UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC., *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 10-0499 (ABJ)
KATHLEEN G. SEBELIUS, Secretary Of Health & Human Services, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiffs Association of American Physicians & Surgeons, Inc. ("AAPS") and Alliance for Natural Health USA ("ANH-USA"), bring this case challenging several unrelated government actions, each of which could have been challenged in a distinct and separate case. The challenged government actions are:

- Three sections of the Social Security Program Operations Manual System ("POMS"), POMS HI 00801.002; POMS HI 00801.034; POMS GN 00206.020, which state that any individual who receives social security benefits is automatically entitled to Medicare Part A benefits;

- The employer and individual insurance mandate sections of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered titles of U.S. Code) ("ACA");

- Provisions of a Center for Medicare and Medicaid Services ("CMS") manual and accompanying change requests, Change Requests 6417, 6421 ("CR6417/6421"), as well as a Department of Health and Human Services ("HHS") Interim Final Rule with Comment Period, 75 Fed. Reg. 24,437 (May 5, 2010) ("IFR"), that require physicians and other eligible professionals to obtain a National Provider Identifier ("NPI") and an HHS-approved enrollment or opt-out record in the electronic Provider Enrollment, Chain, and Ownership System ("PECOS"), in order to make covered referrals under Medicare Part B; and

- Alleged violations by Secretary of HHS Kathleen G. Sebelius and Commissioner of Social Security Administration Michael J. Astrue of their fiduciary and equitable duties to the American people by allowing Medicare and Social Security, respectively, to face insolvency.

Defendant filed a motion to dismiss for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), and for failure to state a claim upon which relief can be granted under Rule 12(b)(6). *See* Defs.' Mot. to Dismiss [Dkt. # 32] ("Defs.' Mot."). After filing the motion to dismiss, defendants moved to stay this case pending decisions in two cases before the D.C. Circuit, and later, one case before the United States Supreme Court, which raised claims identical to the first two counts of plaintiffs' complaint. *See* Defs.' Mot. to Stay Summ. J. Briefing and Discovery [Dkt. # 33]. The Court granted the motion to stay. *See* Minute Entry (Nov. 8, 2011).

Decisions in all of the relevant appeals have now been issued. In *Hall v. Sebelius*, 667 F.3d 1293 (D.C. Cir. 2012), the D.C. Circuit upheld the POMS provisions that are challenged in this case as consistent with the Social Security Act, 42 U.S.C. § 426(a). In *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2012) ("*NFIB*"), the Supreme Court upheld the individual mandate provision of the ACA as a valid exercise of Congress's taxing powers.

Accordingly, the stay on this action has been lifted, and defendants' motion to dismiss is ripe for decision. The parties have filed supplemental memoranda addressing whether the recent decisions require the dismissal of any counts and, notwithstanding the Supreme Court's determination, plaintiffs soldier on. In light of the original pleadings in this case, the supplemental pleadings, and the recent controlling decisions from the D.C. Circuit and the United States Supreme Court, this Court will grant defendants' motion to dismiss because plaintiffs lack standing to bring some of their claims, and the others fail to state a claim upon which relief can be granted.

FACTUAL BACKGROUND

Plaintiffs AAPS and ANH-USA are both associations whose members include medical caregivers, employers, owners and managers of medical businesses, and consumers of healthcare. Second Am. Compl. [Dkt. # 26] ("Compl.") ¶¶ 3–4, 13–14. AAPS was founded "to preserve the practice of private medicine, ethical medicine, and the patient-physician relationship." *Id.* ¶ 3. ANH-USA seeks "to promote sustainable health and freedom of choice in healthcare" and to promote an "integrative" approach to preventative medicine that incorporates food, dietary supplements, and lifestyle changes. *Id.* ¶ 4.

On September 13, 2010, plaintiffs filed the six-count second amended complaint ("complaint") in this action on behalf of their members. *See* Compl. ¶¶ 13–34. Count I alleges that the issuance of the three POMS provisions, which state that any individual who receives social security benefits is automatically entitled to Medicare Part A benefits, was arbitrary, capricious, an abuse of discretion, without observance of notice-and-comment rulemaking procedure required by law, not otherwise in accordance with the law, and in excess of statutory authority. *Id*. ¶¶ 90–93. Counts II and III allege that both the employer and individual insurance mandate provisions of the ACA contravene the United States Constitution. *Id.* ¶¶ 94–99. Count IV alleges that CR6417/6421 and HHS's Interim Final Rule with Comment Period, 75 Fed. Reg. at 24437, which require medical professionals who decide to opt out of Medicare but wish to make referrals under Medicare Part B to obtain an NPI and an approved enrollment record or a valid opt-out record in the PECOS, are arbitrary, capricious, an abuse of discretion, without observance of the notice-and-comment rulemaking procedure required by law, not otherwise in accordance with the law, and in excess of statutory authority. *Id.* ¶¶ 100–05. Finally, Counts V

and VI allege that defendants Sebelius and Astrue violated their fiduciary and equitable duties. *Id.* ¶¶ 106–117. The complaint requests declaratory and equitable relief. *Id.* ¶ 118.

STANDARD OF REVIEW

In evaluating a motion to dismiss under either Rule 12(b)(1) or 12(b)(6), the Court must "treat the complaint's factual allegations as true . . . and must grant plaintiff 'the benefit of all inferences that can be derived from the facts alleged.'" *Sparrow v. United Air Lines, Inc.*, 216 F.3d 1111, 1113 (D.C. Cir. 2000), quoting *Schuler v. United States*, 617 F.2d 605, 608 (D.C. Cir. 1979) (citations omitted). Nevertheless, the Court need not accept inferences drawn by the plaintiff if those inferences are unsupported by facts alleged in the complaint, nor must the Court accept plaintiff's legal conclusions. *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002).

I. Subject Matter Jurisdiction

Under Rule 12(b)(1), the plaintiff bears the burden of establishing jurisdiction by a preponderance of the evidence. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); *Shekoyan v. Sibly Int'l Corp.*, 217 F. Supp. 2d 59, 63 (D.D.C. 2002). Federal courts are courts of limited jurisdiction and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *see also Gen. Motors Corp. v. Envtl. Prot. Agency*, 363 F.3d 442, 448 (D.C. Cir. 2004) ("As a court of limited jurisdiction, we begin, and end, with examination of our jurisdiction."). Because "subject-matter jurisdiction is an 'Art[icle] III as well as a statutory requirement . . . no action of the parties can confer subject-matter jurisdiction upon a federal court.'" *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003), quoting *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982) (second alteration in original).

When considering a motion to dismiss for lack of jurisdiction, unlike when deciding a motion to dismiss under Rule 12(b)(6), the court "is not limited to the allegations of the complaint." *Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64 (1987). Rather, a court "may consider such materials outside the pleadings as it deems appropriate to resolve the question of whether it has jurisdiction to hear the case." *Scolaro v. D.C. Bd. of Elections & Ethics*, 104 F. Supp. 2d 18, 22 (D.D.C. 2000), citing *Herbert v. Nat'l Acad. of Sciences*, 974 F.2d 192, 197 (D.C. Cir. 1992); *see also Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1253 (D.C. Cir. 2005).

II. Failure to State a Claim

"To survive a [Rule 12(b)(6)] motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotation marks omitted); *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is facially plausible when the pleaded factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged – but it has not 'show[n]' – 'that the pleader is entitled to relief.'" *Id.* at 679, quoting Fed. R. Civ. Pro. 8(a)(2). A pleading must offer more than "labels and conclusions" or a "formulaic recitation of the elements of a cause of action," and "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Id.* at 678, quoting *Twombly*, 550 U.S. at 555. In ruling upon a motion to dismiss, a court may ordinarily consider only "the facts alleged in the

complaint, documents attached as exhibits or incorporated by reference in the complaint, and matters about which the Court may take judicial notice." *Gustave-Schmidt v. Chao*, 226 F. Supp. 2d 191, 196 (D.D.C. 2002) (citations omitted).

ANALYSIS

I. Plaintiffs lack standing to assert Count I.

Count I of the complaint challenges three provisions of the POMS which affirm that any individual who receives Social Security benefits is automatically entitled to Medicare Part A benefits. There is now binding precedent from the D.C. Circuit upholding these provisions as a valid exercise of agency authority, *Hall*, 667 F.3d at 1293, so plaintiffs cannot succeed on this claim. However, because plaintiffs argue that they have raised a challenge that was not addressed by the D.C. Circuit – a procedural challenge – the Court will first address plaintiffs' standing.

A. Statutory Background

The federal Medicare program was established by Title XVIII of the Social Security Act of 1935 to provide health insurance to the elderly and disabled. *Amgen Inc. v. Smith*, 357 F.3d 103, 105 (D.C. Cir. 2004). Part A of the Medicare program provides insurance coverage for hospital services, home health care, and hospice services. *See id.*, citing 42 U.S.C. § 1395c. Part B is a voluntary program that provides supplemental coverage for other types of care, including physician services. *See id.* at 106, citing 42 U.S.C. §§ 1395j, 1395k; *United Seniors Ass'n v. Shalala*, 182 F.3d 965, 967 (D.C. Cir. 1999). By statute, every individual who has attained age 65 and is entitled to Social Security benefits, is also "entitled to hospital insurance benefits" through Medicare Part A. *Hall*, 667 F.3d at 1294–95, citing 42 U.S.C. § 426(a). However, any individual who is entitled to Medicare Part A benefits may choose to decline them. *Id.* at 1295,

citing *Medicare Claims Processing Manual*, ch. 1, § 50.1.5 (2011). Furthermore, an individual may avoid entitlement to Medicare Part A altogether by choosing not to file an application for Social Security benefits, 42 U.S.C. § 426(a), or by withdrawing a previously submitted application, 20 C.F.R. § 404.640 (2012).

The POMS is a Social Security Administration ("SSA") handbook designed for internal use by SSA employees in processing claims. *See Hall v. Sebelius*, 770 F. Supp. 2d 61, 66 (D.D.C. 2011), *aff'd by Hall*, 667 F.3d at 1293. The three POMS provisions challenged here explain the interrelationship between Social Security retirement benefits and Medicare Part A benefits:

- POMS HI 00801.002, titled "Waiver of Hospital Insurance Entitlement by Monthly Beneficiary," states that a person who is entitled to monthly Social Security benefits may not "waive" Medicare Part A entitlement, but may avoid such entitlement by withdrawing her application for monthly Social Security retirement benefits, which requires repaying all benefits received. POMS HI 00801.002, *available at* https://secure.ssa.gov/apps10/poms.nsf/lnx/0600801002.
- POMS HI 00801.034, titled "Withdrawal Considerations," explains how an individual who is entitled to Social Security retirement benefits may withdraw from Medicare Part A, in accordance with POMS HI 00801.002. POMS HI 00801.034, *available at* https://secure.ssa.gov/poms.nsf/lnx/0600801034.
- POMS GN 00206.020, titled "Withdrawal Considerations When Hospital Insurance is Involved," similarly explains the process for withdrawing from Medicare Part A. It states, in relevant part: "[A] claimant who is entitled to monthly [Social Security retirement] benefits cannot withdraw [from Medicare Part A] coverage only since

entitlement to [Medicare Part A] is based on entitlement to monthly [Social Security retirement] benefits (see HI 00801.002)." POMS GN 00206.020, *available at* https://secure.ssa.gov/apps10/poms.nsf/links/0200206020.

B. Plaintiffs fail to allege a sufficient injury in fact.

"The defect of standing is a defect in subject-matter jurisdiction." *Haase v. Session*, 835 F.2d 902, 906 (D.C. Cir. 1987). In order to establish constitutional standing, a plaintiff must demonstrate that a case or controversy exists by showing (1) that he has suffered an "injury in fact" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical"; (2) that the injury is "fairly traceable" to the challenged action of the defendant; and (3) that it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *Ariz. Christian Sch. Tuition Org. v. Winn*, 131 S. Ct. 1436, 1442 (2011), quoting *Lujan*, 504 U.S. at 560; *see also Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 180–81 (2000). Standing is a claim-specific inquiry. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). In addition to the limitations on standing imposed by the Constitution, the Court's jurisdiction is also restricted by "judicially self-imposed" prudential limitations on standing. *United Food and Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 544, 551 (1996). These limitations are "founded in concern about the proper – and properly limited – role of the courts in a democratic society." *Warth v. Seldin*, 422 U.S. 490, 498 (1975).

In this case, plaintiffs are two associations that do not claim that they have suffered injuries as entities, but instead claim that their members have suffered injuries. Compl. ¶¶ 13–35. Under the associational standing doctrine, "an organization may sue to redress its members' injuries, even without a showing of injury to the association itself" because "the association and

its members are in every practical sense identical." *United Food and Commercial Workers Union Local 751*, 517 U.S. at 552 (citations and internal quotation marks omitted). To qualify for associational standing, a plaintiff must satisfy a three-prong test: (a) the organization's 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. *Id.* at 553.

In *Summers v. Island Earth Institute*, the Supreme Court held that a plaintiff association must specifically identify members who have suffered the requisite harm in order to satisfy the standing requirement. 555 U.S. 488, 499 (2009). The Court rejected a statistical probability standard, opting instead for a standard that requires a showing that one or more of the association's members would be "directly affected by the alleged illegal activity." *Id.* at 497–98.

Since *Summers*, however, several Courts have found that a plaintiff need not identify the affected members by name at the pleading stage. *See, e.g.*, *Bldg. & Constr. Trades Council of Buffalo, N.Y. & Vicinity v. Downtown Dev., Inc.*, 448 F.3d 138, 145 (2d Cir. 2006); *Hancock Cty. Bd. of Supervisors v. Ruhr*, No. 11-60446, 2012 WL 3792129, at *6 n.5 (5th Cir. Aug. 31, 2012); *Perez v. Texas*, No. 11-CA-360-OLG-JES-XR, 2011 WL 9160142, at *9 (W.D. Tex. Sept. 2, 2011). Although those decisions are not binding on this Court, the Court finds them persuasive. "[E]ach element of Article III standing 'must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation.'" *Bennet v. Spear*, 520 U.S. 154, 167–68 (1997), quoting *Lujan*, 504 U.S. at 561. At the pleading stage, the Court presumes that general allegations encompass the specific facts necessary to support the claim, *id.*, so the plaintiff need not identify an affected member by name.

As to Count I, the complaint alleges that some AAPS and ANH-USA members who are retired would like to cease participating in Medicare Part A, without losing their entitlement to Social Security retirement benefits. Compl. ¶ 16. It also alleges that AAPS and ANH-USA physician members who have opted out of Medicare are harmed by the "compelled participation" of their patients in Medicare Part A. Compl. ¶ 17. It claims that "compelled participation" makes it more difficult for patients to retain doctors who do not participate in Medicare than doctors who do, and that puts doctors who choose not to participate in Medicare at a competitive disadvantage.[1] Compl. ¶ 17.

Plaintiffs' claims overstate the impact of the POMS provisions. First of all, the internal handbook does not create or eliminate any legal entitlements; it simply states what they are under existing law. And second, plaintiffs are not harmed by the statutory sections the POMS describes: they merely provide that an individual who receives Social Security retirement benefits is automatically *entitled* to Medicare Part A benefits. *Browning*, 292 F.3d at 242 (explaining that at the pleading stage, a court need not accept inferences drawn by the plaintiff if those inferences are unsupported by facts alleged in the complaint, nor must the Court accept plaintiff's legal conclusions). The provisions do not declare that the recipient must *participate* in Medicare Part A. In fact, any individual who is entitled to Medicare Part A may decline all of the benefits the program provides. *Hall*, 667 F.3d at 1295, citing *Medicare Claims Processing*

1 Although plaintiffs also submit declarations from several of their members and executives in support of standing, none of them identify any member who is injured by the POMS provisions at issue, or provide any details about the nature of the injuries alleged in the complaint.

In addition, plaintiffs' opposition to the motion to dismiss further addresses their grounds for standing, but it provides little assistance for the claim-by-claim assessment the Court is required to make. *See DaimlerChrysler Corp.*, 547 U.S. at 352. The opposition discusses the types of injuries courts have recognized in general terms, but it does not connect the recognized injuries to the claims in this case. *See* Pls.' Opp. to Mot. to Dismiss [Dkt. # 38] ("Pls.' Opp.") at 7–20.

Manual, ch. 1, § 50.1.5. So there is nothing stopping plaintiffs' members from ceasing their participation in Medicare Part A, without losing their Social Security retirement benefits.

Moreover, plaintiffs do not show that their members suffer any injury by becoming entitled to Medicare Part A. This factor distinguishes the instant case from *Hall*, in which the D.C. Circuit found that the plaintiffs had standing to challenge the same POMS provisions challenged here based on allegations of concrete harms they were suffering from mere entitlement to Medicare Part A benefits. *Id*. The plaintiffs in *Hall* were individuals over 65 years old who received Social Security retirement benefits and thus were automatically entitled to Medicare Part A benefits. *Id.* One of the plaintiffs submitted an affidavit in which he declared that his legal entitlement to Medicare Part A benefits led his private insurance plan to reduce coverage without a matching reduction in premium. *Id.* Another plaintiff declared that his private insurance company stopped acting as his primary payer because of his entitlement to Medicare Part A benefits. *Id.* Both showed that their private insurance coverage had been curtailed as a direct result of their legal entitlement to Medicare Part A benefits and that they could obtain additional coverage from their private insurance plans if allowed to disclaim their legal entitlement to Medicare Part A benefits. *Id.* Unlike in *Hall*, AAPS and ANH-USA make no showing that mere entitlement to Medicare Part A benefits will have any effect on their retirement-age members.[2]

2 In their opposition to the motion to dismiss, plaintiffs assert an additional theory of injury: that when a patient becomes entitled to Medicare Part A, his physician must comply with the Medicare "opt-out" procedures contained in 42 U.S.C. §1395a(b) in order to receive compensation directly from the patient and outside of Medicare. Pls.' Opp. at 60. This is not supported by the statute. Medicare Part A does not cover physician services, so the opt-out requirement only attaches when the physician sees a patient who is a Medicare Part B beneficiary. 42 C.F.R. § 405.400 (defining "beneficiary" for purposes of this subpart as "an individual who is enrolled in Part B of Medicare"); *see also* 42 U.S.C. § 1395a(b); *see also United Seniors Ass'n*, 182 F.3d at 967.

Also unavailing is plaintiffs' statement that the POMS provisions at issue disadvantage AAPS and ANH-USA members who are physicians that do not accept Medicare Part A. Compl. ¶ 17. The injury claimed here is not economic, per se. Rather, plaintiffs rely on the competitor standing doctrine, under which the mere exposure to competition may be a sufficient injury in-fact if the challenged action "will almost surely cause [plaintiffs] to lose business." *El Paso Natural Gas Co. v. FERC*, 50 F.3d 23, 27 (D.C. Cir. 1995); *see also Bristol-Myers Squibb Co. v. Shalala*, 91 F.3d 1493, 1499 (D.C. Cir. 1996). But the alleged harm to physicians is too conjectural to satisfy the injury-in-fact requirement. The basis for the disadvantage, according to plaintiffs, is that retired patients have greater difficulty retaining the AAPS and ANH-USA member physicians because the POMS provisions "compel their participation in Medicare Part A." Compl. ¶ 17. Since the provisions challenged do not actually compel participation, *see Hall*, 667 F.3d at 1295, the allegations in the complaint cannot support the inference that plaintiffs' member physicians are actually disadvantaged by the POMS provisions.

Even more damaging to plaintiffs' argument: the POMS provisions at issue concern Medicare Part A, which covers care provided by institutional health care providers, such as hospitals. *See United Seniors Ass'n*, 182 F.3d at 967. Care provided by physicians is covered by Medicare Part B. *Id.* So the inference that plaintiffs ask the Court to make – that a patient's entitlement to Medicare Part A will effect his choice of which physician to see – is unreasonable. At the pleading stage, however, the Court is required to make only *reasonable* inferences in a plaintiff's favor. *Iqbal*, 556 U.S. at 678.

In sum, the chain of inferences that plaintiffs ask the Court make – (1) that patients who are entitled to, but not forced to, participate in Medicare Part A have more difficulty retaining cash-only physicians, despite the fact that Medicare Part A does not cover physician services,

and (2) that this exposes those physicians to more competition – is too speculative. *See Grocery Mfrs. Ass'n v. EPA*, 693 F.3d 169, 175 (D.C Cir. 2012) (finding that a long chain of hypothetical chain events fails as a showing of Article III standing).

In the alternative, plaintiffs argue that they are entitled to third-party standing on behalf of the patients that their member physicians treat. Compl. ¶ 18. In other words, plaintiffs wish to assert the rights of individuals who are two steps removed from them.

Ordinarily, a plaintiff may not assert the rights of third persons who are not parties to the litigation. *Singleton v. Wulff*, 428 U.S. 106, 114 (1976). This is a prudential standing requirement that the courts have adopted for two primary reasons:

> First, the courts should not adjudicate such rights unnecessarily, and it may be that in fact the holders of those rights either do not wish to assert them, or will be able to enjoy them regardless of whether the in-court litigant is successful or not. . . . Second, third parties themselves usually will be the best proponents of their own rights.

Id. at 113–14 (citations omitted).

There are exceptions to this bar, including the one that plaintiffs assert here – where the plaintiff has a particularly close relationship with the third-party and there is some genuine obstacle to the third party's assertion of its own right. *Id.* at 114–116. However, the Court need not determine whether plaintiffs here fall within that exception because the prudential bar on third-party standing does not waive the Constitutional standing requirements. *Id.* at 112. In other words, in addition to showing that they fall within an exception to the prudential bar on third-party standing, plaintiffs must also make a showing that at least one of their physician members suffers an injury in fact that is fairly traceable to the challenged POMS provisions. As the Court has already discussed, plaintiffs fail to meet that burden.

Finally, plaintiffs argue that their members have suffered procedural injury because they were not afforded the opportunity to provide comments on the POMS provisions before they were issued. Compl. ¶¶ 31–32. This argument too is flawed. The redressability and immediacy requirements are relaxed for an individual who has been accorded a procedural right. *See Lujan*, 504 U.S. 572 n.7. Accordingly, standing might exist even if the right to comment likely would not have succeeded in persuading the agency to change its mind. *Nat'l Ass'n of Home Builders v. EPA*, 667 F.3d 6, 15 (D.C. Cir. 2011). However, "deprivation of a procedural right without some concrete interest that is affected by the deprivation – a procedural right *in vacuo* – is insufficient to create Article III standing." *Summers*, 555 U.S. at 496. Since plaintiffs have not alleged a substantive injury in fact that is fairly traceable to the challenged POMS provisions, the alleged procedural injury is insufficient to confer standing on plaintiffs to assert Count I. *Id.*; *see also Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664 (D.C. Cir. 1996) (allegation of a procedural injury does not waive the substantive injury in fact requirement). Accordingly, the Court will dismiss Count I for lack of standing.[3]

3 Even if the Court were to find that plaintiffs have standing to assert Count I, it would dismiss the count on the merits, based on the D.C. Circuit's recent binding decision in *Hall*, 667 F.3d at 1293. *Hall* squarely rejected a challenge to HHS's authority to issue the POMS provisions that are challenged in this case. *Id.* at 1294. The only claim asserted here that was not directly rejected in *Hall* is that the POMS provisions are unlawful because they were promulgated without the required notice-and-comment rulemaking procedure. However, since the Circuit Court found that the automatic entitlement is required by the Medicare statute itself, *id.*, the Court would find the POMS provisions to be interpretive rules, which are not subject to formal notice and comment. 5 U.S.C. § 553(b)(3)(A); *see Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1307–08 (D.C. Cir. 1991), quoting *Citizens to Save Spencer Cnty v. EPA*, 600 F.2d 844, 876 & n.153 (D.C. Cir. 1979) ("An interpretive rule simply states what the administrative agency thinks the statute means, and only 'reminds affected parties of existing duties.'").

II. Counts II and III fail to state a claim upon which relief can be granted.

Counts II and III of the complaint, respectively, challenge the employer and individual insurance mandate provisions of the ACA. ACA §§ 1501, 1511–1515. In light of the Supreme Court's decision in *NFIB*, the Court finds that these counts both fail to state a claim upon which relief can be granted.

A. Statutory Background

1. *ACA Employer Insurance Mandate*

The ACA imposes requirements on, and offers incentives to, certain employers for providing insurance to their employees. ACA §§ 1421, 1513. In general terms, certain small employers are eligible for tax credits under the act if they provide contributions toward health insurance coverage for their employees. *Id.* § 1421. Certain large employers are subject to an "assessable payment" under the act if they fail to offer insurance coverage of at least a minimum threshold level to full-time employees and their dependents. *Id.* § 1511–1513. This payment is assessed through tax returns. *Id.* § 1513. Plaintiffs challenge the latter requirement. Compl. ¶¶ 95–96. The mandate takes effect in 2014. *Id.* § 1513(d).

2. *ACA Individual Insurance Mandate*

The individual insurance mandate requires all Americans to maintain a minimum level of health insurance coverage or pay an assessable penalty through their tax returns. ACA §§ 1501, 10106. Congress expressly found that by "significantly reducing the number of the uninsured, the requirement, together with the other provisions of this Act, will lower health insurance premiums." *Id.* §§ 1501(a)(2)(F), 10106(a). Like the employer insurance mandate, the individual mandate takes effect in 2014. *Id.* § 1501(d).

B. Plaintiffs have standing to bring their claims under Counts II and III.

The complaint alleges that plaintiffs' members include businesses with more than fifty full-time employees who are subject to the employer insurance mandate. Compl. ¶ 19. It alleges that if these employers continue their current employee coverage practices, they will be subject to the assessment of a penalty under the ACA. *Id.* Furthermore, the complaint claims that "[t]he addition of these major new costs in 2014 and subsequent years has reduced the value of these businesses *today*. Removing those new costs would restore the lost value." *Id.* Although plaintiffs do not identify any particular member that has suffered a reduction in value, the allegations in their complaint are sufficient to satisfy the requirements of Constitutional and prudential standing at the motion to dismiss stage.

Plaintiffs also raise several theories of injury resulting from the individual insurance mandate. First, the complaint alleges that the ACA will injure AAPS and ANH-USA member physicians who do not accept medical insurance because it will cause patients to pay more money for insurance premiums or penalties, thereby decreasing the resources those patients can devote to healthcare expenditures out of pocket. Compl. ¶ 20; DuBeau Decl., Ex. 2 to Pls.' Opp. ¶ 8. This in turn will disadvantage physicians that accept only cash for their services. Compl. ¶ 20; DuBeau Decl., Ex. 2 to Pls.' Opp. ¶ 8. The complaint goes on to allege that the insurance mandates will render the "cash practice" business model of AAPS and ANH-USA members economically non-viable, putting those members out of business or causing them to have to invest in a different business model. Compl. ¶ 21.

Separately, some of the declarations that plaintiffs attach to their opposition to the motion to dismiss assert that the declarants, who are members of AAPS and ANH-USA, are consumers of medical services that are and will imminently be injured by the individual insurance mandate.

See Christman Decl., Ex. 1 to Pls.' Opp. ¶¶ 6–9; Orient Decl., Ex. 5 to Pls.' Opp. ¶¶ 18–21; Smith Decl., Ex. 6 to Pls.' Opp. ¶¶ 11–15.[4] The Smith declaration asserts that Mr. Smith, an AAPS member, retains high deductible insurance for himself and his children; he does not qualify for Medicare, Medicaid, or Social Security and will not qualify in or before 2014; and he will be harmed financially if compelled to purchase health care insurance coverage under the APA or to pay a penalty. Smith Decl. ¶¶ 11–15. The Christman Declaration asserts that Mr. Christman, an AAPS member, does not have health insurance for himself, his wife, or his children; he does not qualify for Medicare, Medicaid, or Social Security and does not expect to qualify in or before 2014; and he will be harmed financially if compelled to purchase health care coverage or pay penalties under the ACA. Christman Decl. ¶¶ 6–9.

There is a question whether at the time the complaint was filed, the alleged injuries were too hypothetical to satisfy the imminence requirement because the individual mandate provision does not take effect until 2014. Mem. in Support of Defs.' Mot. to Dismiss ("Defs.' Mem.") [Dkt. # 32] at 25–26; *see Davis v. FEC*, 554 U.S. 724, 734 (2008) ("T[]he standing inquiry [is] focused on whether the party invoking jurisdiction had the requisite stake in the outcome when

4 Plaintiffs do not assert that any member of ANH-USA suffers this type of injury. The DuBeau declaration asserts that the membership of ANH-USA generally opposes the individual insurance mandate under the APA, but does not cite the economic harms it imposes as one of the bases for this general opposition. DuBeau Decl. ¶¶ 5–7. General opposition to a government action is not sufficient injury in fact to confer standing. Nonetheless, the Court will reach the merits of this Count based on the injury shown to AAPS members. *See Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1232 (D.C. Cir. 1996) (If standing can be shown for at least one plaintiff, the Court "need not consider the standing of the other plaintiffs to raise that claim.").

the suit was filed.").[5] Another court in this district addressed the same question in *Mead v. Holder*, 766 F. Supp. 2d 16, 25 (D.D.C. 2011), *aff'd on other grounds, NFIB*, 132 S. Ct. at 2566. The court found that the plaintiffs' claims of future injury resulting from the individual insurance mandate provision of the ACA were imminent enough to satisfy the injury in fact standing requirement. *Id.* at 25. The Court reasoned that there was a substantial probability that the plaintiffs would be adversely affected, given the finality of the act, the fact that it will take effect at a definite point in time, and the high likelihood that the plaintiffs will qualify as individuals subject to the requirement. *Id.* Following that reasoning, the Court has grounds to find that plaintiffs' alleged injuries are imminent enough to satisfy the injury in fact requirement. The Court also finds that these harms are fairly traceable to the acts of defendants and redressable by an order enjoining enforcement of the individual mandate provision. In addition, the requirements of associational standing are met because the interests that plaintiffs seek to protect here are germane to both associations' purposes, and neither the claims asserted nor the relief requested requires the participation of individual members in the lawsuit.

C. Counts II and III are ripe for decision.

"[I]f a threatened injury is sufficiently 'imminent' to establish standing, the constitutional requirements of the ripeness doctrine will necessarily be satisfied. At that point, only the prudential justiciability concerns of ripeness can act to bar consideration of the claim." *Nat'l Treasury Employees Union v. United States*, 101 F.3d 1423, 1428 (D.C. Cir. 1996). The balancing test for prudential ripeness requires the Court to balance the "fitness of the issues for

5 Indeed in *NFIB*, 132 S. Ct. at 2566, decided by the Supreme Court on the merits, the plaintiffs alleged that they were suffering actual harm at the time the complaint was filed. *See Florida ex rel. Bondi v. U.S. Dept. of Health and Human Servs.*, 780 F. Supp. 2d 1256 (N.D. Fla. 2011), *overturned on other grounds by NFIB*, 132 S. Ct. at 2566. There is no such allegation here.

judicial decision" and the "hardship to the parties of withholding [its] consideration." *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977).

The fitness of the issue for judicial decision depends on whether there are "contingent future events that may not occur as anticipated, or indeed may not occur at all." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 580–81 (2012) (internal citation and quotation marks omitted). As noted above, there is some risk that circumstances could change between the time this complaint was filed and the 2014 deadline when the individual mandate provision takes effect. However, for the reasons already given, the Court finds that this risk is not so great as to render this issue unfit for judicial decision. This is supported by the fact that the Supreme Court has already considered Congress's authority to enact the mandate in *NFIB*. As to the hardship to the parties of the Court's withholding consideration of these issues, "absent institutional interests favoring the postponement of review, a [plaintiff] need not show that delay would impose individual hardship to show ripeness." *Sabre, Inc. v. Dep't of Transp.*, 429 F.3d 1113, 1120 (D.C. Cir. 2005). Again, since the Supreme Court has already taken up the constitutionality of this particular provision, the Court can find no institutional interest in postponing review here. Although plaintiffs have not identified any actual hardship that postponement of review would cause their members, it can infer that individuals who will be affected by this provision will need to start preparing in advance of the date it actually takes effect, *see Mead*, 766 F. Supp. 2d at 27, so the issue is sufficiently ripe for decision.

D. Counts II and III fail to state a claim upon which relief can be granted.

In *NFIB*, the Supreme Court unequivocally held that review of the individual insurance mandate provision of the ACA is not barred by the Anti-Injunction Act and that Congress had

the authority to enact it under its Article I, Section 8 power to "lay and collect Taxes." 132 S. Ct. at 2583–84, 2594–2600. The Court also found that this tax is not a capitation or direct tax, but is a type of tax permitted by the Constitution. *Id.* at 2598–2600. While the Court did not address the employer insurance mandate that plaintiffs challenge here under Count III, the similar manner in which the penalties are assessed under the individual and employer mandate provisions compels this Court to treat the two provisions alike for purposes of the constitutional inquiry. Accordingly, the Court will uphold both provisions.

Refusing to concede that the Supreme Court's decision definitively establishes the constitutionality of the mandate provisions, plaintiffs have now submitted a supplemental brief, which argues that the provisions, construed as imposing taxes, violate the Origination Clause, U.S. Const. art. 1, § 7, cl. 1. Pls.' First Supplemental Br. at 4–8. The Court declines to address this argument since plaintiffs waived it by failing to assert it in their complaint or opposition to the motion to dismiss, even though defendants argued in their motion to dismiss that the

provisions are justified under Congress's taxation power.[6] *Cf. Iweala v. Operational Techs. Servs., Inc.*, 634 F. Supp. 2d 73, 80 (D.D.C. 2009) ("It is well understood in this Circuit that when a plaintiff files an opposition to a motion to dismiss addressing only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded.").

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6 The Court will also dismiss any Tenth Amendment claims that might have been asserted in the complaint for the same reason.

The language under Counts II and III is incredibly broad, and could be read to encompass any Constitutional challenge to the mandate provisions. Compl. ¶¶ 95–96, 98–99 ("Nothing in Article I or elsewhere in the U.S. Constitution authorizes the federal government to [impose the employer or individual mandate requirements]," and "[f]or the foregoing reasons, [the mandate provisions are] in excess of authority granted by law, not in accordance with the law, and *ultra vires*."). However, the complaint also makes express allegations about particular powers accorded by the Constitution that do not support the individual mandate, and particular provisions of the Constitution that the individual mandate allegedly violates. *See id.* ¶¶ 51–54, 66–71. The Origination Clause is not one of them. *See, e.g.*, *id.* ¶ 69 (alleging that "[i]f a tax, the penalties associated with [the ACA's] insurance mandates are either an un-apportioned capitation or direct tax or a non-uniform excise tax, all of which violate Article I, sections 2 and 9 of the Constitution," but not alleging that they violate the Origination Clause). Moreover, as stated above, plaintiffs make no mention of the Origination Clause argument in their opposition to the motion to dismiss.

In their supplemental briefs, plaintiffs also assert – for the first time – that their complaint challenges the mandate provisions both facially and as applied to the plaintiffs in this case. The Court has reviewed the complaint extensively, and finds no as-applied challenge. *See generally* Compl. ¶¶ 94–99. Moreover, plaintiffs do not mention an as-applied challenge in their opposition to the motion to dismiss. The first time they raise this argument is in the supplemental brief they submitted after the Court lifted the stay. *See* Pls.' First Supplemental Br. at 4, 8; *see also* Pls.' Supplemental Br. in Resp. to the Ct.'s Minute Order Dated Oct. 3, 2012, [Dkt. # 57] at 1–2. However, even if the Court were to find that the complaint asserts an as-applied challenge to the mandate provisions, the Court would find that the complaint fails to allege sufficient facts to state a claim under Federal Rule of Civil Procedure 12(b)(6) for the same reasons that it fails to state a facial claim.

Plaintiffs also argue that the mandate provisions violate the Takings Clause of the Fifth Amendment.[7] Compl. ¶¶ 53, 68; Pls.' Opp. at 49–53. They claim that the provision authorizes the government to take property from some individuals (some portion of the ACA-mandated premium or penalty) and transfer it to others by subsidizing the ACA's lowered premiums for those with pre-existing conditions and other conditions that previously elevated their insurance rates. Pls.' Opp. at 49. This is an argument that lacks any vitality in light of the Supreme Court's decision upholding the individual mandate as a tax; if the government were prohibited from using tax money for the benefit of the American people, or if it was required to give the money back, its taxation powers would be useless.

Under Supreme Court precedent, the Due Process Clause of the Constitution should not be read to limit the taxing power, with the possible rare exception for cases where "the act complained of was so arbitrary as to constrain to the conclusion that it was not the exertion of taxation, but a confiscation of property." *Brushaber v. Union Pac. R.R. Co.*, 240 U.S. 1, 24 (1916).[8] That is not the case here. As the Supreme Court held in *NFIB*, the mandate provisions impose taxes on those who choose not to invest in comprehensive insurance. This is neither arbitrary, nor a confiscation of property.

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7 The Court notes that it has jurisdiction to consider the takings claim despite the fact that plaintiffs have not sought compensation in the Court of Federal Claims under the Tucker Act, 28 U.S.C. § 1491, because the relief that plaintiffs seek is declaratory and equitable, not compensatory. *See E. Enters. v. Apfel*, 524 U.S. 498, 521–22 (1998); *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 71 n.15 (1978).

8 The complaint also alleges that the mandates violate the Due Process Clause as compelled contracts and undue burdens on privacy and liberty. Compl. ¶¶ 53, 68. However, like the Origination Clause argument, plaintiffs do not raise these arguments in their opposition to the motion to dismiss, so the Court treats them as waived. Even if the Court were to consider these claims, it would dismiss them for the same reason it dismisses the Fifth Amendment takings argument.

Finally, to the extent the complaint claims that the mandates violate the Equal Protection Clause of the Fifth Amendment, Compl. ¶¶ 53, 68; *see* Pls.' Opp. at 53–54, the Court finds this argument unavailing as well. "[L]egislatures have especially broad latitude in creating classifications and distinctions in tax statutes." *Armour v. City of Indianapolis*, 132 S. Ct. 2073, 2080 (2012) (internal citation and quotation marks omitted). Since the classification drawn by the mandate provisions does not involve a "fundamental right" or a "suspect classification," the provisions will be upheld if "there is any reasonably conceivable state of facts that could provide a rational basis for the classification." *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313 (1993). The burden rests with plaintiffs to "negative every conceivable basis which might support [the provisions]." *Armour*, 132 S. Ct. at 2080–81 (internal citation and quotation marks omitted). Here, Congress could rationally distinguish between individuals with high-deductible, catastrophic risk policies or no insurance on the one hand, and individuals with lower deductible, higher coverage plans on the other. Congress had a rational interest in providing incentives for individuals to purchase comprehensive health insurance in order to lower premium prices and to increase the number of covered individuals. *See* ACA §§ 1501(a)(2)(F), 10106(a). Imposing a tax on individuals who choose not to purchase qualifying insurance plans is a rational way to introduce that incentive structure. The same logic holds for the employer insurance mandate.

Since plaintiffs cannot show that the individual or employer mandates were issued in violation of the United States Constitution, the Court will dismiss Counts II and III of the complaint.

III. Parts of Count IV are barred for lack of standing and the rest fails to state a claim upon which relief can be granted.

Plaintiffs next challenge an Interim Final Rule with Comment Period, 75 Fed. Reg. at 24,437, and two change requests that accompany the CMS Manual System (Change Requests 6417 and 6421).

A. Statutory and Regulatory Background

Physicians are free to choose whether to accept patients who are Medicare Part B beneficiaries. If a physician chooses to treat a patient who receives Medicare Part B benefits, the physician may opt to enroll in Medicare, submit a claim, and obtain payment according to the Medicare fee schedule. 42 U.S.C. §§ 1395cc, 1395n, 1395w-4. This option requires the physician to submit an enrollment application, as explained below. 42 C.F.R. §§ 424.505, 424.510 (2012). Alternatively, the physician may enter into a private contract with the patient whereby the patient compensates the physician out of pocket. 42 U.S.C. § 1395a(b); 42 C.F.R. § 405.405. This latter option allows the physician to circumvent Medicare fee limitations. *See United Seniors Ass'n, Inc. v. Shalala*, 182 F.3d 965, 967–68 (D.C. Cir. 1999). To do this, the physician must opt out of Medicare for a two-year period by submitting a supporting affidavit and entering into a written contract with the patient that meets certain statutory criteria. 42 C.F.R. §§ 405.405– 405.520; *see also United Seniors Ass'n, Inc.*, 182 F.3d at 966–68.

Medicare Part B also covers certain medical items or services, but only when they are referred by an eligible medical professional. *See* 42 U.S.C. §§ 1395k, 1395x(s). Even a physician who has opted out of Medicare Part B may still be able to refer medical items or services for a patient in a way that allows the patient to use his Medicare Part B benefits. The IFR and change requests to HHS's internal claims processing manual that plaintiffs challenge here set out the steps such a physician must take in order to refer under Medicare Part B.

The requirements are better understood within the larger context of the administration of the Medicare program in general. Public and private insurance companies identify physicians by unique provider numbers. And in 1996, the Health Insurance Portability and Accountability Act, 42 U.S.C. § 201 *et seq*. ("HIPAA"), standardized the provider number system. The regulations implementing HIPAA adopted the National Provider Identifier ("NPI") as the universally recognized identifier. 45 C.F.R. § 162.406 (2012). A physician may obtain a free NPI by submitting an application, in paper or online, containing basic information about herself, her practice, and her specialty. NPI Application/Update Form, CMS-10114 (Nov. 2008), *available at* http://www.cms.gov/cmsforms/downloads/CMS10114.pdf. Under the implementing regulations, HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers, 69 Fed. Reg. 3434-01 (Jan. 23, 2004) (codified at 45 C.F.R. Pt. 162), all physicians who engage in standard electronic transactions, such as submitting electronic claims to insurers, are required to obtain an NPI and to use it on all standard transactions where the NPI is required. 45 C.F.R. § 162.410(a). In addition, insurers – including Medicare – are required to use the NPI as the identifier for health care providers on all standard electronic transactions that require a health care provider identifier, 45 C.F.R. §§ 162.406(b)(1), 162.412(a), and are permitted to use the NPI for any other lawful purpose, 45 C.F.R. 162.406(b)(2).

In 2006, the Medicare program established more stringent enrollment requirements. Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment, 71 Fed. Reg. 20754, 20754–55 (Apr. 21, 2006) (codified at 42 C.F.R. Pts. 420, 424, 489, 498). Under the new requirements, any physician who has not opted out of Medicare is required to submit an enrollment application (paper or electronic) containing her NPI in order to obtain Medicare billing privileges. 42 C.F.R. §§ 424.505, 424.510; *see also* 75

Fed. Reg. at 24440. Those physicians must also recertify the accuracy of their enrollment information every five years. 42 C.F.R. § 424.515. The information from the enrollment applications is stored in an electronic data repository that has existed since 2003, called the Provider Enrollment, Chain, and Ownership System ("PECOS"). *Cf.* 42 C.F.R. § 424.505, 424.510, 424.515. The affidavits of physicians who validly opt out of Medicare are also stored in the PECOS. 75 Fed. Reg. at 24440.

In 2008, the Medicare program began requiring all enrolled physicians to have an NPI. *Id*. It also began requiring that all Medicare claims submitted by any enrolled health care provider must contain the NPI of that provider as well as the NPIs any other providers or suppliers whose identification on the claim is required, such as ordering and referring providers. *Id.*

The agency actions at issue here are the CMS Manual System along with two change requests (Change Request 6417 and 6421), and a Final Interim Rule with Comment Period, 75 Fed. Reg. at 24,437. The change requests were issued by HHS in 2009. The changes expand the automated claim editing verification process. They ensure that the claim for any billed service that requires an ordering or referring provider will be paid only if the NPI for the ordering or referring provider is on the claim, the provider is on the national PECOS file, and the NPI on the claim matches the NPI in the PECOS file for that provider. Change Request 6421, CMS Manual System, Pub. 100-20, Transmittal 643, Attachment at 1–2 (Feb. 26, 2010).

Later, the ACA amended the Medicare Act in ways that essentially ratified the existing regulatory scheme. It requires the Secretary of HHS to promulgate a regulation that requires, in relevant part, that no later than January 1, 2011, all physicians and suppliers that qualify for an NPI must include their NPI on applications to enroll in Medicare and all claims for payment

submitted under Medicare. ACA § 6402(a). It also expressly authorizes the Secretary of HHS to require any physician who orders certain items, such as home health services and durable medical equipment, to be enrolled in Medicare in order for the claim for that item to be paid. *Id.* § 6405(a). Finally, it authorized the Secretary to extend this requirement to "all other categories of items or services . . . that are ordered, prescribed, or referred" by an eligible professional. *Id.* § 6405(c).

On May 5, 2010, the Secretary of HHS implemented these ACA provisions by issuing the IFR challenged under Count IV. 75 Fed. Reg. at 24437. The IFR announced that any physician enrolling in Medicare must report an NPI, and any physician who enrolled in Medicare before obtaining an NPI must update her enrollment by submitting her NPI, unless the physician has validly opted out of the Medicare program. 42 C.F.R. 424.506(b). Second, it announced that any provider or supplier who submits a claim to Medicare must include its NPI and the NPIs of any other providers or suppliers "required to be identified." *Id.* § 424.506(c)(1). Third, in order to receive payment of claims for Part B items or services, (1) the billing supplier must submit a claim that contains the legal name and NPI of the referring or ordering physician, and (2) the ordering or referring physician must have an approved enrollment record or a valid opt-out record in the PECOS. *Id.* § 424.507(a)(1)–(2). The requirements for payment of claims for home health services are similar. *Id.* § 424.507(b).

B. Plaintiffs lack standing to bring parts of Count IV.

Defendants assert that plaintiffs lack standing to bring the claims set out in Count IV.

The complaint alleges that AAPS and ANH-USA member physicians will be economically injured if they decline to enroll in or opt out of Medicare because they will lose significant numbers of patients and be put at an economic disadvantage as compared to other

competing physicians. Compl. ¶ 25–27. Moreover, the complaint alleges that enrolling in or completing the Medicare opt-out procedures causes them injury because the "up-front and ongoing paperwork and monitoring" imposes "non-trivial costs." *Id.* ¶ 26. Although the Court has serious doubts about the extent of the costs that obtaining an NPI and PECOS record impose – particularly because HHS provides NPIs free of charge once a valid application has been submitted – the Court finds these allegations sufficient to meet the injury-in-fact requirement at the pleading stage under the standard outlined above. *See United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 689 n.14 (1973) ("[An] identifiable trifle is enough [injury] for standing.").

Defendants next challenge the redressability of plaintiffs' claims. They argue that the relief plaintiffs seek is not likely to redress their alleged injuries because the requirements that they claim are injuring them were established by rules that existed before the change requests and IFR were issued, and they were ratified by the ACA. Defs.' Mem. at 65–66; Reply in Support of Defs.' Mot. to Dismiss ("Defs.' Reply") [Dkt. # 45] at 33. In other words, even if the Court were to strike down the Interim Final Rule and change requests, plaintiffs would continue to suffer the same alleged injuries.

At the outset, the Court emphasizes that the only agency actions challenged under Count IV are the two change requests and the IFR. Compl. ¶ 105. So the Court looks to whether these two agency actions add any new requirements that were not imposed by existing statutes, rules, and regulations. According to the complaint, the requirements that allegedly cause plaintiffs' injuries are: (1) that "non-medicare providers" must comply with the statutory opt-out procedures before treating and obtaining outside payment from Medicare beneficiaries; (2) that ordering and referring physicians must obtain a record in PECOS (either to enroll in Medicare or

to opt-out); and (3) that ordering and referring physicians must obtain an NPI. Compl. ¶¶ 2(g)–(h), 59–61, 101–04. The Court addresses each theory separately.

First, plaintiffs allege that nothing in Medicare or any other provision of law requires "non-Medicare providers" to comply with the statutory opt-out requirement before treating and obtaining payment from Medicare-eligible beneficiaries outside the Medicare system.[9] Compl. ¶ 104. This allegation suffers from a causation problem. The Medicare statute itself requires physicians who treat Medicare beneficiaries, but receive compensation from those patients outside of Medicare, to comply with the opt-out requirements. 42 U.S.C. § 1395a(b). Although the complaint classifies physicians who refer under Medicare Part B as "non-Medicare providers," these physicians are actually just the type of providers to whom that requirement applies: they treat Medicare beneficiaries, but require payment outside of Medicare. Accordingly, any injuries to referring physicians that result from the opt-out requirement are caused by statutes and regulations that pre-date the agency actions plaintiffs' challenge. These are not redressable by the relief plaintiffs' seek, so the Court finds that plaintiffs lack standing to challenge the change requests and interim final rule on this basis. *See Atlantic Urological Associates, P.A. v. Leavitt*, 549 F. Supp. 2d 20, 28 (finding that plaintiffs could not satisfy the redressability prong of the standing analysis because their alleged injuries were caused by a previously issued rule, not the rule they were challenging: "Since the Final Order did not change anything for these Plaintiffs, invalidating it would not afford them any relief.").

Second, plaintiffs allege that HHS lacks the authority to require the filing of an enrollment or opt out record in the PECOS as a prerequisite to referring items or services under

9 Plaintiffs identify the statutory safe harbor provision as 42 U.S.C. § 1395(b). Compl. ¶ 103. However, that section of the code does not exist, so the Court will assume plaintiffs intended to refer to the opt-out requirements under 42 U.S.C. § 1395a(b).

Medicare. Compl. ¶ 102. To the extent this claim is simply a restatement of the first claim, the Court similarly finds plaintiffs lack standing to bring it. However, this claim appears to be challenging the requirement that referring physicians must obtain a PECOS record. Defendants point out that since 2003, the submission of either an enrollment application or an opt-out affidavit has automatically generated a record in PECOS. *See* 75 Fed. Reg. at 24440. Moreover, under pre-existing regulations, all physicians that refer under Medicare Part B are required to either update their enrollment information every five years, 42 C.F.R. § 424.515, or to comply with the opt-out procedures every two years, 42 U.S.C. § 1395a(b). So, under pre-existing regulations, it is inevitable that all referring physicians will be required to obtain a PECOS record. Accordingly, neither the challenged change requests or IFR actually cause the alleged injuries that result from that requirement, so the Court has no jurisdiction to review it.

Third, plaintiffs allege that "[n]othing in [the ACA] authorizes HHS to require non-Medicare providers to obtain an NPI, outside a specific action by that provider that independently requires an NPI (*e.g.*, HIPAA transactions)." Compl. ¶ 104. The Court construes this as a challenge to the requirement that referring physicians must obtain an NPI.[10] Although the HIPAA regulations first required the NPI of the referring physicians to be identified on Medicare claims, it appears that this requirement may not have had any enforcement mechanism until the introduction of the two challenged change requests.[11] Under the change requests,

10 None of the challenged agency actions require a physician who never treats Medicare beneficiaries to obtain an NPI. Plaintiffs do not allege otherwise.

11 Indeed, the Notification for Change Request 6417 notes that its implementation invalidates the previous version of the CMS, as amended by Change Request 6093, which allowed the billing provider to use her own NPI to identify the ordering or referring physician if the NPI of the ordering or referring physician could not be determined. Change Request 6417, Attachment at 2. Under Change Request 6417, the ordering or referring physician's NPI must be identified on the claim in order for the claim to be paid by Medicare. *Id.*

Medicare will actually deny any claim that is submitted without the NPI of the referring physicians. So the Court will find that at this stage of the litigation, plaintiffs do have standing to challenge the portion of the change requests and IFR that require referring physicians to obtain an NPI.

Finally, plaintiffs allege that "with respect to its PECOS-related requirements," the change requests and interim final rule were issued in violation of the APA's notice-and-comment rulemaking requirement. Compl. ¶ 101. The phrase "PECOS-related requirements" is vague, and plaintiffs' opposition to the motion to dismiss sheds no additional light on its meaning, but in the interest of giving plaintiffs the benefit of all inferences in their favor, the Court construes it to encompass the requirements that physicians who refer under Medicare Part B either obtain an enrollment or opt out record in the PECOS, and that all claims for referred items and services contain the NPI of the referring physician.

This challenge is based on a procedural injury. As noted above, the redressability component of standing is relaxed where the alleged injury is procedural, so the plaintiff need not show that better procedures would have led to a different substantive result. *Nat'l Ass'n of Home Builders*, 667 F.3d at 15. However, "though the plaintiff in a procedural-injury case is relieved of having to show that proper procedures would have caused the agency to take a different substantive action, the plaintiff must still show that the agency action was the cause of some redressable injury to the plaintiff." *Renal Physicians Ass'n v. U.S. Dept. of Health and Human Servs.*, 489 F.3d 1267, 1279 (D.C. Cir. 2007). So whether plaintiffs have standing to assert these procedural claims depends upon whether the relief sought is likely to change plaintiffs' position. Based on the causation problems described above, the Court finds that plaintiffs have standing to assert only the following claims: that the portions of the change requests and IFR requiring

referring physicians to obtain an NPI: (1) exceed statutory authority, and (2) were promulgated without the necessary notice and comment rulemaking. The Court will address these two claims on the merits.

C. The remainder of Count IV fails to state a claim upon which relief can be granted.

The Court will begin with the change requests, since those were issued before the challenged IFR.

1. *Defendants had the substantive authority to issue the change requests.*

Defendants clearly had the statutory authority to introduce the change requests. For over a decade, the Social Security Act, as amended, has required suppliers of Medicare Part B items or services to identify the referring physician by name and unique physician identification number. 42 U.S.C. § 1395*l*(q)(1). Under HIPAA, the NPI became the standard identification number. *Id.* § 1320d-2; *see also* 45 C.F.R. 162.406. Furthermore, the Social Security Act, as amended, delegates general authority to the Secretary of HHS to prescribe regulations for the efficient administration of the Medicare program. *Id.* §§ 1302, 1395hh. Existing HHS regulations require insurers, including Medicare, to use the NPI for standard electronic transactions, such as processing claims in electronic form, 45 C.F.R. §§ 162.406(b)(1), 162.412(a), and permit insurers to use the NPI for any other lawful purpose, *id.* § 162.406(b)(2). Indeed, by 2008, Medicare required that all paper and electronic Medicare claims contain an NPI for any secondary provider, such as the ordering or referring provider. Change Request 6093, CMS Manual System, Pub. 100-08, Transmittal 270, Manual Instruction at 1–2 (Oct. 15, 2008). Moreover, the ACA ratifies this requirement: it authorizes the Secretary of HHS to require any physician who orders or refers under Part B to be enrolled in Medicare, ACA §§ 5405(b), (c), and it requires that all physicians "include their [NPI] on all applications to enroll." *Id.*

§ 6402(a). In their Supplemental Brief on *Hall* and *NFIB*, plaintiffs appear to acknowledge that the ACA, if upheld, ratifies the referring physician NPI requirement. Pls.' Supplemental Br. on *Hall v. Sebelius* and *NFIB v. Sebelius* ("Pls.' First Supplemental Br.") [Dkt. # 55] at 10 (arguing that if the ACA is invalidated, defendants lack authority for the agency actions challenged in Count IV, but "even if [the ACA] could survive and provide *substantive* authority, Count IV's *procedural* claims would remain unsettled.").

Accordingly, it was well within defendants' authority, and not arbitrary and capricious, to change the automated claims verification process for to check the NPI for the referring physician as reported on the claim against the NPI in that physician's PECOS record.

2. *Defendants observed the procedure required by law in issuing the change requests.*

Plaintiffs' procedural challenge also fails. Final agency actions give rise to notice and comment obligations, with exceptions. One recognized exception is for "rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(3)(A). To determine whether a rule falls under this exemption, courts ask whether it "encodes a substantive value judgment." *Public Citizen v. Dep't of State*, 276 F.3d 634, 640 (D.C. Cir. 2002) (internal citation and quotation marks omitted). A judgment about "what mechanics and processes are most efficient" is not a substantive value judgment under this standard. *Id.* (internal citation and quotation marks omitted). The change requests at issue here do not encode any substantive value judgment, but simply dictate the verification processes that HHS will use to ensure that claims for referred items or services were validly referred by a qualified physician. The change requests make no distinction between claims on the basis of subject matter. *See id.* (finding that a State Department policy of declining to search for documents produced after the date of the requester's letter encoded no "substantive value judgment" because it applied to all FOIA requests and made

no distinction on the basis of subject matter). Accordingly, the Court finds the change requests to be valid.

3. *The Court will not invalidate the challenged portions of the interim final rule.*

Having concluded that the change requests are valid, the Court need not assess the validity of the portions of the IFR at issue because those portions just replicate the requirements imposed by the change requests and the HIPAA implementing regulations. In other words, even if this Court were to invalidate the challenged portions of the interim final rule, that would not redress plaintiffs' alleged injuries. Nonetheless, the Court notes that the statutes and regulations discussed above, including the ACA, supply ample authority for the IFR provisions at issue. Moreover, the agency did not violate the APA by declining to subject the rule to formal notice-and-comment rulemaking because the rule falls under the section 553(b)(3)(B) exemption, which applies "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B); *see* 75 Fed. Reg. at 24445. The interim final rule includes a finding that notice-and-comment rulemaking was unnecessary for the portions of the rule at issue here because they do not "add any new burdens for Medicare or Medicaid providers and suppliers." 75 Fed. Reg. at 24445–46. This is sufficient good cause for foregoing notice and comment rulemaking since the reassertion of a preexisting requirement is insignificant and inconsequential. *Cf. Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 94 (D.C. Cir. 2012) ("[The unnecessary] prong of the good cause inquiry is confined to those situations in which the administrative rule is a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.") (internal quotation marks and citation omitted).

II. Plaintiffs lack standing to assert Counts V and VI.

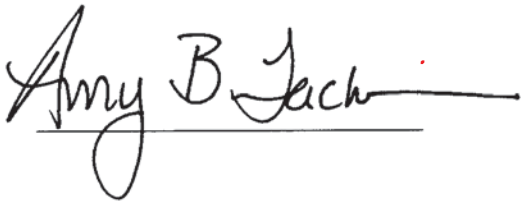
Finally, plaintiffs claim that defendants Sebelius and Astrue have violated their fiduciary and equitable duties to the American people by allowing the Medicare and Social Security programs to face insolvency, Compl. ¶¶ 106–117, 118(A)(xii), and the complaint demands an honest accounting of both programs, Compl. ¶¶ 118(B)(vi), (vii). Plaintiffs, however, fail to identify any actual or imminent injury that is sufficiently concrete and particularized. Rather, this challenge rests on a generalized grievance about the unforeseeable future of Medicare and Social Security.

"[A] plaintiff raising only a generally available grievance about government – claiming only harm to his and every citizen's interest in proper application of the Constitution and laws, and seeking relief that no more directly and tangibly benefits him than it does the public at large – does not state an Article III case or controversy." *Lujan*, 504 U.S. at 573–74. Plaintiffs argue that their claim is particularized because their members "obviously have a financial interest in the solvency of the programs that provide benefits to them" and that "[p]laintiffs' physician members have an interest in the solvency of Medicare on behalf of Medicare-eligible patients . . . even if those physicians do not themselves use Medicare." Pls.' Opp. at 66 n.34. But the financial interest of their members is no stronger than the financial interest of all Americans who will reach the age of Social Security and Medicare eligibility. Moreover, the problem here is not just that the alleged harm at issue is widely shared, but that it is too abstract and indefinite in nature to satisfy the concrete and particularized requirement. *Cf. FEC v. Akins*, 524 U.S. 11, 34 (1998) (Explaining that in the cases the Supreme Court has found to present "generalized

grievances" that do not satisfy the standing requirements, "the harm at issue is not only widely shared, but is also of an abstract and indefinite nature.").[12]

CONCLUSION

Because plaintiffs have no standing to assert the claims under Counts I, V, VI and portions of Count IV, and because Counts II and III and the remainder of Count IV fail to state a claim upon which relief can be granted, the Court will grant defendants' motion to dismiss this action in full. A separate order will issue.



AMY BERMAN JACKSON
United States District Judge

DATE: October 31, 2012

12 Even if the Court were to find that plaintiffs have standing to bring these claims, it would have to conclude that the complaint fails to state a claim upon which relief can be granted. The complaint asserts that both Medicare and Social Security "face[] insolvency because of federal mismanagement." Compl. ¶¶ 107, 113. This is a conclusory assertion that the Court need not accept without a pleaded factual basis. *See Iqbal*, 556 U.S. at 678. Yet the complaint contains no facts to support the conclusions that Medicare and Social Security "face insolvency" or that defendants Sebelius and Astrue have mismanaged the programs. The only relevant factual allegations are: (1) Sebelius has "stated that [the ACA] . . . would reduce the federal deficit, when she knows that the opposite is true in reality" and (2) Astrue "knows that [ACA's] budget scoring would redirect in excess of $50 billion from Social Security, but has not taken any appropriate action to protect Social Security from [the ACA]." Compl. ¶¶ 109, 115. These allegations, even accepted as true, do not show that the two defendants have mismanaged the programs, or that there is any legal basis to subject executive branch officials to suit in this Court on a breach of fiduciary duty theory. The first allegation merely challenges the truthfulness of a general statement Sebelius made. The second allegation is too vague to satisfy the test set out in *Iqbal*.