

**United States Court of Appeals for the
District of Columbia Circuit**

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS
AND ALLIANCE FOR NATURAL HEALTH USA

APPELLANTS,

v.

KATHLEEN SEBELIUS, SECRETARY OF HEALTH & HUMAN
SERVICES, IN HER OFFICIAL CAPACITY, *ET AL.*,

APPELLEES.

No. 13-5003

Argued January 10, 2014

Decided March 7, 2014

Appeal from the United States District Court for the
District of Columbia (No. 1:10-cv-00499)

Before: ROGERS, *Circuit Judge*, and WILLIAMS and
SENTELLE, *Senior Circuit Judges*.

WILLIAMS, *Senior Circuit Judge*: Plaintiff-appellants Association of American Physicians & Surgeons, Inc. and Alliance for Natural Health USA sued the Secretary of Health and Human Services and the Commissioner of the Social Security Administration¹ in district court, raising a wide variety of claims: (1) constitutional challenges to the Patient Protection and Affordable Care Act (“ACA”), (2) statutory (including Administrative Procedure Act) challenges to actions of HHS and the Commissioner relating to the implementation

¹ The Secretary of the Treasury is also named as a defendant, but appellants direct no arguments specifically to him.

of ACA and prior Medicare legislation, and (3) a somewhat amorphous attack on the failure of the defendants to render an “accounting” that would (they argue) alert the American people to the insolvency towards which the Medicare and Social Security programs are heading. The district court dismissed the challenges variously for lack of jurisdiction or for failure to state a claim upon which relief can be granted. *Association of American Physicians & Surgeons, Inc. v. Sebelius*, 901 F. Supp. 2d 19 (D.D.C. 2012) (“AAPS I”); see Fed. R. Civ. P. 12(b)(1), (6). Each of the challenges ultimately fails, for the reasons set forth below.

Constitutional Challenges

We take the constitutional claims first. If successful, they would radically alter the context for the statutory claims, while there is no chance that the statutory claims, if successful, would avoid the constitutional questions.

Appellants attack 26 U.S.C. § 5000A, often spoken of informally as the ACA’s individual health insurance mandate, which was sustained as a valid exercise of the taxing power in *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566 (2012) (“NFIB”).² *Id.* at 2593-2600; *Id.* at 2609

² Appellants mentioned the corresponding provision for employers in their opening brief but provided no rationale for treating it differently from the individual mandate. Appellants also mentioned an equal protection argument in their opening brief, but only in the standing section, not in the merits section. Later they appeared to advance arguments involving the equal protection clause and the employer provisions in letters filed under Fed. R. App. P. 28(j) (e.g., letters of July 15, 2013). Under these circumstances we have no occasion to address the claims involving the employer mandate or the

(Ginsburg, J., joined by Breyer, Kagan, and Sotomayor, JJ., concurring) (agreeing that “the minimum coverage provision is a proper exercise of Congress’ taxing power”). They argue that the tax violates both the Fifth Amendment’s prohibition of the taking of private property without just compensation and the origination clause, U.S. Const. art. I, § 7, cl. 1, which provides that “All Bills for raising Revenue shall originate in the House of Representatives; but the Senate may propose or concur with Amendments as on other Bills.”

As to takings, the district court applied the Supreme Court’s opinion in *Brushaber v. Union Pac. Railroad Co.*, 240 U.S. 1, 24-25 (1916), holding that an otherwise valid tax could run afoul of the takings clause only in a “case where, although there was a seeming exercise of the taxing power, 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.” See *AAPS I*, 901 F. Supp. 2d at 38- 39.

In an apparent effort to squeeze § 5000A into that narrow category, appellants argue that the tax (and the insurance program of which it is a part) asks “healthy private individuals to support unhealthy private individuals.” Appellants’ Br. 32. In support they cite the Court’s observation in *Kelo v. City of New London, Conn.*, 545 U.S. 469 (2005), that “it has long been accepted that the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation.” *Id.* at

equal protection clause.

477. But it is impossible to read that sentence in *Kelo* (even if we were to treat it as a holding, which it isn't) as suggesting that any redistributive purpose sweeps an otherwise valid tax into the narrow group of measures condemned by *Brushaber*.

Appellants make much of an assertion that their takings clause challenge is as-applied rather than facial. But other than saying so, they give us no reason why this should yield a more favorable outcome for the claim. We thus affirm the district court.

In support of their origination clause claim, appellants argue that though the bill ultimately eventuating in the ACA originated in the House, it was not, as it left that chamber, a revenue bill; only amendments added in the Senate that made it such a bill. Appellants raised this argument for the first time only after an order by the district court, after the Court issued its decision in *NFIB*, inviting supplemental pleadings, well after appellants filed their opposition to the government's motion to dismiss. The district court dismissed the claim on the principle that when a plaintiff files an opposition to a motion to dismiss, and addresses only some of the defendant's arguments, the ones not addressed may be taken as conceded. *AAPS I*, 901 F. Supp. 2d at 37-38 (citing *Iweala v. Operational Techs. Servs., Inc.*, 634 F. Supp. 2d 73, 80 (D.D.C. 2009)). Appellants do not contest the general principle, but argue that because they raised the origination clause claim in supplemental briefing ordered by the district court, there was no waiver or forfeiture.

Insofar as the government recognizes that the order for supplemental briefing renders this situation atypical, it focuses on the fact the order required both parties to file their supplemental briefs simultaneously. It's hard to see how the mere fact of simultaneous filing helps the government. If it felt that appellants had improperly raised new arguments, it was free to seek leave to object on that ground, to offer contrary arguments on the merits, or to move to amend its pleadings, Fed. R. Civ. P. 15. It did none of these.

Regardless of the simultaneous filings, two considerations support the district court's decision to treat the argument as conceded. First, the briefing in *NFIB* and the lower court decisions reviewed in *NFIB*, long before the decision issued, clearly raised the possibility that § 5000A would be sustained as a tax. See, e.g., *NFIB*, 132 S. Ct. at 2593-2600 (opinion of Chief Justice Roberts) (addressing the government's tax theory), 2650-55 (opinion of Justices Scalia, Kennedy, Thomas and Alito) (same). The government offered that theory as a defense in this very case, see Motion to Dismiss 5, 44-47, and appellants resisted the claim with roughly five pages of their opposition to that motion, see Opposition to Motion to Dismiss 41-46. Thus the decision in *NFIB* did no more than render the tax theory more salient than it had been.

Second, the district court called for supplemental briefing only to address "whether [*NFIB*] and *Hall v. Sebelius* [667 F.3d 1293 (D.C. Cir. 2012), addressed below] require the dismissal of any counts." It was thus much more limited than plaintiffs now suggest; it did not invite briefing "on

the impact” of *NFIB*. Compare Reply Br. 17-18. The district court was therefore perfectly reasonable in applying the standard rule inferring concession from gaps in a plaintiff’s opposition to a motion to dismiss.

We note, though we do not rely on, the presence of an origination clause challenge to § 5000A in *Sissel v. U.S. Dep’t of Health & Human Servs.*, 951 F. Supp. 2d 159 (D.D.C. 2013), *appeal pending*, No. 13-5202 (D.C. Cir.).

Statutory (Including APA) Claims

Appellants’ first statutory claim is an objection to provisions in a Social Security Administration (“SSA”) handbook, the Social Security Program Operations Manual System (“POMS”). These provisions explain that individuals entitled to social security benefits are automatically entitled to Medicare Part A benefits. POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020. Appellants argue that the handbook provisions exceed the SSA’s statutory authority and that their adoption should have been preceded by notice- and-comment rulemaking. The district court dismissed the claim on a variety of standing theories. *AAPS I*, 901 F. Supp. 2d at 29-34. We affirm on a somewhat simpler basis.

First, appellants’ substantive attack on the POMS provisions is clearly foreclosed by our decision in *Hall v. Sebelius*, 667 F.3d 1293 (D.C. Cir. 2012), holding that the statutory text establishing Medicare Part A precludes any option not to be entitled to its benefits (though eligible persons are free not to *exercise* their entitlement). *Id.* at 1295-97. Although *Steel Co. v. Citizens for a*

Better Environment, 523 U.S. 83, 94-95 (1998), normally bars a court from addressing a substantive merits claim before addressing all jurisdictional vulnerabilities (the government presses several, such as the channeling provision of 42 U.S.C. § 405(h)), there is an exception within *Steel Co.* for a merits decision resting entirely on prior or simultaneous rulings on an identical merits question, *id.* at 98-101.

Second, appellants' claim to notice-and-comment procedures under the APA fails because our decision in *Hall* eliminates any possibility that such procedures could remedy appellants' alleged injury. It is true that a party asserting a procedural injury enjoys a somewhat relaxed test as to whether compliance with the procedural requirement would lead to "redress" of the party's substantive injury (i.e., lead to a less injurious outcome), see *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 572 n.7 (1992), but here there is no way whatsoever that notice-and-comment procedures could help appellants, see, e.g., *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 38, 41-43 (1976). *Hall* did not hold that the POMS permissibly interpreted the statute to preclude withdrawal by eligible persons from the entitlement to Medicare Part A. Rather it held that the *statute* itself barred any such effort to escape entitlement. *Hall*, 667 F.3d at 1296 ("under the law, plaintiffs remain legally entitled to the benefits regardless of whether they accept them"); *id.* ("plaintiffs' position is inconsistent with the statutory text"). Accordingly, all the procedure in the world could not lawfully lead the SSA to a

conclusion that would redress appellants' substantive injury.

Appellants' second statutory claim attacks an interim final rule, Changes in Medicare and Medicaid Programs, 75 Fed. Reg. 24,437 (May 5, 2010) ("IFR"), and two 2009 changes to a Medicare claims processing manual, Change Requests 6417 and 6421, on both procedural and substantive grounds. ("Change Request" is the term for an update to HHS's online manual, see Complaint, ¶ 76). The district court rejected the claims in part on a standing theory and in part on the merits. *AAPS I*, 901 F. Supp. 2d at 39-46. The government argues that the claims are moot, and we agree.

The district court's discussion thoroughly describes the IFR and the Change Requests. It is enough for our purposes to observe that they govern the process by which physicians may "opt out" of participation in Medicare Part B, and, having opted out, may nonetheless refer patients for services covered by Part B.

As is common with interim final rules, the IFR here was superseded by a rule promulgated after notice and comment, Changes in Medicare and Medicaid Programs, 77 Fed. Reg. 25,284 (Apr. 27, 2012), issued while this case was pending in the district court. The government argues that the procedures accompanying adoption of the 2012 rule clearly moot appellants' procedural claim. Moreover, the Secretary made substantive changes to the interim rule as a result of the comments. See, e.g., *id.* at 25,291-92. Appellants do not dispute these points.

In their opening brief, appellants make the startling argument that their claim is not moot because, “once the 2012 rule is invalidated, the Administration will need to retreat to the procedurally defective actions challenged here.” Appellants’ Br. 49. Appellants cite no case or reasoning to support the idea that a claim can be saved from mootness by the court’s blithely hypothesizing that a whole other set of rules, not at issue in the present case, or so far as appears even challenged in any proceeding, may be invalid. Appellants also argue that when we hold ACA unconstitutional as a violation of the origination clause, the IFR, etc., will inevitably fall. We may assume *arguendo* that the second step in this argument is sound, but that is of no help to appellants: their premise—that we would vindicate their origination clause claim—has proven incorrect. Appellants further argue that the “substantive defects” carry over from the IFR to the 2012 rule, and that this commonality defeats mootness. But it is clearly preferable as a general matter to review a set of claims in the context of an extant rather than a defunct rule, and appellants do not even argue that the passages to which they object are so isolated as to defeat that general principle.

Claim for an “Accounting”

Finally, appellants claim that the Social Security Commissioner and the Secretary have violated their “fiduciary and equitable duties,” Compl. ¶¶ 111, 117, by failing to provide an “honest accounting” of the financial situation facing Social Security and Medicare. *Id.* at ¶¶ 106-117.

The district court held that plaintiffs did not identify an injury sufficient for standing and dismissed on that ground, *AAPS I*, 901 F. Supp. 2d at 46, a position endorsed by the government on appeal. The plaintiffs stress that, contrary to the conclusion of the district court, they have asserted such an injury, pointing to the particular interest in the solvency of the Medicare Program held by the physician members of appellant organizations.

We need not address whether appellants' alleged injury should be classified as merely an abstract interest "in proper application" of the laws, as the district court found, *AAPS I*, 901 F. Supp. 2d at 46, citing *Lujan*, 504 U.S. at 573-74, or as a harm that, though very widely shared, is sufficiently concrete to satisfy Article III's injury requirement, *FEC v. Akins*, 524 U.S. 11, 23-25 (1998). Appellants provide no legal argument for their claims against the Commissioner and Secretary. They do not cite a statute, the Constitution, or any case law for the foundation of the alleged fiduciary duties; they do not even sketch a penumbra possibly emanating from any part of the laws or Constitution of the United States. Although "[i]t is firmly established in our cases that the absence of a valid (as opposed to arguable) cause of action does not implicate subject-matter jurisdiction," *Steel Co.*, 523 U.S. at 89, it is equally clear that where a claim is "wholly insubstantial and frivolous," it may be dismissed for want of jurisdiction. *Bell v. Hood*, 327 U.S. 678, 682-83 (1946). As the filings in the district court and before this court do not disclose even an

arguable theory, we find a want of jurisdiction over the claim to an “accounting.

* * *

For the reasons stated above, the judgment of the district court is

Affirmed.

**United States District Court for the
District of Columbia**

ASS'N OF AMERICAN PHYSICIANS & SURGEONS, *ET AL.*,
PLAINTIFFS,

v.

KATHLEEN G. SEBELIUS, SECRETARY OF HEALTH &
HUMAN SERVICES, *ET AL.*,
DEFENDANTS.

Civil Action No. 10-0499 (ABJ)

Before: Amy Berman Jackson, District Judge.

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 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. Env’tl. 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 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/lrx/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/lrx/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.

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

¶ 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 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

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.

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

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

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.

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

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

Counts II and III of the complaint, respectively,

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.’”).

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

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.”).

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 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

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.

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 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.*

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

Operational Techs. Servs., Inc., 634 F. Supp. 2d 73, 80 (D.D.C. 2009) (“It is well understood in this

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.

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.”).

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

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).

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.

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

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.

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

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).

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 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, 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

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.*

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. § 1395l(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

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

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.

/s/ AMY BERMAN JACKSON

United States District Judge

DATE: October 31, 2012

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*.

**United States Court of Appeals for the
District of Columbia Circuit**

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS
AND ALLIANCE FOR NATURAL HEALTH USA

APPELLANTS,

v.

KATHLEEN SEBELIUS, SECRETARY OF HEALTH & HUMAN
SERVICES, IN HER OFFICIAL CAPACITY, ET AL.,

APPELLEES.

No. 13-5003

SEPTEMBER TERM, 2013

1:10-cv-00499-ABJ

Filed On: April 28, 2014

Before: ROGERS, *Circuit Judge*, and WILLIAMS and
SENTELLE, *Senior Circuit Judges*.

ORDER

Upon consideration of appellants' petition for
panel rehearing filed on April 21, 2014, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:

Mark J. Langer, Clerk

By: /s/

Jennifer M. Clark

Deputy Clerk

U.S. CONST. art. 1, §7, cl. 1

All Bills for raising Revenue shall originate in the House of Representatives; but the Senate may propose or concur with Amendments as on other Bills.

U.S. CONST. art. I, §8

The Congress shall have Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States; but all Duties, Imposts and Excises shall be uniform throughout the United States;

* * *

To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes;

* * *

To make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers, and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.

U.S. CONST. art. I, §9

The Migration or Importation of such Persons as any of the States now existing shall think proper to admit, shall not be prohibited by the Congress prior to the Year one thousand eight hundred and eight, but a Tax or duty may be imposed on such Importation, not exceeding ten dollars for each Person.

* * *

No Capitation, or other direct, Tax shall be laid, unless in Proportion to the Census or Enumeration herein before directed to be taken.

No Tax or Duty shall be laid on Articles exported from any State.

U.S. CONST. amend. V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the Militia, when in actual service in time of War or public danger; nor shall any person be subject for the same offence to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

U.S. CONST. amend. XVI

The Congress shall have power to lay and collect taxes on incomes, from whatever source derived, without apportionment among the several States, and without regard to any census or enumeration.

42 U.S.C. §405(h)

The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331

or 1346 of title 28 to recover on any claim arising under this subchapter.

42 U.S.C. §1395a

(a) Basic freedom of choice

Any individual entitled to insurance benefits under this subchapter may obtain health services from any institution, agency, or person qualified to participate under this subchapter if such institution, agency, or person undertakes to provide him such services.

(b) Use of private contracts by medicare beneficiaries

(1) In general

Subject to the provisions of this subsection, nothing in this subchapter shall prohibit a physician or practitioner from entering into a private contract with a medicare beneficiary for any item or service—

(A) for which no claim for payment is to be submitted under this subchapter, and

(B) for which the physician or practitioner receives—

(i) no reimbursement under this subchapter directly or on a capitated basis, and

(ii) receives no amount for such item or service from an organization which receives reimbursement for such item or service under this subchapter directly or on a capitated basis.

(2) Beneficiary protections

(A) In general

Paragraph (1) shall not apply to any contract unless—

(i) the contract is in writing and is signed by the medicare beneficiary before any item or service is provided pursuant to the contract;

(ii) the contract contains the items described in subparagraph (B); and

(iii) the contract is not entered into at a time when the medicare beneficiary is facing an emergency or urgent health care situation.

(B) Items required to be included in contract

Any contract to provide items and services to which paragraph (1) applies shall clearly indicate to the medicare beneficiary that by signing such contract the beneficiary—

(i) agrees not to submit a claim (or to request that the physician or practitioner submit a claim) under this subchapter for such items or services even if such items or services are otherwise covered by this subchapter;

(ii) agrees to be responsible, whether through insurance or otherwise, for payment of such items or services and understands that no reimbursement will be provided under this subchapter for such items or services;

(iii) acknowledges that no limits under this subchapter (including the limits under section 1395w-4 (g) of this title) apply to amounts that may be charged for such items or services;

(iv) acknowledges that Medigap plans under section 1395ss of this title do not, and other supplemental insurance plans may elect not to, make payments for such items and services because payment is not made under this subchapter; and

(v) acknowledges that the medicare beneficiary has the right to have such items or services provided by other physicians or practitioners for whom payment would be made under this subchapter.

Such contract shall also clearly indicate whether the physician or practitioner is excluded from participation under the medicare program under section 1320a-7 of this title.

(3) Physician or practitioner requirements

(A) In general

Paragraph (1) shall not apply to any contract entered into by a physician or practitioner unless an affidavit described in subparagraph (B) is in effect during the period any item or service is to be provided pursuant to the contract.

(B) Affidavit

An affidavit is described in this subparagraph if—

(i) the affidavit identifies the physician or practitioner and is in writing and is signed by the physician or practitioner;

(ii) the affidavit provides that the physician or practitioner will not submit any claim under this subchapter for any item or service provided to any medicare beneficiary (and will not receive any reimbursement or amount described in paragraph (1)(B) for any such item or service) during the 2-year period beginning on the date the affidavit is signed; and

(iii) a copy of the affidavit is filed with the Secretary no later than 10 days after the first contract to which such affidavit applies is entered into.

(C) Enforcement

If a physician or practitioner signing an affidavit under subparagraph (B) knowingly and willfully submits a claim under this subchapter for any item or service provided during the 2-year period described in subparagraph (B)(ii) (or receives any reimbursement or amount described in paragraph (1)(B) for any such item or service) with respect to such affidavit—

(i) this subsection shall not apply with respect to any items and services provided by the physician or practitioner pursuant to any contract on and after the date of such submission and before the end of such period; and

(ii) no payment shall be made under this subchapter for any item or service furnished by the physician or practitioner during the period described in clause (i) (and no reimbursement or payment of any amount described in paragraph (1)(B) shall be made for any such item or service).

(4) Limitation on actual charge and claim submission requirement not applicable

Section 1395w-4 (g) of this title shall not apply with respect to any item or service provided to a medicare beneficiary under a contract described in paragraph (1).

(5) Definitions

In this subsection:

(A) Medicare beneficiary

The term “medicare beneficiary” means an individual who is entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter.

(B) Physician

The term “physician” has the meaning given such term by paragraphs (1), (2), (3), and (4) of section 1395x (r) of this title.

(C) Practitioner

The term “practitioner” has the meaning given such term by section 1395u (b)(18)(C) of this title.

26 U.S.C. §5000A

(a) Requirement to maintain minimum essential coverage

An applicable individual shall for each month beginning after 2013 ensure that the individual, and any dependent of the individual who is an applicable individual, is covered under minimum essential coverage for such month.

(b) Shared responsibility payment

(1) In general

If a taxpayer who is an applicable individual, or an applicable individual for whom the taxpayer is liable under paragraph (3), fails to meet the requirement of subsection (a) for 1 or more months, then, except as provided in subsection (e), there is hereby imposed on the taxpayer a penalty with respect to such failures in the amount determined under subsection (c).

(2) Inclusion with return

Any penalty imposed by this section with respect to any month shall be included with a taxpayer’s return under chapter 1 for the taxable year which includes such month.

(3) Payment of penalty

If an individual with respect to whom a penalty is imposed by this section for any month—

(A) is a dependent (as defined in section 152) of another taxpayer for the other taxpayer's taxable year including such month, such other taxpayer shall be liable for such penalty, or

(B) files a joint return for the taxable year including such month, such individual and the spouse of such individual shall be jointly liable for such penalty.

(c) Amount of penalty

(1) In general

The amount of the penalty imposed by this section on any taxpayer for any taxable year with respect to failures described in subsection (b)(1) shall be equal to the lesser of—

(A) the sum of the monthly penalty amounts determined under paragraph (2) for months in the taxable year during which 1 or more such failures occurred, or

(B) an amount equal to the national average premium for qualified health plans which have a bronze level of coverage, provide coverage for the applicable family size involved, and are offered through Exchanges for plan years beginning in the calendar year with or within which the taxable year ends.

(2) Monthly penalty amounts

For purposes of paragraph (1)(A), the monthly penalty amount with respect to any taxpayer for any month during which any failure described in subsection (b)(1) occurred is an amount equal to 1/12 of the greater of the following amounts:

(A) Flat dollar amount

An amount equal to the lesser of—

(i) the sum of the applicable dollar amounts for all individuals with respect to whom such failure occurred during such month, or

(ii) 300 percent of the applicable dollar amount (determined without regard to paragraph (3)(C)) for the calendar year with or within which the taxable year ends.

(B) Percentage of income

An amount equal to the following percentage of the excess of the taxpayer's household income for the taxable year over the amount of gross income specified in section 6012 (a)(1) with respect to the taxpayer for the taxable year:

(i) 1.0 percent for taxable years beginning in 2014.

(ii) 2.0 percent for taxable years beginning in 2015.

(iii) 2.5 percent for taxable years beginning after 2015.

(3) Applicable dollar amount

For purposes of paragraph (1)—

(A) In general

Except as provided in subparagraphs (B) and (C), the applicable dollar amount is \$695.

(B) Phase in

The applicable dollar amount is \$95 for 2014 and \$325 for 2015.

(C) Special rule for individuals under age 18

If an applicable individual has not attained the age of 18 as of the beginning of a month, the applicable dollar amount with respect to such individual for the month shall be equal to one-half of

the applicable dollar amount for the calendar year in which the month occurs.

(D) Indexing of amount

In the case of any calendar year beginning after 2016, the applicable dollar amount shall be equal to \$695, increased by an amount equal to—

(i) \$695, multiplied by

(ii) the cost-of-living adjustment determined under section 1 (f)(3) for the calendar year, determined by substituting “calendar year 2015” for “calendar year 1992” in subparagraph (B) thereof.

If the amount of any increase under clause (i) is not a multiple of \$50, such increase shall be rounded to the next lowest multiple of \$50.

(4) Terms relating to income and families

For purposes of this section—

(A) Family size

The family size involved with respect to any taxpayer shall be equal to the number of individuals for whom the taxpayer is allowed a deduction under section 151 (relating to allowance of deduction for personal exemptions) for the taxable year.

(B) Household income

The term “household income” means, with respect to any taxpayer for any taxable year, an amount equal to the sum of—

(i) the modified adjusted gross income of the taxpayer, plus

(ii) the aggregate modified adjusted gross incomes of all other individuals who—

(I) were taken into account in determining the taxpayer’s family size under paragraph (1), and

(II) were required to file a return of tax imposed by section 1 for the taxable year.

(C) Modified adjusted gross income

The term “modified adjusted gross income” means adjusted gross income increased by—

(i) any amount excluded from gross income under section 911, and

(ii) any amount of interest received or accrued by the taxpayer during the taxable year which is exempt from tax.

(d) Applicable individual

For purposes of this section—

(1) In general

The term “applicable individual” means, with respect to any month, an individual other than an individual described in paragraph (2), (3), or (4).

(2) Religious exemptions

(A) Religious conscience exemption

Such term shall not include any individual for any month if such individual has in effect an exemption under section 1311(d)(4)(H) of the Patient Protection and Affordable Care Act which certifies that such individual is—

(i) a member of a recognized religious sect or division thereof which is described in section 1402 (g)(1), and

(ii) an adherent of established tenets or teachings of such sect or division as described in such section.

(B) Health care sharing ministry

(i) In general Such term shall not include any individual for any month if such individual is a

member of a health care sharing ministry for the month.

(ii) Health care sharing ministry The term “health care sharing ministry” means an organization—

(I) which is described in section 501 (c)(3) and is exempt from taxation under section 501 (a),

(II) members of which share a common set of ethical or religious beliefs and share medical expenses among members in accordance with those beliefs and without regard to the State in which a member resides or is employed,

(III) members of which retain membership even after they develop a medical condition,

(IV) which (or a predecessor of which) has been in existence at all times since December 31, 1999, and medical expenses of its members have been shared continuously and without interruption since at least December 31, 1999, and

(V) which conducts an annual audit which is performed by an independent certified public accounting firm in accordance with generally accepted accounting principles and which is made available to the public upon request.

(3) Individuals not lawfully present

Such term shall not include an individual for any month if for the month the individual is not a citizen or national of the United States or an alien lawfully present in the United States.

(4) Incarcerated individuals

Such term shall not include an individual for any month if for the month the individual is

incarcerated, other than incarceration pending the disposition of charges.

(e) Exemptions

No penalty shall be imposed under subsection (a) with respect to—

(1) Individuals who cannot afford coverage

(A) In general

Any applicable individual for any month if the applicable individual's required contribution (determined on an annual basis) for coverage for the month exceeds 8 percent of such individual's household income for the taxable year described in section 1412(b)(1)(B) of the Patient Protection and Affordable Care Act. For purposes of applying this subparagraph, the taxpayer's household income shall be increased by any exclusion from gross income for any portion of the required contribution made through a salary reduction arrangement.

(B) Required contribution

For purposes of this paragraph, the term "required contribution" means—

(i) in the case of an individual eligible to purchase minimum essential coverage consisting of coverage through an eligible-employer-sponsored plan, the portion of the annual premium which would be paid by the individual (without regard to whether paid through salary reduction or otherwise) for self-only coverage, or

(ii) in the case of an individual eligible only to purchase minimum essential coverage described in subsection (f)(1)(C), the annual premium for the lowest cost bronze plan available in the individual market through the Exchange in the State in the

rating area in which the individual resides (without regard to whether the individual purchased a qualified health plan through the Exchange), reduced by the amount of the credit allowable under section 36B for the taxable year (determined as if the individual was covered by a qualified health plan offered through the Exchange for the entire taxable year).

(C) Special rules for individuals related to employees

For purposes of subparagraph (B)(i), if an applicable individual is eligible for minimum essential coverage through an employer by reason of a relationship to an employee, the determination under subparagraph (A) shall be made by reference to required contribution of the employee.

(D) Indexing

In the case of plan years beginning in any calendar year after 2014, subparagraph (A) shall be applied by substituting for “8 percent” the percentage the Secretary of Health and Human Services determines reflects the excess of the rate of premium growth between the preceding calendar year and 2013 over the rate of income growth for such period.

(2) Taxpayers with income below filing threshold

Any applicable individual for any month during a calendar year if the individual’s household income for the taxable year described in section 1412(b)(1)(B) of the Patient Protection and Affordable Care Act is less than the amount of gross income specified in section 6012 (a)(1) with respect to the taxpayer.

(3) Members of Indian tribes

Any applicable individual for any month during which the individual is a member of an Indian tribe (as defined in section 45A (c)(6)).

(4) Months during short coverage gaps

(A) In general

Any month the last day of which occurred during a period in which the applicable individual was not covered by minimum essential coverage for a continuous period of less than 3 months.

(B) Special rules

For purposes of applying this paragraph—

(i) the length of a continuous period shall be determined without regard to the calendar years in which months in such period occur,

(ii) if a continuous period is greater than the period allowed under subparagraph (A), no exception shall be provided under this paragraph for any month in the period, and

(iii) if there is more than 1 continuous period described in subparagraph (A) covering months in a calendar year, the exception provided by this paragraph shall only apply to months in the first of such periods.

The Secretary shall prescribe rules for the collection of the penalty imposed by this section in cases where continuous periods include months in more than 1 taxable year.

(5) Hardships

Any applicable individual who for any month is determined by the Secretary of Health and Human Services under section 1311 (d)(4)(H) to have

suffered a hardship with respect to the capability to obtain coverage under a qualified health plan.

(f) Minimum essential coverage

For purposes of this section—

(1) In general

The term “minimum essential coverage” means any of the following:

(A) Government sponsored programs

Coverage under—

(i) the Medicare program under part A of title XVIII of the Social Security Act,

(ii) the Medicaid program under title XIX of the Social Security Act,

(iii) the CHIP program under title XXI of the Social Security Act,

(iv) medical coverage under chapter 55 of title 10, United States Code, including coverage under the TRICARE program;

(v) a health care program under chapter 17 or 18 of title 38, United States Code, as determined by the Secretary of Veterans Affairs, in coordination with the Secretary of Health and Human Services and the Secretary,

(vi) a health plan under section 2504 (e) of title 22, United States Code (relating to Peace Corps volunteers); or

(vii) the Nonappropriated Fund Health Benefits Program of the Department of Defense, established under section 349 of the National Defense Authorization Act for Fiscal Year 1995 (Public Law 103–337; 10 U.S.C. 1587 note).

(B) Employer-sponsored plan

Coverage under an eligible employer-sponsored plan.

(C) Plans in the individual market

Coverage under a health plan offered in the individual market within a State.

(D) Grandfathered health plan

Coverage under a grandfathered health plan.

(E) Other coverage

Such other health benefits coverage, such as a State health benefits risk pool, as the Secretary of Health and Human Services, in coordination with the Secretary, recognizes for purposes of this subsection.

(2) Eligible employer-sponsored plan

The term “eligible employer-sponsored plan” means, with respect to any employee, a group health plan or group health insurance coverage offered by an employer to the employee which is—

(A) a governmental plan (within the meaning of section 2791(d)(8) of the Public Health Service Act), or

(B) any other plan or coverage offered in the small or large group market within a State.

Such term shall include a grandfathered health plan described in paragraph (1)(D) offered in a group market.

(3) Excepted benefits not treated as minimum essential coverage

The term “minimum essential coverage” shall not include health insurance coverage which consists of coverage of excepted benefits—

(A) described in paragraph (1) of subsection (c) of section 2791 of the Public Health Service Act; or

(B) described in paragraph (2), (3), or (4) of such subsection if the benefits are provided under a separate policy, certificate, or contract of insurance.

(4) Individuals residing outside United States or residents of territories

Any applicable individual shall be treated as having minimum essential coverage for any month—

(A) if such month occurs during any period described in subparagraph (A) or (B) of section 911 (d)(1) which is applicable to the individual, or

(B) if such individual is a bona fide resident of any possession of the United States (as determined under section 937 (a)) for such month.

(5) Insurance-related terms

Any term used in this section which is also used in title I of the Patient Protection and Affordable Care Act shall have the same meaning as when used in such title.

(g) Administration and procedure

(1) In general

The penalty provided by this section shall be paid upon notice and demand by the Secretary, and except as provided in paragraph (2), shall be assessed and collected in the same manner as an assessable penalty under subchapter B of chapter 68.

(2) Special rules

Notwithstanding any other provision of law—

(A) Waiver of criminal penalties

In the case of any failure by a taxpayer to timely pay any penalty imposed by this section, such

taxpayer shall not be subject to any criminal prosecution or penalty with respect to such failure.

(B) Limitations on liens and levies

The Secretary shall not—

(i) file notice of lien with respect to any property of a taxpayer by reason of any failure to pay the penalty imposed by this section, or

(ii) levy on any such property with respect to such failure.

**Patient Protection and Affordable Care Act,
Pub. L. No. 111-148, §6405(c), 124 Stat. 119, 768-
69 (2010)**

The Secretary may extend the requirement applied by the amendments made by subsections (a) and (b) to durable medical equipment and home health services (relating to requiring certifications and written orders to be made by enrolled physicians and health professions) to all other categories of items or services under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including covered part D drugs as defined in section 1860D-2(e) of such Act (42 U.S.C. 1395w-102), that are ordered, prescribed, or referred by a physician enrolled under section 1866(j) of such Act (42 U.S.C. 1395cc(j)) or an eligible professional under section 1848(k)(3)(B) of such Act (42 U.S.C. 1395w-4(k)(3)(B)).

D.C. Code §11-501

In addition to its jurisdiction as a United States district court and any other jurisdiction conferred on it by law, the United States District Court for the District of Columbia has jurisdiction of the following:

* * *

**Centers for Medicare and Medicaid Services,
Office of Public Affairs, “CMS to Review
PECOS Enrollment Process” (June 30, 2010)**

**Medicare Working with Ordering and Referring
Providers and Suppliers to Streamline Enrollment
Process**

The Centers for Medicare & Medicaid Services (CMS) is working with providers to address concerns about enrollment in the Provider Enrollment, Chain and Ownership System (PECOS) to ensure that Medicare beneficiaries continue to receive the health care services and items they need. PECOS is the electronic system used to enroll physicians and eligible professionals into the Medicare program.

As part of those efforts, CMS will, for the time being, not implement changes that would automatically reject claims based on orders, certifications, and referrals made by providers that have not yet had their applications approved by July 6, 2010. While more than 800,000 physicians and other health professionals have enrolled and have approved applications in the PECOS system, some providers have encountered problems. CMS is continuing to update and streamline the process, and more providers have been enrolled in the past few days.

CMS issued an interim final regulation on May 5, 2010 implementing provisions of the Affordable Care Act that permit only a Medicare enrolled physician or eligible professional to certify or order home health services, durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), and certain items and services under Medicare Part B. The new law applies to orders, referrals and

certifications made on or after July 1. The comment period for the regulation closes on July 6, after which the comments will be reviewed and considered before a final regulation is issued.

The Affordable Care Act provisions and the regulation were designed as steps to prevent fraud in Medicare by ensuring that only eligible and identifiable providers and suppliers can order and refer covered items and services to Medicare beneficiaries.

Many physicians and other providers and suppliers have continued to make good faith efforts to comply with the requirements of the law and regulation. These efforts will be a significant factor in determining the procedures and processes that will be incorporated in the final rule.

While the regulation will be effective July 6, 2010, CMS will not implement automatic rejections of claims submitted by providers that have attempted to enroll in PECOS. However, until the automatic rejections are operational, providers should not see any change in the processing of submitted claims, they will continue to be reviewed and paid as they have historically been reviewed and paid.

Additionally, though CMS is taking a more deliberative approach to using the PECOS enrollment system, the agency will employ a contingency plan to meet the ACA requirement that written orders and certifications are only issued by eligible professionals effective July 1.

CMS will continue to send informational notices to providers reminding them of the need to submit or update their enrollment and will work with the

provider community to provide guidance on enrollment and will process all applications expeditiously.

**Centers for Medicare & Medicaid Services,
MLN Matters No: SE1305, Full Implementation
of Edits on the Ordering/Referring Providers
in Medicare Part B, DME, and Part A Home
Health Agency (HHA) Claims (Change Requests
6417, 6421, 6696, and 6856) (Nov. 6, 2013)**

Note: This article was revised on November 6, 2013, to provide updated information regarding the effective date of the edits (January 6, 2014). Additional clarifying information regarding the Advance Beneficiary Notice, CARC codes and DME rental equipment has also been updated. Please review the article carefully for these changes. All other information remains the same.

* * *

Phase 2: Effective January 6, 2014, CMS will turn on the Phase 2 edits. In Phase 2, if the ordering/referring provider does not pass the edits, the claim will be denied. This means that the billing provider will not be paid for the items or services that were furnished based on the order or referral.

* * *

**77 Fed. Reg. 25,284 (2012) (excerpts)
DEPARTMENT OF HEALTH AND HUMAN
SERVICES**

**Centers for Medicare & Medicaid Services
42 CFR Parts 424 and 431
[CMS-6010-F] RIN 0938-AQ01**

Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule finalizes several provisions of the Affordable Care Act implemented in the May 5, 2010 interim final rule with comment period. It requires all providers of medical or other items or services and suppliers that qualify for a National Provider Identifier (NPI) to include their NPI on all applications to enroll in the Medicare and Medicaid programs and on all claims for payment submitted under the Medicare and Medicaid programs. In addition, it requires physicians and other professionals who are permitted to order and certify covered items and services for Medicare beneficiaries to be enrolled in Medicare.

Finally, it mandates document retention and provision requirements on providers and supplier that order and certify items and services for Medicare beneficiaries.

DATES: Effective June 26, 2012 the interim final rule amending 42 CFR parts 424 and 431 that published on May 5, 2010 (75 FR 24437) is confirmed as final with changes.

* * *

The effective date for the provisions contained in sections 6405 and 6406 of the Affordable Care Act, remains July 6, 2010. Because this rule was issued as an interim final rule with comment period, the

provisions that implemented the statutory provisions became effective 2 months after the publication in the Federal Register. That interim final rule remains in effect until modified and finalized by this final rule.

* * *

The Affordable Care Act requires that physicians who order certain items or services must be enrolled in Medicare. As previously stated, we have changed the enrollment requirement from one mandating enrollment in PECOS to one requiring enrollment in Medicare—including PECOS or other legacy Medicare enrollment systems. In addition, as we have indicated in this final rule and in open door forums, we have not yet activated the automated edits that would cause claims for services or supplies not to be paid for lack of an approved enrollment record in Medicare. We will provide advance notice of activation of the automated edits.

* * *

We will provide advance notice to providers and suppliers of the date we plan to activate the automated edits that would cause a claim not to be paid for the lack of an enrollment record in Medicare.

* * *

To allow physicians and eligible professionals sufficient time to enroll to order and certify, we will provide ample notice of our plans to activate the automated edits that will cause a claim not to be paid due to the lack of an approved enrollment record in Medicare to order and certify.

* * *

As stated previously, we will provide ample notice of our plans to activate the automated edits that will cause a claim not to be paid due to the lack of an approved enrollment record in Medicare to order and certify.

* * *

However, as already stated, we will provide advance notice of the activation of the automated edits that pertain to these claims.

* * *

In addition, we will provide notice well in advance of activation of the automated edits that would cause claims for services or supplies not to be paid for lack of an approved enrollment record in Medicare.

* * *

We have further clarified that we will provide ample notice to these providers when we decide to activate the edits that will cause a claim not to be paid for the lack of an approved enrollment record in Medicare or valid opt-out record in Medicare.

* * *

Moreover, we will provide advance notice of the activation of the automated edits pertaining to these claims.

* * *

As stated in previous responses, we have not yet activated the automated edits that would cause a claim not to be paid because a physician or, where applicable, eligible professional who ordered or certified the service does not have an approved enrollment record in Medicare, and we will provide ample notice prior to activating the edits.

* * *

However, until further notice, we will not activate the automated edits that would cause a claim not to be paid for lack of an approved enrollment record in Medicare or a valid opt-out status. We want to assure the beneficiary, provider, and supplier communities that we will provide advance notice before activating the edits by conducting appropriate outreach through our established channels including listservs, Medicare Learning Network (MLN) articles, and open door forums.

* * *

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is confirming as final the interim final rule amending 42 CFR parts 424 and 431 that published on May 5, 2010 (75 FR 24437) with the following changes:

* * *

FED. R. CIV. P. 15(b)(2)

When an issue not raised by the pleadings is tried by the parties' express or implied consent, it must be treated in all respects as if raised in the pleadings. A party may move—at any time, even after judgment—to amend the pleadings to conform them to the evidence and to raise an unpleaded issue. But failure to amend does not affect the result of the trial of that issue.