NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

HEALTH SCIENCE FUNDING, LLC,

Plaintiff,

v.

NEW JERSEY DIVISION OF HUMAN SERVICES et al., Civil Action No. 15-2933

OPINION

Defendants.

THIS MATTER comes before the Court by way of Defendants New Jersey Division of Human Services ("DHS") and Elizabeth Connolly's (collectively, "Defendants") motion to dismiss Plaintiff Health Science Funding, LLC's complaint. Dkt. No. 12. For the reasons set forth below, the motion is **GRANTED**.

I. BACKGROUND

This case arises out of allegations that DHS failed to comply with provisions of the Medicaid statute requiring it to reimburse Plaintiff for a drug it produces. The following facts from Plaintiff's complaint are taken as true.

Plaintiff sells a lupus treatment product. Dkt. No. 1, Compl. ¶ 3. In November 2014, the U.S. Center for Medicare and Medicaid Services ("CMS") signed a Rebate Agreement with Plaintiff. Declaration of J. Mark. Pohl ("Pohl Decl.") Ex. 2, Dkt. No. 4. Plaintiff alleges that the Rebate Agreement obligates CMS to provide Plaintiff's product to Medicaid patients. Compl. ¶ 5. Therefore, CMS' agent in New Jersey, DHS, must pay for it. Compl. ¶ 5, 18-19. But DHS refuses to do so and has rejected prescriptions submitted for payment. Id. ¶ 19.

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DHS gave several reasons for non-payment. First, DHS claimed that their database did not list Plaintiff's product. <u>Id.</u> ¶ 21. But Plaintiff alleges that the product is listed. <u>Id.</u> Second, they claimed that the product was not a "Covered Outpatient Drug," as defined by the Medicare statute. <u>Id.</u> ¶ 22. But Plaintiff alleges that it is a covered drug under 42 U.S.C. 1396r-8(k)(2)(A)(ii). <u>Id.</u>

Third, DHS claimed they could not pay for the product because they were unable to determine its price from their database, which is a price catalogue created by a private company called First DataBank. Id. ¶¶ 23, 28. But Plaintiff alleges that DHS's use of the First DataBank catalogue is improper. First DataBank only has pricing data for a few drugs, and therefore CMS Guidelines discourage its use. Id. ¶ 28. More comprehensive pricing information is available from several sources, including CMS itself and companies like MediSpan. Id. ¶¶ 24-26. Plaintiff alleges that DHS has failed to comply with its payment obligations to Plaintiff because it does not source complete pricing data from one of these other databases. Id. ¶ 28.

Plaintiff brought this suit asserting two causes of action. In Count One, Plaintiff claims that its product is a Covered Outpatient Drug, and "DHS' refusal to pay for [it] violates the Medicare statute, 42 U.S.C. 1396 <u>et seq.</u>" <u>Id.</u> ¶¶ 42-45. In Count Two, Plaintiff claims that DHS' reliance on an incomplete wholesale pharmaceutical price catalogue, in direct contravention of Medicaid guidelines, "violates the Federal Administrative Procedure Act. <u>See</u> 5 U.S.C. 570(e)(1)." <u>Id.</u> ¶¶ 46-48.

The Court denied Plaintiff's ex parte application for relief on April 28, 2015 and its motion for a preliminary injunction on December 1, 2015. Dkt. Nos. 5, 17.

II. STANDARD OF REVIEW

When considering a Rule 12(b)(6) motion to dismiss, the court accepts as true all of the facts in the complaint and draws all reasonable inferences in favor of the plaintiff. <u>Phillips v. Cnty.</u>

of Allegheny, 515 F.3d 224, 231 (3d Cir. 2008). The facts alleged must be "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." <u>Bell Atl.</u> <u>Corp. v. Twombly</u>, 550 U.S. 544, 555 (2007). The allegations in the complaint "must be enough to raise a right to relief above the speculative level." <u>Id.</u> A complaint will survive a motion to dismiss if it provides a sufficient factual basis such that it states a facially plausible claim for relief. <u>Ashcroft v. Iqbal</u>, 556 U.S. 662, 678 (2009).

The Court may also raise subject matter jurisdiction concerns sua sponte. <u>Nesbit v. Gears</u> <u>Unlimited, Inc.</u>, 347 F.3d 72, 77 (3d Cir. 2003). Where, as here, questions arise over a statute's grant of a private right of action, the Court has an independent obligation to ensure that it has jurisdiction to hear the claim. <u>See id.</u> at 76-77; <u>Horan v. Wilcox & Fetzer Ltd.</u>, 153 F. App'x 100, 102 (3d Cir. 2005).

III. Analysis

A. Count 1: Medicaid Claim

In response to Plaintiff's vague citation to the Medicaid statute in Count 1, the Court directed it to identify the specific statutory section underlying its claim. Dkt. No. 17. Plaintiff identified 42 U.S.C. § 1396a(a)(54) and asserts a private right of action to enforce the section under 42 U.S.C. § 1983. However, § 1983 does not provide a private right of action to enforce Section (54).

"In order to seek redress through § 1983 . . . a plaintiff must assert the violation of a federal right, not merely a violation of federal law." <u>Blessing v. Freestone</u>, 520 U.S. 329, 340 (1997). To determine whether a particular statutory provision gives rise to federal right, we look to whether: (1) Congress intended that the provision in question benefit the plaintiff; (2) the right assertedly protected by the statute is not so "vague and amorphous" that its enforcement would strain judicial

competence; and (3) the statute unambiguously imposes a binding obligation on the States. <u>Id.</u> at 340-41 (citations omitted). The primary question, above all, is "whether Congress <u>intended to</u> <u>create a federal right</u>." <u>Gonzaga University v. Doe</u>, 536 U.S. 273, 284 (2002) (original emphasis). Only an unambiguously conferred right to support a cause of action brought under § 1983 will stand. <u>Gonzaga</u>, 536 U.S. at 283.

Section (54) fails this inquiry. 42 U.S.C. § 1396a(a) of the Medicaid Act generally addresses the required contents of any state plan for providing medical assistance under the Medicaid regime. Section (54) of that provision, in particular, requires that "a State plan that provides medical assistance for covered out-patient drugs (as defined in section 1396r-8(k)) [must] comply with the applicable requirements of section 1396r-8 of this title." 42 U.S.C. § 1396a(a)(54).¹

This language does not bespeak Congress' intent to create a federal right. It does not contain any "rights-creating" language that gives rise to an enforceable right. It speaks only to the states in terms of how their rebate plans must comply with the Medicaid Drug Rebate Program's requirements in Section 1396r-8. It therefore regulates the state's policies alone, and does not create a right for, let alone mention, drug providers like Plaintiff. Importantly, a statute does not grant a privately enforceable right simply because Plaintiff may "fall[] within the general zone of interest that the statute is intended to protect." <u>Gonzaga</u>, 536 U.S. at 284. It will only confer a federal right when "its text [is] 'phrased in terms of the person benefitted."" <u>See id.</u> Section (54)

¹ Under Section 1396r-8, the Medicaid Drug Rebate Program, a participating drug manufacturer agrees to pay rebates to state Medicaid programs in exchange for those programs covering the cost of a manufacturer's drugs. <u>U.S. ex rel. Schumann v. Astrazeneca Pharm. L.P.</u>, 769 F.3d 837, 841 (3d Cir. 2014) (internal citations omitted). It governs things like the terms a rebate agreement must contain, how rebates are determined, how drug coverage may be limited, etc.

is not phrased in such terms. It therefore cannot be invoked to support a cause of action under § 1983.

The cases that Plaintiff relies on do not hold otherwise. Plaintiff's main argument that § 1396a(a), in general, creates a private right is based on misinterpretations of <u>Wilder v. Virginia</u> <u>Hospitals Association</u>, 496 U.S. 498 (1990) and <u>West Virginia University Hospitals v. Casey</u>, 885 F.2d 11 (3d Cir. 1989). <u>Wilder and Casey</u> did not confer a general right of action to all subsections under § 1396a(a). They both found that a private right exists under a specific provision, Section 1396a(a)(13). <u>Wilder</u>, 496 U.S. at 510; <u>Casey</u>, 885 F.2d at 19-20. Moreover, the right only existed under that section because of clear statutory language requiring payment to hospitals, nurses, and intermediate care facilities. <u>Wilder</u>, 496 U.S. at 510; <u>Casey</u>, 885 F.2d at 20. No such unambiguous language exists in Section (54).²

Because Plaintiff lacks a private right of action to enforce the requirements of § 1396a(a)(54), the Court lacks jurisdiction to consider this claim. Count 1 is **DISMISSED WITH**

PREJUDICE.

B. Count 2: Federal Administrative Procedure Act Claim

In response to Plaintiff's incorrect citation to the Federal Administrative Procedure Act ("APA") in Count 2, the Court directed Plaintiff to identify the specific statutory section underlying its claim.³ Dkt. No. 17. Plaintiff identified 5 U.S.C. § 702. That section reads:

A person suffering legal wrong because of <u>agency action</u>, or adversely affected or aggrieved by <u>agency action</u> within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than

² Plaintiff also cites several cases to support that private rights under Medicaid are enforceable by providers as well as patients. But because the Court finds no private right under Section (54), any distinction about the right's availability to providers and patients is moot.

³ Plaintiff's initial citation to 5 U.S.C. § 570(e)(1) was incorrect. No such subsection exists under § 570.

money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party.

5 U.S.C. § 702 (emphasis added).

By its plain language, this provision does not apply to DHS. Section 702 only reaches wrongs committed by "agency action." Section 701 defines "agency" as "each authority of the Government of the United States" 5 U.S.C. 701(b)(1). Thus, APA "claims may be asserted only against federal agencies and their employees." <u>Griffith v. Bell-Whitley Cmty. Action Agency</u>, 614 F.2d 1102, 1105 (6th Cir. 1980). DHS is a state agency that employs state employees. The statute therefore does not reach DHS' conduct in this case. <u>See Johnson v. Rodriguez</u>, 943 F.2d 104, 109 n.5 (1st Cir. 1991) ("[The APA] does not purport to affect the review processes of state agencies or commissions").

Plaintiff argues that the APA reaches DHS through an agency theory. That is, DHS stands in the shoes of the United States because it acts as CMS's local agent when it conducts Medicaid activity. Plaintiff relies on three cases, but none of them support the proposition that a state agency can be sued under § 702 based on this theory. <u>Natural Resources Defense Council v. U.S.</u> <u>Environmental Protection Agency</u> provides only that States issuing discharge permits under the National Pollutant Discharge Elimination System statute stand in the shoes of the EPA for the purposes of those provisions. 859 F.2d 156, 183 (D.C. Cir. 1988). And neither <u>In re Series 7</u> <u>Broker Qualification Exam Scoring Litigation</u>, 510 F. Supp. 2d 35 (D.D.C. 2007) nor <u>Student</u> <u>Public Interest Research Group of New Jersey v. P.D. Oil & Chemical Storage</u>, 627 F. Supp. 1074 (D.N.J. 1986) involve the APA at all. Plaintiff's legal theory is therefore unpersuasive. Count 2 is **DISMISSED WITH PREJUDICE**.

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is **GRANTED** and Plaintiff's complaint is **DISMISSED WITH PREJUDICE**. An appropriate order accompanies this opinion. **Dated: December 21, 2015**

<u>/s Madeline Cox Arleo</u> HON. MADELINE COX ARLEO UNITED STATES DISTRICT JUDGE