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

PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION, Plaintiff, vs. NICK GERHART, in his official capacity as INSURANCE COMISSIONER OF THE STATE OF IOWA, and THOMAS J. MILLER, in his official capacity as ATTORNEY GENERAL OF THE STATE OF IOWA, Defendants.	No. 4:14-cv-000345 **ORDER**

This matter comes before the Court pursuant to Defendants' June 11, 2015, motion to dismiss pursuant to Federal Rules of Civil Procedure 12(b)(6) and 12(b)(1). Plaintiff responded to this motion first by filing a motion to strike Defendants' 12(b)(6) motion as procedurally improper, which the Court denied on July 30, 2015. Plaintiff then replied to Defendants' motion to dismiss for failure to state a claim on August 14, 2015. Defendants filed their reply brief on September 2, 2015. In their motion to dismiss, Defendants first claim that the Court lacks jurisdiction to hear Plaintiff's vagueness claim. Defendants then argue that Plaintiff's claims fail to state a claim upon which relief can be granted. Plaintiff responds that it has adequately pleaded its remaining claims and that this Court should certify questions to the Iowa Supreme Court before proceeding further.

Plaintiff's claims challenge the constitutionality of Iowa House File 2297 ("HF 2297"), codified at Iowa Code § 510B.8,[1] a law regulating pharmacy benefits managers. Plaintiff claims § 510B.8 violates the United States Constitution's dormant Commerce Clause and that § 510B.8 is unconstitutionally vague. This Court has previously dismissed Plaintiff's claims that § 510B.8 is preempted by the Employee Retirement Income Security Act and that § 510B.8 violates the Takings Clauses of both the United States and the Iowa Constitution. Defendants ask the Court to dismiss Plaintiff's remaining dormant Commerce Clause and Vagueness claims.

[1] The Court uses "§ 510B.8" and "HF 2297" interchangeably for purposes of this order. The portion of HF 2297 that was codified at § 510B.1(6) simply defines "maximum reimbursement amount" and is not at issue here.

I. BACKGROUND

Many Iowa residents receive prescription drug benefits through health plans. Health plans often provide plan participants with prescription drugs through contracts with pharmacy benefits managers ("PBMs"). PBMs are third-party administrators who administer the plans' prescription drug benefits. In so doing, PBM's maintain retail pharmacy networks and negotiate discounts from network pharmacies for prescription drugs and pharmacy services. PBMs' contracts with these pharmacies include agreements about the maximum amount that the PBM will reimburse a pharmacy for distributed name-brand and generic drugs. PBMs use what is called maximum allowable cost ("MAC") methodology to determine the amount they will reimburse pharmacies for their sale of certain generic drugs. Each PBM develops and maintains its own MAC pricing lists, using its own methodology. Pharmacies complain that MAC reimbursements can be so low that pharmacies are forced to sell drugs at a loss or refuse to dispense certain drugs altogether.

On July 1, 2014, HF 2297 went into effect in Iowa. HF 2297 has been codified at Iowa Code §§ 510B.1(6) and 510B.8. HF 2297 regulates PBMs by overseeing PBMs' use of MAC methodology. HF 2297, as codified at § 510B.8, requires PBMs to submit certain information to the Iowa Insurance Commissioner upon the Commissioner's request, and requires PBMs to utilize nationally recognized data when setting maximum reimbursement amounts for certain prescription drugs. Section 510B.8 also requires PBMs to disclose the data they use in calculating their reimbursement amounts in any contracts with Iowa pharmacies and give contracting pharmacies a chance to contest the reimbursement amount.

II. ANALYSIS

Defendants move to dismiss amended Counts V and VI[2] for failure to state a claim upon which relief can be granted under Federal Rule of Civil Procedure 12(b)(6). Federal Rule of Civil Procedure 8 requires that a complaint present "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *Braden v. Wal-Mart Stores, Inc.*, 588 F.3d 585, 594 (8th Cir. 2009). To survive a 12(b)(6) motion to dismiss, "[a] complaint must contain sufficient factual matter,

[2] The Court dismissed four of Plaintiff's claims, including Plaintiff's ERISA preemption claims, in February, 2015. [Dkt. 56]. At that time, the Court dismissed all of Plaintiff's claims except for the dormant Commerce Clause claim that is the subject of this motion. Thereafter, Plaintiff was allowed to amend its complaint, at which time it added its Vagueness claim, also the subject of this motion, as Count VI. Therefore, taken together, this order and the Court's February 18, 2015 order address all of Plaintiff's claims. All citations to Plaintiff's claims contained herein refer to the claims contained in Plaintiff's First Amended Complaint ("FAC").

accepted as true, to 'state a claim to relief that is plausible on its face.'" *Braden*, 558 F.3d at 594 (*citing Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Twombly*, 550 U.S. at 570. The claim "may be supported by showing any set of facts consistent with the allegations in the complaint." *Twombly*, 550 U.S. at 563. The complaint must "be grounded in enough of a factual basis to move the claim from the realm of mere possibility to one that shows entitlement by presenting a 'claim to relief that is plausible on its face.'" *Iqbal*, 556 U.S. at 678 (*quoting Twombly*, 550 U.S. at 570). While not a "probability standard," the "plausibility standard requires a plaintiff to show at the pleading stage that success on the merits is more than a 'sheer possibility.'" *Id.*

Furthermore, while a court must accept specific factual allegations as true on a motion to dismiss, it is not required to accept legal conclusions. *Twombly*, 550 U.S. at 570 (noting the Court is "not bound to accept as true a legal conclusion couched as a factual allegation"). Plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id.* at 555. When analyzing the adequacy of a complaint's allegations under Rule 8, the Court must accept as true all of the complaint's factual allegations. *Id.* at 555–56. "All complaints must be read liberally; dismissal on the pleadings never is warranted unless the plaintiff's allegations are doomed to fail under any available legal theory." *Amron v. Morgan Stanley Inv. Advisors, Inc.*, 464 F.3d 338, 343 (2d Cir. 2006) (*citing Phillips v. Girdich*, 408 F.3d 124, 128 (2d Cir. 2005)).

A. Plaintiff's Dormant Commerce Clause Claim

Defendants first argue that Plaintiff's dormant Commerce Clause claim, First Amended Complaint ("FAC") Count V, should be dismissed for failure to state a claim pursuant to Federal Rule of Civil Procedure 12(b)(6). The United States Constitution's Commerce Clause provides that "Congress shall have the power . . . [t]o regulate Commerce . . . among the several states." U.S. CONST. ART. I § 8, cl. 3. "This clause of the Constitution is also understood to have a negative or dormant application which 'denies the States the power unjustifiably to discriminate against or burden the interstate flow of articles of commerce.'" *Poor Richard's Inc. v. Ramsey Cnty., Minn.*, 922 F. Supp. 1387, 1394 (D. Minn. 1996) (*quoting Oregon Waste Sys., Inc. v. Dep't of Envtl. Quality of Oregon*, 511 U.S. 93, (1994)). Therefore, "the dormant Commerce Clause prohibits certain state regulation even when Congress has failed to legislate on the subject." *Hampton Feedlot, Inc. v. Nixon*, 249 F.3d 814, 818 (8th Cir. 2001) (citation omitted). When a law "overtly discriminates against interstate commerce," the Court "will strike the law unless the state or

locality can demonstrate, 'under rigorous scrutiny, that it has no other means to advance a legitimate local interest.'" *Id.* (*citing U & I Sanitation v. City of Columbus*, 205 F.3d 1063, 1067 (8th Cir. 2000)). When "a law does not overtly discriminate against interstate commerce, the law will be stricken if the burden it imposes upon interstate commerce is 'clearly excessive in relation to the putative local benefits,'" even if that impact is only incidental. *Id.* 249 F.3d at 818 (*citing U & I Sanitation*, 205 F.3d at 1067); *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 471 (1981) (*citing Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970)).

Here, Plaintiff does not contend that § 510B.8 overtly discriminates against interstate commerce, but instead alleges that § 510B.8 imposes an undue burden on interstate commerce. Therefore, the Court must "balance[] the statute's burden on interstate commerce against the statute's putative local benefits." *Hampton Feedlot, Inc.*, 249 F.3d at 819. In balancing these interests, the Court takes into account the nature of the state's interest and if there is a less burdensome alternative. *See Clover Leaf Creamery Co*., 449 U.S. at 471 (citation omitted) ("[T]he extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities."). In balancing these interests at the motion to dismiss stage, the Court takes Plaintiff's factual allegations as true.

Plaintiff argues that § 510B.8(1)'s disclosure requirement burdens interstate commerce by requiring PBM's to disclose their MAC pricing methodology without any protection against disclosure to third parties. *See* FAC P. 27 [Dkt. 97]. Plaintiff argues that because MAC pricing is important to competition between PBMs, lack of protection for this disclosure burdens interstate commerce by generating anticompetitive effects. Plaintiff further argues that § 510B.8(2)'s limitation on the use of MAC pricing in some circumstances burdens interstate commerce by forcing PBMs to develop MAC lists unique to the state of Iowa. Plaintiff argues that creating a separate pricing mechanism in some circumstances for some Iowa transactions "drastically increas[es] the costs of doing business in Iowa and eventually [will raise] generic drug prices for health plans and their participants nationwide." FAC P. 28 [Dkt. 97].

Plaintiff argues that the State has no legitimate interest in requiring PBMs to disclose their pricing methodology without protection or in restricting PBM's use of MAC pricing. Defendants argue that, on the contrary, § 510B.8 benefits Iowans by protecting them from unfair trade practices and helping pharmacies in rural areas stay in business. Defendants argue that § 510B.8's purpose

is to "protect the health and welfare of Iowans," and that such a purpose is a legitimate state interest. Deft. Brief P. 9 [Dkt. 99].

Here, the Court cannot say that § 510B.8 advances no legitimate state interest. Section 510B.8 by its terms regulates PBMs, which are entities that are heavily involved in the administration of healthcare to Iowans. Plaintiff cited the House of Representatives meeting at which proposed HF 2297 was discussed as the source of § 510B.8's purpose. FAC P. 16 [Dkt. 96]. In that hearing, one Iowa legislator explained that HF 2297's creation was spurred by unregulated PBMs who have engaged in "unfair business practices that hurt community pharmacies and their patients." Another legislator noted that lack of regulation was "eroding local pharmacies." Legislators remarked that HF 2297's goal was to increase transparency. *See* Video Remarks, *available at* http://coolice.legis.iowa.gov/Cool-ICE/default.asp?Category=Billinfo&Service=ArchiveBill&vid=934&offset=6646&iDate=2014-03-04&hbill=HF2297, 1:50:00–1:57:30. The State has a legitimate interest in regulating and preserving the health of its citizens. *See Great Atl. & Pac. Tea Co., Inc. v. Cottrell*, 424 U.S. 366, 371 (1976) ("It is no less true, of course, that under our constitutional scheme the States retain 'broad power' to legislate protection for their citizens in matters of local concern such as public health…and that not every exercise of local power is invalid merely because it affects in some way the flow of commerce between the States." citations omitted)). Furthermore, the dormant Commerce Clause balancing analysis established in *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970), takes into account the *putative* benefits of the challenged statute. *Pike*, 397 U.S. at 142 (citation omitted). "It matters not whether these benefits actually come into being at the end of the day." *Pharmaceutical Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 313 (1st Cir. 2005). Section 510B.8 has putative benefits such that the State is not without a legitimate interest in promoting the statute.

Assuming the harms Plaintiff alleges would be caused by § 510B.8 are true, Plaintiff has not pleaded facts sufficient to establish that § 510B.8's harms are "clearly excessive in relation to the putative local benefits.'" *Clover Leaf Creamery Co.*, 449 U.S. at 471 (*citing Pike*, 397 U.S. at 142). Plaintiff's bare assertion that § 510B.8 will eventually raise drug prices nationwide does not advance beyond a "label," "conclusion," or "formulaic recitation" of that which has previously been held to constitute a dormant Commerce Clause violation. *See Hampton Feedlot, Inc.*, 249 F.3d at 819 (distinguishing cases where statutes necessarily require out of state commerce to be conducted according to one State's terms in the context of determining whether a statute

discriminates against interstate commerce). Furthermore, any burden placed on Plaintiff's member PBMs by allegedly being forced to disclose secret MAC pricing formulas is mitigated by the recent passage of House File 395 ("HF 395"), to be codified at 510B.3(1D). HF 395 clarifies that:

> When the commissioner conducts . . . an examination, audit, or inspection under chapter 510, all information received from the pharmacy benefits manager, and all notes, work papers, or other documents related to the examination, investigation, audit, or inspection of the pharmacy benefits manager are confidential records under chapter 22 and shall be accorded the same confidentiality as notes, work papers, investigatory materials, or other documents related to the examination of an insurer as provided in chapter 507.

HF 395 (*to be codified at* IOWA CODE § 510B.3(1)) (*available at* http://coolice.legis.iowa.gov/Cool-ICE/default.asp?Category=billinfo&Service=Billbook&frame=1&GA=86&hbill=HF395).[3]

On the other side of the equation, the State has an established interested in protecting and promoting the health of its citizens. *See, e.g., Great Atl.*, 424 U.S. at 371; *R & M Oil & Supply, Inc. v. Saunders*, 307 F.3d 731, 737 (8th Cir. 2002) ("State statutes passed for the protection of the public's health and safety are generally constitutional despite the incidental burden they may impose on interstate commerce."). While § 510B.8 may indirectly burden interstate commerce by requiring PBMs to modify their practices within the State of Iowa in a way they may not be required to do elsewhere, "not every exercise of local power is invalid merely because it affects in some way the flow of commerce between the States." *Great Atlantic*, 424 U.S. at 371. Whatever burden HF 2297 imposes on interstate commerce is not sufficiently significant to declare the law unconstitutional. *See Pike*, 397 U.S. at 145 (finding law unconstitutional when "the nature of [the] burden is, constitutionally, more significant than" the State's interest in promoting its reputation for producing high quality cantaloupes). Because the Plaintiff has failed to plead facts supporting a plausible claim that § 510B.8's incidental burden on interstate commerce exceed the State's interest in regulating the distribution of prescription drugs, Defendants' motion to dismiss Plaintiff's dormant Commerce Clause claim is granted.

B. Plaintiff's Vagueness Claim

Defendants also argue that the Court should dismiss Plaintiff's Count VI. Defendants first assert that the Court lacks jurisdiction to consider Count VI because Plaintiff has failed to exhaust

[3] Plaintiff disputes whether this applies to Chapter 510B. However, Plaintiff agrees that the same act (HF 395) does apply to Chapter 510B in terms of its enforcement provisions, as discussed below. Furthermore, the fact that HF 395 is codified at § 510B.3 seems to imply that it relates to Chapter 510B. However, even if these protections did not cover Plaintiff's required disclosures pursuant to § 510B.8, the burdens allegedly imposed by § 510B.8 would still not sufficiently outweigh the putative benefits.

administrative remedies and therefore Count VI should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1). Defendants further argue that, even if the Court has jurisdiction to consider Count VI, Count VI should be dismissed pursuant to Federal Rule 12(b)(6) for failure to state a claim upon which relief can be granted.

i. The Court's Jurisdiction and Ripeness

Defendants first argue that the Court does not have jurisdiction to hear Plaintiff's Count VI pursuant to Federal Rule of Civil Procedure 12(b)(1) because Plaintiff has failed to exhaust administrative remedies and because Plaintiff's claim is not ripe. Plaintiff alleges §§ 510B.8(2) and (3) are so vague as to lack any standard at all, and therefore violate the United States Constitution's Fourteenth Amendment Due Process Clause. FAC PP. 28–29. Defendants argue that because Plaintiff's vagueness claim sounds in procedural due process, Plaintiff must exhaust State administrative remedies before the Court has jurisdiction to hear this claim. Plaintiff responds that Defendants overstate the relationship between void-for-vagueness claims and procedural due process, and, to the extent that the two are related, administrative exhaustion requirements that may apply to other procedural due process claims do not apply to void-for-vagueness claims.

Defendants fail to cite any cases in which a court has required a plaintiff to exhaust administrative remedies before pursuing a vagueness claim. Furthermore, courts have addressed facial void-for-vagueness challenges prior to enforcement and without any further clarification through provided administrative procedure. *See, e.g.*, *Vill. of Hoffman Estates v. The Flip Side, Hoffman Estates, Inc.*, 455 U.S. 489, 491, 493 (1982) (explaining that the "case presents a pre-enforcement facial challenge to a drug paraphernalia ordinance on the ground that it is unconstitutionally vague and overbroad," and that "instead of applying for a license or seeking clarification via the administrative procedures that the village had established for its licensing ordinances," the defendant filed the lawsuit at issue before upholding the challenged statute); *Garner v. White*, 726 F.2d 1274, 1276 (8th Cir. 1984) (addressing a pre-enforcement facial challenge "principally alleging that [an act] was unconstitutionally vague and overbroad"). Therefore, the Court finds that Plaintiff was not required to ask the State to clarify the law before bringing this claim and the Court has jurisdiction to hear Plaintiff's void-for-vagueness claim.

Defendants further argue that the Court cannot entertain Plaintiff's Count VI because it is not ripe. "The ripeness doctrine is 'drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction.'" *Nat'l Park Hospitality Ass'n v.*

Dept. of Interior, 538 U.S. 803, 808 (2003) (*quoting Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43, 57 n. 18 (1993)). Ripeness requires that "before a federal court may address itself to a question, there must exist a 'real, substantial controversy between parties having adverse legal interests, a dispute definite and concrete, not hypothetical or abstract.'" *Neb. Public Power Dist. v. MidAmerican Energy Co.*, 234 F.3d 1032, 1037–38 (8th Cir. 2000) (*quoting Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). "Parties may not simply submit questions of general interest or curiosity to the federal court." *Nebraska Pub. Power Dist.*, 234 F.3d at 1038. "[T]he question of ripeness turns on 'the fitness of the issues for judicial decision' and 'the hardship to the parties of withholding court consideration.'" *Pac. Gas and Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 201 (1983) (*quoting Abbott Labs. v. Gardner*, 387 U.S. 136, 148–49 (1967)).

Here, Plaintiff's claim is ripe for review. Plaintiff's claim is fit for judicial decision and it will benefit both parties to adjudicate the issue sooner rather than later. Both parties agree that Plaintiff is presently obligated to comply with § 510B.8, and has been required to do so since HF 2297 became law. Both Plaintiff and Defendants indicate that Plaintiff has already modified its MAC pricing practices in response to HF 2297 to at least some extent. *See* FAC ¶ 21, Def. Brief P. 8 [Dkt. 99] ("In fact, at least some PCMA members have already changed their business practices to comply [with HF 2297, codified at § 510B.8]."). Furthermore, Plaintiff argues that Plaintiff's member PBMs have already been presented with warrants demanding examination of proprietary information. *See* FAC P. 47. The parties have adverse legal interests that became concrete when Plaintiff's members were forced to modify their practices to comply with § 510B.8.

The Court holds without deciding that Plaintiff's vagueness claim is ripe and that the Court has jurisdiction to decide Plaintiff's vagueness claim on the merits. Ultimately, these issues are not determinative because the Court dismisses Plaintiff's vagueness claim on the merits, as discussed below.

ii. Vagueness Analysis

"The void for vagueness doctrine is based on the due process clauses of the Fifth and Fourteenth Amendments." *United States v. Articles of Drug*, 825 F.2d 1238, 1243 (8th Cir. 1987) (citation omitted). "The Fourteenth Amendment's guarantee of Due Process proscribes law so vague that persons 'of common intelligence must necessarily guess at [their] meaning and differ as to [their] application.'" *Women's Med. Ctr. of Nw. Houston v. Bell*, 248 F.3d 411, 421 (5th Cir.

2001) (*quoting Smith v. Goguen*, 415 U.S. 566, 572 n.8 (1974)). Due process mandates that a law is "void for vagueness if its prohibitions are not clearly defined." *Articles of Drug*, 825 F.2d at 1243 (*quoting D.C. & M.S. v. City of St. Louis*, 795 F.2d 652, 653 (8th Cir. 1986) (internal quotation marks omitted)).

The parties first dispute the appropriate standard under which the Court should assess § 510B.8's vagueness. Defendants argue that, because § 510B.8 is an economic regulation, and because "'economic regulation is subject to a less strict vagueness test' than criminal laws," the Court must require that the Plaintiff show the statute is unconstitutional as applied to his specific conduct and in every possible instance. Def. Brief P. 12 [Dkt. 99]; *Chalmers v. City of Los Angeles*, 762 F.2d 753, 758 (9th Cir. 1985) (*citing Hoffman*, 455 U.S. at 498); *Woodis v. Westark Cmty. Coll.*, 160 F.3d at 438 ("An enactment imposing criminal sanctions or implicating constitutionally protected rights demands more definiteness than one which regulates the economic behavior of businesses."). Plaintiff replies that, though economic statutes typically are subject to a less strict vagueness test, § 510B.8 warrants greater scrutiny because it constitutes a "quasi-criminal" statute. Pl. Brief P. 14 [Dkt. 14].

Section 510B.8 is clearly a civil, rather than a criminal, statute. "Quasi-criminal" statutes that have a "stigmatizing effect" warrant "relatively strict" scrutiny. *See Articles of Drug*, 825 F.2d at 1244; *Hoffman Estates*, 455 U.S. at 499. A statute may be considered quasi-criminal when it carries substantial fines and is found in the "Crimes and Punishment" chapter of the State Code. *Video Software Dealers Ass'n v. Webster*, 968 F.2d 684, 690 (1992) (finding statute quasi-criminal when it is contained in the "Crimes and Punishment" chapter of the state code and each violation carries a fine of up to $200). Recently enacted HF 395, to be codified at 510B.3(1), details about potential punishment for violation of Chapter 510. It states:

> The commissioner shall enforce the provisions of this chapter. After notice and hearing, the commissioner may impose any or all of the sanctions set out in section 507B.7 and may suspend or revoke a pharmacy benefits manager's certificate of registration as a third-party administrator pursuant to chapter 510, upon finding that the pharmacy benefits manager violated any of the requirements of this chapter or of chapter 510 pertaining to third-party administrators.

HF 395 (*to be codified at* IOWA CODE § 510B.3(1)) (*available at* http://coolice.legis.iowa.gov/Cool-ICE/default.asp?Category=billinfo&Service=Billbook&frame=1&GA=86&hbill=HF395).

Because § 510B has no "stigmatizing effect," the Court finds that it is not quasi-criminal, despite PBMs potential to lose their state licenses as a result of violation of the section. *See Hoffman Estates*, 455 U.S. at 499 (parties agree statute is quasi-criminal and that its "prohibitory and stigmatizing effect may warrant a relatively strict test."). The Court declines to hold that any civil statute with the potential penalty of license revocation constitutes a quasi-criminal statute. Therefore, the Court treats § 510B as a civil statute and applies the level of scrutiny appropriate for economic regulation. As a general matter, "economic regulation is subject to a less strict vagueness test." *Hoffman*, 455 U.S. at 498; *Chalmers*, 762 F.2d at 757 (*quoting Hoffman*, 455 U.S. at 498–99) ("[G]reater tolerance is permitted with legislation imposing only civil rather than criminal penalties." (internal quotation marks omitted)). There are two justifications for a less strict test for economic or business regulations. First, "its subject matter is often more narrow, and [] businesses ... can be expected to consult relevant legislation in advance of action." *Chalmers*, 762 F.2d at 757 (citation omitted). Second, "the regulated enterprise may have the ability to clarify the meaning of the regulation by its own inquiry, or by resort to an administrative process." *Id.* (citation omitted).

Here, Plaintiff brings a facial void-for-vagueness challenge to the validity of § 510B.8. Plaintiff does not allege that § 510B.8 has any First Amendment implications. "A law that does not reach constitutionally protected conduct . . . may nevertheless be challenged on its face as unduly vague, in violation of due process. To succeed, however, the complainant must demonstrate that the law is impermissibly vague in all of its applications." *Hoffman Estates*, 455 U.S. at 497. "In reviewing a business regulation for facial vagueness, however, the principal inquiry is whether the law affords fair warning of what is proscribed." *Id.* at 503. In assessing whether § 510B.8 is unconstitutionally vague on its face, the Court looks to see whether § 510B.8 fails to establish a standard of conduct, keeping in mind that one single clear application of the law does not in itself defeat a vagueness challenge, despite the language of the Supreme Court's prior mandate requiring a party show a challenged law is "impermissibly vague in *all* of its applications." *Hoffman*, 455 U.S. at 497 (emphasis added); *Johnson v. United States*, 135 S. Ct. 2551, 2559–60, 2562 (2015) ("[A]lthough statements in some of our opinions could be read to suggest otherwise, our holdings squarely contradict the theory that a vague provision is constitution merely because there is come conduct that clearly falls within the provision's grasp."). The Court also takes into account the context of the law. "The applicable standard . . . is not one of wholly consistent academic definition

of abstract terms. It is, rather, the practical criterion of fair notice to those to whom the statute is directed. The particular context is all important." *Am. Comms. Ass'n, C.I.O. v. Douds*, 339 U.S. 382, 412 (1050); *Hoffman*, 455 U.S. at 503 (finding a "business person of ordinary intelligence" could understand the economic regulation); *Grayned v. City of Rockford*, 408 U.S. 102, 110–12 (1972) (taking into account both the preamble to the statute as evidence of the appropriate context in which to assess its vagueness). "A plaintiff who engages in some conduct that is clearly proscribed cannot complain of the vagueness of the law as applied to the conduct of others." *Hoffman*, 455 U.S. at 495. The Court therefore conducts the following analysis focusing on whether Plaintiff's conduct is clearly proscribed by § 510B.8.

Plaintiff argues that § 510B.8(2) and § 510B.8 (3) are both unconstitutionally vague. With respect to § 510B.8(3), the Court can easily dismiss Plaintiff's vagueness claim. Section 510B.8(3) reads as follows:

> For those prescription drugs to which maximum reimbursement amount pricing applies, a pharmacy benefits manager shall *include in a contract* with a pharmacy information regarding which of the national compendia is used to obtain pricing data used in the calculation of maximum reimbursement amount pricing and shall provide a process to allow a pharmacy to comment on, contest, or appeal the maximum reimbursement amount rates or maximum reimbursement amount list. The right to comment on, contest, or appeal the maximum reimbursement amount rates or maximum reimbursement amount list shall be limited in duration and allow for retroactive payment in the even that it is determined that maximum reimbursement pricing has been applied incorrectly.

IOWA CODE § 510B.8(3) (emphasis added). Plaintiff argues that this section is unconstitutionally vague because it fails to (1) enumerate the grounds on which a pharmacy may contest a price or list, (2) detail who adjudicates any conflict between the PBM and the pharmacy as a result of this procedure, (3) provide the standard governing an adjudicator's decisions, and (4) define what "limited duration" means in this context, and therefore is not "a rule or standard at all." Pl. Brief P. 20 [Dkt. 111]. In response, Defendants argue that these terms are sufficient to allow a person of reasonable intelligence to understand the law's requirements. The Court agrees.

Section 510B.8(3) does not create an appeals process outside the control of the parties to a contract between a PBM and a pharmacy. Rather, § 510B.8(3) mandates that the PBMs "include in a contract with a pharmacy" both information about pricing data and a process to allow the pharmacy to contest the resultant price. While it is true that § 510B.8(3) does not precisely spell out how one must draft this contractual provision, and indeed is "marked by flexibility and

reasonable breadth, rather than meticulous specificity," that does not make 510B.8(3) vague to the extent that a business person or PBM of ordinary intelligence could not understand what general information the parties' agreed upon contract provisions must include. *Grayned*, 408 U.S. at 110 (citation omitted) (internal quotation marks omitted). It is clear that the statute requires the parties to agree on a mechanism by which a pharmacy will be made aware of the data underlying a PBM's calculation—not the method of calculation itself—and have an opportunity to negotiate should it disagree with the ultimate pricing conclusion. The statute leaves the parties free to negotiate the specifics of this required process in forming their contract. Furthermore, as PBMs' main business is to contract with retail pharmacies, this statute undoubtedly applies to PBMs' activities. Section 510B.8(3) is not unconstitutionally vague.

The Court now turns to Plaintiff's argument that § 510B.8(2) is unconstitutionally vague. Section 510B.8(2) reads as follows:

> 2. For purposes of the disclosure of pricing methodology, maximum reimbursement amounts shall be implemented as follows:
>
> a. Established for multiple source prescription drugs prescribed after the expiration of any generic exclusivity period.
>
> b. Established for any prescription drug with at least two or more A-rated therapeutically equivalent, multiple source prescription drugs with a significant cost difference.
>
> c. Determined using comparable prescription drug prices obtained from multiple nationally recognized comprehensive data sources including wholesalers, prescription drug file vendors, and pharmaceutical manufacturers for prescription drugs that are nationally available and available for purchase locally by multiple pharmacies in the state.

IOWA CODE § 510B.8(2). Plaintiff argues that § 510B.8(2) is unconstitutionally vague because it fails to define several key terms, fails to clarify whether it imposes substantive limitations on the use of MAC pricing or only disclosure obligations, and fails to specify whether its Subparts are conjunctive or disjunctive. Pl. Brief PP. 17–19 [Dkt. 111].

The Court begins by acknowledging and reiterating its prior statements—cited by Plaintiff in its brief—that § 510B.8(2) is a poorly drafted law whose affirmative requirements are not easily deciphered and whose regulations leave much clarity to be desired. [Dkt. 56]. However, the Court's prior statements regarding § 510B.8's clarity were made in the context of an ERISA pre-emption analysis. The Court's constitutional vagueness analysis differs from the Court's ERISA pre-emption analysis. Though the Court agrees that this law remains poorly drafted and confusing,

such an opinion does not mandate a finding of unconstitutional vagueness. Here, the Court focuses on whether a reasonable business person of ordinary intelligence could understand § 510B.8(2) and on whether § 510B.8(2) provides adequate warning to those who the law will be enforced against. *Hoffman Estates*, 455 U.S. at 503; *see also Woodis*, 160 F.3d at 439 (having determined the law implicates no first amendment concerns, the Court looks to whether the facially challenged law "define[s] the proscribed behavior with sufficient particularity to provide a person of ordinary intelligence with reasonable notice of prohibited conduct and to encourage non-arbitrary enforcement of the provision" in the criminal context).

The Court finds that § 510B.8(2) is not void for vagueness. The Court first looks at the specific terms used in the statute and alleged by Plaintiff to be vague both in isolation and viewed as a whole. The words "established" and "determined" are not inherently vague words. These are commonly understood words meaning to bring about, set up, or decide. Furthermore, these words make sense in the context of a discussion about the creation of maximum reimbursement amounts, which are a figure that a PBM's "develop and maintain" as a main part of their work. *See* FAC ¶ 4. The requirement that the law be clear does not "preclude the use of ordinary terms to express ideas which find adequate interpretation in common usage and understanding." *St. Croix Waterway Ass'n v. Meyer*, 178 F.3d 515, 520 (8th Cir. 1999) (*quoting Sproles v. Binford*, 286 U.S. 374, 393 (1932) (internal quotation marks omitted)). It is clear that Plaintiff is aware—as any reasonable business person would be—of what these words commonly mean, that the words "determined" and "establish" mean nothing outside of their ordinary definition in this context, and that these words are not vague in and of themselves.

Similarly, the words "significant," "nationally recognized," "comprehensive," and "locally" cited by Plaintiff's as vague are not unconstitutionally vague in this context. The Court does not deny that several of these terms are troubling and give the Court pause. The troubling terms include "significant," "nationally recognized," and "local." *See, e.g.*, *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 394 (1926) (questioning clarity of use of word "locality," as well as other vague language in context of a criminal statute). With respect to the term "nationally recognized," however, the statute includes examples of "nationally recognized comprehensive data sources," listing as included in this category: "wholesalers, prescription drug file vendors, and pharmaceutical manufacturers." IOWA CODE § 510B.8(2). Plaintiff's member PBMs are familiar with using aggregate data and can reasonably be expected to understand what "nationally

recognized comprehensive" aggregate data means. The Court reiterates the principal that economic regulation need not include the precise language required of a criminal statute to be upheld as constitutional. *Hoffman*, 455 U.S. at 498. The Court finds that, taking into account that this statute applies to PBMs, who already calculate MAC pricing "based on aggregate data that show what pharmacies pay on average for generic drugs," FAC ¶ 4, and taking into account the statute's included clarification of sources, use of "nationally recognized" is not such that a reasonable PBM could not understand the law's requirement. *See Grayned*, 408 U.S. at 113–114 (vagueness of individual terms dispelled by other clarifications in the statute and the context of the statute); *St. Croix Waterway Ass'n*, 178 F.3d at 520 (taking context of criminal law into account in finding its terms are readily understandable by ordinary people).

With respect to the law's use of the word "local," the Court also finds that, while a close call, the term is not unconstitutionally vague in this context. A sizable portion of Iowa's population lives in a rural area with reasonable access to only a very few pharmacy options. *See Rural Iowa Indep. Tel. Ass'n v. Iowa Utilities Bd.*, 385 F. Supp. 2d 797, 801 (S.D. Iowa 2005) (aff'd 476 F.3d 572 (8th Cir. 2007) (Iowa is a rural state). In such cases, determining what is locally available is not unreasonably difficult such that "local" takes on an unconstitutional lack of clarity.

The specific terms highlighted above are not so inherently subjective as to make § 510B.8 subject to arbitrary enforcement. *Cf. Coates v. City of Cincinnati*, 402 U.S. 611, 613–14 (finding a law banning "annoying" conduct unconstitutionally broad, vague, and requiring "men of common intelligence" to "guess at its meaning"). The Court finds, viewing both the questionable words in isolation and within the context of the statute, the statute's language is not impermissibly vague. Section 510B.8(2) undoubtedly does contain ambiguities. However, the allegedly ambiguous provisions are "sufficiently clear to cover at least some of" Plaintiff's members' conduct. *Hoffman*, 455 U.S. at 502. "Whether further guidelines, administrate rules, or enforcement policy will clarify the more ambiguous scope of the standard in other respects is of no concern to this facial challenge." *Hoffman*, 455 U.S. at 502.

Finally, Plaintiff argues that the grammatical structure of 510B.8(2) is unclear, leading to confusion as to whether the statute implements substantive requirements or requirements in relation only to disclosure of information to the insurance commissioner. In assessing what the statute requires, the Court has previously held that the statute requires no specific pricing methodology. [Dkt. 56]. Furthermore, the opening clause of § 510B.8(2) explicitly states the

clause's purpose: "For the purposes of the disclosure of pricing methodology . . . ." Iowa Code § 510B.8(2). This preamble explicitly establishes that § 510B.8(2) imposes requirements related to disclosure rather than substantive pricing methodology requirements or any sort of specifically required formula, aside from its requirement that PBMs utilize nationally recognized data. Plaintiff also highlights the lack of subject in Subparts a, b, and c. However, in addition to the additional clarity provided by § 510B.8(2)'s first sentence, the entirety of § 510B.8 is labelled "Pricing Methodology for Maximum Reimbursement Amount." IOWA CODE § 510B.8. It is clear that the subject of clauses Subparts a, b, and c is intended to be the same as the subject of the preamble: maximum reimbursement amounts. A reasonable business person can be expected to decipher the intended subject of these Subparts and the fact that the Subpart imposes no substantive requirements—particularly in the light of the Court's prior holding that it does not do so. Section 510B.8(2) is therefore not unconstitutionally vague due to its ill-conceived grammatical structure.

Section 510B.8(2) is not without ambiguity. The State "may adopt administrative regulations that will sufficiently narrow potentially vague or arbitrary interpretations of the ordinance. In economic regulation especially, such administrative regulation will often suffice to clarify a standard with an otherwise uncertain scope." *Hoffman*, 455 U.S. at 504. The Court finds that this law does not fail to "afford[] fair warning of what is proscribed." *Id.* at 503. The law puts a business person of ordinary intelligence on notice of the mandates of the law. *Id.* At least some, if not all, of Plaintiff's described conduct comes clearly within the purview of the law. *Id.* at 495. Although a close question, the Court concludes that § 510B.8 is not impermissibly vague.

C. Defendants' Appeal of Magistrate's Order

Lastly, Defendants appeal Magistrate Judge Adams's ruling granting Plaintiff's motion to amend its complaint. [Dkt 94]. Defendants appeal the order to the extent that it disallows them from filing the instant motion to dismiss. Defendants also object to the amendment of Counts I through IV, which the Court has previously dismissed. [Dkt. 56]. Because the Court finds it appropriate to consider Plaintiff's instant motion to dismiss and because the FAC is substantively identical to Plaintiff's original complaint, adding only language related to the unresolved claims, the Court denies Defendants' appeal from Magistrate Judge Adams' ruling.

III. CONCLUSION

Plaintiff PCMA has failed to state a claim upon which relief can be granted with respect to its dormant Commerce Clause and Vagueness claims. Taking the allegations of the complaint as

true, Plaintiff has failed to show that any burdens imposed by § 510B.8 outweigh its putative local benefits or that § 510B.8 is not subject to understanding by an ordinary business person. Because the Court was able to decide Defendants' motion to dismiss without further clarification from the Iowa Supreme Court, Plaintiff's Motion to Certify Question(s) of Law and Stay the Case, [Dkt. 82], is dismissed as moot. Plaintiff has failed to demonstrate that success on the merits is more than a "sheer possibility." *Iqbal*, 556 U.S. at 678 (2009) (*quoting Twombly*, 550 U.S. at 570).

Upon the foregoing,

IT IS ORDERED that Defendants' motion to dismiss is **GRANTED**. Defendants' appeal of Magistrate Judge Adams' order and Plaintiff's Motion to Certify Questions of law are both **DENIED**. The Clerk shall enter judgment accordingly.

DATED this 8th day of September, 2015.

JOHN A. JARVEY, Chief Judge
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF IOWA