UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

LONG TERM CARE PHARMACY ALLIANCE, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 07-1115 (ESH)**
MICHAEL O. LEAVITT, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

This case arises from the implementation of the recently enacted Medicare Part D prescription drug program under the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA"). Pub. L. No. 108-173, 117 Stat. 2066 (2003). The plaintiff organizations, which represent long term care pharmacies and pharmacists, have sued the Department of Health and Human Services ("HHS"), its Secretary, Michael O. Leavitt, and the Centers for Medicare and Medicaid Services ("CMS"), which oversees this program. Plaintiffs allege that CMS has failed to provide accurate and timely information regarding the eligibility of Medicare and Medicaid beneficiaries as required by the MMA, and that the erroneous data that CMS provides has caused the prescription drug plans with whom plaintiffs' members have a contractual relationship to erroneously withhold full reimbursement for the co-payments for prescription drugs that are dispensed to indigent nursing home residents by the plaintiffs' members. Defendants have moved to dismiss under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6) on standing and sovereign immunity grounds and for failure to state a claim upon which relief may be granted. For the reasons set forth herein, the Court concludes

that plaintiffs lack standing to bring their claims, and it will therefore grant defendants' motion.

BACKGROUND

In December 2003, Congress enacted the MMA, which provides prescription drug coverage to Medicare beneficiaries. (Am. Compl. ¶ 16.) The benefit became effective on January 1, 2006. (*Id.*) Various private prescription drug plans ("PDPs") have contracts with CMS to administer the prescription drug program, commonly referred to as Medicare Part D. (*Id.* ¶ 24.) The PDPs, in turn, have contracts with the many pharmacies that provide the drugs. (*Id.* ¶ 25.) After a pharmacy dispenses drugs to a beneficiary, it bills the PDP for reimbursement pursuant to contract. (*Id.* ¶ 28.) Typically the pharmacy collects any co-payment that may be due from the beneficiary under the Medicare Part D plan, and the PDP reimburses the pharmacy an agreed-upon amount for the medication, less any co-payment collected from the beneficiary. (*Id.*) Although no individual contracts between the PDPs and the pharmacies have been provided, it is undisputed that these contracts set forth the terms of this reimbursement process. (*See id.* ¶¶ 25-28.)

The plaintiff organizations represent long term care ("LTC") pharmacies and pharmacists. (*Id.* ¶ 14.) These pharmacies do not dispense prescription drugs on a retail basis but provide them to individuals who reside in long term care facilities, such as nursing homes.[1]

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[1]Plaintiff Long Term Care Pharmacy Alliance ("LTCPA") is "organized for the purposes of protecting the interests of LTC pharmacies and long-term care facility residents and advocating on their behalf before governmental and other entities." (*Id.* ¶ 6.) Its members include the "two leading long-term care pharmacy companies in the United States." (*Id.* ¶ 7.) Plaintiff the American Society of Consultant Pharmacists ("ASCP") "serves as the international professional society representing thousands of practicing senior care and consultant pharmacists . . . by providing leadership, education, advocacy, and resources to advance the practice of senior care pharmacy." (*Id.* ¶ 8.)

(*Id.*) At issue in this case is the LTC pharmacies' provision of prescription drugs to a subset of Medicare beneficiaries, commonly known as "institutionalized dual eligibles," who are covered by both Medicare and Medicaid. (*Id.* ¶ 18.) These "institutionalized dual eligibles" are defined in the MMA as dual eligibles who are "inpatient[s] in a medical institution or nursing facility for which payment is made under Medicaid throughout a month," and they are not required to make any co-payments for covered medications obtained through their PDPs. 42 C.F.R. §§ 423.772, 423.782(a)(2)(ii). (*See* Am. Compl. ¶¶ 20, 22.)

The LTC pharmacies therefore do not collect any co-payment for prescriptions dispensed to those patients that they identify as institutionalized dual eligibles. (*Id.* ¶ 28.) Instead, plaintiffs claim that per their contracts with the LTC facilities, LTC pharmacies "provide all medically necessary prescription drugs, without regard to which patient is liable for payment, in order to enable the long-term care facilities to fulfill their federal statutory obligations to their residents to provide medications." (*Id.* ¶ 27.) According to the declarations of plaintiffs' witnesses, the LTC pharmacies determine which patients qualify as institutionalized dual eligibles in the first instance based on patient censuses from each LTC facility to which they provide drugs. (Rutkowski Decl. ¶ 7; Amorosi Decl. ¶ 5.) Because these patients reside in a nursing home, the declarants state, they are "necessarily 'institutionalized,' as that term is defined by CMS," and if the census identifies an institutionalized patient as "Medicaid eligible," the LTC pharmacy has "no reason" to charge that individual a co-payment, because the pharmacy is at that point "almost virtually certain" that the individual is an "institutionalized full benefit dual eligible" from whom no co-payment is due. (Rutkowski Decl. ¶¶ 7-9; *see also* Amorosi Decl. ¶¶ 5-8.) The LTC pharmacies then seek reimbursement from the PDPs for the

full amount of the medications it provided to the patients it identified as institutionalized dual eligibles. (Am. Compl. ¶ 28.)

Per the MMA, the Secretary of HHS is charged with establishing a process for providing the PDPs with eligibility data regarding all covered individuals and the amount of cost-sharing that each individual owes. Specifically, the statute states that the Secretary "shall provide a process whereby . . . (A) the Secretary provides for a notification of the PDP sponsor . . . that the individual is eligible for a subsidy and the amount of the subsidy . . . , [and] (B) the sponsor or organization involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Secretary information on the amount of such reduction." 42 U.S.C. § 1395w-114(c)(1). (Am. Compl. ¶ 29.) The MMA implementing regulations further provide that CMS is to "notif[y] the Part D sponsor offering the Part D plan, in which a subsidy eligible individual is enrolled, of the individual's eligibility for a subsidy under this section and the amount of the subsidy." 42 C.F.R. § 423.800(a). (Am. Compl. ¶ 30.) The PDPs in turn use the eligibility data they receive from CMS to determine the appropriate amount of reimbursement to be paid to the pharmacies. (Am. Compl. ¶ 31.) For example, if the CMS data indicate that a particular beneficiary does not owe any co-payment, the PDP would reimburse the pharmacy for the full amount of the prescription, without deducting any co-payment amount. (*See* Pls.' Opp'n at 6.) The PDPs are then reimbursed in turn by CMS for these prescriptions consistent with CMS's eligibility data. 42 U.S.C. § 1395w-114(c)(1)(C). (*See* Defs.' Mot. at 7.)

The Medicare Part D program was instituted in 2006, involving some six million beneficiaries, and, not surprisingly, the roll out of such a large and novel program was not

without operational problems. (*See* Defs.' Supp. Reply at 8.) For instance, as plaintiffs allege, certain PDPs have often refused to reimburse the LTC pharmacies for the full cost of the prescriptions they dispense to institutionalized dual eligibles because the information from CMS sometimes erroneously fails to recognize these beneficiaries as institutionalized dual eligibles. (Am. Compl. ¶¶ 33, 40, 41.) According to plaintiffs, there has been and continues to be a "significant lag time" between a beneficiary's enrollment, CMS's collection of the data, and CMS's provision of the data to the PDPs, and in "many instances," CMS has provided eligibility data on specific beneficiaries to PDPs "several months" after the LTC pharmacies have dispensed medications to those beneficiaries and submitted reimbursement claims to the PDPs. (*Id.* ¶ 32.) In addition, plaintiffs claim that "for an estimated 15% of persons known to LTC Pharmacies to be institutionalized dual eligibles, the data currently provided by CMS to PDPs still fail to reflect the fact that those beneficiaries are institutionalized and/or eligible under both the Medicare and Medicaid programs." (*Id.* ¶ 33.) As a result of this untimely and erroneous data from CMS, plaintiffs claim that "[t]hese failures have created and perpetuate a systemic data-based impediment to the proper functioning of the Part D program" (*id.* ¶ 3), because the PDPs improperly assess co-payments to dual eligible beneficiaries, and therefore wrongfully withhold the corresponding reimbursement amounts "indisputably owed" to the LTC pharmacies for these prescriptions. (*Id.* ¶ 40.) The LTC pharmacies have thereby "been deprived of reimbursements owed to them and forced to carry tens of millions of dollars of cost-sharing debt on behalf of misclassified institutionalized dual eligibles." (*Id.* ¶ 50.)

Defendants explain that there is an "inherent" lag time of at least one to seven weeks in the process by which CMS compiles data regarding which beneficiaries qualify as

institutionalized dual eligibles because CMS relies on information it receives from states to identify these individuals. (Defs.' Supp. Reply at 6-7.) This is because an institutionalized full-benefit dual eligible is defined as someone who has Medicare Part D coverage for an entire month, who has been "determined eligible by the State" for full Medicaid benefits for the same month, and who has been an inpatient in a medical institution, with the stay paid for by Medicaid, throughout the entire month. 42 U.S.C. §§ 1396u-5(c)(6), 1369u-5(a)(2); *see also* 42 C.F.R. §§ 423.902, 423.904(d)(4). According to defendants, the states transmit eligibility information to CMS once per month via electronic files. (Defs.' Supp. Reply at 7.) CMS then checks the information it receives from the states against its own database, sets each individual's co-payment level accordingly, and transmits this data to the PDPs. (*Id.*) Because the data accurately reflecting a beneficiary's status may not be available until after prescriptions have been dispensed to these individuals, CMS reimburses the PDPs through estimated interim payments based on the "actuarial value of the subsidies," and it later makes retroactive adjustments to "reconcile[] the amount it has paid PDP sponsors for cost-sharing through interim payments and the costs PDP sponsors claim they have actually incurred." (Defs.' Mot. at 7-8.) *See* 42 U.S.C. § 1395w-114(c)(2); 42 C.F.R. § 423.343(d). After they receive updated data regarding cost-sharing eligibility, the PDPs are required to "reimburse subsidy eligible individuals, and organizations paying cost-sharing on behalf of such individuals, any excess premiums and cost-sharing paid by such individual or organization after the effective date of the individual's eligibility for a subsidy." 42 C.F.R. § 423.800(c). However, CMS guidances have clarified that this regulation does not require the PDPs to reimburse a beneficiary where an LTC pharmacy did not actually collect a co-payment from that individual. (Defs.' Supp. Reply at 8;

Ex. C to Defs.' Supp. Reply at L000171.)

Apparently recognizing that the transfer of six million beneficiaries into the new Medicare Part D program at the beginning of 2006 would entail data inaccuracies attributable both to the system's inherent lag time and the problems associated with starting a program of this magnitude, CMS instituted measures aimed at alleviating the reimbursement problems that could be caused by delayed or incorrect eligibility data. (Defs.' Supp. Reply at 8.) Specifically, under CMS's "Best Available Evidence" ("BAE") policy, when a PDP sponsor has evidence that a beneficiary's cost-sharing level is not accurately reflected in the data, CMS requires the PDPs to update their records "to reflect the true cost sharing status" of that beneficiary. (*Id.* at 10; Ex. F to Defs.' Supp. Reply at L000173.) In 2006, CMS required the PDPs to keep records of the corrections it made to the cost sharing status of the beneficiaries, but it did not limit the type of evidence that the PDPs could rely on to substantiate these corrections, and it did not require the PDPs to provide any supporting documentation to CMS. (Defs.' Supp. Reply at 10.) Beginning in 2007, however, CMS required the PDPs to verify a correction to a beneficiaries' cost sharing status based on specific types of acceptable documentation, and it instituted a process by which the PDPs could submit "correction requests" to CMS, based on the acceptable documentation, to correct the beneficiaries' eligibility status in CMS's data systems. (*Id.* at 11.)

In their initial attempt to seek reimbursement for the co-payments that they claim were erroneously withheld, plaintiffs originally brought suit against only one PDP -- United Health Group, which is one of the nation's largest. *See LTCPA v. United Health Group*, Civ. No. 06-1221, (D.D.C. filed July 6, 2006). This Court dismissed that suit, concluding that the plaintiff organizations lacked representational standing to sue on behalf of the individual pharmacies in

what, in effect, amounted to a claim for money damages that required the participation of the individual pharmacies. *See LTCPA v. United Health Group*, Civ. No. 06-1221, 2007 WL 2172793, at * 8 (D.D.C. July 30, 2007). Plaintiffs suggest that it is too cumbersome and expensive for their member pharmacies to seek reimbursement through individual contract actions against the PDPs (Am. Compl. ¶ 51), though at least one such action is apparently ongoing. *See Omnicare, Inc. v. Blue Cross Blue Shield of Mich.*, Civ. No. 07-12346 (E.D. Mich. filed May 31, 2007).

After having failed in their efforts to recover money on behalf of their members against one PDP and having apparently concluded that individual contract actions against PDPs will not be cost effective, plaintiffs have adopted a new approach in their attempt to resolve their reimbursement problems by suing the agency responsible for administering the Medicare Part D program. In Count I, plaintiffs seek relief under § 706(1) of the Administrative Procedures Act ("APA"), 5 U.S.C. § 706(1), which provides that a reviewing court shall "compel agency action unlawfully withheld or unreasonably delayed." Plaintiffs argue that CMS has a statutory duty under the MMA to "provide complete, updated and accurate eligibility data to PDPs in a timely fashion," and that CMS's failure to fulfill its duty has caused the PDPs to improperly assess co-payments to institutionalized dual eligibles and has thereby deprived the LTC pharmacies of reimbursement amounts that they are "indisputably" owed. (Am. Compl. ¶¶ 40, 41, 49, 50.) Plaintiffs also claim in Count II that CMS's "procedural inadequacies and attendant failure[]" to timely provide complete and accurate eligibility data to the PDPs have wrongfully deprived the LTC pharmacies of their property interest in complete reimbursement for prescription drugs dispensed to institutionalized dual eligibles in violation of their members' right to due process

under the Fifth Amendment. (*Id.* ¶ 55.) Though plaintiffs allege that their members have been injured since the inception of the Medicare Part D program because they have been "forced to carry tens of millions of dollars of cost-sharing debt on behalf of misclassified institutionalized dual eligibles" (*id.* ¶ 50), they do not seek money damages in this lawsuit. Instead, plaintiffs request only prospective equitable relief consisting of (1) a declaratory judgment stating that relief under the APA is warranted because defendants have failed to timely provide complete and accurate eligibility data, and that this failure has also violated plaintiffs' members' due process rights; and (2) a writ of mandamus compelling defendants to "[p]rovide complete, updated and accurate eligibility data to PDPs within a time to be defined by the Court." (*Id.* at 14-15.)

In response, defendants have moved to dismiss for a variety of reasons, arguing that: (1) plaintiffs lack standing under Article III of the Constitution because defendants' actions did not cause the LTC pharmacies' injuries and the relief requested cannot redress those injuries (Defs.' Mot. at 22-29); (2) plaintiffs fail to meet prudential standing requirements because their grievance does not fall within the zone of interests protected by the MMA (*id.* at 30); (3) the United States has not waived sovereign immunity for this suit under the APA because plaintiffs' members have adequate alternative remedies available to them (*i.e.*, individual contract actions against the PDPs) (*id.* at 17); (4) plaintiffs fail to state a claim under the APA because the conduct that they challenge is not subject to judicial review and the actions that they seek to compel are not legally required (*id.* at 34-36); and (5) plaintiffs' Fifth Amendment claim is without merit because the government -- as opposed to the PDPs -- has not deprived plaintiffs' members of any property interest without due process of law. (*Id.* at 39.)

For the reasons explained below, the Court concludes that plaintiffs lack constitutional

standing and that their claim is not cognizable under the APA. The Court will therefore dismiss plaintiffs' complaint under Rule 12(b)(1), and it need not reach defendants' alternative arguments.

ANALYSIS

I. Article III Standing

To establish that this Court has jurisdiction to hear plaintiffs' claims, plaintiffs must show that they have standing. *See Florida Audubon Soc'y v. Bentsen*, 94 F.3d 658, 663, 666 (D.C. Cir. 1996) (en banc). Standing under Article III requires that plaintiffs demonstrate, at an "irreducible constitutional minimum," that (1) they have suffered a concrete and particularized injury -- the invasion of a legally protected interest ("injury in fact"); (2) the injury can fairly be traced to the challenged action of the defendant and is "not the result of the independent action of some third party not before the court" ("causation"); and (3) it is "likely, as opposed to merely speculative," that the relief sought will alleviate plaintiffs' alleged injury ("redressability"). *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992) (internal quotation marks omitted). An organization, such as the plaintiffs in this action, may have "standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977). Here, there is no suggestion that plaintiffs do not satisfy the latter two requirements for "representational standing," and the Court's inquiry must therefore focus on whether at least one of plaintiffs' members would have standing to sue in its own right.

In ruling on a motion to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), a court must construe plaintiffs' complaint liberally, giving them the benefit of all favorable inferences that can be drawn from the alleged facts. *See Barr v. Clinton*, 370 F.3d 1196, 1199 (D.C. Cir. 2004). Nonetheless, plaintiffs bear the burden of establishing subject matter jurisdiction. *Pitney Bowes, Inc. v. U.S. Postal Serv.*, 27 F. Supp. 2d 15, 19 (D.D.C. 1998). In addition, "[w]hen a court rules on a Rule 12(b)(1) motion, it may 'undertake an independent investigation to assure itself of its own subject matter jurisdiction,'" and it may consider "facts developed in the record beyond the complaint." *Settles v. U.S. Parole Comm'n*, 429 F.3d 1098, 1107 (D.C. Cir. 2005) (quoting *Haase v. Sessions*, 835 F.2d 902, 908 (D.C. Cir. 1987)). In order to give plaintiffs the opportunity to develop the record on standing, the Court permitted them to take jurisdictional discovery relating to the issues of causation and redressability. Specifically, plaintiffs were allowed seven interrogatories, a deposition of defendants' Rule 30(b)(6) witness, and related document requests, and in reaching its decision, the Court has considered the entire record, including plaintiffs' declarations and the facts adduced during discovery.

A. Causation

First, plaintiffs have failed to present sufficient facts to satisfy the causation requirement for Article III standing. The LTC pharmacies' rights to reimbursement for the prescriptions that they dispense to institutionalized dual eligibles are governed by their contracts with the PDPs, for the pharmacies have no independent contractual relationship with CMS. It is also clear that CMS does not govern the process by which the PDPs reimburse the LTC pharmacies, and CMS does not require, for example, that the PDPs only reimburse the pharmacies for the full amount of prescriptions when the CMS data indicates that no co-payment is owed. Accordingly,

plaintiffs' members' asserted injuries arise from "the government's allegedly unlawful regulation (or lack of regulation)" of third parties that are not before this Court. *Lujan*, 504 U.S. at 562. In such a case, "when the plaintiff is not [it]self the object of the government action or inaction [it] challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish," *id.* (quoting *Allen v. Wright*, 468 U.S. 737, 758 (1984)), and it is "the burden of the plaintiff to adduce facts showing that th[e] choices of [the intervening independent actors] have been or will be made in such a manner as to produce causation . . . ." *Id.*; *see also Nat'l Wrestling Coaches v. Dep't of Educ.*, 366 F.3d 930, 941 (D.C. Cir. 2004) (requiring that "the record present[] substantial evidence of a causal relationship between the government policy and the third-party conduct, leaving little doubt as to causation and the likelihood of redress"). In such circumstances, the D.C. Circuit has required that the plaintiff make "a showing that 'the agency action is at least a substantial factor motivating the third parties' actions'" that directly cause the injuries. *Tozzi v. U.S. Dep't of Health & Human Servs.*, 271 F.3d 301, 308 (D.C. Cir. 2001) (quoting *Cmty. for Creative Non-Violence v. Pierce*, 814 F.2d 663, 669 (D.C. Cir. 1987)).

To meet this test, plaintiffs argue that their injury is caused by CMS's inaccurate and untimely data because "PDP reimbursement decisions for cost-sharing amounts for institutionalized dual eligibles are substantially influenced (indeed, actually dictated) by whether the data in the CMS system recognizes the eligibility of such beneficiaries for zero co-payments (full subsidies by the government)." (Pls.' Supp. Opp'n at 6.) They assert that "[t]he PDPs consistently and repeatedly have refused to reimburse [plaintiffs'] members . . . for only one reason -- CMS has incorrectly identified those beneficiaries in the CMS system as owing a co-payment." (*Id.* at 7-8.) But this claim is belied by the record, for plaintiffs have failed to

provide sufficient facts to support their contention that the PDPs' failure to reimburse the LTC pharmacies is actually motivated by the untimely or inaccurate data. Indeed, representations by plaintiffs' counsel in the prior lawsuit indicate that at least some PDPs (but not United Health Group) have allowed the LTC pharmacies to seek reimbursement regardless of CMS's data. In that case, plaintiffs claimed that while "many PDPs . . . work[ed] with the LTC Pharmacies and reimbursed the backlog of inappropriately withheld copayments directly to the LTC Pharmacies," *see LTCPA v. United Health Group*, Civ. No. 06-1221, Am. Compl. ¶ 27 (D.D.C. filed May 4, 2007), United Health Group would not do the same, but instead it insisted that plaintiffs' members resubmit their claims in order to be reimbursed, claiming that this approach was required by the contracts between itself and the LTC pharmacies. *LTCPA v. United Health Group*, Civ. No. 06-1221, Tr. of Hr'g. at 18:7-18 (D.D.C. Mar. 29, 2007). According to counsel for United Health Group, reimbursement of the LTC pharmacies was not prevented by errors in CMS data, but rather by the pharmacies' failure to follow the contractual procedure for processing their claims. *Id.* ("The dispute, if we move forward with litigation under the contracts of them, will be whether or not [the LTC pharmacies] adequately or properly or appropriately resubmitted those claims to us within the timelines provided by the contracts and by the extensions, the multiple extensions we've given to those contracts. They have not resubmitted them as we have been requesting all these months."); *see also Omnicare, Inc.*, Civ. No. 07-12346, Answer at 4 (E.D. Mich. filed July 6, 2007) (asserting as an affirmative defense to the breach of contract claim that the plaintiff LTC pharmacy "failed to provide the required attestations").

The fact that at least some PDPs, despite receiving the same data from CMS, have

reimbursed the LTC pharmacies for co-payments that were erroneously assessed strongly suggests that the terms of the PDP-LTC pharmacy contracts or the independent actions of some PDPs are the real impediments to reimbursement, not the actions of the government. *See LTCPA v. United Health Group*, Civ. No. 06-1221, Tr. of Hr'g. at 13:4-12 (D.D.C. Mar. 22, 2007) (where plaintiffs' counsel stated, "I got to tell you that there are a lot of other P.D.P.s around the country who figured out a way to navigate this process. Most of them said give me a one-page certification that these are legitimate claims. Give me a C.D. of your claims and we're done. And that's what happened . . . . United is one of the very few, and certainly, out of the largest P.D.P.[s], they have asked for resubmission of claims and rebilling."). For if, as plaintiffs claim, defendants' "failures have created and perpetuate a systemic data-based impediment to the proper functioning of the Part D program" (Am. Compl. ¶ 3), there should be no difference among the PDPs. Yet, that is apparently not the case. Therefore, the reasonable inference is that any injury stems either from the terms of the LTC pharmacies contracts with the PDPs or the contracting parties' failure to follow those terms.[2]

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[2]Plaintiffs argue that the fact that the PDPs have reimbursed the LTC pharmacies for the amount of the claims less the co-payment amounts demonstrates that there is no other "infirmity" with these claims and that this defeats defendants' argument that a PDP's failure to pay an LTC pharmacy could result from the pharmacy's failure to follow the claims procedures in the contract. (Pls.' Supp. Opp'n at 7 n.6.) The issue, however, is not whether the pharmacies correctly followed the procedures for submitting these claims initially, but whether the pharmacies have correctly followed any contractual procedures relating to the correction of the data where they believe the PDP is misclassifying a beneficiary who should be recognized as an institutionalized dual eligible. For example, in the PDPs' relationship with CMS, CMS allows the PDPs to present certain types of documentation to establish that the beneficiary is eligible for zero co-payment when the data shows otherwise. It is logical that PDPs would require similar documentation from the LTC pharmacies, since they would need that documentation to support their ultimate request for reimbursement from CMS. And at least in some cases, it appears that one or more PDPs have refused to reimburse the LTC pharmacies on the basis that they have failed to provide the paperwork required (or requested) by the PDP. *See LTCPA v. United*

Inexplicably, plaintiffs have not provided the Court with any examples of the contracts between the PDPs and the LTC pharmacies, so the Court is unable to verify plaintiffs' unsubstantiated claim that the CMS data alone "dictate[s]" when and how much the PDPs will reimburse the LTC pharmacies. (*See* Pls.' Supp. Opp'n at 6.) The fact that CMS itself does not condition its reimbursement to the PDPs on the eligibility data alone also undermines plaintiffs' assertion that reimbursement of their pharmacies can only occur as dictated by the CMS data. As explained herein, CMS makes estimated reimbursement payments to the PDPs, and it provides a process by which the PDPs can initiate corrections to the CMS data when they believe it is incorrect. *See* 42 U.S.C. § 1395w-114(c)(2); 42 C.F.R. § 423.343(d). (*See* Defs.' Supp. Reply at 10-11; Ex. F to Defs.' Supp. Reply at L000173.) Nothing prevents the LTC pharmacies from negotiating a similar process in their contracts with the PDPs, and those contracting parties are free to allocate the risks posed by late or erroneous CMS data should they so choose.

In sum, without providing more information about the contracts that govern the process by which PDPs must reimburse the LTC pharmacies or any evidence to indicate how a PDP would change its behavior if it received accurate data more quickly from CMS,[3] plaintiffs cannot

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Health Group, Civ. No. 06-1221, Tr. of Hr'g. at 18:7-18 (D.D.C. Mar. 29, 2007); *Omnicare, Inc.*, Civ. No. 07-12346, Answer at 4 (E.D. Mich. filed July 6, 2007).

[3]In the cases where the D.C. Circuit has found a sufficient causal relationship between a government policy and third-party conduct, plaintiffs have provided substantial evidence demonstrating exactly how the third party would act differently if the requested relief were granted. In *National Wrestling Coaches*, the Court examined what type of evidence has typically met this test. For example, in *Tozzi*, 271 F.3d at 309, the Court relied on affidavits and other record evidence that "demonstrat[ed]" that the third parties had acted "as a direct result of the [government's] decision." *Nat'l Wrestling Coaches*, 366 F.3d at 941 (discussing *Tozzi*). Similarly, in *Block v. Meese*, 793 F.2d 1303, 1308 (D.C. Cir. 1986), the plaintiffs submitted "several declarations and affidavits detailing specific instances in which" the government action motivated the third parties' conduct. *Nat'l Wrestling Coaches*, 366 F.3d at 942 (discussing

meet their burden of establishing that CMS's actions are a substantial cause of their members' injury.[4]

B. Redressability

But perhaps more importantly, plaintiffs lack standing because any relief the Court could grant would not redress plaintiffs' injuries. "Redressability examines whether the relief sought, assuming that the Court chooses to grant it, will likely alleviate the particularized injury alleged by the plaintiff." *Florida Audubon*, 94 F.3d at 663-64 (footnote omitted). "Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence

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Block).

By contrast, plaintiffs have not provided any competent evidence from the PDPs, but rather, they rely only on the statements of witnesses from the LTC pharmacies regarding the refusal of PDPs to reimburse the pharmacies due to data errors and delays. (*See* Rutkowski Decl. ¶ 12; Amorosi Decl. ¶ 11.) These general statements, which fail to identify or cite any specific statement by a PDP representative, are insufficient to meet the high burden set by the D.C. Circuit for proof of causation, especially given the contrary representations made by counsel for United Health Group in the prior lawsuit. *See LTCPA v. United Health Group*, Civ. No. 06-1221, Tr. of Hr'g. at 18:7-18 (D.D.C. Mar. 29, 2007); *see also Nat'l Wrestling Coaches*, 366 F.3d at 941(requiring that plaintiffs adduce "substantial evidence" that leaves "little doubt as to causation and the likelihood of redress").

[4]Indeed, based on plaintiffs' declarations, defendants may in fact be correct in their speculation that many of the plaintiffs' members' reimbursement problems are caused by the LTC pharmacies' misidentification of institutionalized dual eligibles in the first instance. (*See* Defs.' Supp. Reply at 20 n.17.) Both of plaintiffs' LTC pharmacy witnesses state that all of the patients in the LTC facilities they serve are "necessarily" or "obviously" institutionalized as that term is defined by the MMA, and that the LTC pharmacies make their initial determination of who qualifies for zero co-payment accordingly. (Amorosi Decl. ¶ 5; Rutkowski Decl. ¶ 7.) Yet, these statements appear to ignore the CMS regulations that define "institutionalized dual-eligibles" as dual eligibles who are "inpatient[s] in a medical institution or nursing facility *for which payment is made under Medicaid throughout a month*." 42 C.F.R. §§ 423.772 (emphasis added). Thus, the fact that an individual resides in an LTC facility on a given day does not guarantee that such an individual is "obviously" entitled to the full subsidy under the Medicare Part D plan.

of the redressability requirement." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998). Redressability thus requires "that prospective relief will remove the harm," *Warth v. Seldin*, 422 U.S. 490, 505 (1975), and plaintiffs must show that they "would benefit in a tangible way from the court's intervention." *Id.* at 508 (footnote omitted).

Here, plaintiffs ask the Court to compel defendants to "[p]rovide complete, updated and accurate eligibility data to PDPs within a time defined by the Court," and going forward "[o]n an ongoing basis, [to] timely provide complete, updated and accurate eligibility data to PDPs." (Am. Compl. at 15.) Plaintiffs assert that "[i]f CMS complies with a Court order to properly characterize dual eligibles, [p]laintiffs' members' harm will be cured." (Pls.' Supp. Opp'n at 15.) Yet, while CMS is required by statute to "provide a process" whereby the PDP is notified that an individual is eligible for a subsidy and the amount of the subsidy, 42 U.S.C. § 1395w-114(c)(1)(A), Congress gave CMS the discretion to design and implement that process. For example, nothing in the MMA establishes any benchmarks for data accuracy or mandates any time tables by which CMS must provide eligibility data. In the exercise of its discretion, CMS relies on a system whereby it initially receives eligibility data from the states and ultimately passes that data along to the PDPs. (*See* Defs.' Supp. Reply at 6-7.) Obviously, this process was not designed with the intention of producing inaccurate data, but to the extent that there are errors in the eligibility status of the beneficiaries, CMS has established a mechanism whereby the PDPs can immediately pass on the subsidy to a beneficiary who they believe is eligible and then later initiate corrections to the CMS eligibility data, backed up by supporting documentation. (*See id.* at 9-11.) And while the notification process provided by CMS has an unavoidable lag time in obtaining up-to-date eligibility information because the information first

comes from the states, CMS compensates for that lag time by reimbursing the PDPs with estimated interim payments and later making retroactive adjustments to reconcile the amount it has paid PDP sponsors and the costs PDP sponsors claim they have actually incurred. *See* 42 U.S.C. § 1395w-114(c)(2); 42 C.F.R. § 423.343(d). (Defs.' Mot. at 7-8.)

Given that no process that CMS could design would produce completely accurate eligibility data instantaneously, the notification process that it has instituted is a reasonable exercise of its discretion. In this situation, an order from this Court directing CMS to be *more* timely or *more* accurate will do little to alleviate the pharmacies' difficulties. Since these terms are not defined by statute, the Court would have no basis for determining what would be sufficiently timely or accurate. *See Chemical Mfrs. Ass'n v. E.P.A.*, 217 F.3d 861, 868 (D.C. Cir. 2000) (noting that judges "cannot second guess [an agency's] approach as long as the agency acted pursuant to statutory authority and did so reasonably"). Furthermore, because of the lag time inherent in CMS's current process, in reality the only remedy that could have any hope of redressing the plaintiffs' members' alleged injuries is an order directing the agency to revamp its eligibility notification system.[5] But such an order would exceed the Court's authority. *See Norton v. S. Utah Wilderness Alliance ("SUWA")*, 542 U.S. 55, 66 (2004) (noting that courts are not "empowered to enter general orders compelling compliance with broad statutory mandates"). Plaintiffs cannot establish standing by requesting relief that the Court lacks the authority to grant, as well as any means for monitoring defendants' compliance, and then insisting that such a

[5]While they insist that they are not asking the Court to direct the manner in which CMS must fulfill its statutory obligation to provide data, plaintiffs at the same time point to the statement of CMS's 30(b)(6) witness to suggest that there are "alternate ways," other than relying on state data, to "verify a beneficiary's eligibility status." (Pls.' Supp. Opp'n at 15.)

purely hypothetical and unrealistic remedy would redress their injuries. For these reasons, as the Supreme Court has observed, suits like this one, which "challeg[e] not specifically identifiable Government violations of law[] but the particular programs agencies establish to carry out their legal obligations" present "obvious difficulties insofar as proof of causation or redressability is concerned, " and they are therefore "rarely if ever appropriate for federal-court adjudication." *Lujan*, 504 U.S. at 568 (quoting *Allen*, 468 U.S. at 759-60) (internal quotation marks omitted).

Accordingly, given plaintiffs' failure to demonstrate causation and redressability, they have not met the "irreducible constitutional minimum" of Article III standing, *id.* at 560, and as a result, the Court has no subject matter jurisdiction over any of their claims.

II. Standing under the APA

"A federal court's subject matter jurisdiction, constitutionally limited by article III, extends only so far as Congress provides by statute." *Commodity Futures Trading Comm'n v. Nahas*, 738 F.2d 487, 492 (D.C. Cir. 1984). For substantially the same reason that their requested relief would not redress their members' losses, they cannot proceed on their APA claim, for their broad attack on CMS's alleged "systemic data failures" is not legally cognizable under that statute. (Pls.' Supp. Opp. at 16.)

Citing § 706(1) of the APA, plaintiffs purport to challenge defendants' failure to meet their "statutory and regulatory duties" by "timely provid[ing] complete, updated and accurate eligibility data to PDPs." (Am. Compl. ¶¶ 49, 52.) Section 706 permits a reviewing court to "compel agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1). The Supreme Court has confirmed that this provision "sometimes" permits litigants to challenge an agency's inaction, but "only where a plaintiff asserts that an agency failed to take a *discrete*

action that it is *required to take*." *SUWA*, 542 U.S. at 61, 64 (emphasis in original). The APA defines "agency action" as "the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, *or failure to act.*" *Id.* at 62 (quoting 5 U.S.C. § 551(13)) (emphasis in original). In *SUWA*, the Supreme Court explained that the term "failure to act," as it is used in the APA, is "properly understood as a failure to take an *agency action* -- that is, a failure to take one of the agency actions (including their equivalents)" defined by the APA. *Id.* at 62 (emphasis in original). "The important point," the Court noted, "is that a 'failure to act' is properly understood to be limited . . . to a *discrete* action." *Id.* at 63 (emphasis in original).

In that reaching this conclusion, the Supreme Court relied on its previous opinion in *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871 (1990), where it considered a challenge to the Bureau of Land Management's land withdrawal review program and concluded that the administration of the program was not an "agency action." *Lujan*, 497 U.S. at 879, 890. The *Lujan* Court held that a litigant "cannot seek *wholesale* improvement of this program by court decree, rather than in the offices of the Department or the halls of Congress, where programmatic improvements are normally made. Under the terms of the APA, [the litigant] must direct its attack against some particular 'agency action' that causes it harm." *Id.* at 891 (emphasis in original). The *SUWA* Court's "limitation" of § 706(1) "to discrete agency action precludes the kind of broad programmatic attack" that was rejected by *Lujan*. *SUWA*, 542 U.S. at 64.

Applying this precedent, the Court concludes that plaintiffs are not challenging a discrete agency action but rather a "[g]eneral deficienc[y] in compliance" that "lack[s] the specificity requisite for agency action." *SUWA*, 542 U.S. at 66. Plaintiffs point to nothing remotely equivalent to a "rule, order, license, sanction, [or] relief" that CMS has failed to enact. *Id.* at 62.

Rather, they generally attack the adequacy (*i.e.*, the accuracy and timeliness) of the eligibility notification process that CMS has instituted under the MMA and the "systemic data failures" that it has allegedly produced. (*See* Pls.' Supp. Opp. at 16.) Such "[c]laims that agency action is insufficient or inadequate do not fall within the scope of permissible judicial review under APA § 706(1)." *S. Utah Wilderness Alliance v. Babbitt*, Civ. No. 99-852, 2000 WL 33914094, at *2 (D. Utah Dec. 22, 2000).

Indeed, plaintiffs are not truly challenging agency inaction at all, for, indisputably, CMS *has* acted to provide a process whereby the PDPs are notified of eligibility data, as required by the MMA. *See* 42 C.F.R. § 423.800(a). (*See* Am. Compl. ¶ 32 (acknowledging that CMS does provide such data to the PDPs).) Plaintiffs simply object to the efficacy of the process CMS has adopted on the grounds that the inherent delay in providing the data and the errors that sometimes occur exacerbate the process by which the pharmacies are reimbursed by the PDPs. (*See* Am. Compl. ¶¶ 31-33.) *See Sierra Club v. Peterson*, 228 F.3d 559, 568 (5th Cir. 2000) (en banc) (noting that the agency "has been acting, but the [plaintiffs] simply do not believe its actions have complied" with the relevant statute); *Public Citizen v. Nuclear Regulatory Comm'n*, 845 F.2d 1105, 1108 (D.C. Cir. 1988) ("The agency has acted . . . . Petitioners just do not like what [it] did."). As the D.C. Circuit has noted, "[a]lmost any objection to an agency action can be dressed up as an agency's failure to act," *Public Citizen v*, 845 F.2d at 1108, but where a plaintiff does not allege a *discrete* agency action that the agency failed to take, its claims are not cognizable under the APA. *SUWA*, 542 U.S. at 63.

Furthermore, as discussed *supra*, the relief that plaintiffs are asking the Court to compel is not legally required by the MMA or any other statute. A court's authority to act under the

APA is limited to directing the agency to "perform a ministerial or non-discretionary act, or to take action upon a matter, without directing *how* it shall act." *SUWA*, 542 U.S. at 64 (emphasis in original) (internal quotation marks omitted). This "limitation to *required* agency action rules out judicial direction of even discrete agency action that is not demanded by law." *Id.* at 65 (emphasis in original). In the *SUWA* case, the statutory requirement at issue was a provision of the Federal Land Policy and Managment Act of 1976 that required the Secretary of the Interior to manage so-called wilderness study areas "in a manner so as not to impair the suitability of such areas for preservation as wilderness." *Id.* at 59 (quoting 43 U.S.C. § 1782(c)). The Supreme Court noted that while this statutory requirement was "mandatory as to the object to be achieved," it left the Bureau of Land Management "a great deal of discretion in deciding how to achieve it." *Id.* at 66. Therefore, the Court determined that the statute "assuredly" did not require any specific action by the agency "with the clarity necessary to support judicial action under § 706(1)." *Id.*

Similarly, in this case, the MMA imposes on CMS a general duty to provide a process by which the PDPs are notified of eligibility information, but leaves the details of that process to the agency's discretion. Congress has established no statutory deadlines by which CMS must notify the PDPs, nor has it dictated any other specific requirements regarding the notification process.[6] Since Congress has left these matters to the agency's discretion, a court may not mandate greater timeliness and accuracy (even there was a rational way to define such requirements). *See Friends of the Earth, Bluewater Network Div. v. U.S. Dept. of Interior*, 478 F. Supp. 2d 11, 27

[6]Indeed, Congress did not even require that the eligibility data must be provided by CMS. Rather, CMS is only required to "provide a process" for the transmission of such data to the PDPs. *See* 42 U.S.C. § 1395w-114(c)(1).

(D.D.C. 2007) ("What plaintiffs seek is not actually a review of agency inaction, but a review of the exercise of agency discretion, which is generally not reviewable under *Heckler v. Chaney*, 470 U.S. 821, 832-33 (1985).").

Accordingly, because plaintiffs do not allege that defendants have failed to take any discrete action that they are legally required to take, they lack standing to bring their claims under the APA. *See Ctr. for Biological Diversity v. Veneman*, 394 F.3d 1108, 1115 (9th Cir. 2005) (affirming district court's dismissal for lack of standing under § 706(1) in light of *SUWA*).[7]

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[7]While several leading cases address this question as an issue of standing and subject matter jurisdiction under Rule 12(b)(1), *see SUWA*, 542 U.S. at 73 (upholding trial court's dismissal for lack of subject matter jurisdiction); *Ctr. for Biological Diversity*, 394 F.3d at 1115 (holding that plaintiff had no standing under APA § 706(1), "[g]iven the Supreme Court's holding in *SUWA*," because plaintiff failed to allege a discrete agency action that the defendant failed to take); *Gros Ventre Tribe v. United States*, 469 F.3d 801, 814 (9th Cir. 2006) (upholding trial court's dismissal for lack of subject matter jurisdiction under *SUWA* where the government was not required to take discrete, nondiscretionary actions), other courts have resolved the issue under Rule 12(b)(6). *See Friends of the Earth*, 478 F. Supp. 2d at 23 ("A dismissal for failure to satisfy the APA's requirements for judicial review of agency action is . . . a dismissal for failure to state a claim under Rule 12(b)(6), not a dismissal for want of subject matter jurisdiction under Rule 12(b)(1).") Thus, to the extent that the issue of whether plaintiffs' claims are cognizable under the APA is more properly addressed under Rule 12(b)(6), the Court's analysis would remain the same, and Count I would be dismissed for failure to state a claim.

Similarly, if the Court were to reach the merits of Count II, it too would fail. In that count, plaintiffs allege that defendants have violated plaintiffs' members' Fifth Amendment rights to due process because the agency's failure to timely provide complete and accurate eligibility data to the PDPs has wrongfully deprived the LTC pharmacies of their property interest in complete reimbursement for prescription drugs dispensed to institutionalized dual eligibles. (Am. Compl. ¶ 55.) However, what the Fifth Amendment guarantees is "notice" and "some form of a hearing" before "an individual is finally deprived of a property interest" by the government. *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). Even assuming *arguendo* that the government could be held responsible for plaintiffs' members' alleged deprivation in this case, "it is not the deprivation of the protected interest itself that violates procedural due process; rather, it is the deprivation *without due process of law*." *Doe v. Dist. of Columbia*, 93 F.3d 861, 869 (D.C. Cir. 1996) (emphasis in original). Yet plaintiffs do not identify the additional *procedural* safeguards that they believe are constitutionally mandated. *See id.* at 870 ("[A] procedural due process claim requires the plaintiff to identify the process that is due.") To the

CONCLUSION

In sum, because plaintiffs have failed to establish standing, defendant's motion to dismiss under Rule 12(b)(1) is granted. A separate Order accompanies this Memorandum Opinion.

/s/
ELLEN SEGAL HUVELLE
United States District Judge

Date: January 11, 2008

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contrary, plaintiffs complain that the BAE policy -- the process CMS put in place to allow the PDPs the opportunity to initiate corrections to CMS data with appropriate documentation to obtain reimbursement -- is an "abdication" of CMS's statutory duty. (Pls.' Supp. Reply at 10.) Thus, even if the Court were to reach this claim, it would be subject to dismissal under Rule 12(b)(6).