryhill, 2017 WL 4236974 *15 (D.E.D. Mo. Sept. 25, 2017) ("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) ("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) (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) ("[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 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). 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 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 because its injuries cannot be fully compensated through an award of damages." General Motors Corp., 563 F.3d at 319. 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.

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 the 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. 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; Glenwood Bridge, Inc., 940 F.2d at 372.

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 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 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. As a result, the party seeking relief bears the burden of establishing its propriety with "clear proof." Frejlach, 573 F.2d at 1027. 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* factors, and finds that the Plaintiff has not met its burden for establishing the necessity of a preliminary injunction. 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

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No: 18-2926

Pharmaceutical Care Management Association

Appellant

v.

Mylynn Tufte, in her official capacity as the State Health Officer of North Dakota, et al.

Appellees

Appeal from U.S. District Court for the District of North Dakota – Bismarck
(1:17-cv-00141-DLH)

ORDER

The petition for rehearing en banc is denied. The petition for rehearing by the panel is also denied.

Judge Colloton and Judge Erickson did not participate in the consideration or decision of this matter.

September 02, 2020

Order Entered at the Direction of the Court:
Clerk, U.S. Court of Appeals, Eighth Circuit.

/s/ Michael E. Gans

N.D. Cent. Code § 19-02.1-16.1

19-02.1-16.1. Pharmacy claim fees and pharmacy rights - Pharmacy benefits managers - Penalty.

1. As used in this section:
   a. "Pharmacy benefits manager" has the same meaning as in section 19-03.6-01.
   b. "Plan sponsor" has the same meaning as in section 19-03.6-01.
   c. "Third-party payer" has the same meaning as in section 19-03.6-01.
2. A pharmacy benefits manager or third-party payer may not directly or indirectly charge or hold a pharmacy responsible for a fee related to a claim:
   a. That is not apparent at the time of claim processing;
   b. That is not reported on the remittance advice of an adjudicated claim; or
   c. After the initial claim is adjudicated at the point of sale.
3. Pharmacy performance measures or pay for performance pharmacy networks shall utilize the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.
   a. A pharmacy benefits manager or third-party payer may not collect a fee from a pharmacy if the pharmacy's performance scores or metrics

fall within the criteria identified by the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.

b. If a pharmacy benefits manager or third-party payer imposes a fee upon a pharmacy for scores or metrics or both scores and metrics that do not meet those established by the electronic quality improvement platform for plans and pharmacies or other nationally recognized entity aiding in improving pharmacy performance measures, a pharmacy benefits manager or third-party payer is limited to applying the fee to the professional dispensing fee outlined in the pharmacy contract.

c. A pharmacy benefits manager or third-party payer may not impose a fee relating to performance metrics on the cost of goods sold by a pharmacy.

4. A pharmacy benefits manager or third-party payer may not charge a patient a copayment that exceeds the cost of the medication. If a patient pays a copayment, the dispensing provider or pharmacy shall retain the adjudicated cost and the pharmacy benefits manager or third-party payer may not redact the adjudicated cost.

5. 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 [Pub. L. 104-191; 110 Stat. 1936; 29 U.S.C. 1181 et seq.].

6. A pharmacist or pharmacy that belongs to a pharmacy service administration organization may receive a copy of a contract the pharmacy service administration organization entered with a pharmacy benefits manager or third-party payer on the pharmacy's or pharmacist's behalf.

7. A pharmacy or pharmacist may provide relevant information to a patient if the patient is acquiring prescription drugs. This information may include the cost and clinical efficacy of a more affordable alternative drug if one is available. Gag orders of such a nature placed on a pharmacy or pharmacist are prohibited.

8. A pharmacy or pharmacist may mail or deliver drugs to a patient as an ancillary service of a pharmacy.

9. A pharmacy benefits manager or third-party payer may not prohibit a pharmacist or pharmacy from charging a shipping and handling fee to a patient requesting a prescription be mailed or delivered.

10. Upon request, a pharmacy benefits manager or third-party payer shall provide a pharmacy or pharmacist with the processor control number, bank identification number, and group number for each pharmacy network established or administered by a pharmacy benefits manager to enable the pharmacy to make an informed contracting decision.

11. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state.

12. A pharmacy benefits manager or other third-party payer that violates this section is guilty of a class B misdemeanor per violation occurrence.

N.D. Cent. Code § 19-02.1-16.2

19-02.1-16.2. Specialty pharmacy services and patient access to pharmaceuticals - Pharmacy benefits managers - Penalty.

1. As used in this section:

   a. "Pharmacy benefits manager" has the same meaning as in section 19-03.6-01.

   b. "Plan sponsor" has the same meaning as in section 19-03.6-01.

   c. "Specialty drug" means a prescription drug that:

      (1) Is not available for order or purchase by a retail community pharmacy and long-term care pharmacy, regardless of whether the drug is meant to be self-administered; and

      (2) Requires special storage and has distribution or inventory limitations not available at a retail community pharmacy or long-term care pharmacy.

   d. "Third-party payer" has the same meaning as in section 19-03.6-01.

2. If requested by a plan sponsor contracted payer, a pharmacy benefits manager or 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.

3. A pharmacy benefits manager or a pharmacy benefits manager's affiliates or subsidiaries may not own or have an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the pharmacy benefits manager, affiliate, or subsidiary agrees to not participate in a transaction that benefits the pharmacy benefits manager, affiliate, or subsidiary instead of another person owed a fiduciary duty.

4. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements to participate in a network which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state.

5. A licensed pharmacy or pharmacist may dispense any and all drugs allowed under that license.

6. A pharmacy benefits manager or other third-party payer that violates this section is guilty of a class B misdemeanor for each violation occurrence.

N.D. Cent. Code § 19-03.6-01

19-03.6-01. Definitions.

For the purposes of this chapter:

1. "Entity" means a managed care company, an insurance company, a third-party payer, a pharmacy benefits manager, or any other organization that represents an insurance company, a third-party payer, or a pharmacy benefits manager.
2. "Insurance company" includes any corporation, association, benefit society, exchange, partnership, or individual engaged as principal in the business of insurance.
3. "Managed care company" is an entity that handles both health care and health care financing.
4. "Pharmacy benefits manager" means a person that performs pharmacy benefits management and includes any other person 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.
5. "Plan sponsor" means 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, an association, joint board of trustees, committee, or

other similar group that establishes or maintains the plan.

6. "Third-party payer" means an organization other than the patient or health care provider involved in the financing of personal health services.