

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,	:	
	:	
Plaintiff,	:	Civil Action No.: 01-1453 (RMU)
	:	
v.	:	
	:	
TOMMY G. THOMPSON <i>et al.</i> ,	:	Document Nos.: 8, 10, 17, 18
	:	
Defendants,	:	
	:	
and	:	
	:	
KEVIN W. CONCANNON,	:	
	:	
Intervenor-Defendant.	:	

MEMORANDUM OPINION

**GRANTING THE DEFENDANTS’ MOTION FOR SUMMARY JUDGMENT;
GRANTING THE INTERVENOR-DEFENDANT’S MOTION FOR SUMMARY JUDGMENT;
DENYING THE PLAINTIFF’S MOTION FOR SUMMARY JUDGMENT**

I. INTRODUCTION

This case concerns one state’s use of a manufacturer-rebate scheme to act as a solution for the lack of a prescription drug benefit program for low-income citizens. By bringing the present action, Pharmaceutical Research and Manufacturers of America (“the plaintiff”) challenges the approval of the State of Maine’s Medicaid demonstration project by the Centers for Medicare and Medicaid Services (“CMS”), under the U.S. Department of Health and Human Services (“HHS”). As such, the target defendants in the case are the HHS Secretary and the CMS Administrator (collectively, “the defendants”). The plaintiff alleges violations of Title XIX of the Social Security Act (“the SSA”), as amended 42 U.S.C. § 1396 *et seq.*, and the Administrative Procedure Act, (“the APA”) as amended 5 U.S.C. § 701 *et seq.* Before the court

are the parties' cross-motions for summary judgment. After consideration of the parties' submissions and the relevant law, the court grants the defendants' motion for summary judgment and denies the plaintiff's motion for summary judgment. In addition, the court grants the intervenor-defendant's motion for summary judgment.

II. BACKGROUND

A. Factual Background

The plaintiff challenges the State of Maine's Medicaid demonstration project, known as the Healthy Maine Prescription ("HMP"), which the HHS Secretary approved on January 18, 2001. *See* Defs.' Mot. for Summ. J. at 7. Maine put the HMP into effect on June 1, 2001, intending "to do something about the lack of a prescription drug benefit for its low-income citizens" by expanding "Medicaid eligibility for prescription drugs to all individuals with household income up to 300 percent of the Federal Poverty Level." Administrative Record ("Admin. R.") at 5. Defendant Tommy G. Thompson, the HHS Secretary, is charged with the responsibility to implement the provisions of Title XIX of the SSA, as amended 42 U.S.C. § 1396 *et seq.* (the "Medicaid statute"). *See* Compl. ¶ 13. The HHS Secretary administers the Medicaid program through CMS, a component of HHS. *See id.* The Secretary is sued in his official capacity only. *See id.*

The plaintiff challenges the January 18, 2001 decision by the HHS Secretary approving a Medicaid demonstration to be conducted by Maine and allowing Maine to pursue the HMP. *See* Compl. ¶ 2. The Secretary's "reason for approving the project was 'not to restrict Maine's ability to invest state funds in the health of its citizens,' but to achieve 'expanded access to medically necessary drugs' by making them 'more affordable to primarily low-income Maine

residents who are not eligible for Medicaid.” *See* Defs.’ Mot. for Summ. J. at 17 (quoting Admin. R. at 28).

The HMP uses a manufacturer-rebate mechanism set forth in 42 U.S.C. § 1396r-8. *See* Compl. ¶¶ 24-25. Under the HMP, Maine collects rebates from manufacturers quarterly and deposits the rebates into a revolving fund. *See* Compl. ¶ 26. Providers charge the HMP beneficiaries prices for prescriptions that equal the Medicaid price for a prescription, (i.e., the price that Maine has agreed to pay pharmacies for prescriptions filled under Medicaid) minus a fixed percentage subsidy of 18 percent. *See* Compl. ¶ 38. Specifically, beneficiaries receive a 14-percent reduction off the available prescription price, calculated by reducing the manufacturers’ rebate of 18 percent by the four percent Maine estimates it would cost on a per-prescription basis to administer the HMP. *See* Admin. R. at 176-177.

Under the rebate program described in 42 U.S.C. § 1396r-8(a)(1), for a state to receive federal funds to pay for any manufacturer’s drugs, the manufacturer must enter into an agreement with the HHS Secretary to pay a rebate to every state on all of its covered outpatient drugs paid for by Medicaid. *See* Compl. ¶ 24. The plaintiff contends this program violates the SSA because it costs Maine nothing, but requires drug companies to cover 15 to 18 percent of the cost of covered prescription drugs. *See* Compl. ¶¶ 39-41, 45-46, 73. The plaintiff claims this feature violates the statutory requirement that a Medicaid plan include some “payment under a state plan” of the cost of “medical assistance.” *See* 42 U.S.C. §§ 1396r-8, (a); Compl. ¶¶ 4, 44-54. In addition, the plaintiff avers the defendants fail to satisfy the requirement in 42 U.S.C. § 1396o, which provides that states not charge Medicaid beneficiaries more than a “nominal” co-payment. *See* Compl. ¶¶ 4, 44-54; Mem. of Law in Supp. of Pl.’s Mot. for Summ. J. at 5, 26-28. The plaintiff argues that HMP beneficiaries are paying more than 80 percent of the cost of each

prescription they fill. *See id.* Thus, the plaintiff concludes that such copayments imposed by Maine clearly exceed the “nominal” limit set forth in 42 U.S.C. § 1396o. *See id.*

To support these arguments, the plaintiff relies on a recent D.C. Circuit decision that addresses a similar program instituted by the State of Vermont. *See Pharm. Research and Mfrs. of America v. Thompson (“PhRMA”)*, 251 F.3d 219 (D.C. Cir. 2001); Compl. ¶¶ 1, 5; Mem. of Law in Supp. of Pl.’s Mot. for Summ. J. at 1-5, 8, 13-19, 21, 23-25, 28.

In *PhRMA*, the plaintiff states that the D.C. Circuit struck down a plan “essentially identical” to the Maine HMP, known as the Vermont Pharmacy Discount Program (“PDP”). *See* Compl. ¶¶ 1, 5. The D.C. Circuit held that the purchases of drugs under the portion of the project designed to be equal to the anticipated manufacturer rebate could not be deemed purchases for which a “payment” was made by Vermont, as that term is defined under 42 U.S.C. § 1396r-8(b)(1)(A) because “payments are fully reimbursed by manufacturer rebates” and therefore “the rebates produce no savings for the Medicaid program.” *See* Defs.’ Mot. for Summ. J. at 10 (quoting *PhRMA*, 251 F.3d at 225).

Shortly after the D.C. Circuit issued its *PhRMA* decision, Maine initiated a policy in which the State makes a contribution of two percent toward the cost of HMP beneficiaries’ prescriptions using “State-only” money (i.e., money for which no federal-matching funds are paid). *See* Mem. of Law in Supp. of Pl.’s Mot. for Summ. J. at 13. The plaintiff argues that the Maine HMP is indistinguishable from the Vermont PDP and CMS lacks the authority to approve the HMP, thereby violating Section 1927 of the SSA (42 U.S.C. § 1396r-8). *See* Compl. ¶¶ 4-5, 60-66. Consequently, the plaintiff urges this court to rule that the defendants’ approval of the program violates the APA, 5 U.S.C. § 706 (2)(A), (C). Compl. ¶¶ 7, 59, 64, 74, B.

Specifically, the plaintiff requests a declaration, pursuant to 28 U.S.C. § 2201, that CMS approval of the HMP violates Sections 1927, 1901 (as defined in section 1905(a)), 1916(b), and

1115 of the SSA, and, along those same lines, that CMS approval, or any like approval in the future, is unlawful under the APA. *See* Compl. ¶ B. Additionally, the plaintiff seeks “preliminary and permanent injunctive relief enjoining the Secretary of HHS from granting approval of a Medicaid demonstration program in Maine or any other state that contains any or all of the features of the Maine HMP, including: (1) purporting to require rebates from prescription drug manufacturers even though no payments are made by the state under that state’s plan; (2) failing to provide ‘medical assistance’ under the SSA, and; (3) requiring copayments by Medicaid beneficiaries that exceed the ‘nominal’ limit allowed under Medicaid.” Compl. ¶ C.

1. The Medicaid Program

The federal government enacted the Medicaid program in 1965 as a cooperative undertaking between the federal and state governments to help the states provide medical care to low-income individuals. *See* Compl. ¶ 17. Medicaid provides services pursuant to plans developed by the states and approved by the HHS Secretary. *See* 42 U.S.C. §§ 1396a(a)-(b); Compl. ¶ 17. States pay doctors, hospitals, pharmacies, and other providers of medical goods and services according to established rates. *See* 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1); Compl. ¶ 22. The federal government then pays each state a statutorily established share of “the total amount expended . . . as medical assistance under the State plan . . .” *See* 42 U.S.C. § 1396b(a)(1); Compl. ¶ 22. This federal-to-state payment is known as federal financial participation. *See* Compl. ¶ 20. The Medicaid statute prohibits state governments from charging the beneficiaries more than a “nominal” copayment for prescription drugs and other benefits. *See* 42 U.S.C. §§ 1396o(a)(3), (b)(3); Compl. ¶ 23. The plaintiff claims that current Medicaid prescription drug sales nationwide total about 20 billion dollars per year. Compl. ¶ 28. About

10 percent of all prescription drugs in the United States are purchased by Medicaid recipients.

See Defs.’ Mot. for Summ. J. at 5.

2. Medicaid Prescription Drug Rebate Agreements

Pharmaceutical manufacturers participating in Medicaid programs rebate to the states a portion of the price of drugs purchased for Medicaid purposes. *See* 42 U.S.C. § 1396r-8(a)(1); Compl. ¶¶ 24-25. Manufacturers do this because the Medicaid statute, 42 U.S.C. §§ 1396a-u, permits the federal government to reimburse states only for drugs purchased from manufacturers who have agreed to pay statutorily specified rebates to those states. *See* 42 U.S.C. 1396r-8(a)(1); Compl. ¶¶ 24-26, 28. Thus, pharmaceutical manufacturers that want their drugs available to Medicaid beneficiaries under the Medicaid program must enter into agreements with the HHS Secretary to provide rebates to states in order to reduce the cost of prescription drug coverage. *See* 42 U.S.C. § 1396r-8(a)(1); Compl. ¶ 25. Specific rebate amounts are based on state reports on the utilization of each manufacturer’s covered outpatient drugs by Medicaid beneficiaries in the state. *See* 56 Fed. Reg. 7049, Section II(a); Compl. ¶ 26. In language central to this case, Section 1396r-8 provides that rebate agreements shall require manufacturers to pay rebates on drugs for which “payment was made under the State plan.” *See* 42 U.S.C. § 1396r-8(b)(1)(A); Compl. ¶¶ 4, 44-45.

3. Waivers and Medicaid “Pilot” or “Demonstration” Projects

The relevant Medicaid statute authorizes HHS to approve experimental “pilot” or “demonstration” projects that the HHS Secretary determines are “likely to assist in promoting the objectives of [Medicaid].” 42 U.S.C. § 1315(a); *see* Compl. ¶¶ 31-33; Defs.’ Mot. for Summ. J. at 3-4. The SSA authorizes the Secretary to waive certain Medicaid requirements for such demonstration projects. *See id.* With respect to such projects, the Secretary is empowered to take two separate actions. *See* Defs.’ Mot. for Summ. J. at 3-4. First, the Secretary may

waive compliance with certain Medicaid provisions to the extent and for the period that the Secretary finds necessary to facilitate the project. *See* 42 U.S.C. § 1315(a)(1); Defs.’ Mot. for Summ. J. at 4. Second, the Secretary may designate that state expenditures, “which would not otherwise be included as expenditures” under the state plan, “shall, to the extent and for the period prescribed by the Secretary, be regarded as expenditures under the state plan.” 42 U.S.C. § 1315(a)(2); *see also* Defs.’ Mot. for Summ. J. at 4. In this case, the Secretary’s approval letter states that all “expenditures for extending pharmacy-only benefits” under the HMP “shall be regarded as expenditures under the State’s [Medicaid] plan,” subject to the condition that the State will be eligible for federal financial participation only to the extent that those expenditures do not exceed average rebate amounts (as reconciled on a quarterly basis). *See* Admin. R. at 29, 41.

According to the defendants, expenditures that generate federal financial participation and “State only” expenditures that do not generate federal financial participation are therefore both “regarded” as being made “under the State plan,” for purposes of determining whether a rebate obligation attaches under 42 U.S.C. § 1396r-8(b)(1)(A). *See* 42 U.S.C. § 1315(a)(2); Defs.’ Mot. for Summ. J. at 16. The SSA, however, does not authorize the Secretary to waive any requirements of Section 1396r-8’s rebate provision or the requirement that Medicaid beneficiaries contribute no more than a “nominal” amount to the cost of medical benefits they receive. *See* 42 U.S.C. § 1315(a)(1); Compl. ¶¶ 33, 48, 63. Moreover, CMS regulations require a state to show that any pilot project will be “budget neutral,” i.e., that the federal government’s costs over the life of the project will not exceed the contribution the federal government would make to the state under the state Medicaid plan in the absence of the waiver. *See* Demonstration Proposals Pursuant to § 1115(a) of the Social Security Act, 59 Fed. Reg. 49,249, 49,250 (Sept. 27, 1994); Compl. ¶ 34.

In contrast, the defendants argue “it was not necessary for the copayment statute to be ‘waived’ to facilitate the HMP, because the copayment statute is not applicable to persons who are not eligible for Medicaid to begin with.” Defs.’ Mot. for Summ. J. at 25. The defendants aver that “HMP participants may receive Medicaid-like benefits, but they do not become eligible for Medicaid by enrolling in the demonstration project.” *Id.*

4. Maine’s Demonstration Project: The Healthy Maine Prescription (“HMP”)

On January 5, 2001, Maine officials sought a waiver from CMS allowing Maine to expand Medicaid eligibility for prescription drugs through a demonstration project. *See* Compl. ¶ 35. Maine’s proposed project is designed to help an estimated 225,000 people with low incomes, who are not otherwise eligible for Medicaid, to obtain Medicaid pharmacy benefits. *See id.* More than 60,000 people are currently enrolled in the HMP. *See* Int.-Defs.’ Mot. for Summ. J. at 7. The Maine DHS expects total enrollment to reach 200,000 to 225,000 by the time the demonstration project ends in 2006. *See id.* Maine envisioned that the “project would also provide important information on health status and utilization patterns of beneficiaries, as well as contribute to State public policy and planning.” Mem. of Law in Supp. of Defs.’ Mot. for Summ. J. at 7. In a letter dated January 18, 2001, the Secretary approved the waiver (“the waiver letter”) and determined that the demonstration project was “likely to assist in promoting the objectives of the Medicaid program.” *See id.* at 8; Mem. of Law in Supp. of Pl.’s Mot. for Summ. J. at 10. As a condition for approving the waiver, the waiver letter requires the Maine DHS to submit an “operational protocol” to the Secretary, and requires it to be the “single source for the policy and operating procedures” for the program. *See* Admin. R. at 28-47; Mem. of Law in Supp. of Pl.’s Mot. for Summ. J. at 11; Defs.’ Mot. for Summ. J. at 9. The waiver letter states that the Secretary would regard all “expenditures for extending pharmacy-only supplemental

benefits” to this new population as “expenditures under the State’s Medicaid plan.” *See* Admin. R. at 28-29.

The HMP consists of two parts. *See* Defs.’ Mot. for Summ. J. at 8. The first part is called the “Drugs for the Elderly” (“DEL”) component. *See id.* This aspect of the project provides a prescription-drug benefit for elderly and disabled persons whose household income does not exceed 185 percent of the Federal Poverty Level (“FPL”). *See id.*; Admin. R. at 7-8. The State pays 80 percent of the cost for “generic drugs, drugs related to certain conditions, and catastrophic expenditures” that exceed \$1,000.00 per year. *See* Defs.’ Mot. for Summ. J. at 8. The defendants contend that the Secretary regards State subsidies as expenditures made under the Medicaid State plan, thereby making the drug purchases subject to manufacturer rebates. *See* Admin. R. at 28-29; Defs.’ Mot. for Summ. J. at 8. Under the “Special Terms and Conditions” of the project, the Secretary is responsible for paying federal financial participation to the State on DEL payments, but only up to the average percentage of manufacturer rebates. *See* Admin. R. at 41; Defs.’ Mot. for Summ. J. at 8. The remainder of the payment qualifies as a “State-only expense that is not subject to federal financial participation.” *See* Defs.’ Mot. for Summ. J. at 8.

The second part of the HMP has no specific name, but Maine refers to it as the “non-DEL” component. Defs.’ Mot. for Summ. J. at 8. It covers all non-DEL drugs purchased by people with incomes below 300 percent of the Federal Poverty Level. *See id.* Just like the DEL component, the Secretary has agreed to regard all payments to pharmacists made by the State for non-DEL drugs as expenditures under the State plan, making the drug purchases subject to manufacturer rebates. *See id.*; Admin. R. at 28. The Secretary agreed to pay federal financial participation on State expenditures, but once again only up to the average rebate percentage. *See* Defs.’ Mot. for Summ. J. at 8-9; Admin. R. at 41. State payments that exceed the rebates are a “State-only” expense. *See id.* According to the defendants, Maine is free to pay whatever

subsidies it wants, so long as the “amount for which federal financial participation is claimed is limited to the rebate amount.” *See* Defs.’ Mot. for Summ. J. at 9.

The HMP went into effect on June 1, 2001. *See id.* at 10. On June 8, 2001, the D.C. Circuit handed down its decision in the *PhRMA* case. *See PhRMA*, 251 F.3d at 219. As stated earlier, the case involved a Vermont demonstration project designed to make prescription drugs more affordable to elderly and low-income people who are not eligible for Medicaid. *See PhRMA*, 251 F.3d at 219; Defs.’ Mot. for Summ. J. at 10. In one portion of the prescription drug initiative, the State of Vermont paid 50 percent of the price of certain drugs purchased by project participants. *See id.* The other portion of the prescription drug initiative was a subsidy that Vermont tied to the anticipated average manufacturers’ rebate. *See PhRMA*, 251 F.3d at 219; Mem. of Law in Supp. of Pl.’s Mot. for Summ. J at 3. The D.C. Circuit struck down this portion of the prescription drug initiative, holding that “because Vermont’s PDP payments are fully reimbursed by manufacturer rebates, and because the rebates produce no savings for the Medicaid program, the State’s payments to pharmacies are not ‘payments’ within the meaning of the statute” (42 U.S.C. § 1396r-8(b)(1)(A)). *PhRMA*, 251 F.3d at 225; *see also* Mem. of Law in Supp. of Pl.’s Mot. for Summ. J at 3; Defs.’ Mot. for Summ. J. at 10.

On July 3, 2001, in response to the D.C. Circuit’s decision in the *PhRMA* case, Maine changed its non-DEL portion of the HMP by increasing non-DEL payments to pharmacists by two percent or about one dollar per drug purchase.¹ *See* Defs.’ Mot. for Summ. J. at 11.

According to the defendants, “this additional payment required no approval by the Secretary

¹ The defendants contend “the reasoning of the *PhRMA* decision did not cast any doubt on the validity of the DEL portion of the Maine project, since the State was already paying well in excess of the anticipated rebates.” Defs.’ Mot. for Summ. J. at 10. “The DEL payment here is similar to the 50 percent Vermont payment that was not challenged.” *Id.*

because the State did not intend to seek federal financial participation for it.” *Id.* The State did, however, “inform the Secretary of the increase in non-DEL payments, and the Secretary has not objected.” *Id.*

5. The Challenged Expansion of the Non-DEL Portion of the HMP

The plaintiff challenges CMS’s approval of Maine’s decision to implement a two-percent increase from the use of “State only” funds.² *See* Pl.’s Mot. for Summ. J. at 4. The plaintiff contends the change was made “without any official federal or state action and . . . there is not a single document that requires Maine to make the two percent payments.” Mem. in Supp. of Pl.’s Mot. for Summ. J. at 13. Also, the plaintiff claims that the HMP does not include any payments by Maine for prescription drugs.³ In doing so, the plaintiff claims that “Maine is not making any such payments because the new payments are . . . funded by the administrative cost savings Maine achieved when it integrated the DEL into the HMP.” *Id.* at 18. Thus, the plaintiff argues that Maine is still not making the “net expenditure of funds” required to trigger manufacturer

² Although the plaintiff seeks to invalidate the entire HMP, the plaintiff fails to challenge or argue that any of the DEL’s features are unlawful. As such, the defendants ask this court to consider any challenge to the DEL component as waived. Defs.’ Mot. for Summ. J. at 11.

³ To counter the plaintiff’s assertion, the defendants state that the two-percent increase in non-DEL payments costs Maine between \$500,000.00 and one-million dollars per year. *See* Defs.’ Stat. of Mat. Facts at ¶ 12. DHS is making this additional payment from the \$19,750,292.00 of “State-only” funds that are appropriated to pay for the HMP. *See* Gessow Decl. ¶¶ 10, 12. Since DHS will not ask the federal government for federal financial participation on the two-percent subsidy, and implementation of the additional subsidy requires no change to the existing Special Terms and Conditions or Operational Protocols of the HMP, no federal approval is necessary and none was sought. *See id.* ¶ 9.

rebates.⁴ *See id.* (quoting *PhRMA*, 251 F.3d at 225). The defendants argue that the additional two-percent payment requires no approval from the Secretary since only “major changes in policy or operating procedures” must be “submitted for review” by the Secretary.⁵ *See* Defs.’ Stat. of Mat. Facts at 4.

B. Procedural History

The plaintiff filed a complaint for declaratory, injunctive, and other relief on June 29, 2001. Since the filing of the complaint, Kevin W. Concannon, Commissioner of the Maine Department of Human Services, filed a motion on July 23, 2001 to intervene in the case as an intervenor-defendant. The court granted this motion because Maine’s strong interest in providing affordable prescription drugs to its low-and-moderate-income citizens gives rise to a strong interest in defending the HMP. *See* Order dated September 27, 2001. On August 28, 2001, the defendants filed the administrative record and an answer to the plaintiff’s complaint. On October 22, 2001, the plaintiff filed a motion for summary judgment and a joint status report

⁴ The plaintiff argues that “it is no coincidence that the \$500,000.00 to 1 million dollars Maine believes it will spend annually on the two percent subsidies to HMP recipients falls directly in the range of monies Maine is saving from administrative integration of the DEL.” Pl.’s Mot. for Summ. J. at 22. Thus, “Maine has merely shifted its expenditures from one program - the DEL, in the form of administrative costs - to another - the HMP, in the form of two percent subsidies.” *Id.* The plaintiff sees this as a “classic ‘shell game’ in which Maine has moved prior expenditures into the HMP for the purpose of creating illusory ‘payments’ that do not amount to new ‘net expenditures’ sufficient to trigger rebates.” *Id.* In contrast, the defendants argue that the DEL portion of the project did not produce administrative savings and the expansion of drugs subject to the DEL coverage cost Maine hundreds of thousands of dollars. *See* Defs.’ Mot. for Summ. J. at 19-20.

⁵ “The State did, however, inform the Secretary of the increase in non-DEL payments, and the Secretary has not objected.” Defs.’ Stat. of Mat. Facts at 4.

on October 25, 2001. On November 5, 2001, the defendants filed a motion for summary judgment and, on the same day, the intervenor-defendant filed a motion for summary judgment. On November 13, 2001, the plaintiff filed a memorandum in support of its motion for summary judgment. On December 5, 2001, the parties filed a joint status report. These cross motions for summary judgment are now ripe for resolution.⁶ For the reasons that follow, the court grants the defendants' and intervenor-defendant's motions for summary judgment and correspondingly denies the plaintiff's motion for summary judgment.

III. ANALYSIS

A. Legal Standards

1. Legal Standard for a Motion for Summary Judgment

Summary judgment is appropriate when “the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law.” FED. R. CIV. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). To determine which facts are “material,” a court must look to the substantive law on which each claim rests. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A “genuine issue” is one whose resolution could establish an element of a claim or defense and, therefore, affect the outcome of the action. *See Celotex*, 477 U.S. at 322; *Anderson*, 477 U.S. at 248.

⁶ All the parties have filed joint status reports apprising the court on recent developments in the case. The parties have informed the court that the case can be decided on cross-motions for summary judgment. *See* Dec. 5, 2001 J.S. Rep. ¶¶ 1, 6, 12, 13, 14.

In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true. *See Anderson*, 477 U.S. at 255. A nonmoving party, however, must establish more than "the mere existence of a scintilla of evidence" in support of its position. *See id.* at 252. To prevail on a motion for summary judgment, the moving party must show that the nonmoving party "fail[ed] to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *See Celotex*, 477 U.S. at 322. By pointing to the absence of evidence proffered by the nonmoving party, a moving party may succeed on summary judgment. *See id.*

In addition, the nonmoving party may not rely solely on allegations or conclusory statements. *See Greene v. Dalton*, 164 F.3d 671, 675 (D.C. Cir. 1999); *Harding v. Gray*, 9 F.3d 150, 154 (D.C. Cir. 1993). Rather, the nonmoving party must present specific facts that would enable a reasonable jury to find in its favor. *See Greene*, 164 F.3d at 675. If the evidence "is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (internal citations omitted).

2. Legal Standard for Standing

Article III of the Constitution limits United States courts to "cases" or "controversies." *See U.S. CONST. ART. III, § 2, cl. 1.* Article III's prerequisites reflect the "common understanding of what it takes to make a justiciable case." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998). Consequently, in order for this court to have jurisdiction over a case, each plaintiff must have standing to bring their claim. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992).

An individual must satisfy a three-prong test in order to establish standing. *See id.* First, the individual must have suffered some injury in fact – an invasion of a legally protected interest that is concrete and particularized and actual or imminent. *See id.* at 560; *MD Pharmaceutical Inc. v. Drug Enforcement Admin.*, 133 F.3d 8, 11 (D.C. Cir. 1998) (concluding that current manufacturer had standing to seek review of actions taken by the DEA). In some cases, a plaintiff may be injured when the “discriminatory classification prevent[s] the plaintiff from competing on an equal footing.” *Northeastern Fla. Chapter, Associated Gen. Contractors of America v. Jacksonville*, 508 U.S. 656, 667 (1993) (holding that when the government erects a barrier, in order to establish standing, a group seeking to challenge the barrier need not allege they would have attained the benefit but for the barrier).

Second, the injury must be fairly traceable to the governmental conduct alleged. *See Warth v. Seldin*, 422 U.S. 490, 504 (1975) (finding lack of standing where city residents failed to show a causal relationship between town’s zoning practices and alleged injury); *National Maritime Union v. Commander, Military Sealift Command*, 824 F.2d 1228 (D.C. Cir. 1987) (holding that the plaintiff failed the second and third prongs of standing). A plaintiff will not have standing if this court must accept a speculative inference or assumption to link the alleged injury to the challenged action. *See id.*; *Andrx Pharm., Inc. v. Bovail Corp. Int’l*, 256 F.3d 799, 815 (D.C. Cir. 2001) (declaring that the potential manufacturer’s damages were not too speculative assuming it could claim its intent and preparedness to enter the market); *Advanced Mgmt. Tech. v. FAA*, 211 F.3d 633, 637 (D.C. Cir. 2000) (holding that a contractor lacked standing on the theory of reputational injury).

Third, the plaintiff must prove that the alleged injury is likely to be redressed by a favorable decision of this court. *See Lujan*, 504 U.S. at 561 (1992); *Tozzi v. U.S. Dep’t of Health*

and Human Servs., 271 F.3d 301 (D.C. Cir. 2001) (recognizing that upgrade classification change from “reasonably anticipated” to “known” carcinogen caused some economic injury that could be redressed by reversing the classification).

An organization has standing only if it meets a separate three-prong test. *See Truckers United for Safety v. Mead*, 251 F.3d 183 (D.C. Cir. 2001) (holding that a motor carriers’ association has standing to sue on behalf of its members for Department of Transportation’s alleged abuses of agency authority). Such standing exists where the organization’s members (1) would have standing to sue in their own right, (2) the interests that the organization seeks to protect are germane to its purposes, and finally, (3) neither the claims asserted nor the relief requested requires the participation of each of the organization’s individual members. *See id.*; *Friends of the Earth, Inc. v. Laidlaw Env’tl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000); *Hunt v. Wash. State Apple Comm’n*, 432 U.S. 333, 342-43 (1977) (agreeing with the district court’s determination that a commission has standing to assert the claims of apple growers and dealers in its representational capacity); *Fund Democracy, LLC v. SEC*, ___ F.3d ___, No. 01-1367, 2002 WL 125761 at *2, 2002 U.S. App. LEXIS 1550 at *4 (D.C. Cir. 2002) (applying test from *Laidlaw* and determining no standing exists where a company has failed to show individuals would have standing to sue in their own right).

B. The Plaintiff Does Not Have Standing to Challenge the HMP Beneficiaries’ Copayment

As stated before, the Medicaid statute imposes limits on copayments or other cost-sharing charges that states may impose on “individuals . . . who are eligible under the [state Medicaid] plan.” *See* 42 U.S.C. § 1396o(b)(3). Such “deduction, cost sharing or similar charges imposed under the plan” must be “nominal in amount.” *Id.* HHS has promulgated regulations

defining what constitutes the “nominal” copayments that may be required of individuals purchasing prescription drugs. For instance, where the state payment for a drug is \$10.00 or less, the copayment may not exceed 50 cents; where the state payment is more than \$50.00, the copayment may not exceed \$3.00. *See* 42 C.F.R. § 447.54(a)(3); 42 U.S.C. § 1396r-8(b)(1)(A).

In the plaintiff’s view, the HMP violates these statutory and regulatory limitations because it requires beneficiaries to pay more than 85 percent of a drug’s Medicaid price, far beyond any reasonable conception of a “nominal” copayment. *See* Compl. ¶¶ 14, 17-18; Pl.’s Mot. for Summ. J. at 26-28 (discussing regulatory and dictionary definitions of “nominal”). The plaintiff asserts that the Secretary’s approval of the Maine HMP exceeds the Secretary’s statutory authority in violation of the APA. *See* Compl. ¶¶ 7, 59. Additionally, the plaintiff argues that the Secretary abused his discretion in approving “nominal” copayments that exceed the Secretary’s own regulatory definition of what constitutes a “nominal” copayment. *See* 5 U.S.C. § 706(2)(A), (C); Compl. ¶¶ 4-5, 23, 55-58; Pl.’s Mot. for Summ. J. at 28. Specifically, the plaintiff claims that it was an abuse of discretion for the Secretary to approve the HMP because it includes unlawfully high copayments. *See* Pl.’s Mot. for Summ. J. at 28 (quoting *Union of Concerned Scientists v. Nuclear Regulatory Comm’n*, 711 F.2d 370, 381 (D.C. Cir. 1983) (holding that “[w]hen an agency’s interpretation of its own rules flies in the face of the language of the rules themselves, it is owed no deference.”)).

In this case, the defendants argue that the copayment provision of 42 U.S.C. § 1396o applies only to Medicaid recipients and not to the expansion population of the HMP beneficiaries. *See* Defs.’ Mot. for Summ. J. at 21. Thus, the defendants conclude that there are no statutory restrictions on copayments for non-Medicaid participants in the subject demonstration project. *Id.* Assuming *arguendo* that there were statutory restrictions on

copayments for non-Medicaid participants in the demonstration project, the plaintiff would fail to satisfy the first prong required to assert organizational standing because the plaintiff's members do not "have standing to sue in their own right." *See Friends of the Earth*, 528 U.S. at 181. Here, no legally cognizable relationship exists between the plaintiff's individual members and the HMP beneficiaries.

Applying the second prong of the organizational standing analysis, the plaintiff also fails to assert that "the interests their organization seeks to protect are germane to its purposes." *See id.* Nowhere in the record do the plaintiffs claim that the HMP beneficiary copayments they seek to protect are related to the purpose of their organization. As the defendants aver, the copayment provision in 42 U.S.C. § 1396o is "designed to protect Medicaid beneficiaries and regulate states . . . it has nothing to do with the business of drug manufacturers." Def.'s Mot. for Summ. J. at 22. The court agrees with the defendants' argument and concludes that the plaintiff fails to satisfy the second prong of the standing requirement. *See Friends of the Earth*, 528 U.S. at 181.

Additionally, the court determines that the plaintiff fails to satisfy the third prong of the organizational standing requirement. To satisfy the third prong, the plaintiff must show that "neither the claims asserted nor the relief requested requires the participation of each of the organization's individual members." *Id.* Regardless of whether the plaintiff or the individual members of the plaintiff's organization assert claims that the "nominal" copayment requirement of 42 U.S.C. 1396o is unlawful, standing does not exist because the plaintiff and its individual members are not among the parties protected by the provision. *See id.* Thus, the court concludes that the plaintiff lacks standing to challenge the "nominal" copayment requirement of

42 U.S.C. 1396o because none of the individual members of the plaintiff's organization are among the parties to be protected by the "nominal" copayment provision. *See id.*

In addition to asserting it has standing to challenge the "nominal" copayment requirement of 42 U.S.C. § 1396o(b)(3), the plaintiff also alleges that it has standing to challenge all other violations of the SSA. *See* Pls.' Mot. for Summ. J. at 26-29. The plaintiff, however, fails to state why any grounds for standing exist to challenge "all other violations" of the SSA. *See id.* The plaintiff does state that "numerous cases have permitted industry associations to challenge administrative actions that were not directed primarily at their interests, but which injured them." *Id.* at 29. Although the plaintiff cites several cases to that effect, the plaintiff fails to show this court why it has standing to challenge administrative actions that are not directed primarily at its interests. This failure defeats the plaintiff's assertion.

All the parties recognize that this court previously decided this question vis-a-vis the plaintiff's standing to challenge Vermont's PDP copayment structure in *Pharmaceutical Research and Mfrs. of America v. United States*, 135 F. Supp.2d 1, 10 (D.D.C. 2001). *See* Pl.'s Mot. for Summ. J. at 5; Defs.' Mot. for Summ. J. at 25; Int.-Def.'s Mot. for Summ. J. at 24. In that case, this court held that the plaintiff lacked standing to pursue the "nominal" copayment claims. *See id.* Additionally, the plaintiff and the defendants acknowledge that the D.C. Circuit did not address the issue of standing with regard to the "nominal" copayment claims. *See generally PhRMA*, 251 F.3d 219; Pl.'s Mot. for Summ. J. at 5; Defs.' Mot. for Summ. J. at 25. Here, the situation is unchanged. Further, this court's conclusion that the plaintiff has standing to challenge other aspects of the HMP on behalf of its members does not give it standing to contest the copayments that are the exclusive responsibility of Maine's HMP beneficiaries because "standing must be demonstrated separately for each form of relief sought." *See Friends of the*

Earth, 528 U.S. at 185. The plaintiff does not allege that it represents the HMP beneficiaries. Nor does the plaintiff allege that it has any relationship with the HMP beneficiaries authorizing the plaintiff to advance their putative interests in this matter. Thus, the court grants the defendants' and intervenor-defendant's motions for summary judgment with respect to the HMP beneficiaries' copayment challenge because no standing exists. In doing so, the court denies the plaintiff's motion for summary judgment on this point.

C. The Plaintiff Has Standing to Contest the HMP on Behalf of its Members

The plaintiff is a trade association that represents American biotechnology and pharmaceutical companies. *See* Compl. ¶¶ 8-11. The plaintiff represented its members' interests during HHS's consideration and approval of Maine's prescription-drug pilot project under 42 U.S.C. § 1315. *See* Bantham Decl. ¶ 6. Most of the plaintiff's members have entered into Medicaid prescription-drug rebate agreements with HHS, including, for example, American Home Products and its Wyeth-Ayerst Laboratories Division, Novartis Pharmaceuticals Corporation, and Pfizer Inc. *See* Bantham Decl. ¶ 9; Alvermini Decl. ¶ 3; McEnroe Decl. ¶ 3; Oxner Decl. ¶ 3. On a quarterly basis, each of these companies pay rebates directly to each state based on the number of units of its drugs that have been dispensed under the subject state's Medicaid program. *See* 56 Fed. Reg. 7049, Section II(a), (b); Compl. ¶ 40. If these companies violate the rebate agreements by refusing to pay rebates mandated under a state's Medicaid program, the defendants have the authority to terminate their participation in Medicaid drug programs nationwide. *See* Demonstration Proposals Pursuant to § 1115(a) of the SSA, 59 Fed. Reg. 49,249, 49,250 (Sept. 27, 1994); Waiver Letter, "Special Terms and Conditions" at 14; Compl. ¶ 28. CMS permits Maine to suspend or modify payments under the HMP if manufacturers do not pay rebates in a timely manner to the State. *See id.* Thus, the court

concur with the plaintiff's view that it has standing to assert the legal rights of its members in this controversy. Indeed, "[i]t has long been settled that even in the absence of injury to itself, an association may have standing solely as the representative of its members." *United Auto., Aerospace and Agric. Implement Workers of Am. v. Brock*, 477 U.S. 274, 280 (1986) (citations omitted); see also *United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 688-89 (1973) (recognizing standing for an environmental group based on the adverse effect of an International Commerce Commission decision on its members). Along this same line of reasoning, the plaintiff has sufficiently "alleged facts that demonstrate that the actions of the defendants threaten to harm the cognizable interests of" its member companies. See *National Wildlife Fed'n v. Burford*, 835 F.2d 305, 314 (D.C. Cir. 1987). Specifically, the parties agree that about 225,000 individuals will be eligible to participate in the HMP. See Compl. ¶ 35; Int.-Defs.' Mot. for Summ. J. at 7. As stated before, an association has standing to bring suit on behalf of its members when: (1) its members would otherwise have standing to sue in their own right; (2) the interests it seeks to protect are germane to the organization's purpose, and; (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. See *Friends of the Earth*, 528 U.S. at 181.

In this case, the plaintiff satisfies all three of the aforementioned requirements. Each of the plaintiff's members will be affected by the HMP, thus providing each pharmaceutical company with standing to sue in their own right. See *id.* The plaintiff's members that participate in Medicaid and have drug rebate agreements with HHS will be forced to select between two potentially costly options. Compl. ¶¶ 28-29. If the manufacturers make the rebate payments and the HMP is ultimately invalidated, Maine's sovereign immunity may prevent the manufacturers

from recovering the rebates.⁷ *See* Compl. ¶ 28. Additionally, if the manufacturers refuse to make the rebate payments and the court later determines that the HMP is lawful, HHS could terminate the manufacturers' rebate agreements and their eligibility to participate in all 50 states' Medicaid prescription-drug programs. *See* Compl. ¶ 28-29; Pl.'s Mot. for Summ. J. at 25-26. As such, the court agrees that each of the above scenarios are well defined interests pertaining to each member of the plaintiff's association and "germane to the organization's purpose." *See Friends of the Earth*, 528 U.S. at 181. Furthermore, each member of the organization asserts identical claims and requests the same relief. *See id.* For these reasons, the court concludes that the plaintiff has standing to raise its non-copayment objections to the Maine HMP on behalf of its affected members. The court now turns to the outcome of these challenges.

D. The HMP is Not Unlawful Because It Does Not Lack the Requisite Payment Under the State Plan Pursuant to 42 U.S.C. § 1396r-8.

The plaintiff moves the court for summary judgment, asking the court to invalidate the HMP because Maine's two-percent payment is not a "payment . . . made under the State plan" necessary to trigger manufacturer rebates under 42 U.S.C. § 1396r-8(b)(1)(A). The plaintiff argues that the HMP is "indistinguishable" from the Vermont PDP "in the critical respect that it does not include any payments by the State of Maine for prescription drugs." *See* Mem. in Supp. of Pl.'s Mot. for Summ. J. at 15. The plaintiff contends that Maine's act of combining the HMP with the DEL program "eliminates the administrative costs of the DEL, which are approximately the same amount as the total amount of the two percent HMP payment." Pl.'s Mot. for Summ. J. 5, 21-22. The plaintiff argues that "under the HMP, those administrative costs are accounted for

⁷ Neither party asks the court to provide an opinion as to whether Maine actually has sovereign immunity against such claims.

through a reduction in DEL beneficiaries' discounts." *Id.* Specifically, the plaintiff contends that "of the 18 percent manufacturers' rebates, beneficiaries receive a 14 percent discount while Maine uses the four percent to cover the State's anticipated administrative costs, and no longer pays the DEL administrative costs the State covered prior to the HMP." *Id.* Thus, the plaintiff claims that "there is no net expenditure under the Maine HMP." *See id.* The defendants argue to the contrary, stating the following:

When Maine integrated the DEL into the HMP, the administration of the DEL benefit was assumed by the HMP program. This means that the cost of administering the DEL component of the HMP is now shared by the federal government under the demonstration project agreement. [The plaintiff's] argument however, ignores the fact that 66.58 percent of the DEL rebates that Maine formerly retained must now be shared with the federal government. As a result, any gross administrative costs that are "saved" by integrating the DEL into the [HMP] are more than offset by a net reduction of 66.58 in rebate revenue for DEL prescriptions.

See Nolan Decl. ¶ 5. Additionally, the defendants argue that integrating the DEL into the HMP increased the net cost of the DEL component because DEL beneficiaries now qualify for the 80 percent subsidy on many more drugs than were previously available under the "old" DEL program. *See Gessow Decl.* ¶ 13.

While Maine states that it has appropriated funds for the HMP, the plaintiff is not convinced. *See Int.-Def.'s Mem. in Supp. of Mot. for Summ. J. at 11.* The plaintiff fails, however, to allege any facts that demonstrate that Maine's elimination of the administrative costs of the DEL is equivalent to the two-percent payment. The plaintiff seeks to invalidate the entire HMP by concluding that Maine has not committed a "net expenditure of funds" due to

savings in administrative costs.⁸ See Pl.’s Mot. for Summ. J. at 18 (quoting *PhRMA*, 251 F.3d at 225). Maine’s two-percent payment, however, appears to fit within the meaning of "payment" according to the D.C. Circuit’s decision in the *PhRMA* case. See 251 F.3d at 225-26. Indeed, the D.C. Circuit stated that “[p]roperly understood, ‘payment’ here means only payments with state or federal funds appropriated for Medicaid expenditures; absent such payments, pharmaceutical rebates would not contribute to reducing the cost of the taxpayer-funded Medicaid program, and the legislative history makes quite clear that Congress’ purpose in requiring rebates was to do just that.” *Id.* The plaintiff fails to provide the court with a figure that would constitute an appropriate “payment” under the SSA. For example, deduced from the plaintiff’s reasoning, this court is unsure as to whether or not a 2.1 percent payment, or for that matter a 2.2 percent payment, would qualify as an adequate “payment” under 42 U.S.C. § 1396r-8(b)(1)(A).

To address the question of whether Maine’s two-percent “payment” is derived from funds appropriated for Medicaid expenditures, the court relies on the facts of this case. The intervenor-defendant states that “rebates under Maine’s HMP are expected to amount to \$5,451,494.00 annually (Gessow Decl. ¶11), whereas total state-only appropriations amount to \$19,750,292.00 annually.” Int.-Def.’s Mot. for Summ. J. at 11. Additionally, the defendants argue that “the two percent increase in non-DEL payments cost[s] the [S]tate between \$500,000.00 and \$1 million dollars per year.” Defs.’ Stat. of Mat. Facts at ¶ 12. Thus, applying the reasoning of the D.C. Circuit in the *PhRMA* case to the facts of the case at bar, the court

⁸ The defendants state that the plaintiff’s complaint, in seeking to invalidate the entire HMP, fails to argue that the features of the DEL component are unlawful. See Defs.’ Mot. for Summ. J. at 11. Thus, the defendants ask this court to render any challenge to the DEL component as abandoned. See *id.*

determines the “payment” requirement is satisfied since “only payments with state or federal funds appropriated for Medicaid expenditures” will suffice. *PhRMA* 251 F.3d at 225. Having determined Maine’s two-percent payment to be a “payment” under 42 U.S.C. 1396r-8(b)(1)(A), this court also determines that Maine’s two-percent “payment,” which triggers the rebate requirement from pharmaceutical manufacturers, “redu[ces] the cost of the taxpayer funded Medicaid program.” *PhRMA* 251 F.3d at 225. As stated in the *PhRMA* opinion, “‘payment’ excludes situations where no government funds are spent.” *PhRMA*, 251 F.3d at 225. Here, the parties present the court with concrete facts that Maine appropriated funds for the HMP to satisfy the “payment” requirement. Int.-Def.’s Mem. in Supp. of Mot. for Summ. J. at 11. Moreover, since Maine’s two-percent payments are in addition to and separate from the 18-percent subsidy provided by the manufacturer rebates, the court also concludes that Maine’s HMP funds are not from “fully reimbursed manufacturer rebates.” *See PhRMA*, 251 F.3d at 225; Int.-Def.’s Mot. for Summ. J. at 9.

E. The HHS Secretary Has the Authority to Approve Maine's Two-Percent Payment as an Appropriate Medicaid Expenditure

Finally, the court turns to the question of whether the HHS Secretary may approve Maine’s two-percent payment as Medicaid expenditures (i.e., “payments made under the State plan” pursuant to 42 U.S.C. § 1396r-8(b)(1)(A)). As the D.C. Circuit held in *PhRMA*, “[W]hen Congress said ‘payment,’ it meant payment with funds appropriated for Medicaid purposes.” *PhRMA*, 251 F.3d at 225. In determining whether the HHS Secretary correctly exercised his authority in determining that Maine’s two-percent payment is a “payment” under the State’s Medicaid plan, the court once again considers the reasoning of the D.C. Circuit’s decision in *PhRMA* and applies that reasoning herein. The defendants contend that Maine’s two-percent

payment is a “non-conforming” payment because the DEL payments are not “made under the State plan” as required by 42 U.S.C. § 1396r-8. *See* Pl.’s Mot. for Summ. J. at 17; Defs.’ Mot. for Summ. J. at 15-16. Thus, the defendants argue that it is “by virtue of the Secretary’s exercise of demonstration project authority that these otherwise non-conforming payments are ‘regarded’ as payments ‘made under the State plan’ to ‘the extent and for the period prescribed by the Secretary.’” 42 U.S.C. § 1315(a)(2); Defs.’ Mot. for Summ. J. at 15. As mentioned earlier, the plaintiff and the defendants disagree on the issue of whether these “non-conforming” payments can be considered “payments” under the SSA. As the waiver letter states, “all expenditures for extending pharmacy-only benefits” under the HMP “shall be regarded as expenditures under the State’s [Medicaid] plan . . . subject to the condition that the State will be eligible for federal financial participation only to the extent that those expenditures do not exceed average rebate amounts (as reconciled on a quarterly basis).” *See* Admin. R. at 29, 41; Defs.’ Mot. for Summ. J. at 15; Pl.’s Mot. for Summ. J. at 18-19. The plaintiff contends, however, that the Secretary lacked the authority to impose a rebate requirement on drug purchases that were not made with State and federal funds under the Medicaid program. *See* Pl.’s Mot. for Summ. J. at 25. To resolve this difference, the court utilizes the D.C. Circuit’s reasoning in *PhRMA* to determine the degree of deference the court must give to the Secretary’s decision regarding the two-percent payments as “expenditures under the State’s [Medicaid] plan” in the waiver letter. *See* 42 U.S.C. § 1315(a)(2).

In addressing the question of statutory interpretation, the D.C. Circuit proceeded in accordance with *Chevron U.S.A., Inc. v. Natural Res. Defense Council, Inc.*, 467 U.S. 837, 842 (1984), by first inquiring “whether Congress has directly spoken to the precise question at issue.” *See Chevron* at 842; *PhRMA*, 251 F.3d at 224. If Congress has directly spoken on the

issue, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* The D.C. Circuit, however, also recognized that "not all agency interpretations of statutes warrant *Chevron* deference." *PhRMA*, 251 F.3d at 224 (quoting *Christensen v. Harris County*, 529 U.S. 576, 587 (2000)). To wit, in addressing this issue, the Supreme Court held in *Christensen* that "[i]nterpretations such as those in opinion letters--like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law--do not warrant *Chevron*-style deference." *Christensen*, 529 U.S. at 587. Although the D.C. Circuit interpreted "payment" as excluding situations where no government funds are spent, it did not address the "degree of deference needed in deciding whether or not HHS's approval of the Vermont PDP would be entitled to *Chevron* deference," since it found that "Congress had directly spoken to the precise question at issue" and concluded that "payment does not include expenditures that are fully reimbursed by manufacturer rebates." *PhRMA*, 251 F.3d at 225. In the instant case, however, the facts vary. Maine has spent government funds by its election to increase its "payment" by two percent under the HMP demonstration project. *See* Defs.' Mot. for Summ. J. at 10-11. As such, this case presents the court with a question that the D.C. Circuit was not called to answer, that is, whether HHS's approval of the HMP is entitled to heightened deference under *Chevron*, or the less deferential standard under *Christensen*.

In applying the principles of *Chevron* and *Christensen* to the given facts, the court determines that the Secretary's decision to approve the HMP expressed in the waiver letter is entitled to the heightened *Chevron* deference because Congress, pursuant to 42 U.S.C. § 1315(a)(2)(A), has directly and unambiguously spoken to the question of whether Maine's two-percent payment constitutes a "payment under the State plan," and has thereby expressly granted

the HHS Secretary the authority to approve such Medicaid demonstration projects. *See Chevron* at 842; *PhRMA*, 251 F.3d at 224. Along this same line of reasoning, the Secretary's cause for approving the HMP was "not to restrict Maine's ability to invest [S]tate funds in the health of its citizens, but to achieve 'expanded access to medically necessary drugs' by making them 'more affordable to primarily low-income Maine residents who are not eligible for Medicaid.'" Pl.'s Mot. for Summ. J. at 17; Admin. R. at 28.

Nevertheless, the plaintiff contends that CMS's approval of Maine's two-percent payment does not warrant deference. Pl.'s Mot. for Summ. J. at 19. In advancing this argument, the plaintiff relies on the Supreme Court's ruling in *Christensen* regarding agency interpretations of statutes. *See* Pl.'s Mot. for Summ. J. at 20. In contrast to *Chevron*, the court notes that interpretations contained in formats such as opinion letters are 'entitled to respect' under the Supreme Court's decision in *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944), "but only to the extent that those interpretations have the power to persuade." *See Christensen*, 529 U.S. at 587. Assuming *arguendo* that the court views the Secretary's interpretation of 42 U.S.C. § 1315(a)(2) as persuasive, the court's analysis would end, therefore deferring judgment to the defendants' approval of the HMP. *See id.*; *Skidmore*, 323 U.S. at 140.

Likewise, even if the court does not view the Secretary's interpretation of the statute as "persuasive," the court may rely on the Supreme Court's *Auer* standard in deferring judgment to the Secretary's interpretation. *See Auer v. Robbins*, 519 U.S. 452 (1997). In *Auer*, the Court held that an agency's interpretation of its own regulations is entitled to deference. *See id.* at 461. *Auer* deference, however, "is only warranted when the language of the regulation is ambiguous." *Christensen*, 529 U.S. at 588. In a more recent decision, the Court considered the limits of *Chevron* deference owed to administrative practice in applying a statute and held "that an

administrative implementation of a particular statutory provision qualifies for *Chevron* deference when it appears that Congress delegated authority to the agency generally to make rules carrying the force of the law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.” *United States v. Mead Corp.*, 121 S. Ct. 2164, 2171 (2001). The Court reaffirmed the principal that formal agency regulations that apply to all cases and have the force of law, like the one presented in the case at bar, are entitled to *Chevron* deference. *See id.* at 2171-73 (assuming “generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force”). *Chevron* deference, however, would not be extended to agency classification rulings that do not carry the force of law and do not apply beyond the specific case. *See id.* This is consistent with the policy that “[t]he well reasoned views of the agencies implementing a statute ‘constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance[]’ . . .” *Id.* at 2171 (quoting *Bragdon v. Abbott*, 524 U.S. 624, 642 (1998) (quoting *Skidmore*, 323 U.S. at 139-40)). To wit, the Court has “long recognized that considerable weight should be accorded to an executive department’s construction of a statutory scheme it is entrusted to administer . . .” *Id.* (quoting *Chevron*, 467 U.S. at 844 (footnote omitted)).

Here, there is no reason to consider the statute in question ambiguous because Congress expressly authorizes the Secretary under 42 U.S.C. § 1315(a)(2) to treat payments made in demonstration projects (such as Maine’s HMP) as if they are Medicaid expenditures “under the State plan” to the extent that such payments are made “for extending pharmacy-only benefits to adults with income at or below 300 percent of the federal poverty level as part of the Pharmacy Discount Program demonstration.” 42 U.S.C. § 1315(a)(2); Int.-Def.’s Mem. in Supp. of Mot.

for Summ. J. at 9; Admin R. at 29. It is therefore clear to this court that Medicaid treats payments made in demonstration projects as though they were expenditures under the State plan “to the extent . . . prescribed by the Secretary.” 42 U.S.C. § 1315(a)(2); Int.-Def.’s Mem. in Supp. of Mot. for Summ. J. at 9. As such, the court affords *Chevron* deference to the agency’s formal decision applied to this case, thus, ending this line of inquiry by the court.

In sum, this court would abrogate Congress’ intent underlying the Medicaid statute and the D.C. Circuit’s decision in *PhRMA* by failing to recognize Maine’s two-percent payment as a “payment” under the SSA. *See* 42 U.S.C. 1396r-8(b)(1)(A); *PhRMA* 251 F.3d at 224-225. In this vein, the court concludes that no genuine issue of material fact exists as to the legality of the HMP and the court, therefore, denies the plaintiff’s motion for summary judgment. *See* FED. R. CIV. P. 56(c); *Celotex Corp.*, 477 U.S. at 322; *Diamond*, 43 F.3d at 1540. Accordingly, the court grants summary judgment to the defendants and the intervenor-defendant.

IV. CONCLUSION

For all of the foregoing reasons, the court grants the defendants’ and the intervenor-defendant’s motions for summary judgment, and denies the plaintiff’s motion for summary judgment. An order directing the parties in a manner consistent with this Memorandum Opinion is separately and contemporaneously issued this _____ day of February 2002.

Ricardo M. Urbina
United States District Judge

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,	:	
	:	
Plaintiff,	:	Civil Action No.: 01-1453 (RMU)
	:	
v.	:	
	:	Document Nos.: 8, 10, 17, 18
TOMMY G. THOMPSON <i>et al.</i> ,	:	
	:	
Defendants,	:	
	:	
and	:	
	:	
KEVIN W. CONCANNON,	:	
	:	
Intervenor-Defendant.	:	

ORDER

**GRANTING THE DEFENDANTS' MOTION FOR SUMMARY JUDGMENT;
GRANTING THE INTERVENOR-DEFENDANT'S MOTION FOR SUMMARY JUDGMENT;
DENYING THE PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT**

For the reasons stated in the court's Memorandum Opinion separately and contemporaneously issued,

it is this _____ day of February 2002,

ORDERED that the defendants' motion for summary judgment is **GRANTED**; and it is **FURTHER ORDERED** that the intervenor-defendant's motion for summary judgment is **GRANTED**; and it is

ORDERED that the plaintiff's motion for summary judgment is **DENIED**.

SO ORDERED.

Ricardo M. Urbina
United States District Judge

Pharmaceutical Research and Manufacturers of America v. Thompson et al.
#2001-cv-1453

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