No. 13-5003

In the U.S. Court of Appeals for the District of Columbia Circuit

AMERICAN PHYSICIANS & SURGEONS, INC. AND
ALLIANCE FOR NATURAL HEALTH USA,
Plaintiffs-Appellants,

vs.

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

APPEAL FROM U.S. DISTRICT COURT FOR THE
DISTRICT OF COLUMBIA, CIVIL CASE NO. 1:10-cv-00499-ABJ,
HON. AMY BERMAN JACKSON

APPELLANTS' EMERGENCY MOTION FOR INTERIM RELIEF ON COUNT IV

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GLOSSARY

AAPS	Association of American Physicians & Surgeons
Add.	Addendum
AMC	*Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106 (D.C. Cir. 1993)
ANH-USA	Alliance for Natural Health USA
APA	Administrative Procedure Act, 5 U.S.C. §§551-706
CR6417/6421	Change Requests 6417 and 6421
FAIR	*Rumsfeld v. Forum for Academic & Inst'l Rights, Inc.*, 547 U.S. 47 (2006)
HHS	Department of Health & Human Services
Medicare	Medicare Act, 42 U.S.C. §§1395-1395kkk-l
NFIB	*Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S.Ct. 2566 (2012)
PECOS	Provider Enrollment, Chain and Ownership System
PPACA	Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by Pub. L. No. 111-152, 124 Stat. 1029 (2010)
SAC	Second Amended Complaint
SMHOTA	Service Members Home Ownership Tax Act of 2009, H.R. 3590, 111th Cong., 1st Sess. (Oct. 8, 2009)

INTRODUCTION

Plaintiffs-appellants Association of American Physicians & Surgeons, Inc. ("AAPS") and Alliance for Natural Health USA (collectively for purposes of this motion, "Physicians") ask this Court to preliminarily enjoin defendants-appellees Kathleen Sebelius, Secretary of the Department of Health & Human Services ("HHS"), *et al.* (collectively, the "Administration") from requiring referrers for Medicare services to register in the Provider Enrollment, Chain and Ownership System ("PECOS"). Without relief from this Court, under an HHS notice issued March 1, 2013 (Add. 39-48), that change will take effect May 1, 2013.

Although their Second Amended Complaint ("SAC") seeks preliminary relief on these issues, SAC ¶¶2(g), 118.C (Add. 51, 79), Physicians did not move for a preliminary injunction below because the Administration delayed implementing the precursor actions, namely two "change requests" and the accompanying provisions of the Center for Medicare and Medicaid Services Manual System (hereinafter, "CR6417/6421"), Add. 13-25, and an "Interim Final Rule with Comment Period" ("IFC"), 75 Fed. Reg. 24,437 (2010), Add. 26-38. At the request of the initial judge, the parties agreed that they would brief preliminary relief if and when the need arose, given that HHS "represented to [Physicians] that, before implementing claims edits that would automatically reject claims for failure to comply with the new regulations, it will provide [Physicians] with sufficient

notice to move the Court for preliminary relief," which eliminated the "need to brief a motion for a preliminary injunction with respect to Count IV at this time." Joint Ltr. to Hon. Amy Berman Jackson, 1-2 (June 27, 2010) (Add. 90-91). HHS also relied on its deferral of the challenged actions to refute any claims of irreparable harm from those actions while "Defendants … have delayed the implementation of claims edits that would automatically reject Medicare claims for failure to comply with them." Reply in Support of Defendants' Motion to Stay Case Pending Resolution of Appeals Raising Identical Issues, at 8 (Add. 99).

Physicians challenge these PECOS-related actions procedurally as violating notice-and-comment rulemaking requirements of the Administrative Procedure Act ("APA") and substantively as *ultra vires.* Substantively, the Patient Protection & Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) ("PPACA") provides some substantive authority in these areas, *id.* §§6402, 6405(c); but PPACA is void in its entirety for constitutional infirmities not addressed in *Nat'l Fed'n of Indep. Bus. v. Sebelius,* 132 S.Ct. 2566 (2012) ("*NFIB*").[1]

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[1] Although *NFIB* binds this Court, *Agostini v. Felton,* 521 U.S. 203, 237 (1997), three points bear emphasis: (1) issue preclusion cannot bind on those who did not participate in the prior litigation, *Baker v. Gen'l Motors Corp.*, 522 U.S. 222, 237-38 & n.11 (1998); *cf. U.S. v. Mendoza,* 464 U.S. 154 (1984) (no non-mutual preclusion against United States); (2) *stare decicis* does not extend to issues that were not conclusively settled, *Cooper Indus., Inc. v. Aviall Serv., Inc.,* 543 U.S. 157, 170 (2004); *Waters v. Churchill,* 511 U.S. 661, 678 (1994); and (3) *stare decisis* should not – and lawfully cannot – apply so conclusively that it violates due process, *S. Cent. Bell Tel. Co. v. Alabama,* 526 U.S. 160, 167-68 (1999).

STANDARD OF REVIEW

Circuit Rule 8 sets out a four-part test for interim relief: (1) whether movants have a substantial likelihood of success on the merits, (2) whether they would suffer irreparable injury without interim relief, (3) whether interim relief would harm other parties, and (4) the public interest. Circuit Rule 8(a)(1)(i)-(iv). Courts apply this familiar test on a "sliding scale," where "an unusually strong showing on one of the factors" allows "not necessarily hav[ing] to make as strong a showing on another factor." *Davis v. Pension Ben. Guar. Corp.*, 571 F.3d 1288, 1291-92 (D.C. Cir. 2009); *but see Sherley v. Sebelius*, 644 F.3d 388, 392-93 (D.C. Cir. 2011). These factors are addressed in Sections II-IV, *infra*.

When it applies, Rule 8 "ordinarily" requires seeking relief in district court unless "moving first in the district court would be impracticable" FED. R. APP. P. 8(a)(1), (a)(2)(A)(i). Although Federal Rule 8 does not apply by its terms, *compare id. with Nken v. Holder*, 556 U.S. 418, 428-30 (2009), Physicians easily satisfy it. First, as the Administration argued (successfully) below, delayed implementation of its planned PECOS changes negated irreparable injury, which "must be both certain and great; it must be actual and not theoretical." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297-98 (D.C. Cir. 2006) (internal quotations omitted). Second, now that the district court has dismissed this action, resort to the district court would be futile. *McClendon v. City of Albuquerque*, 79 F.3d 1014,

1020 (10th Cir. 1996); *Walker v. Lockhart*, 678 F.2d 68, 70 (8th Cir. 1982). Third, viewing the district court's dismissal of Physicians' action another way, that final action merges into it all interim relief, *Fund for Animals, Inc. v. Hogan*, 428 F.3d 1059, 1063-64 (D.C. Cir. 2005), which is now properly before this Court. Fourth, as the Administration agreed below, Physicians' delay is seeking relief poses no barrier. *Gordon v. Holder*, 632 F.3d 722, 724-25 (D.C. Cir. 2011).

I. PHYSICIANS HAVE STANDING FOR COUNT IV

The district court found Physicians to lack standing because several HHS actions that Physicians did not challenge allegedly cause the same injuries that the challenged HHS actions cause, so the requested relief against CR6417/6421 and the IFC is insufficient to redress Physicians' injuries. Add. 140. At a surface level, the district court's reasoning is flawed. Absent the challenged actions, the PECOS changes would never take effect, which is the status-quo redress that Physicians seek. Below the surface, the district court's reasoning is even more misguided.

Most basically, the district court's analysis improperly viewed standing from HHS's merits views, not (as required) *from Physicians' merits views:* "court … must … assume that on the merits the plaintiffs would be successful in their claims." *City of Waukesha v. EPA*, 320 F.3d 228, 235 (D.C. Cir. 2003). Thus, the district court ignored Physicians' requested relief that "[n]on-Medicare providers lawfully may see Medicare-eligible patients and charge those patients a fee that is

lawful under applicable state laws, without complying with [§1395a(b)'s] safe harbor, and Medicare imposes no obligations on such providers beyond any applicable requirements of state law." SAC ¶118.A(xi) (Add. 77-78). Thus, the district court erred in concluding that Physicians sought relief against only the IFC and CR6417/6421. This overlooked extra relief cures any redressability problem.

In any event, the district court (like the Administration) is substantively wrong about §1395a(b). Medicare does not require state-licensed physicians to subject themselves to §1395a(b)'s opt-out provisions before treating Medicare-eligible patients. Spending Clause legislation like Medicare operates as a contract, in which recipients and beneficiaries agree to the federal terms as conditions of federal funds or benefits. *Rumsfeld v. Forum for Academic & Inst'l Rights, Inc.*, 547 U.S. 47, 59 (2006) ("*FAIR*"). But recipients and beneficiaries remain free to forgo the federal funds and the federal conditions. *Id.* Indeed, plaintiff AAPS preclusively established that principle in *Ass'n of Am. Physicians & Surgeons v. Weinberger*, 395 F.Supp. 125, 140 (N.D. Ill.), *aff'd* 423 U.S. 975 (1975);[2] *Mandel v. Bradley*, 432 U.S. 173, 176 (1977). Preclusion aside, this principle – reaffirmed in *FAIR* – is incontrovertible. While physicians who follow §1395a(b)'s opt-out

[2] This prior AAPS litigation upheld the Medicare program as "a voluntary one in which a physician may freely choose whether or not to participate," such that physicians "must then comply with [Medicare] requirements in order to be compensated for [their] services" "should a physician choose to participate." *Weinberger*, 395 F.Supp. at 140.

procedures have the valuable benefit of *HHS's* recognizing that those physicians may treat Medicare-eligible patients outside Medicare (albeit in accordance with §1395a(b)), Medicare does not and cannot require state-licensed physicians who decline to participate to file *anything* under Medicare. To the contrary, courts apply a presumption against preemption in fields like medicine traditionally occupied by the states. *Wyeth v. Levine*, 555 U.S. 555, 565 & n.3 (2009).[3] Nothing in Medicare requires those who want nothing to do with Medicare to comply with §1395a(b).

II. THE PECOS CHANGES ARE PROCEDURALLY INVALID

Although the APA exempts matters "relating to … grants, benefits, or contracts," 5 U.S.C. §553(a)(2), HHS enforceably committed itself to following notice-and-comment rulemaking for such matters. *Nat'l Welfare Rights Org'n v. Mathews*, 533 F.2d 637, 646 (D.C. Cir. 1976) (*citing* 36 Fed. Reg. 2532 (1971)). Thus, to the extent that the challenged actions qualify as substantive rules and do not qualify for any APA exemptions, the failure to follow notice-and-comment

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[3] *See also Chemical Mfrs. Ass'n v. Natural Resources Defense Council, Inc.*, 470 U.S. 116, 128 (1985) ("absent an expression of legislative will, we are reluctant to infer an intent to amend the Act so as to ignore the thrust of an important decision"); *U.S. v. Bass*, 404 U.S. 336, 349 (1971) ("[u]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance"); *accord Gonzales v. Oregon*, 546 U.S. 243, 275 (2006); *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 662 (2007) ("repeals by implication are not favored and will not be presumed unless the intention of the legislature to repeal [is] clear and manifest") (interior quotations omitted, alteration in original).

rulemaking renders the challenged actions null and void. Moreover, as explained in Section I, *supra*, the district court and HHS are simply wrong about §1395a(b)'s requiring compliance with §1395a(b)'s opt-out process, and that error undercuts the district court's and HHS's analysis of the APA procedural requirements.

A. The PECOS Changes Are Substantive Rules

This Circuit recognizes four general criteria that trigger the notice-and-comment procedure: (1) whether, absent the rule, the agency would lack adequate authority to confer benefits or require performance; (2) whether the agency promulgated the rule into the C.F.R.; (3) whether the agency invoked its general legislative authority; and (4) whether the rule effectively amends prior legislative rules. *Am. Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993) ("*AMC*"). Together, CR6417/6421 and the IFC trigger the first three of these criteria. In addition,"guidance" that purports to narrow an agency's discretion also requires notice-and-comment procedures, *General Elec. Co. v. E.P.A.*, 290 F.3d 377, 383-84 (D.C. Cir. 2002), which applies here. Finally, an interpretation that changes a prior interpretation requires notice-and-comment rulemaking, *Paralyzed Veterans of Am. v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1997); *Alaska Prof'l Hunters Ass'n v. FAA*, 177 F.3d 1030, 1034 (D.C. Cir. 1999), which the district court acknowledges CR6417/6421 to have done in rescinding HHS's prior allowance for these referrals under change request 6093.

Add. 141 n.11. For the foregoing reasons, HHS's changes required a rulemaking.

B. APA's Good-Cause Exception Does Not Apply

Contrary to the district court (Add. 145), the APA exception where "the agency for good cause finds" that APA procedures "[would be] impracticable, unnecessary, or contrary to the public interest" does not apply. 5 U.S.C. §553(b)(B). First, "it should be clear beyond contradiction or cavil that Congress expected, and the courts have held, that the various exceptions to the notice-and-comment provisions of section 553 will be narrowly construed and only reluctantly countenanced." *State of N.J., Dep't of Envtl. Prot. v. U.S. E.P.A.*, 626 F.2d 1038, 1045-46 (D.C. Cir. 1980); *Mack Trucks, Inc. v. E.P.A.*, 682 F.3d 87, 94 (D.C. Cir. 2012) (same); *see also Northern Arapahoe Tribe v. Hodel*, 808 F.2d 741, 751 (10th Cir. 1987) (*quoting* S.Rep. No. 752, 79th Cong., 1st Sess. 14 (1945)). Second, HHS's purportedly good cause (Add. 145) fails because HHS vastly understates the rule's impact on physicians and patients due to HHS's misunderstanding §1395a(b), as outlined in Section I, *supra*. Finally, the challenged aspects of the IFC and CR6417/6421 are not the type of "exigent circumstances" that fit within the "narrow 'good cause' exception of section 553(b)(B)," such as "emergency situations" or instances where "the very announcement of a proposed rule itself could be expected to precipitate activity by affected parties that would harm the public welfare." *Chamber of Commerce of U.S. v. S.E.C.*, 443 F.3d 890, 908 (D.C.

Cir. 2006) (collecting cases). In short, the good-cause exception does not apply.

C. APA's "Housekeeping" Exception Does Not Apply

Similarly, HHS cannot resort to the APA exception for "rules of agency organization, procedure, or practice." 5 U.S.C. §553(b)(A). When (as here) the agency action determines the availability of a benefit, that exception – which is merely a "housekeeping" measure, *Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979) – does not apply. *AMC*, 995 F.2d at 1112; *Chamber of Commerce of U.S. v. DOL*, 174 F.3d 206, 211 (D.C. Cir. 1999) (exception does not cover rules that alter rights or interests). Moreover, the exception "must be narrowly construed," *U.S. v. Picciotto*, 875 F.2d 345, 347 (D.C. Cir. 1989), and its "distinctive purpose ... is to ensure that agencies retain latitude in organizing their *internal* operations." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1047 (D.C. Cir. 1987) (emphasis added, interior quotations omitted). Indeed, "regardless whether [a rule presents] a new substantive burden," a "change [that] substantively affects the public to a [sufficient] degree" will "implicate the policy interests animating notice-and-comment rulemaking." *Electronic Privacy Info. Ctr v. U.S. Dep't of Homeland Sec.*, 653 F.3d 1, 5-6 (D.C. Cir. 2011). Here again, HHS's misunderstanding of §1395a(b), *see* Section I, *supra*, explains the misplaced reliance on this exception. Far from a mere internal procedure, the changes proposed here would impact the rights and privileges of countless physicians and patients.

III. THE PECOS CHANGES ARE SUBSTANTIVELY INVALID

The merits question hinges on PPACA's validity because – without PPACA §§6402, 6405(c) – HHS would lack the authority to require referrers to register with HHS. The next two sections address the relevant two arguments.

A. PECOS Changes Would Be *Ultra Vires* without PPACA

PPACA §6405(c) gave HHS discretionary authority over various services ordered, prescribed, or referred under Medicare. If this Court invalidates PPACA in its entirety, HHS would lack substantive authority for the relevant actions that PPACA authorized. Accordingly, the next section argues that PPACA is facially invalid as a tax. Significantly, even if PPACA survives (and HHS thus retains whatever substantive authority PPACA provides), HHS still must comply with the APA's procedural requirements.

B. PPACA's Mandates Violate the Origination Clause as Revenue Measures that Originated in the Senate

Under *NFIB,* PPACA is a strange and unprecedented type of bill. First, Congress lacked authority for 26 U.S.C. §5000A under any enumerated powers except the taxing power. 132 S.Ct. at 2585-93. Second, for *statutory* purposes (*i.e.*, those subject to the Anti-Injunction Act), §5000A is not a tax, *id.* 2582-84, but for *constitutional* purposes, it could be a tax, which would make it constitutional, *id.* 2593-600, provided that it meets the other constitutional criteria for valid taxes. *Id.* 2598 ("any tax must still comply with other requirements in the Constitution"). But

NFIB did not consider – and thus did not decide – whether the *NFIB* tax originating in a Senate amendment is invalid under the Origination Clause: "All bills for raising revenue shall originate in the House of Representatives; but the Senate may propose and concur with amendments as on other bills." U.S. CONST. art. 1, §7, cl. 1. Similarly, although it held that §5000A is not a direct tax requiring apportionment, *NFIB* did not determine what other type of tax §5000A might be.

1. Physicians Raised the Origination Clause Below

The district court held that Physicians could not rely on the Origination Clause because they did not raise it in their complaint. Add. 131-33. Like Physician's SAC, virtually every complaint in federal court requests "such other relief as the Court deems proper" or words to that effect. This ubiquitous line is known as the "general pleading," and it entitles the pleader to relief on theories not contained in a complaint's specific pleadings. *Scheduled Airlines Traffic Offices, Inc., v. Dep't of Defense,* 87 F.3d 1356, 1358-59 (D.C. Cir. 1996); *People for the Ethical Treatment of Animals, Inc., v. Gittens,* 396 F.3d 416, 421 (D.C. Cir. 2005); *Bemis Brothers Bag Co. v. U.S.,* 289 U.S. 28, 34 (1933); *Metro-North Commuter R. Co. v. Buckley,* 521 U.S. 424, 455 (1997); *Lockhart v. Leeds,* 195 U.S. 427, 436-37 (1904). As soon as *NFIB* declared §5000A a tax, Physicians argued against PPACA and the PECOS changes under the Origination Clause. Add. 105-111. They could not have done so sooner, and neither the Administration nor the district

court protested (or could protest) when Physicians did so. *Cf.* FED. R. CIV. P. 15(b).

2. PPACA Is a Senate-Originated Revenue Bill

Although the Supreme Court has declined definitively to outline what qualifies as raising revenue under the Origination Clause, *Twin City Bank v. Nebeker*, 167 U.S. 196, 202 (1897), the Court's decisions have done so sufficiently to classify PPACA: "revenue bills are those that levy taxes in the strict sense of the word, and are not bills for other purposes which may incidentally create revenue." *Id.* (*citing* 1 J. Story, COMMENTARIES ON THE CONSTITUTION §880, pp. 610-611 (3d ed. 1858)); *U.S. v. Norton*, 91 U.S. 566, 569 (1875). PPACA meets that test.[4]

Under "this general rule … a statute that creates a particular governmental program and that raises revenue to support that program, as opposed to a statute that raises revenue to support Government generally, is not a 'Bil[l] for raising Revenue' within the meaning of the Origination Clause." *Munoz-Flores*, 495 U.S. at 397-98. As justified by *NFIB* solely as a tax, §5000A does not qualify as part of larger governmental program. It survives solely as a tax.[5]

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[4] Because the PPACA mandates originated *as taxes* in the Chief Justice's "saving construction" contrary to the legislative intent that those mandates *were not taxes*, institutional and separation-of-powers concerns that otherwise might counsel for looking no farther than PPACA's enrolled bill number (H.R. 3590), *see, e.g., Rainey v.U.S.*, 232 U.S. 310, 317 (1914); *U.S. v. Munoz-Flores*, 495 U.S. 385, 408-10 (1990) (Scalia, J., concurring), are inapposite.

[5] Because Congress lacks Commerce-Clause authority (or any other authority than the taxing power) for the PPACA mandates, *NFIB*, 132 S.Ct. at 2585-93, the

The "general rule" in *Munoz-Flores* applies to governmental programs that raise revenue via targeted provisions such as the "special assessment provision at issue in th[at] case." *Id.* at 398; *accord Nebeker*, 167 U.S. at 202-03; *Millard v. Roberts*, 202 U.S. 429, 436-37 (1906). Here, however, §5000A can avoid other constitutional infirmities (*e.g.*, non-uniform excise taxation[6]) only as an income tax under the Sixteenth Amendment. Unlike special-purpose taxes, income taxes go to the general funds of the U.S. Treasury. 44 Cong. Rec. 4420 (1909) (Mr. Heflin); *Haskin v. Secretary of the Dep't of Health & Human Serv.*, 565 F.Supp. 984, 986-87 (E.D.N.Y. 1983) (*citing* 2 H. McCormick, SOCIAL SECURITY CLAIMS AND PROCEDURES 418 (3d ed. 1983)).

Contrary to *Munoz-Flores*, *Nebeker*, and *Millard*, where "special assessment provision[s were] passed as part of a particular program to provide money for that program" and where "[a]ny revenue for the general Treasury … create[d] is thus 'incidenta[l]' to that provision's primary purpose," *Munoz-Flores*, 495 U.S. at 399, *NFIB* justifies the tax here solely for its revenue-raising purpose by providing funds into the general Treasury. Indeed, while PPACA as a whole included

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cases that uphold revenue-raising measures under the Commerce Power are irrelevant here. *See, e.g.*, *Mulroy v. Block*, 569 F.Supp. 256, 265 (N.D.N.Y. 1983), *aff'd*, 736 F.2d 56 (2d Cir.1984); *Rodgers v. U.S.*, 138 F.2d 992, 994-95 (6th Cir. 1943); *U.S. v. Stangland*, 242 F.2d 843, 848 (7th Cir. 1957).

6 *Compare* U.S. CONST. art. I, §8 *with* 26 U.S.C. §5000A(e)(1)(B)(ii), (f)(1)(C), (f)(2)(A)-(B); 42 U.S.C. §300gg-91(d)(8); 29 U.S.C. §1002(32).

provisions related to health insurance, it also focused on deficit reduction. SAC ¶¶84, 86 (Add. 71). For the PPACA components at issue here – the so-called employer and individual mandates, 26 U.S.C. §§4980H, 5000A – *NFIB* justifies them solely as taxes that raise revenue.

Significantly, the Origination Clause applies not only to whole bills but also to discrete sections and amendments, *Nebecker*, 167 U.S. at 202-03 (looking to whether the "act, or by *any of its provisions*" had the purpose of "rais[ing] revenue to be applied in meeting the expenses or obligations of the government") (emphasis added), subject to a germaneness test. *Flint v. Stone Tracy Co.*, 220 U.S. 107, 142-43 (1911), *abrogated in part on other grounds, Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 540-43 (1985). This Circuit has cited *Flint* for the proposition that the "Senate may propose any amendment 'germane to the subject-matter of the bill.'" *Moore v. U.S. House of Representatives*, 733 F.2d 946, 949 n.8 (D.C. Cir. 1984), *abrogated in part on other grounds, Raines v. Byrd*, 521 U.S. 811 (1997). In *Flint*, the Senate substituted a corporation tax for a House-originated inheritance tax in a "general bill for the collection of revenue." *Flint*, 220 U.S. at 142-43. Here, by contrast, the House-originated version of H.R. 3590 primarily concerned minor tax breaks for members of the armed forces, *see* Service Members Home Ownership Tax Act of 2009, H.R. 3590, 111th Cong., 1st Sess. (Oct. 8, 2009) (Add. 6-12) ("SMHOTA"), not a "general bill for the collection of

revenue" as in *Flint.* As such, the Senate Majority Leader's wholesale substitution of PPACA for SMHOTA was in no way "germane" to SMHOTA's limited scope.

In summary, to the extent that they could be constitutional at all, PPACA's mandates qualify as income taxes that supply revenue to the Treasury. As income taxes, PPACA's mandates therefore "levy taxes in the strict sense of the word," rather than "incidentally create revenue." *Nebeker*, 167 U.S. at 202. Even while deeming special assessments levied against criminals to compensate victims as falling outside the Origination Clause's reach, *Munoz-Flores* acknowledged that "[a] different case might be presented if the program funded were entirely unrelated to the persons paying for the program." *Munoz-Flores*, 495 U.S. at 401 n.7. As applied to individuals like Dr. Smith with adequate – but PPACA-noncompliant – insurance, PPACA's mandates are "entirely unrelated to the persons paying for the program," *id.*, with no "element of contract" to justify the exchange. *Roberts*, 202 U.S. at 437. For all of the foregoing reasons, PPACA's individual and employer tax penalties fall within the Origination Clause's scope and thus are void because they did not originate in the House.

3. The House's Actions on H.R. 3590 Have No Bearing on the Origination Clause

The Administration likely will argue that H.R. 3590 originated in the House and that the House acquiesced in the Senate's revenue-raising amendments. This Court should reject both arguments.

First, the House could hardly acquiesce to an Origination-Clause violation that had not yet occurred, given that §5000A (as passed by Congress) was not even a tax as far as Congress was concerned. *NFIB*, 132 S.Ct. at 2582-84. The Senate cannot avoid the Origination Clause merely by "enact[ing] revenue-raising bills so long as it merely describes such bills as 'user fees'" or (here) penalties. *Sperry Corp. v. U.S.*, 925 F.2d 399, 402 (Fed. Cir. 1991). Only now that §5000A is unambiguously a tax, and *only a tax*, is the Origination Clause violation made plain. In any event, the House cannot acquiesce to a violation of the Constitution. *Munoz-Flores*, 495 U.S. at 391 ("congressional consideration of constitutional questions does not foreclose subsequent judicial scrutiny"). This case thus presents a separation-of-powers issue over which the courts have the final word. *Id.* at 393.

Second, as it originated in the House, H.R. 3590 was not a revenue bill, and the Senate's authority to attach revenue-raising amendments to House bills applies only to House *revenue* bills. 2 HINDS' PRECEDENTS OF THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES §1489 (1907); *Sperry Corp. v. U.S.*, 12 Cl. Ct. 736, 742 (1987), *rev'd on other grounds*, 853 F.2d 904 (Fed. Cir. 1988); Thomas L. Jipping, *TEFRA and the Origination Clause: Taking the Oath Seriously*, 35 BUFF. L. REV. 633, 688 (1986) (Senate cannot amend "a bill for some purpose other than raising revenue into a bill that raises revenue"). None of H.R. 3590's provisions qualify as "bills for raising revenue" as the Origination Clause requires:

- SMHOTA §§2-3 modified the first-time homebuyers' tax credit by waiving recapture of the credit for members of the armed forces ordered to extended duty service overseas. In the absence of this waiver, first-time homebuyers who sold their homes soon after claiming the credit would lose the credit. *See* 26 U.S.C. §36(a), (f). This "willingness ... to sink money" into valuable government programs – namely, national defense and foreign policy – is not indicative of a "bill for raising revenue" under the Origination Clause. *See Norton*, 91 U.S. at 567-68. These provisions *lowered* revenues.
- SMHOTA §4 expanded exclusions from income for fringe benefits that are "qualified military base realignment and closure fringe" under 26 U.S.C. §132, which does not raise revenue for the same reason that SMHOTA §§2-3 do not raise revenue. *Norton*, 91 U.S. at 567-68.
- SMHOTA §5 increased filing penalties by $21 (from $89 to $110) for failure to file certain returns. While certainly *related* to taxation, filing penalties do not "levy taxes in the strict sense of the word" required to trigger the Origination Clause. *Nebeker*, 167 U.S. at 202.
- SMHOTA §6 amended the Corporate Estimated Tax Shift Act of 2009, Pub. L. 111-42, tit. II, §202(b), 123 Stat. 1963, 1964 (2009), to increase the amount of *estimated* tax that certain corporations must pay. While certainly *related* to taxation, "[w]ithholding and estimated tax remittances are not

taxes in their own right, but methods for collecting the income tax." *Baral v. U.S.*, 528 U.S. 431, 436 (2000). Because estimated-tax payments are not "revenue," §6 cannot make H.R. 3590 a revenue bill.

As it passed the House, H.R. 3590 was not a revenue bill. The Origination Clause thus prohibited substituting the Senate's revenue-raising PPACA for SMHOTA.

"Any and all violations of constitutional requirements vitiate a statute," even if they represent merely "this kind of careless journey work" in originating a revenue bill in the wrong body. *Hubbard v. Lowe*, 226 F. 135, 140 (S.D.N.Y. 1915). As revised by *NFIB*, PPACA would not have passed either legislative body. But if the House wants to re-enact PPACA as revised, the House is free to do so.

IV. RULE 8'S OTHER THREE FACTORS FAVOR INTERIM RELIEF

As explained below, Physicians' requested injunction readily satisfies the other three factors for interim relief. Accordingly, the Administration has no basis on which to deny Physicians' members the continued ability to refer Medicare services for their Medicare-eligible patients.

First, the challenged PECOS rules will cause the loss of necessary medical care, *see, e.g.*, Decl. of Laura Hammons, M.D., ¶¶4-7 (Add. 80-81),[7] which courts

[7] Dr. Hammons is an AAPS member and the *pro bono* medical director at Little Sisters of the Poor Home for the Aged in Gallup, New Mexico; her elderly patients there (who cannot afford market-priced medical care) will suffer the loss of urgently needed medical care (*e.g.*, oxygen, physical therapy, x-rays, bloodwork) under the challenged PECOS rules. *Id.* The situations described by the

uniformly have recognized as constituting irreparable harm. *United Steelworkers of Am. v. Textron, Inc.*, 836 F.2d 6, 8-9 (1st Cir. 1987) (Breyer, J.); *Comm. Workers of Am., Dist. 1, AFL–CIO v. NYNEX Corp.*, 898 F.2d 887, 891 (2d Cir. 1990); *U.A.W. v. Exide Corp.*, 688 F.Supp. 174, 186–87 (E.D. Pa.), *aff'd mem.*, 857 F.2d 1464 (3d Cir. 1988); *Yolton v. El Paso Tenn. Pipeline Co.*, 435 F.3d 571, 584 (6th Cir. 2006); *Risteen v. Youth for Understanding, Inc.*, 245 F.Supp.2d 1, 16 (D.D.C. 2002). Comprehensive, rationed-care regimes like Medicaid, Medicare, and their counterparts in other countries such as Canada create scarcity that covered beneficiaries can avoid only by going outside their coverage to physicians who offer their services outside the rationed-care regime. *See* Decl. of George Keith Smith, M.D., ¶¶4-5 (Add. 83-84). As such, the irreparable harm caused by the challenged PECOS rules represents a nationwide problem.

Second, the requested relief will not cognizably harm others. Competitors of Physicians' members have no cognizable interest in denying the ability to refer under Medicare, and HHS remains free to proceed by the rulemaking process that Congress ordained and to which HHS bound itself for benefits program, provided that HHS indeed has the statutory authority. The "results do not constitute substantial harm for the purpose of delaying injunctive relief" where "[they] are no

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district-court declarants have not changed materially in the intervening two years. Second Decl. of Lawrence Joseph, ¶¶2-4 (Add. 88-89).

different from the Department's burdens under the statutory scheme." *Nat'l Ass'n of Farmworkers Orgs. v. Marshall,* 628 F.2d 604, 615 (D.C. Cir. 1980). Moreover, the three-year delay in implementing these PECOS changes demonstrates that HHS will not suffer significant harm from a preliminary injunction's further delay.

Third, the requested relief would serve the public interest, which collapses into the merits. 11A CHARLES ALAN WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FED. PRAC. & PROC. Civ.2d §2948.4. To the extent that the merits are in question, there is a public interest in preserving the status quo until a court reaches the merits, *Maryland Undercoating Co. v. Paine,* 603 F.2d 477, 481 (4th Cir. 1979); *Valdez v. Applegate,* 616 F.2d 570, 572 (10th Cir. 1980), as part of the "greater public interest in having governmental agencies abide by the federal laws that govern their… operations." *Washington v. Reno,* 35 F.3d 1093, 1103 (6th Cir. 1994). Finally, this Court should strike a balance in favor of the beneficiaries that Congress intended Medicare to protect. *Marshall,* 628 F.2d at 616.

CONCLUSION

At least with respect to AAPS and ANH-USA members, the PECOS changes should be preliminarily enjoined pending final judgment.

Dated: March 13, 2013

Respectfully submitted,

/s/ Lawrence J. Joseph

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No. 13-5003

In the U.S. Court of Appeals for the District of Columbia Circuit

AMERICAN PHYSICIANS & SURGEONS, INC. AND
ALLIANCE FOR NATURAL HEALTH USA,
Plaintiffs-Appellants,

vs.

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

APPEAL FROM U.S. DISTRICT COURT FOR THE
DISTRICT OF COLUMBIA, CIVIL CASE NO. 1:10-cv-00499-ABJ,
HON. AMY BERMAN JACKSON

ADDENDUM TO
APPELLANTS' EMERGENCY MOTION FOR
INTERIM RELIEF ON COUNT IV

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Corporate Disclosure Statement

Pursuant to FED. R. APP. P. 26.1 and Circuit Rules 8(a)(4) and 26.1, counsel for appellants provides the following statements:

1. Association of American Physicians & Surgeons, Inc. states (a) that it is an Arizona-based nonprofit membership organization that conducts educational activities and represents the collective interests of medical professionals and patients before the federal and state executive, legislative, and judicial branches of government; (b) that it is an umbrella group for several thousand members from all sectors and modes of medical practice; and (c) that it has no parent corporations and that no publicly held company owns any stock in it.

2. Alliance for Natural Health USA states (a) that it is a District of Columbia-based nonprofit membership-based organization that conducts educational activities and represents the collective interests of medical professionals and patients interested in an "integrative" approach incorporating food, dietary supplements, and lifestyle changes into medical care and practice; (b) that it is an umbrella group for several thousand members and practitioners, patients, and suppliers interested in that integrative approach to medical care and practice; and (c) that it has no parent corporations and that no publicly held company owns any stock in it.

Dated: March 13, 2013

Respectfully submitted,

/s/ Lawrence J. Joseph

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Counsel for Appellants Association of American Physicians & Surgeons and Alliance for Natural Health USA

Certificate as to Parties, Rulings, and Related Cases

Pursuant to Circuit Rule 8(a)(4), counsel for appellants Association of American Physicians & Surgeons, Inc. ("AAPS") and Alliance for Natural Health USA ("ANH-USA") present the following certificate as to parties and *amici curiae*, rulings, and related cases.

A. Parties and *Amici*

The parties and *amici curiae* are as follows:

1. AAPS and ANH-USA were the only plaintiffs before the District Court and are the only appellants in this Court;
2. The Secretary of Health & Human Services, the Social Security Administrator, and the Secretary of the Treasury in their official capacities and the United States were the only defendants in District Court and the only appellees in this Court; and
3. No entity has appeared as an intervener or *amicus curiae.*

B. Rulings Under Review

AAPS and ANH-USA appeal (1) the dismissal of each count of the operative complaint by the District Court's Memorandum Opinion and Order (docket items #59 and #58, respectively) filed October 31, 2012; (2) the transfer of the case from Judge Collyer to Judge Leon by the Order (docket item #13) filed June 11, 2010; and (3) the subsequent transfer of the case from Judge Leon to

Judge Jackson by the Minute Order (no docket number) filed March 30, 2011, which Minute Order would mooted by the reversal of the transfer from Judge Collyer to Judge Leon (*i.e.*, if this matter should not have been before Judge Leon to transfer in the first place). In their emergency motion for interim relief, however, AAPS and ANH-USA seek only to stay the effectiveness of changed policies with respect to referring Medicare services addressed in Count IV of the Second Amended Complaint.

C. Related Cases

This issues presented here are related to the issues raised in *Hall v. Sebelius,* 667 F.3d 1293 (D.C. Cir. 2012), and *Nat'l Fed'n of Indep. Bus. v. Sebelius,* 132 S.Ct. 2566 (2012), but this appeal also presents additional jurisdictional and merits issues not resolved by those cases. In *Sissel v. U.S. Dep't of Health & Human Services,* No. 1:10-cv-1263-BAH (D.D.C.), the plaintiff raises one of the merits issues – namely, whether the Patient Protection and Affordable Care Act violated the Origination Clause of the U.S. Constitution – that AAPS and ANH-USA ask this Court to address in this appeal.

Dated: March 13, 2013

Respectfully submitted,

/s/ Lawrence J. Joseph

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111TH CONGRESS
1ST SESSION

H. R. 3590

AN ACT

To amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Service Members Home Ownership Tax Act of 2009".

SEC. 2. WAIVER OF RECAPTURE OF FIRST-TIME HOMEBUYER CREDIT FOR INDIVIDUALS ON QUALIFIED OFFICIAL EXTENDED DUTY.

(a) IN GENERAL.—Paragraph (4) of section 36(f) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

"(E) SPECIAL RULE FOR MEMBERS OF THE ARMED FORCES, ETC.—

"(i) IN GENERAL.—In the case of the disposition of a principal residence by an individual (or a cessation referred to in paragraph (2)) after December 31, 2008, in connection with Government orders received by such individual, or such individual's spouse, for qualified official extended duty service—

"(I) paragraph (2) and subsection (d)(2) shall not apply to such disposition (or cessation), and

"(II) if such residence was acquired before January 1, 2009, paragraph (1) shall not apply to the taxable year in which such disposition (or

cessation) occurs or any subsequent taxable year.

"(ii) QUALIFIED OFFICIAL EXTENDED DUTY SERVICE.—For purposes of this section, the term 'qualified official extended duty service' means service on qualified official extended duty as—

"(I) a member of the uniformed services,

"(II) a member of the Foreign Service of the United States, or

"(III) as an employee of the intelligence community.

"(iii) DEFINITIONS.—Any term used in this subparagraph which is also used in paragraph (9) of section 121(d) shall have the same meaning as when used in such paragraph.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to dispositions and cessations after December 31, 2008.

SEC. 3. EXTENSION OF FIRST-TIME HOMEBUYER CREDIT FOR INDIVIDUALS ON QUALIFIED OFFICIAL EXTENDED DUTY OUTSIDE THE UNITED STATES.

(a) IN GENERAL.—Subsection (h) of section 36 of the Internal Revenue Code of 1986 is amended—

(1) by striking "This section" and inserting the following:

"(1) IN GENERAL.—This section", and

(2) by adding at the end the following:

"(2) SPECIAL RULES FOR INDIVIDUALS ON QUALIFIED OFFICIAL EXTENDED DUTY OUTSIDE THE UNITED STATES.—In the case of any individual who serves on qualified official extended duty service outside the United States for at least 90 days in calendar year 2009 and, if married, such individual's spouse—

"(A) paragraph (1) shall be applied by substituting 'December 1, 2010' for 'December 1, 2009',

"(B) subsection (f)(4)(D) shall be applied by substituting 'December 1, 2010' for 'December 1, 2009', and

"(C) in lieu of subsection (g), in the case of a purchase of a principal residence after December 31, 2009, and before July 1, 2010, the

taxpayer may elect to treat such purchase as made on December 31, 2009, for purposes of this section (other than subsections (e) and (f)(4)(D)).".

(b) COORDINATION WITH FIRST-TIME HOMEBUYER CREDIT FOR DISTRICT OF COLUMBIA.—Paragraph (4) of section 1400C(e) of such Code is amended by inserting "(December 1, 2010, in the case of a purchase subject to section 36(h)(2))" after "December 1, 2009".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to residences purchased after November 30, 2009.

SEC. 4. EXCLUSION FROM GROSS INCOME OF QUALIFIED MILITARY BASE REALIGNMENT AND CLOSURE FRINGE.

(a) IN GENERAL.—Subsection (n) of section 132 of the Internal Revenue Code of 1986 is amended—

(1) in subparagraph (1) by striking "this subsection) to offset the adverse effects on housing values as a result of a military base realignment or closure" and inserting "the American Recovery and Reinvestment Tax Act of 2009)", and

(2) in subparagraph (2) by striking "clause (1) of".

(b) EFFECTIVE DATE.—The amendments made by this act shall apply to payments made after February 17, 2009.

SEC. 5. INCREASE IN PENALTY FOR FAILURE TO FILE A PARTNERSHIP OR S CORPORATION RETURN.

(a) IN GENERAL.—Sections 6698(b)(1) and 6699(b)(1) of the Internal Revenue Code of 1986 are each amended by striking "$89" and inserting "$110".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to returns for taxable years beginning after December 31, 2009.

SEC. 6. TIME FOR PAYMENT OF CORPORATE ESTIMATED TAXES.

The percentage under paragraph (1) of section 202(b) of the Corporate Estimated Tax Shift Act of 2009 in effect on the date of the enactment of this Act is increased by 0.5 percentage points.

Passed the House of Representatives October 8, 2009.

Attest:

Clerk.

111TH CONGRESS
1ST SESSION

H. R. 3590

AN ACT

To amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes.

CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 991	**Date: November 1, 2011**
	Change Request 6417

Transmittal 964, dated October 19, 2011, is being rescinded and replaced by Transmittal 991, dated October 28, 2011, to correct the implementation date. The implementation date was listed as January 3, 2011 but should have been July 5, 2011. All other information remains the same.

SUBJECT: Expansion of the Current Scope of Editing for Ordering/Referring Providers for claims processed by Medicare Carriers and Part B Medicare Administrative Contractors (MACs)

I. SUMMARY OF CHANGES: Section 1833(q) of the Social Security Act requires that all physicians and non-physician practitioners that meet the definitions at section 1861(r) and 1842(b)(18)(C) be uniquely identified for all claims for services that are ordered or referred. Effective January 1, 1992, a physician or supplier that bills Medicare for a service or item must show the name and unique identifier of the ordering/referring provider on the claim if that service or item was the result of an order or referral. The Centers for Medicare and Medicaid Services (CMS) is expanding the claim editing to meet the Social Security Act requirements for ordering and referring providers.

EFFECTIVE DATE: October 5, 2009
IMPLEMENTATION DATE: July 5, 2011

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

For Medicare Administrative Contractors (MACs):

IV. ATTACHMENTS:

One-Time Notification
**Unless otherwise specified, the effective date is the date of service.*

Attachment – One-Time Notification

Pub. 100-20	Transmittal: 991	Date: November 1, 2011	Change Request: 6417

Transmittal 964, dated October 19, 2011, is being rescinded and replaced by Transmittal 991, dated October 28, 2011, to correct the implementation date. The implementation date was listed as January 3, 2011 but should have been July 5, 2011. All other information remains the same.

SUBJECT: Expansion of the Current Scope of Editing for Ordering/Referring Providers for Claims Processed by Medicare Carriers and Part B Medicare Administrative Contractors (MACs)

EFFECTIVE DATE: OCTOBER 5, 2009
IMPLEMENTATION DATE: July 5, 2011

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) is expanding the claim editing to meet the Social Security Act requirements for ordering and referring providers. In this document the word 'claim' mean both electronic and paper claims. The following are the only providers who can order/refer beneficiary services:

- doctor of medicine or osteopathy;
- dental medicine;
- dental surgery;
- podiatric medicine;
- optometry;
- physician assistant;
- certified clinical nurse specialist;
- nurse practitioner;
- clinical psychologist;
- certified nurse midwife;
- clinical social worker.

The claim editing is being expanded to verify the ordering/referring provider on a claim is eligible to order/refer and is enrolled in Medicare. The editing expansion will be done in two phases.

Phase 1 - The multi-carrier system (MCS) will receive a national file from the Provider Enrollment, Chain and Ownership System (PECOS) of only the physicians and non-physician practitioners who are in PECOS, including inactive and deceased providers, who are of the specialty eligible to order or refer under the Medicare program. Nightly thereafter, MCS will receive a national PECOS file of newly added physicians and non-physician practitioners and of physicians and non-physician practitioners whose data have been updated. When a claim is received, MCS will determine if the ordering/referring provider is required for the billed service. If the billed service requires an ordering/referring provider and the ordering/referring provider is not on the claim, the claim will not be paid. If the ordering/referring provider is on the claim, MCS will verify that the ordering/referring provider is on the national PECOS file. If the ordering/referring provider is not on the national PECOS file, MCS will search the contractor's master provider file next for the ordering/referring provider. If the ordering/referring provider is not on the national PECOS file and is not on the contractor's master provider file, or if the ordering/referring provider is on the contractor's master provider file but is not of the specialty eligible to order or refer, the claim, during Phase 1, will continue to process but a message will be included on the remittance advice notifying the billing provider that the claims may not be paid in the future if

the ordering/referring provider is not enrolled in Medicare or if the ordering/referring provider is not of the specialty eligible to order or refer.

Phase 2 – As stated above, MCS will still receive a national file from PECOS and will determine if the ordering/referring provider is required for the billed service. If the billed service requires an ordering/referring provider and the ordering/referring provider is not on the claim, the claim will not be paid. If the ordering/referring provider is on the claim, MCS will verify that the ordering/referring provider is on the national PECOS file. If the ordering/referring provider is not on the national PECOS file, MCS will search the contractor's master provider file for the ordering/referring provider. If the ordering/referring provider is not on the national PECOS file and is not on the contractor's master provider file, or if the ordering/referring provider is on the contractor's master provider file but is not of the specialty eligible to order or refer, the claim, during Phase 2, will not be paid.

In both phases, MCS will use this process to determine if the ordering/referring provider on the claim matches the providers in the national PECOS file or in the contractor's master provider file: MCS will verify the National Provider Identifier (NPI) of the ordering/referring provider reported on the claim against the national PECOS file first, if a match is not found the MCS will verify the NPI of the ordering/referring provider on the claim against the MCS master provider file. If a match is found, the MCS will then compare the first letter of the first name and the first 4 letters of the last name of the matched record. If the names match, the ordering/referring provider on the claim is considered verified.

All providers should be verifying their enrollment on the CMS on-line enrollment systems known as Internet-based PECOS.

When this change request is implemented, the requirement (Transmittal 270, Change Request 6093, dated October 15, 2008, Reporting NPIs for Secondary Providers) to use the billing provider's NPI as the NPI of the ordering/referring provider, and the name of the ordering/referring physician or non-physician practitioner, if the NPI of the ordering/referring provider cannot be determined by the billing provider is no longer valid.

B. Policy: Section 1833(q) of the Social Security Act requires that all physicians and non-physician practitioners that meet the definitions at section 1861(r) and 1842(b)(18)(C) be uniquely identified for all claims for services that are ordered or referred. Effective January 1, 1992, a physician or supplier that bills Medicare for a service or item must show the name and unique identifier of the ordering/referring provider on the claim if that service or item was the result of an order or referral. Effective May 23, 2008, the unique identifier must be an NPI. In addition, only Medicare-enrolled physicians and non-physician practitioners as defined above are eligible to order/refer services for Medicare beneficiaries.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6417.1	The PECOS shall provide an initial file of all physician's and non physician practitioners nationally who are enrolled and are eligible to order /refer. This will include inactive and deceased providers.										PECOS
6417.1.1	The PECOS shall provide a format of the file to MCS.										PECOS

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	The file will consist of the following data element: 1. first, middle and last name; 2. NPI; 3. effective date (if available); 4. Termination date (if available); and 5. CMS specialty code and description.										
6417.1.2	The PECOS file naming convention and file location shall be determined as part of the implementation plan developed between EDS, CMS, and PECOS.							X			PECOS EDS CMS/ DPFS
6417.1.3	The CMS-1500 claim form states to not use periods or commas with in the name. A hyphen can be used for hyphenated names. Therefore, contractors shall ignore special characters received from PECOS except for hyphens.	X			X			X			
6417.2.	Contractors shall not use the effective date, termination dates, CMS specialty code and description. These fields are currently information fields only which may be used in the future.	X			X			X			
6417.3	The PECOS shall provide a nightly file of only physicians or non physician practitioners who are newly added to PECOS or who were on the initial or earlier nightly files and who have a change of information.										PECOS
6417.4	Contractors shall determine if ordering/referring provider is required on a claim which has a date of receipt on or after the implementation date.	X			X			X			
6417.5	The contractors shall deny a claim for a service on a claim which requires an ordering/referring provider and the information is not provided.	X			X			X			
6417.6	If a service on a claim requires ordering/referring provider information and is provided the contractor shall use the NPI legal name submitted to verify provider is on the PECOS file.	X			X			X			
6417.6.1	Contractors shall use the MCS master provider file for verification if the NPI and/or legal name cannot be found on the PECOS file.	X			X			X			
6417.6.2	Contractors shall compare the first letter of the first name and the first four letters of the last name of the matched record. If the names match, the provider on the claim is considered verified.	X			X			X			
6417.7	If multiple provider identification numbers (PINs) are associated to the NPI in MCS, contractors shall use the first active PIN with an eligible specialty to order and refer.	X			X			X			
6417.8	Phase 1 – contractors shall initially process the claim and	X			X			X			

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	add remark messages (RARC codes) N264 (missing/incomplete/invalid ordering physician provider name) and N265 (missing/incomplete/invalid ordering physician primary identifier) to the remittance advice if the ordering/referring provider is not found on the PECOS file or the contractor's provider file or if the ordering/referring provider is on the contractor's master provider file but is not of the specialty eligible to order or refer. For adjusted claims use CARC code 45 along with RARC codes N264 and N265.										
6417.9	Phase 2 (implementation placeholder date July 5, 2011) - contractors shall reject the service if the ordering/referring provider is not found on the PECOS file or the contractor's provider file or if the ordering/referring provider is on the contractor's master provider file but is not of the specialty eligible to order or refer. For adjusted claims, use CARC code 16 along with RARC codes N264 and N265.	X			X			X			
6417.10	Contractors shall reflect the ordering/referring name from the file used for the legal name validation on the MSN.	X			X			X			
6417.10.1	Contractor shall continue to not include a placeholder NPI on the MSN.	X			X			X			
6417.11	In a new report, MCS shall indicate the number of claims which requires an ordering/referring be submitted and the number of claims that are rejected by new online edits/audits.							X			

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6417.12	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it	X			X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Sandra Olson 410-786-1325 sandra.olson@cms.hhs.gov Patricia Peyton 410-786-1812 patricia.peyton@cms.hhs.gov

Post-Implementation Contact(s): Sandra Olson 410-786-1325 sandra.olson@cms.hhs.gov Patricia Peyton 410-786-1812 patricia.peyton@cms.hhs.gov

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-20 One-Time Notification	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 480	**Date: April 24, 2009**
	Change Request 6421

SUBJECT: Expansion of the Current Scope of Editing for Ordering/Referring Providers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplier (DMEPOS) Suppliers Claims Process by Durable Medical Equipment Medicare Administrative Contractors (DMEMACs)

I. SUMMARY OF CHANGES: Section 1833(q) of the Social Security Act requires that all physicians and non-physician practitioners that meet the definitions at section 1861(r) and 1842(b)(18)(C) be uniquely identified for all claims for services that are ordered or referred. Effective January 1, 1992, a physician or supplier that bills Medicare for a service or item must show the name and unique identifier of the ordering/referring provider on the claim if that service or item was the result of an order or referral. The Centers for Medicare and Medicaid Services (CMS) is expanding the claim editing to meet the Social Security Act requirements for ordering and referring providers.

New / Revised Material
Effective Date: Phase 1: October 1, 2009
Phase 2: January 1, 2010
Implementation Date: Phase 1: October 5, 2009 Further development and coding
Phase 2: January 4, 2010 Actual implementation

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. FUNDING:
SECTION A: For Fiscal Intermediaries and Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question

and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

One-Time Notification

Unless otherwise specified, the effective date is the date of service.

Attachment – One-Time Notification

Pub. 100-20	Transmittal: 480	Date: April 24, 2009	Change Request: 6421

SUBJECT: Expansion of the Current Scope of Editing for Ordering/Referring Providers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplier (DMEPOS) Suppliers Claims Process by Durable Medical Equipment Medicare Administrative Contractors (DMEMACs)

Effective Date for Phase 1: October 1, 2009
Implementation Date for Phase 1 - October 5, 2009 (Further development and coding)

Effective Date for Phase 2: January 1, 2010
Implementation date for Phase 2: January 4, 2010 (Actual Implementation)

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) is expanding the claim editing to meet the Social Security Act requirements for ordering and referring providers. The following are the only providers who can order/refer beneficiary services under the Medicare program:

- doctor of medicine or osteopathy
- dental medicine
- dental surgery
- podiatric medicine
- optometry
- chiropractic medicine
- physician assistant
- certified clinical nurse specialist
- nurse practitioner
- clinical psychologist
- certified nurse midwife
- clinical social worker

The claim editing is being expanded to verify that the ordering/referring provider on a claim is eligible to order/refer and is enrolled in Medicare. The editing expansion will be done in two phases.

Phase 1 –Common Electronic Data Interchange (CEDI) and Viable Medicare Systems (VMS) will receive a national file from the Provider Enrollment, Chain and Ownership System (PECOS) of only the physicians and non-physician practitioners who are enrolled in PECOS who are of the specialty eligible to order or refer under the Medicare program. Nightly thereafter, CEDI and VMS will receive a national PECOS file of newly added physicians and non-physician practitioners and of physicians and non-physician practitioners who were on the initial file or any nightly file whose data have been updated. When a claim is received, CEDI will determine if the ordering/referring provider is required for the billed service. If the billed service requires an ordering/referring provider and the ordering/referring provider is not on the claim, the claim will not be paid. If the ordering/referring provider is on the claim, CEDI will verify that the ordering/referring provider is on the national PECOS file. If the ordering/referring provider is not on the national PECOS file, the claim will continue to process.

Phase 2 – As stated above, CEDI and VMS will still receive a national file from PECOS and will determine if the ordering/referring provider is required for the billed service. If the billed service requires an ordering/referring provider and the ordering/referring provider is not on the claim, the claim will not be paid. If the ordering/referring provider is on the claim, CEDI will verify that the ordering/referring provider is on the national PECOS file. If the ordering/referring provider is not on the national PECOS file, the claim will not be paid.

In both phases, CEDI will use this process to determine if the ordering/referring provider on the claim matches the providers in the national PECOS file: CEDI will verify the National Provider Identifier (NPI) of the ordering/referring provider reported on the claim against the national PECOS file. If a match is not found, the claim will not be paid. If a match is found, CEDI will then compare the first letter of the first name and the first 4 letters of the last name of the matched record. If the names match, the ordering/referring provider on the claim is considered verified. If the names do not match, the claim will not be paid. VMS will perform validation on paper claims to verify that the ordering physician is active in one of the accepted specialties.

A provider is considered as enrolled in Medicare for the purpose of ordering /referring a service to a beneficiary if they are found in the PECOS file. All providers should be verifying their enrollment on the CMS on-line enrollment systems known as Internet-based PECOS.

This change request does not apply to National Council of Prescription Drug Programs (NCPDP) retail pharmacy drug claims.

B. Policy: Section 1833(q) of the Social Security Act requires that all physicians and non-physician practitioners that meet the definitions at section 1861(r) and 1842(b)(18)(C) be uniquely identified for all claims for services that are ordered or referred. Effective January 1, 1992, a physician or supplier that bills Medicare for a service or item must show the name and unique identifier of the ordering/referring provider on the claim if that service or item was the result of an order or referral. Effective May 23, 2008, the unique identifier must be an NPI. In addition, only Medicare-enrolled physicians and non-physician practitioners as defined above are eligible to order/refer services for Medicare beneficiaries.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6421.1	PECOS shall provide an initial file of all physician's and non-physician practitioners nationally who are enrolled and are eligible to order /refer. This will include inactive and deceased providers.										PECOS
6421.1.1	PECOS shall provide a format of the file to CEDI and VMS. The file will consist of the following data element: 1. first, middle and last name 2. NPI 3. Effective date (if available) 4. Termination date (if available)										PECOS

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	5. CMS specialty code and description										
6421.1.2	PECOS file naming convention and file location shall be determined as part of the implementation plan developed between CEDI, VMS, CMS and PECOS.										PECOS VMS CMS DPFS CEDI
6421.1.3	The Form CMS 1500 claim form states to not use periods or commas within the name. A hyphen can be used for hyphenated names. Therefore, contractors shall ignore special characters received from PECOS except for hyphens.		X						X		CEDI
6421.1.4	Contractors shall not use the effective date, termination dates, CMS specialty code and description fields. These fields are currently information fields only.		X						X		CEDI
6421.2	PECOS shall provide a nightly file of only physicians or non-physician practitioners who are newly added to PECOS or who were on the initial or earlier nightly files and who have a change of information.										PECOS EDC
6421.3	Contractors shall determine if ordering/referring provider is on a claim which has a date of receipt on or after the implementation date.		X						X		CEDI
6421.4	The contractors shall reject a claim for a service which requires an ordering/referring provider and the information is not provided.		X						X		CEDI
6421.5	If a service on a claim, which requires ordering/referring provider information and is provided, the contractor shall use the NPI and legal name submitted to verify provider is on the PECOS file.										CEDI
6421.6	Phase 1 – contractors shall initially process the claim if the ordering/referring provider is not found on the PECOS file.		X						X		CEDI
6421.7	Phase 2- contractors shall reject service if the ordering/referring provider is not found on the PECOS file.		X						X		CEDI
6421.8	Contractors shall reflect the ordering/referring name received on the first claim line on the MSN, regardless of how may different ordering physicians are received on the claims.		X						X		
6421.8.1	Contractor shall continue to not include a placeholder NPI on the MSN.		X						X		
6421.9	In a new report, CEDI shall indicate the number of claims which require an ordering/referring physician or non-physician that are submitted and the number of claims that are rejected.										CEDI
6421.10	Contractors shall reject as unprocessable a claim		X						X		CEDI

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	submitted with an EY modifier on one or more but not all service lines and an ordering/referring provider is missing.										
6421.11	Contractors shall bypass the PECOS match logic for claims submitted with an EY modifier on all services even if the ordering/referring provider is missing.		X						X		CEDI

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6421.12	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.		X						X		CEDI

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Sandra Olson 410-786-1325 sandra.olson@cms.hhs.gov Patricia Peyton 410-786-1812 patricia.peyton@cms.hhs.gov

Post-Implementation Contact(s): Sandra Olson 410-786-1325 sandra.olson@cms.hhs.gov Patricia Peyton 410-786-1812 patricia.peyton@cms.hhs.gov

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers:*

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs)*:

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

CHAPTER 302—RELOCATION ALLOWANCES

PART 302–6—ALLOWANCE FOR TEMPORARY QUARTERS SUBSISTENCE EXPENSES

■ 28. The authority citation for 41 CFR part 302–6 is revised to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, as amended, 3 CFR, 1971–1973 Comp., p. 586.

§ 302–6.2 [Amended]

■ 29. Amend § 302–6.2 by removing the word "local".

■ 30. Revise § 302–6.18 to read as follows:

§ 302–6.18 May I be reimbursed for transportation expenses incurred while I am occupying temporary quarters?

Transportation expenses incurred in the vicinity of the temporary quarters are not TQSE, and therefore, there is no authority to pay such expenses under TQSE.

PART 302–9—ALLOWANCES FOR TRANSPORTATION AND EMERGENCY STORAGE OF A PRIVATELY OWNED VEHICLE

■ 31. The authority citation for 41 CFR part 302–9 is revised to read as follows:

Authority: 5 U.S.C. 5738; 20 U.S.C. 905(a); E.O. 11609, as amended, 3 CFR, 1971–1973 Comp., p. 586.

§ 302–9.10 [Amended]

■ 32. Amend § 302–9.10, by removing the word "local" wherever it appears.

[FR Doc. 2010–10235 Filed 5–4–10; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 424 and 431

[CMS–6010–IFC]

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: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements several provisions set forth in the Patient Protection and Affordable Care Act (Affordable Care Act). It implements the provision which 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. This interim final rule with comment period also requires physicians and eligible professionals to order and refer covered items and services for Medicare beneficiaries to be enrolled in Medicare. In addition, it adds requirements for providers, physicians, and other suppliers participating in the Medicare program to provide documentation on referrals to programs at high risk of waste and abuse, to include durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), home health services, and other items or services specified by the Secretary.

DATES: *Effective date:* These regulations are effective on July 6, 2010. *Comment date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 6, 2010.

ADDRESSES: In commenting, please refer to file code CMS–6010–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed).

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions for submitting comments on the home page.
- *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6010–IFC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–6010–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.
- *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Patricia Peyton, (410) 786–1812 for Medicare issues. Rick Friedman, (410) 786–4451 for Medicaid issues.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday

through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

The Medicare program, title XVIII of the Social Security Act (the Act), is the primary payer of health care for 42 million enrolled beneficiaries. Under section 1802 of the Act, a beneficiary may obtain health services from an individual or an organization qualified to participate in the Medicare program. Qualifications to participate are specified in statute and in regulations (see, for example, sections 1814, 1815, 1819, 1833, 1834, 1842, 1861, 1866, and 1891 of the Act); and 42 CFR chapter IV, subchapter E, which concerns standards and certification requirements).

Providers and suppliers furnishing services must comply with the Medicare requirements stipulated in the Act and in our regulations. These requirements are meant to ensure compliance with applicable statutes, as well as to promote the furnishing of high quality care. As Medicare program expenditures have grown, we have increased our efforts to ensure that only qualified individuals and organizations are allowed to enroll or maintain their Medicare billing privileges.

Medicaid is a joint Federal and State health care program for eligible low-income individuals. States have considerable flexibility in how they administer their Medicaid programs within a broad Federal framework and programs vary from State to State.

The Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148) makes a number of changes to the Medicaid program, strengthening tools for quality and integrity, adding new benefits, and expanding coverage. To maintain program integrity and assure quality, it is consistent with these changes to assure that only qualified providers participate in the program and that these providers bill accurately for their services. Although our regulations provide States with considerable flexibility, the Federal framework includes some key requirements to ensure program integrity and quality care. For example, Medicaid providers must generally meet all State licensing and scope-of-practice requirements, and may be subject to additional Federal and State quality standards. Additionally, our regulations require timely filing of claims by providers.

Including the NPI on claims and enrollment applications is an important step in controlling fraud and abuse, ensuring a unique identifier so that States can assure that only qualified Medicaid providers have provider agreements and maintain their Medicaid billing privileges. This practice implements the requirement in section 1128J(e) of the Act, as added by section 6402(a) of the Affordable Care Act and will also help in implementing other important protections under the Affordable Care Act that ensure quality health care services for program beneficiaries.

A. Statutory Authority

The following is an overview of the sections that grant this authority.

- Sections 1102 and 1871 of the Act provide general authority for the Secretary of Health and Human Services (the Secretary) to prescribe regulations for the efficient administration of the Medicare program.
- Section 1128J(e) of the Act, added by section 6402(a) of the Affordable Care Act, requires that the Secretary require by regulation that all providers of medical or other items or services and suppliers under titles XVIII and XIX that are eligible for a national provider identifier (NPI) include the NPI on all applications to enroll in such programs and on all claims for payment under such programs.
- Sections 1814(a), 1815(a), and 1833(e) of the Act require the submission of information necessary to determine the amounts due a provider or other person.
- Section 1834(j)(1)(A) of the Act states that no payment may be made for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number. In order to obtain a supplier number, a supplier must comply with certain supplier standards as identified by the Secretary.
- Section 1842(r) of the Act requires the Centers for Medicare and Medicaid Services (CMS) to establish a system for furnishing a unique identifier for each physician who furnishes services for which payment may be made.
- Section 1862(e)(1) of the Act states that no payment may be made when an item or service was at the medical direction of an individual or entity that is excluded in accordance with sections 1128, 1128A, 1156, or 1842(j)(2) of the Act.
- Section 4313 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) amended sections 1124(a)(1) and 1124A of the Act to require disclosure of both the Employer Identification Number (EIN) and Social Security Number (SSN) of each provider or supplier, each person with ownership or control interest in the provider or supplier, any subcontractor in which the provider or supplier directly or indirectly has a 5 percent or more ownership interest, and any managing employees including Directors and Board Members of corporations and non-profit organizations and charities. The "Report to Congress on Steps Taken to Assure Confidentiality of Social Security Account Numbers as Required by the Balanced Budget Act" was signed by the Secretary and sent to the Congress on January 26, 1999. This report outlines the provisions of a mandatory collection of SSNs and EINs effective on or after April 26, 1999.
- Section 4312(a) of the Balanced Budget Act of 1997 amended section 1834(a)(16) of the Act by requiring certain Medicare suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) to furnish CMS with a surety bond. Section 4312(b) requires that a surety bond be in an amount of not less than $50,000.
- Section 31001(i)(1) of the Debt Collection Improvement Act of 1996 (DCIA) (Pub. L. 104–134) amended section 7701 of 31 U.S.C. by adding paragraph (c) to require that any person or entity doing business with the Federal Government must provide their Taxpayer Identification Number (TIN).
- Section 936(j)(1)(A) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) amended the Act to require the Secretary to establish a process for the enrollment of providers of services and suppliers.

We are authorized to collect information on the Medicare enrollment application (that is, the CMS–855, (Office of Management and Budget (OMB) approval number 0938–0685)) to ensure that correct payments are made to providers and suppliers under the Medicare program as established by title XVIII of the Act.

- Section 1902(a)(27) of the Act provides general authority for the Secretary to require provider agreements under the Medicaid State Plans with every person or institution providing services under the State Plan. Under these agreements, the Secretary may require information regarding any payments claimed by such person or institution for providing services under the State plan.

B. Historical Enrollment Initiatives

Historically, Medicare has permitted the enrollment of providers and suppliers whose qualifications for meeting all of our enrollment standards were sometimes questionable. This has raised concern that providers and

suppliers in our program may be underqualified or even fraudulent and has led us to increase our efforts to establish more stringent controls on provider and supplier entry into the Medicare program. The following is a summary of the regulations that we have published over the past 10 years to ensure that only qualified providers and suppliers are participating in the Medicare program.

In the October 11, 2000 **Federal Register**, we published the Additional Supplier Standards final rule with comment period where we established additional standards with which a DMEPOS supplier must comply in order to receive and maintain Medicare billing privileges. This final rule with comment period outlined the supplier requirements to ensure that suppliers of DMEPOS are qualified to furnish DMEPOS and to help safeguard the Medicare program and its beneficiaries from fraudulent or abusive billing practices.

In the April 21, 2006, **Federal Register**, we published the Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment final rule that implemented section 1866(j)(1)(A) of the Act. In this final rule, we required that all providers and suppliers (other than those who have elected to "opt-out" of the Medicare program) complete an enrollment application and submit specific information to CMS in order to obtain Medicare billing privileges. This final rule also required that all providers and suppliers must periodically update and certify the accuracy of their enrollment information to receive and maintain billing privileges in the Medicare program. These regulatory provisions include requirements to protect beneficiaries and the Medicare Trust Fund by preventing unqualified, fraudulent, or excluded providers and suppliers from providing items or services to Medicare beneficiaries or from billing the Medicare program or its beneficiaries.

In the December 1, 2006, **Federal Register** (71 FR 69624), we published a final rule titled, "Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007." In part, this final rule with comment established performance standards for independent diagnostic testing facilities.

In the April 10, 2007, **Federal Register** (72 FR 17992), we published a final rule titled, "Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)." This final rule implemented section 302 of the MMA requiring that DMEPOS suppliers meet certain quality standards and established DME competitive bidding.

In the November 27, 2007 **Federal Register** (72 FR 66222), we published a final rule titled, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E–Prescribing Exemption for Computer Generated Facsimile Transmissions; Final Rule." In this final rule, we clarified our interpretation of several of the existing independent diagnostic testing facility (IDTF) performance standards found at § 410.33(b) and § 410.33(g), proposed a new IDTF performance standard at § 410.33(g)(15), and a new proposed IDTF provision at § 410.33(i).

In the June 27, 2008, **Federal Register** (73 FR 36448), we published a final rule titled, "Appeals of CMS or CMS Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges." This final rule implemented section 936 of the MMA and extended appeal rights to all providers and suppliers, including DMEPOS suppliers, whose enrollment applications for Medicare billing privileges are denied or revoked by CMS or a Medicare contractor (that is, carrier, fiscal intermediary, National Supplier Clearinghouse Medicare Administrative Contractor (MAC), or Part A/Part B MAC). This final rule also allowed providers and suppliers to seek judicial review after they have exhausted the administrative appeals process. In addition, this final rule also implemented provider enrollment provisions that apply to all provider and supplier types.

In the November 19, 2008, **Federal Register** (73 FR 69726), we published a final rule with comment titled, "Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; E–Prescribing Exemption for Computer Generated Facsimile Transmissions; and Payment for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)." In part, this final rule with comment period established a number of provider enrollment provisions affecting physicians, non-physician practitioners, and other providers and suppliers, such as the re-enrollment bar of 1 to 3 years on revoked providers and suppliers, as well as the limitation on retroactive billing by providers and suppliers.

In the January 2, 2009, **Federal Register** (74 FR 166), we published a final rule titled, "Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); Final Rule." Consistent with section 4312(a) of the BBA, this final rule implemented section 1834(a)(16) of the Act by requiring certain Medicare suppliers of DMEPOS to furnish CMS with a surety bond of no less than $50,000.

Historically, the States in operating the Medicaid program have permitted the enrollment of providers and suppliers who meet the State requirements for Medicaid enrollment. Due to the increased risk of fraud and abuse in public health care programs of all types, the NPI requirement will strengthen cross-program integrity efforts.

II. Provisions of the Interim Final Rule With Comment Period

A. Inclusion of the National Provider Identifier (NPI) on all Medicare and Medicaid Enrollment Applications and Claims

1. Background

Section 1128J(e) of the Act builds on the past Congressional mandate to require the adoption of a unique identifier for health care providers and codifies the NPI requirements that Medicare is already requiring for its fee-for-service (FFS) providers and suppliers.

"Health care provider" is defined in the Health Insurance Portability and Accountability Act (HIPAA) definitions found at 45 CFR 160.103. With the exception of organ procurement organizations and Part B CAP drug vendors, the term "health care provider" includes all of the providers and suppliers who are eligible to enroll in the Medicare program and most who are eligible to enroll in the Medicaid program. In this discussion, we use the term "health care provider" when referring to HIPAA and HIPAA regulations, and we use "providers and suppliers" when referring to those health care providers who are eligible to enroll in the Medicare program.

In the January 23, 2004, NPI final rule (69 FR 3434), we adopted the NPI as the standard unique health identifier for health care providers. This fulfilled the

requirement of section 1173(b) of the Act, which was added by HIPAA. The final rule stated that HIPAA does not prohibit health plans from requiring their enrolled health care providers to obtain NPIs. Accordingly, the Medicare program required enrolling fee-for-service (FFS) providers and suppliers (and their subparts, in accordance with the NPI Final Rule) to report their NPIs on their Medicare enrollment applications beginning in May 2006. When FFS providers and suppliers who had enrolled prior to May 2006 submitted enrollment applications to update their enrollment information, they were required to report their NPIs on those enrollment applications. These requirements ensured that the Medicare provider and supplier enrollment records included the NPIs and, in effect, already implemented one of the provisions of section 1128J(e) of the Act.

In accordance with the NPI final rule and the subsequent guidance from the Secretary, beginning May 23, 2008, Medicare required its enrolled FFS providers and suppliers to use NPIs in their electronic claims to identify not only themselves as the billing providers, but any other providers or suppliers who, according to the Implementation Guides for the adopted standard claims transactions, were also required to be identified in those claims. These other health care providers include rendering providers, supervising providers, and ordering and referring providers. The regulations that adopted the HIPAA standard transactions are found at (65 FR 50312, 68 FR 8381, and 74 FR 3296). In addition, at that same time, Medicare required its enrolled FFS providers and suppliers to make this same use of NPIs in their paper claims.

The Provider Enrollment, Chain, and Ownership System (PECOS), implemented in 2003, is the national repository of enrolled Medicare FFS providers and suppliers (except DMEPOS suppliers, who will be added to PECOS later in 2010). PECOS contains the information furnished by providers and suppliers in their Medicare FFS enrollment applications and additional information added as required to keep the information current and to protect the integrity of the Medicare program (for example, fact and date of death, Office of Inspector General exclusions). In 2007, PECOS began sending the NPIs in the daily provider and supplier enrollment data extract going to the Part A and Part B FFS claims systems. In 2009, Medicare added the NPIs to the enrollment records of the DMEPOS suppliers, which are currently housed in the DMEPOS supplier enrollment repository at the National Supplier Clearinghouse MAC. After the DMEPOS supplier enrollment records are added to PECOS, PECOS will send a daily DMEPOS supplier enrollment data extract, which will include the NPIs, to the DMEPOS FFS claims system. Medicare FFS claims systems link the NPIs that are reported in claims with the appropriate enrollment records in order to properly price and pay the claims.

In summary, Medicare has been requiring its providers and suppliers to report their NPIs on their Medicare enrollment applications; its enrolled providers and suppliers to report their NPIs, and the NPIs of other providers and suppliers (as required and as explained previously) in their electronic and paper Medicare claims; and suppliers who order or refer covered items or services for Medicare beneficiaries to have NPIs so that they can be identified, as required, in the claims for the covered items and services that they have ordered and referred. Similarly, consistent with NPI final rule and subsequent guidance from the Secretary, beginning May 23, 2008, Medicaid providers have also been required to report their NPIs on their Medicaid claims. This IFC now requires their NPIs be submitted for Medicaid provider agreements.

2. Provisions of the Affordable Care Act

Section 6402(a) of the Affordable Care Act added a new section 1128J of the Act, entitled "Medicare and Medicaid Program Integrity Provisions." Section 1128J(e), as added by section 6402(a) of the Affordable Care Act, requires the Secretary to promulgate a regulation that requires, not later than January 1, 2011, all providers of medical or other items or services and suppliers under the programs under titles XVIII and XIX that qualify for a NPI to include their NPI on all applications to enroll in such programs and on all claims for payment submitted under such programs. In Medicaid, there is no Federally required process for provider enrollment except that all Medicaid providers are required to enter into a provider agreement with the State as a condition of participating in the program under section 1902(a)(27) of the Act. Therefore, in the Medicaid context we are including the submission of an NPI to the State agency as a requirement under the provider agreement. The NPI requirements in this IFC are thus applicable to the reporting of NPIs—(1) Pursuant to Medicaid provider agreements; (2) on Medicare provider and supplier enrollment applications; and (3) on Medicare and Medicaid claims.

3. Requirements Established by This IFC

For the Medicare program, we are establishing, at § 424.506(b), requirements that a provider or supplier who is eligible for an NPI must report the NPI on the Medicare enrollment application; and, if the provider or supplier enrolled in Medicare prior to obtaining an NPI and the NPI is not in the provider's or supplier's enrollment record, the provider or supplier must report the NPI to Medicare in an enrollment application so that the NPI will be added to the provider's or supplier's enrollment record in PECOS. We are also establishing, at § 424.506(b)(1), a requirement that a provider or supplier who is enrolled in fee-for-service (FFS) Medicare report its NPI, as well as the NPI of any other provider or supplier who is required to be identified in those claims, on any electronic or paper claims that the provider or supplier submits to Medicare. We are also establishing, at § 424.506(b)(2), that a claim submitted by a Medicare beneficiary contain the legal name and, if the beneficiary knows the NPI, the NPI of any provider or supplier who is required to be identified in that claim.

If a Medicare beneficiary does not know the NPI of a provider or supplier who is required to be identified in the claim that he or she is submitting, the beneficiary may submit the claim without the NPI(s) as long as the claim contains the legal name(s) of the health care provider(s). If a beneficiary so desires, he or she can obtain a provider's or a supplier's NPI by requesting it directly from the provider or supplier or from a member of his or her office staff, or by looking it up in the NPI Registry at *https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do.*

Furthermore, we are establishing, at § 424.506(c)(3), that a Medicare claim from a provider or a supplier will be rejected if it does not contain the required NPI(s).

For the Medicaid program, we are establishing, at § 431.107(b)(5), a requirement that the agreement between a State agency and each provider furnishing services under the State plan include a requirement that any Medicaid provider eligible for an NPI furnish its NPI to the State agency under that agreement and on all Medicaid claims.

B. Ordering and Referring Covered Items and Services for Medicare Beneficiaries

1. Background

Section 1833(q) of the Act requires that claims for items or services for

which payment may be made under Part B and for which there was a referral by a referring physician shall include the name and the unique identification number of the referring physician. Physicians are doctors of medicine and osteopathy, optometry, podiatry, dental medicine, dental surgery, and chiropractic. Referring physicians are those who order covered items or services for Medicare beneficiaries from Medicare providers and suppliers as well as those who refer Medicare beneficiaries to Medicare providers and suppliers for covered services. We consider those who "refer" to also be authorized to "order." In this IFC, we refer to physicians who both order and refer as "ordering and referring suppliers" and the act of ordering items or services for Medicare beneficiaries or referring Medicare beneficiaries to other providers or suppliers for services as "ordering and referring."

The Implementation Guides for the adopted HIPAA standard transactions do not use the word "supplier" in their descriptions of the health care providers who must be identified in those transactions. For example, and as stated earlier in this preamble, the Implementation Guides use the terms "billing provider, ordering provider, referring provider" and others. Because this section of this IFC relates only to the Medicare program, and because the statute and regulations use the term "supplier" (not "provider") when referring to physicians and non-physician practitioners, we are using the term "ordering and referring suppliers" in this IFC. This term corresponds to "ordering provider" and "referring provider" described in the Implementation Guides.

The Medicare providers and suppliers who furnish the covered ordered or referred items and services send claims to Medicare for reimbursement for those covered items and services.

With the establishment and implementation of surrogate Unique Physician Identification Numbers (UPINs) in 1992, suppliers could be identified, but not uniquely identified, in claims as ordering and referring suppliers. These suppliers included physicians, physician assistants, clinical nurse specialists, nurse practitioners, clinical psychologists, certified nurse midwives, and clinical social workers.

Sections 6405(a) and (c) of the Affordable Care Act indicate that orders and referrals for DMEPOS and for other categories of items and services may be made by a physician or an "eligible professional under section 1848(k)(3)(B)." Section 1848(k)(3)(B) of the Act discusses covered professional services for which payment may be made under, or is based on, the fee schedule, and which are furnished by: (1) A physician; (2) a practitioner described in section 1842(b)(18)(C) of Act; (3) a physical or occupational therapist or a qualified speech-language pathologist; and (4) a qualified audiologist. Section 1842(b)(18)(C) of the Act discusses billing and payment for Medicare services furnished by physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, clinical psychologists, and registered dietitians or nutrition professionals. Neither section 1848(k)(3)(B) of the Act nor section 1842(b)(18)(C) of the Act discuss the issue of ordering or referring covered items or services for Medicare beneficiaries. Although section 6405(a) of the Affordable Care Act indicates that DMEPOS may be ordered by enrolled physicians or enrolled eligible professionals under section 1848(k)(3)(B) of the Act, our policy has not been to permit all of the eligible professionals listed in that section or in section 1842(b)(18)(C) of the Act to order and refer. Section 6405(c) of the Affordable Care Act gives the Secretary the discretion to determine the professions that can order and refer for all covered items and services under title XVIII that are not mentioned in sections 6405(a) and (b) of the Affordable Care Act (DMEPOS and home health, respectively). In addition, the claims processing edits that we established in 2009 require that the ordering and referring suppliers for DMEPOS and for laboratory, imaging, and specialist services be those physicians and professionals who were eligible for UPINs: Physicians, physician assistants, clinical nurse specialists, nurse practitioners, clinical psychologists, certified nurse midwives, and clinical social workers. In this IFC, the term eligible professional means any of the professionals listed in section 1848(k)(3)(B) of the Act. In this preamble, we distinguish physicians from eligible professionals (even though physicians are included in section 1848(k)(3)(B) as eligible professionals) because sections 6405(a) and (b) of the Affordable Care Act reference physicians separately from eligible professionals. Section 6405(c) of the Affordable Care Act gives the Secretary the discretion to determine the health professions that can order and refer items and services other than DMEPOS and home health.

In the past, prior to the Medicare implementation of the NPI on May 23, 2008, physicians and eligible professionals were identified in claims as ordering or referring suppliers by their UPINs. Physicians and eligible professionals applied for and were assigned UPINs as part of the process of enrolling in the Medicare program; therefore, physicians and eligible professionals were expected to be identified in claims as ordering or referring suppliers by their UPINs.

Surrogate UPINs were established to be used in claims to temporarily identify certain ordering and referring suppliers who had not yet completed the Medicare enrollment process and, therefore, had not yet been assigned UPINs. Surrogate UPINs were used to collectively identify the following: (1) Physicians who were serving in the military or with the Department of Veterans Affairs or the Public Health Service (including the Indian Health Service); (2) interns, residents, and fellows; and (3) retired physicians. There was also a surrogate UPIN (OTH000) that could be used for any other supplier who ordered or referred who could not be identified by any of the other surrogate UPINs.

Over time, providers and suppliers began using surrogate UPINs in their claims to identify ordering and referring suppliers who had been assigned their own UPINs, as well as individuals who had never been assigned UPINs. In addition, they also used UPINs that had been assigned to physicians other than the physicians who they were identifying in their claims as the ordering or referring suppliers. We believe that many providers and suppliers became aware that the use of any UPIN would get their claims processed and paid. They learned, over time, that Medicare claims edits on the ordering and referring suppliers were based on the format of the UPIN, and all UPINs had the same format. The claims process did not verify the UPINs of ordering or referring suppliers. These practices negated the intent of the UPIN, which was to uniquely identify the ordering or referring supplier.

Analysis of Medicare claims data prior to 2008 (UPINs were not permitted to be used in Medicare claims after May 23, 2008) revealed that these practices were widespread and, as a result, we had reason to believe that many physicians and eligible professionals were unaware of the requirement that their assigned UPINs were intended to uniquely identify them as ordering or referring suppliers and, more importantly, that they needed to apply for UPINs. As a result, Medicare may have paid claims for covered ordered and referred items and services that may

have been ordered or referred by professionals who were not of a profession eligible to order and refer; by physicians or eligible professionals who were not enrolled in the Medicare program; or by physicians or eligible professionals who were not in an approved Medicare enrollment status (for example, they were sanctioned, their licenses were suspended or revoked, their billing privileges were terminated, or they were deceased).

With the Medicare implementation of the NPI in May 2008, Medicare discontinued the assignment of UPINs and no longer allowed UPINs to be used in Medicare claims. Medicare required providers and suppliers who were sending claims to Medicare for covered ordered and referred items and services to use the NPI, rather than the UPIN, to identify the ordering and referring suppliers in their claims. Because the NPI Final Rule did not discuss the concept of "surrogate NPIs" nor did it contain a provision for the establishment of "surrogate NPIs," surrogate NPIs do not and cannot exist. Because physicians and non-physician practitioners are eligible for NPIs, only the NPI may be used in Medicare claims to identify ordering and referring suppliers.

We believe that the new requirements discussed below will address concerns expressed by the Department of Health and Human Services' (DHHS) Office of Inspector General (OIG) report titled, "Durable Medical Equipment Ordered with Surrogate Physician Identification Numbers, OEI–03–01–00270, September 2002," which found that the use of surrogate UPINs on Medicare claims poses a vulnerability to the Medicare program. The HHS OIG found a substantial number of documentation problems in the supporting evidence submitted by suppliers for claims processed with surrogate UPINs. The DHHS OIG estimated that, in 1999, Medicare paid $61 million for services ordered with a surrogate UPIN that had missing or incomplete supporting documentation. Finally, the DHHS OIG stated that the findings in its report also revealed misuse of surrogate UPINs on Medicare claims. The HHS OIG found that surrogate UPINs were incorrectly used for many services since the ordering physician had already been issued a permanent UPIN. The HHS OIG believed this to be a significant problem given that the use of a surrogate UPIN on medical equipment claims allows them to be processed automatically whether the equipment has been ordered by a physician or not. The HHS OIG stated that the inappropriate use of surrogate UPINs by suppliers goes unchecked, the Medicare program becomes vulnerable to fraudulent billings and inappropriate payments.

To ensure the unique identification of ordering and referring suppliers and that they were qualified to order and refer, Medicare implemented claims edits in 2009 that require the ordering and referring suppliers identified in Part B claims for items of DMEPOS and services of laboratories, imaging suppliers, and specialists be identified by their legal names and their NPIs and that they have enrollment records in PECOS. Claims edits are under development to ensure that claims for Part A and Part B home health services identify the physicians who ordered the home health services by their legal names and their NPIs and that those physicians have enrollment records in PECOS.

2. Provisions of the Affordable Care Act

Section 6405(a) amended section 1834(a)(11)(B) of the Act to specify, with respect to suppliers of durable medical equipment, that payment may be made under that subsection only if the written order for the item has been communicated to the DMEPOS supplier by a physician who is enrolled under section 1866(j) of the Act or an eligible professional under section 1848(k)(3)(B) who is enrolled under section 1866(j) before delivery of the item. Section 1128J(e) requires that he or she be identified by his or her NPI in claims for those services. Medicare requires the ordering supplier (the physician or the eligible professional) to be identified by legal name and NPI in the claim submitted by the supplier of DMEPOS.

Section 10604 of the Affordable Care Act, amended section 6405(b) of the Affordable Care Act as follows: (1) Section 1814(a)(2) of the Act to specify, with respect to home health services under Part A, that payment may be made to providers of services if they are eligible and only if a physician enrolled under section 1866(j) of the Act certifies (and recertifies, as required) that the services are or were required in accordance with section 1814(a)(1)(C) of the Act; and (2) section 1835(a)(2) of the Act to specify, with respect to home health services under Part B, that payments may be made to providers of services if they are eligible and only if a physician enrolled under section 1866(j) of the Act certifies (and recertifies, as required) that the services are or were medically required in accordance with section 1835(a)(1)(B) of the Act. Section 1128J(e) requires that the physician be identified by his or her NPI in claims for those services. Medicare requires the ordering supplier (the physician) to be identified by legal name and NPI in the claim submitted by the provider of home health services.

In addition, section 6405(c) of the Affordable Care Act gives the Secretary the authority to extend the requirements made by subsections (a) and (b) to all other categories of items or services under title XVIII of the Social Security Act, including covered Part D drugs as defined in section 1860D–2(e) of the Act, that are ordered, prescribed, or referred by a physician enrolled under section 1866(j) of the Act or an eligible professional under section 1848(k)(3)(B) of the Act. Section 1128J(e) requires that he or she be identified by his or her NPI in claims for those services. Medicare requires the ordering or referring supplier (the physician or the eligible professional) to be identified by legal name and NPI in the claims submitted by the suppliers of laboratory, imaging, and specialist services. These amendments are effective on or after July 1, 2010.

3. Requirements of This IFC

To ensure that ordering suppliers (physicians and eligible professionals) are uniquely identified in Medicare claims for covered items of DMEPOS as required by section 6405(a) of the Affordable Care Act, and to ensure that those DMEPOS items are ordered by qualified physicians or eligible professionals, we are requiring at a new § 424.507(a), the following:

- In Part B claims for covered items of DMEPOS that require the identification of the ordering supplier, and with the exception noted below, the ordering supplier be a physician or an eligible professional with an approved enrollment record in PECOS (see the exception below), and be identified in the claim by his or her legal name and by his or her own NPI (that is, by the NPI that was assigned to him or her by the National Plan and Provider Enumeration System [NPPES] as an Entity type 1 [an individual]).

To ensure that ordering suppliers are uniquely identified in Medicare Part A claims for covered Part A or Part B home health services as required by section 6405(b), as amended by section 10604 of the Affordable Care Act, and to ensure that those home health services are ordered by qualified physicians, we are requiring at a new § 424.507, the following:

- In Part A claims for covered Part A and Part B home health items or services that require the identification of the ordering supplier, and with the exception noted below, the ordering supplier be a physician with an approved enrollment record in PECOS

(see the exception below), and be identified in the claim by his or her legal name and by his or her own NPI (that is, by the NPI that was assigned to him or her by the National Plan and Provider Enumeration System [NPPES] as an Entity type 1 [an individual]).

To ensure that ordering or referring suppliers are uniquely identified in Part B claims for covered services of laboratories, imaging suppliers, and specialists, under the discretion afforded the Secretary in section 6405(c), and to ensure that those items or services are ordered or referred by qualified physicians or eligible professionals, we are requiring at a new § 424.507(b), the following:

• In Part B claims for covered services of laboratories, imaging suppliers, and specialists that require the identification of the ordering or referring supplier, and with the exception noted below, the ordering or referring supplier be a physician or an eligible professional with an approved enrollment record in PECOS (see the exception below), and be identified in the claim by his or her legal name and by his or her own NPI (that is, by the NPI that was assigned to him or her by the National Plan and Provider Enumeration System (NPPES) as an Entity Type 1 (an individual).

We are requiring at a new § 424.507(c) that Medicare contractors will reject claims from providers and suppliers for the above-described covered ordered or referred items or services if the legal names and the NPIs are not reported in the claims or, with the exception noted below, if the ordering or referring supplier does not have an approved enrollment record in PECOS.

We are requiring at a new § 424.507(d) that Medicare contractors may deny a claim submitted by a Medicare beneficiary for the above-described ordered or referred covered items and services if the ordering or referring supplier is not identified by his or her legal name or, with the exception noted below, if the ordering or referring supplier does not have an approved enrollment record in PECOS.

Our continuing outreach efforts stress the need for those who order and refer to have approved enrollment records in PECOS.

While we are not including additional categories of ordered or referred covered items or services in this IFC (such as Part B drugs), we reserve the right to apply these requirements to additional categories through future rulemaking once the policies have been developed. We are considering proposing the requirements for covered prescribed Part B drugs within the next year.

A physician or eligible professional who orders or refers must be enrolled in the Medicare program by having an enrollment record in an approved status in PECOS, even if he or she is enrolled only for the purposes of ordering and referring. To ensure that orders and referrals for Medicare beneficiaries are written by qualified physicians and eligible professionals, it is necessary that their credentials be verified; such verification can occur only as part of the Medicare provider/supplier enrollment process. PECOS, as described earlier in this preamble, is the national Medicare FFS provider and supplier enrollment repository. All providers and suppliers who enrolled in Medicare within the past 6 years, as well as those who enrolled more than 6 years ago and who have submitted updates to their enrollment information within the past 6 years, have enrollment records in PECOS that contain verified credentials. Those who enrolled more than 6 years ago and who have not updated their enrollment information in the past 6 (or more) years will need to submit enrollment applications to Medicare to establish enrollment records in PECOS. They may do this by filling out the paper Medicare provider enrollment applications (using the appropriate form(s) from the CMS–855 series of forms) and mailing the completed application(s) to the appropriate Medicare enrollment contractor or by using Internet-based PECOS to submit their enrollment application to the Medicare enrollment contractor over the Internet. With the implementation in 2009 of the claims processing edits to ensure the NPI and the name reported in claims to identify the ordering or referring suppliers matched information in PECOS for physicians and professionals of a profession eligible to order and refer, many enrolled physicians and eligible professionals who do not have enrollment records in PECOS are submitting enrollment applications in order to establish those enrollment records. We expect that most, if not all, of them will have submitted enrollment applications before the end of 2010, including those who are enrolling solely to continue to order and refer. A physician or eligible professional who is deceased, retired, or excluded from the Medicare program, or who otherwise would not have an approved enrollment record in PECOS, would not be eligible to order or refer items or services for Medicare beneficiaries. Please note the following exception for physicians and eligible professionals who do not have an approved enrollment record in PECOS:

Under section 1802(b) of the Act and the implementing regulations at 42 CFR 405.400 *et seq.,* physicians and non-physician practitioners can opt out of the Medicare program and enter into private contracts with Medicare beneficiaries. By entering into these types of contracts, these suppliers do not bill the Medicare program for services that they furnish to Medicare beneficiaries. We require that physicians and eligible professionals who have properly filed an appropriate affidavit with a Medicare contractor in order to opt out of the Medicare program be required to be identified in claims by their names and their NPIs if they order or refer covered items or services for Medicare beneficiaries. We are creating an exception to the requirement that ordering and referring suppliers be required to have an approved enrollment record in PECOS for those physicians and non-physician practitioners who have validly opted out of the Medicare program. Therefore, physicians and non-physician practitioners who have validly opted out of Medicare are eligible to order and refer covered items and services for Medicare beneficiaries. If they have properly completed the appropriate affidavit in order to opt out of Medicare, they will have records in PECOS that contain their NPIs and that indicate that they have validly opted out of the Medicare program. In January 2009, there were approximately 10,000 physicians and eligible professionals who had opted out of the Medicare program. Compared to the more than 800,000 enrolled physicians and eligible professionals, there are relatively few physicians and eligible professionals who have opted out of Medicare.

Accordingly, the physicians or eligible professional that opted out must meet the following:

• A currently enrolled physician or eligible professional who does not have an enrollment record in PECOS is required to establish an enrollment record in PECOS so that he or she can order and refer covered items or services for Medicare beneficiaries. A physician or eligible professional who has validly opted out of the Medicare program will have a valid opt-out record in PECOS and is not required to submit an enrollment application.

• A physician or eligible professional who is employed by the Public Health Service, the Department of Defense, or the Department of Veterans Affairs is required to have an approved enrollment record in PECOS in order to order and refer covered items and services for Medicare beneficiaries, even though he or she would not be

submitting claims to Medicare for services furnished to Medicare beneficiaries. We require, therefore, that these physicians and eligible professionals enroll in Medicare solely to order and refer (and not to be paid for services furnished to Medicare beneficiaries).

- A dentist furnishes many services that are not covered by Medicare and, as a result, most dentists are not enrolled in Medicare. However, a dentist may order services for patients who are Medicare beneficiaries, such as sending oral specimens to laboratories for testing. Doctors of dental medicine or dental surgery are considered physicians and we require that they have approved enrollment records in PECOS if they order or refer covered items or services for patients who are Medicare beneficiaries.
- A pediatrician may treat Medicare beneficiaries (for example, those of any age who are enrolled in the Medicare end-stage renal disease (ESRD) program or those who are entitled to Medicare benefits under other Federal programs), although the volume of such patients is generally so low that most pediatricians are not enrolled in Medicare. We require that a pediatrician have an approved enrollment record in PECOS if he or she orders or refers covered items or services for patients who are Medicare beneficiaries.
- Residents and interns order and refer covered items and services for Medicare beneficiaries. Prior to the implementation of the NPI, residents and interns were identified in claims as the ordering or referring providers by surrogate UPINs. Interns are not issued medical licenses by States; therefore, they are not eligible to enroll in Medicare. Residents have medical licenses if they practice in States that issue medical licenses to residents; as a result, some residents are eligible to enroll in Medicare. Due to the variances in licensure and the necessity for interns and residents to be able to continue to order and refer covered items and services for Medicare beneficiaries, we require that the teaching physician—not the resident or intern—be identified in the claim as the ordering or referring provider whenever a resident or intern orders or refers.

These ordering and referring requirements, when implemented, will allow us to uniquely identify the ordering and referring supplier in claims (except when the teaching physician is identified as the ordering or referring supplier in situations where an intern or a resident ordered or referred) and assure, because of the requirement to have an approved enrollment or valid opt out record in PECOS, that the ordering and referring supplier is qualified to order and refer items and services for Medicare beneficiaries. This will enable us to edit claims for ordering and referring suppliers who do not have approved enrollment records in PECOS (that is, those who are excluded, deceased, or retired, and those whose Medicare billing privileges have been terminated through exclusion, revocation, or otherwise), and those who have voluntarily terminated their relationship with Medicare or who have validly opted out of Medicare.

Further, we are requiring that Part A claims for covered ordered Part A and Part B home health services must include the legal name and the NPI of the ordering supplier, who must be a physician. We are requiring that Part B claims for covered, ordered, and referred Part B items and services (excluding Part B drugs) must include the legal name and the NPI of the ordering or referring supplier. We place these same requirements (except for the NPI) on claims submitted by Medicare beneficiaries for these same ordered or referred items and services. Although suppliers are required to submit claims on behalf of beneficiaries under the mandatory claim submission policy at section 1848(g)(4)(A) of the Act, we recognize that beneficiaries may submit claims to Medicare for payment. In order to fully enforce the ordering and referring requirement established by section 6405 of the Affordable Care Act, we plan to deny a beneficiary claim for a service when the legal name of the ordering or referring supplier is not included on the claim.

We believe that these requirements will promote quality health care services for Medicare beneficiaries because orders and referrals would be written by qualified physicians and eligible professionals, as their credentials would have been verified as part of the Medicare provider/supplier enrollment process.

Additionally, we believe these requirements will eliminate the abusive practice of reporting identifiers in claims as being assigned to specific ordering or referring suppliers when, in fact, those identifiers had not been assigned to those specific ordering or referring suppliers. As a result, our requirements should eliminate these types of problematic claims and ensure the qualifications of the ordering and referring suppliers.

Our requirements will enable us to know the identity of the individual who ordered or referred and, if appropriate, we could establish edits to check for over-ordering specific items or services, over-referring specific services, and/or over-ordering or over-referring to specific providers of services and suppliers.

Furthermore, these requirements support our existing authority, at § 424.516(f), under which the ordering and referring suppliers, and those providers of services and suppliers who furnish covered items or services based on orders or referrals, are required to maintain documentation (to include the NPI) that supports the orders and referrals for 7 years in order to maintain an active enrollment status in the Medicare program.

Lastly, these requirements may lead to a reduction in inappropriate Medicare payments.

We are aware that, in some cases, Medicare beneficiaries may be patients of physicians or eligible professionals who do not have approved enrollment records in PECOS, or may be patients of professionals who are not of a profession that is eligible to order or refer, and that these physicians and professionals may be ordering and referring covered items and services for these Medicare beneficiaries at this time. We expect to conduct outreach activities to educate Medicare beneficiaries, as well as Medicare providers of services and suppliers who furnish covered items and services based on orders and referrals, so that we can eliminate situations where those providers of services and suppliers who would be furnishing covered ordered and referred items and services would not be paid for those covered items or services because their claims failed the edits.

Finally, we believe that the requirements will address the recommendations offered by the DHHS OIG report titled, "Medicare Payments in 2007 for Medical Equipment and Supply Claims with Invalid or Inactive Referring Physician Identifiers, OEI–04–08–00470, February 2009." Specifically, the OIG recommended that CMS:

(1) Determine why Medicare claims with identifiers associated with deceased referring physicians continue to be paid;

(2) Implement claims-processing system changes to ensure that NPIs for both referring physicians and suppliers be listed on medical equipment and supply claims are valid and active.

(3) Emphasize to suppliers the importance of using accurate NPIs for both referring physicians and suppliers when submitting Medicare claims; and

(4) Determine the earliest date to end the provision that allows suppliers to submit claims without referring

physician NPIs while maintaining beneficiary access to services.

With respect to recommendation (4), we began requiring Medicare claims to identify ordering and referring providers by NPIs beginning May 23, 2008. If the provider of services or the supplier submitting the claim for the covered ordered or referred items or services could not determine the NPI of the ordering or referring supplier, we permitted the provider of services or the supplier submitting the claim to use its own NPI in place of the NPI of the ordering or referring provider. These types of claims for DMEPOS items now fail the claims processing edits that were implemented in 2009. Medicare-enrolled physicians and professionals are required to have NPIs. The NPI Registry (available at *https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do*) enables anyone with a computer with Internet access to look up a health care provider's NPI by name or NPI, and the NPPES downloadable file (downloadable from *http://nppesdata.cms.hhs.gov/CMS_NPI_files.html*) contains the NPIs of all health care providers who have active NPIs, as well as identifying information about the health care providers that is publicly disclosable under the Freedom of Information Act. (The National Plan and Provider Enumeration System Data Dissemination Notice, published in the May 30, 2007 **Federal Register**, further describes the NPI Registry and the NPPES downloadable file.) The existing claims processing edits described earlier in this preamble check to ensure that the NPI reported on a Part B claim for ordered or referred covered items or services (excluding Part B home health services and Part B drug claims) belongs to the ordering or referring supplier whose name is also reported in those claims, and not to the supplier who submitted the claim. As stated previously, the provisions of section 6405 of the Affordable Care Act are effective July 1, 2010.

C. Requirement for Physicians, Other Suppliers, and Providers to Maintain and Provide Access to Documentation on Referrals to Programs at High Risk of Waste and Abuse

1. Background

On November 19, 2008, we published a final rule with comment titled, "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; Revisions to the Amendment of the E–Prescribing Exemption for Computer Generated Facsimile Transmissions; and the Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)" in the **Federal Register**. In this IFC, we established § 424.516(f) to require providers and suppliers to maintain ordering and referring documentation, including the NPI, received from a physician or eligible non-physician practitioner. We also established in § 424.516(f) that physicians and eligible professionals are required to maintain written ordering and referring documentation for 7 years from the date of service. Finally, we established in § 424.535(a)(10) that failure to comply with the documentation requirements specified in § 424.516(f) is a reason for revocation.

2. Provisions of the Affordable Care Act

Section 6406 of the Affordable Care Act amends section 1866(a)(1) of the Act and added a new subparagraph (W) which requires providers to agree to "maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider under this title, as specified by the Secretary."

In addition, section 6406 of the Affordable Care Act amended section 1842(h) of the Act by adding a new paragraph which states, "The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary."

Section 6406(b)(3) of the Affordable Care Act amends section 1866(a)(1) of the Act to require that providers and suppliers maintain and, upon request, provide to the Secretary, access to written or electronic documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider as specified by the Secretary. Section 6406(b)(3) does not limit the authority of the Office of Inspector General to fulfill the Inspector General's responsibilities in accordance with applicable Federal law.

3. Requirements of This IFC

In our requirements, in our revision of § 424.516(f), we are replacing the term "eligible non-physician practitioner" with "eligible professional." This change is consistent with our definition of "eligible professional" and correctly identifies the professionals who, in addition to physicians, are eligible to order and refer.

At this time, we are expanding § 424.516(f) to include requirements for documentation and access to documentation related to orders and referrals for covered home health, laboratory, imaging, and specialist services. Section 424.516(f) currently includes requirements for documentation and access to documentation for orders for DMEPOS. We reserve the right to, at a future date, publish proposed requirements for documentation and access to documentation for additional items and services that may be ordered or referred under title XVIII and that are programs of high risk of waste and abuse.

We are revising the existing § 424.516(f) to now read "Maintaining and providing access to documentation." A provider or a supplier who furnishes covered ordered DMEPOS or referred home health, laboratory, imaging, or specialist services is required to maintain documentation for 7 years from the date of service and, upon the request of CMS or a Medicare contractor, to provide access to that documentation. The documentation includes written and electronic documents (including the NPI of the physician who ordered the home health services and the NPI of the physician or the eligible professional who ordered or referred the DMEPOS, laboratory, imaging, or specialist services) relating to written orders and requests for payments for items of DMEPOS and home health, laboratory, imaging, and specialist services. A physician who ordered home health services and a physician and an eligible professional who ordered or referred items of DMEPOS or laboratory, imaging, and specialist services is required to maintain documentation for 7 years from the date of the order, certification, or referral and, upon request of CMS or a Medicare contractor, to provide access to that documentation. The documentation includes written and electronic documents (including the NPI of the physician who ordered the home health services and the NPI of the physician or the eligible professional who ordered or referred the DMEPOS, laboratory, imaging, or specialist services) relating

to written orders or requests for payments for items of DMEPOS and home health, laboratory, imaging, and specialist services. Note that we are clarifying that the documentation includes both written and electronic documentation.

We are revising § 424.535(a)(10) to read, "The Centers for Medicare & Medicaid Services" (CMS) may revoke enrollment, for a period of not more than one year for each act, for a provider or a supplier under section 1866(j) of the Act if such provider or supplier fails to meet the requirements of § 424.516(f). Providers and suppliers will continue to have appeal rights afforded to them in accordance with part 498.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. The NPI requirements set forth in this IFC are necessary to implement the data reporting requirements in section 1128J(e) of the Act, as amended by section 6402(a) of the Affordable Care Act, which require that the Secretary promulgate a regulation to implement this requirement no later than January 2011. Moreover these NPI requirements are needed to implement the Medicare requirements specified in section 6405 of the Affordable Care Act that are effective July 1, 2010. Section 6406 of the Affordable Care Act was effective January 1, 2010. It is imperative that the regulatory provisions be set forth as soon as possible to deliver the guidance necessary to enact the provisions.

In addition, several of these provisions may be issued as an IFC because they fall under the exception in Medicare to the section 1871(b)(1)(B) of the Act rulemaking requirements. Section 1871 of the Act generally requires that we issue a notice of proposed rulemaking prior to issuing a final rule under the Medicare program. However, section 1871(b)(1)(b) provides that the Secretary is not required to issue a notice of proposed rulemaking before issuing a final rule if "* * * a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained." Section 6405 establishes an effective date of July 1, 2010, which is less than 150 days from the date of enactment of this statute. Moreover, section 6406 establishes an effective date of January 1, 2010, which has already passed.

We do not believe that the portions of this rule not exempted from notice and comment rulemaking pursuant to section 1871(b)(1)(B) of the Act add any new burdens for Medicare or Medicaid providers and suppliers. Both Medicare and Medicaid programs generally require unique provider identifiers, and thus delaying this rule is unnecessary. Finally, a delay in implementing these provisions would be contrary to the public interest and to CMS' efforts to reduce and eliminate fraud and abuse in the Medicare and Medicaid programs. For these reasons, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day comment period.

V. Collection of Information Requirements

In accordance with section 3507(j) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection included in this interim final rule with comment period will be submitted for emergency approval to the Office of Management and Budget (OMB). The revised information collection requirements associated with 0938–0685, 0938–0931, and 0938–0999 (see sections V.A. and V.D. of this IFC) will not be effective until approved by OMB.

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding National Provider Identifier (NPI) on All Medicare Enrollment Applications and Claims (§ 424.506)

Section 424.506(b)(1) states that providers and suppliers who are eligible for NPIs be required to report their NPIs on their enrollment applications for Medicare. Similarly, § 424.506 (b)(2) states that if providers or suppliers enrolled in Medicare prior to obtaining NPIs and their NPIs are not in their enrollment records, they must submit enrollment applications containing their NPIs.

The burden associated with the requirements in § 424.506(b) is the time and effort necessary for a provider or a supplier to apply for an NPI and the time and effort necessary to report the NPIs on their enrollment applications for Medicare.

Sections § 424.510 and § 424.515 state that providers and suppliers must submit enrollment information on the applicable enrollment application and update, resubmit, and recertify the accuracy of their enrollment information every 5 years. In addition, § 424.516 lists reporting requirements for providers and suppliers. To submit enrollment information for an initial application (even if enrolling solely to order and refer), a change of information, or to respond to a revalidation request, a provider or supplier must complete and submit the applicable CMS–855 enrollment application or complete and submit the enrollment application over the Internet using Internet-based PECOS. Although we are unable to quantify the number, we do not believe that a significant number of physicians and eligible professionals will enroll in Medicare solely to order and refer. The burden associated with the enrollment requirements found in § 424.510,

§ 424.515, and§ 424.516 is the time and effort necessary to complete and submit applicable Medicare enrollment applications. While this burden is subject to the PRA, it is currently approved under existing OMB control numbers (OCN). Specifically, the burden associated with obtaining an NPI is currently approved under OCN 0938–0931. The burden associated with submitting initial Medicare enrollment applications and updating Medicare enrollment information to include NPI is approved under OCN 0938–0685 (Applications CMS–855 A, B, I, and R) 0938–1056 (Application CMS–855 S).

Section 424.506(b)(1) states that providers and suppliers who are enrolled in Medicare must report their National Provider Identifiers (NPIs) and the NPIs of any other providers or suppliers who are required to be identified in their claims on all paper and electronic claims that they send to Medicare. The burden associated with this requirement is the time and effort necessary to complete and submit a claim form. While this requirement is subject to the PRA, the associated burden is currently approved under OCN 0938–0999.

B. ICRs Regarding Ordering and Referring Covered Items and Services for Medicare Beneficiaries (§ 424.507)

Section 424.507 states that to receive payment for covered Part A or Part B home health services, the claim must contain the legal name and the NPI of the ordering physician; and to receive payment for covered items of DMEPOS, and certain other covered Part B items or services (excluding Part B drugs), the claim must contain the legal name and the NPI of the ordering or referring physician or eligible professional. The burden associated with these requirements is the time and effort necessary to submit a claim with the required information. While these requirements are subject to the PRA, the associated burden is currently approved under OCN 0938–0999.

C. ICRs Regarding Additional Provider and Supplier Requirements for Enrolling and Maintaining Active Enrollment Status in the Medicare Program (§ 424.516)

Section 424.516(f)(1) discusses the documentation requirements for providers and suppliers. A provider or supplier is required for 7 years from the date of service to maintain and upon request of CMS or a Medicare contractor, provide access to documentation, including the NPI of the physician or the eligible professional who ordered or referred the item or service, relating to written orders or requests for payments for items of DMEPOS and referrals for home health, laboratory, imaging, and specialist.

Similarly, § 424.516(f) discusses the documentation requirements for providers and suppliers. At § 424.516(f)(1), providers and suppliers are required for 7 years from the date of service to maintain and, upon request of CMS or a Medicare contractor, provide access to documentation, including the NPI of the physician or the eligible professional who ordered or referred the item or service, relating to written orders or requests for payments for items of DMEPOS and referrals for home health, laboratory, imaging, and specialist. At § 424.516(f)(2), physicians and eligible professionals are required for 7 years from the date of service to maintain and, upon request of CMS or a Medicare contractor, provide access to written and electronic documentation relating to written orders or certifications for items of DMEPOS and home health, laboratory, imaging, and specialist services, written, ordered, referred by such physician or non-physician practitioner.

The burden associated with the requirements in § 424.516(f) is the time and effort necessary to both maintain documentation on file and to furnish the information upon request to CMS or a Medicare contractor. While the requirement is subject to the PRA, we believe the associated burden is exempt. As discussed in the final rule that was published November 19, 2008 (73 FR 69726), we believe the burden associated with maintaining documentation and furnishing it upon request is a usual and customary business practice and thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

D. ICRs Regarding the Reporting of National Provider Identifier by Medicaid Providers (§ 431.507(b)(5))

Section 431.107(b)(5) states that a Medicaid provider has to furnish its NPI (if eligible for an NPI) to its State agency and include its NPI on all claims submitted under the Medicaid program. The burden associated with the Medicaid requirements in § 431.107(b)(5) is the time and effort necessary for a provider to report the NPIs to the State agency and on claims submitted to the Medicaid program.

We are in the process of revising the information collection requirements contained in OCNs 0938–0685, 0938–0931, and 0938–0999 in accordance with the provisions of this rulemaking. These information collection requirements will be sent to OMB for review and approval in accordance with the emergency procedures of the PRA and will not go into effect until approved by OMB.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–6010–IFC]

Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov*

VI. Regulatory Impact Analysis

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804 *et seq.*). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Virtually all providers and suppliers who wish to enroll in Medicare and Medicaid programs have already obtained NPIs. Most enrolled Medicare and Medicaid providers and suppliers who will be affected by the statutory and regulatory requirements are already meeting those requirements. For example, Medicare providers and suppliers have been reporting their NPIs on their enrollment applications for 4 years and have been using NPIs in their paper and electronic Medicare claims as well as electronic Medicaid claims for 2 years. The majority of suppliers who submit claims for ordered or referred DMEPOS and laboratory, imaging, and specialist services are ensuring that their claims meet the requirements of this IFC. In addition, the majority of Medicare physicians and eligible professionals who order and refer but who do not have approved enrollment records in PECOS are aware of the need to establish those records and many have already submitted their enrollment

applications to Medicare in order to do so. Medicare DMEPOS suppliers and those physicians and eligible professionals who order DMEPOS are already maintaining documentation in accordance with the requirements of this IFC. Other Medicare providers and suppliers who will be required to do so by this IFC are likely already in full or partial compliance as part of their routine business operations. Therefore, we do not believe this rule reaches the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 to $31.5 million in any one year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities. We maintain that this final rule would not have an adverse impact on small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $135 million. This rule does not mandate expenditures by either the governments mentioned or the private sector; therefore, no analysis is required. Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

Since this regulation does not impose significant costs on State or local governments, the requirements of E.O. 13132 are not applicable. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

B. Alternatives Considered

Since this final rule is a codification of statutory provisions found in the Affordable Care Act, we did not consider alternatives to this process.

List of Subjects

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. Section 424.506 is added to read as follows:

§ 424.506 National Provider Identifier (NPI) on all enrollment applications and claims.

(a) *Definition. Eligible professional* means any of the professionals specified in section 1848(k)(3)(B) of the Act.

(b) *Enrollment requirements.* (1) A provider or a supplier who is eligible for an NPI must report its National Provider Identifier (NPI) on its Medicare enrollment application.

(2) If a provider or a supplier who is eligible for an NPI enrolled in the Medicare program prior to obtaining an NPI and the provider's or the supplier's NPI is not in the provider's or the supplier's Medicare enrollment record, the provider or the supplier must submit a Medicare enrollment application that contains the NPI.

(3) A physician or an eligible professional who has validly opted out of the Medicare program does not need to submit an enrollment application.

(c) *Claims reporting requirements.* (1) A provider or a supplier who is enrolled in Medicare and who submits a paper or an electronic claim to Medicare include its National Provider Identifier (NPI) and the NPI(s) of any other provider(s) or suppliers(s) who is required to be identified.

(2) A Medicare beneficiary who submits a claim for service to Medicare—

(i) Must include the legal name of any provider or supplier who is required to be identified in that claim; and

(ii) May, if known to the beneficiary, include the National Provider Identifier (NPI) of any provider or supplier who is required to be identified in that claim.

(3) A Medicare contractor will reject a claim from a provider or a supplier if the required NPI(s) is not reported.

■ 3. Section 424.507 is added to read as follows:

§ 424.507 Ordering and referring covered items and services for Medicare beneficiaries.

(a) *Conditions for payment of claims for ordered or referred covered Part B items and services (excluding home health services described in § 424.507(b) and Part B drugs).* (1) *Part B provider and supplier claims.* To receive payment for ordered or referred covered Part B items and services (excluding home health services described in § 424.507(b), and Part B drugs), a provider's or supplier's must meet all of the following requirements:

(i) The Part B items and services must have been ordered or referred by a physician or, when permitted, an eligible professional (as defined in § 424.506(a) of this part).

(ii) The claim from the Part B provider or supplier must contain the legal name and the National Provider Identifier (NPI) of the physician or the eligible professional (as defined in § 424.506(a) of this part) who ordered or referred.

(iii) The physician or the eligible professional who ordered or referred must have an approved enrollment record or a valid opt-out record in the Provider Enrollment, Chain and Ownership System (PECOS).

(iv) If the items or services were ordered or referred by a resident or an intern, the claim must identify the teaching physician as the ordering or referring supplier. The claim must identify the teaching physician by his or her legal name and NPI and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

(2) *Part B beneficiary claims.* To receive payment for ordered or referred covered Part B items and services (excluding home health services described in § 424.507(b), and Part B

drugs), a beneficiary's claim must meet all of the following requirements:

(i) The Part B items and services must have been ordered or referred by a physician or, when permitted, an eligible professional (as defined in § 424.506(a) of this part).

(ii) The claim must contain the legal name of the physician or the eligible professional (as defined in § 424.506(a) of this part) who ordered or referred.

(iii) The physician or the eligible professional who ordered or referred must have an approved enrollment record or a valid opt-out record in the Provider Enrollment, Chain and Ownership System (PECOS).

(iv) If the items or services were ordered or referred by a resident or an intern, the claim must identify the teaching physician as the ordering or referring supplier. The claim must identify the teaching physician by his or her legal name and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

(b) *Conditions for payment of claims for ordered covered home health services.* (1) *Home health provider claims.* To receive payment for ordered, covered Part A or Part B home health services, a provider's home health services claim must meet all of the following requirements:

(i) The Part A or Part B home health services must have been ordered by a physician;

(ii) The claim from the provider of home health services must contain the legal name and the National Provider Identifier (NPI) of the ordering physician;

(iii) The ordering physician must have an approved enrollment record or a valid opt-out record in the Provider Enrollment, Chain, and Ownership System (PECOS); and

(iv) If the services were ordered by a resident or an intern, the claim must identify the teaching physician as the ordering or referring physician. The claim must identify the teaching physician by his or her legal name and NPI and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

(2) *Home health beneficiary claims.* To receive payment for ordered covered Part A or Part B home health services, a beneficiary's home health services claim must meet all of the following requirements:

(i) The Part A or Part B home health services must have been ordered by a physician.

(ii) The claim from the provider of home health services must contain the legal name of the ordering physician.

(iii) The ordering physician must have an approved enrollment record or a valid opt-out record in the Provider Enrollment, Chain, and Ownership System (PECOS).

(iv) If the services were ordered by a resident or an intern, the claim must identify the teaching physician as the ordering or referring physician. The claim must identify the teaching physician by his or her legal name and he or she must have an approved enrollment record or a valid opt-out record in PECOS.

(c) A Medicare contractor will reject a claim from a provider or a supplier for covered services described in paragraphs (a) and (b) of this section if the claim does not meet the requirements of paragraph (a)(1) and (b)(1) of this section, respectively.

(d) A Medicare contractor may deny a claim from a Medicare beneficiary for covered items or services described in paragraphs (a) and (b) of this section if the claim does not meet the requirements of paragraphs (a)(2) and (b)(2) of this section, respectively.

■ 4. Section 424.516 is amended by revising paragraph (f) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(f) *Maintaining and providing access to documentation.* (1) A provider or a supplier who furnishes covered ordered DMEPOS or referred home health, laboratory, imaging, or specialist services is required to maintain documentation for 7 years from the date of service and, upon the request of CMS or a Medicare contractor, to provide access to that documentation. The documentation includes written and electronic documents (including the NPI of the physician who ordered the home health services and the NPI of the physician or the eligible professional who ordered or referred the DMEPOS, laboratory, imaging, or specialist services) relating to written orders and requests for payments for items of DMEPOS and home health, laboratory, imaging, and specialist services.

(2) A physician who ordered home health services and a physician and an eligible professional who ordered or referred items of DMEPOS or laboratory, imaging, and specialist services is required to maintain documentation for 7 years from the date of the order, certification, or referral and, upon request of CMS or a Medicare contractor, to provide access to that documentation. The documentation includes written and electronic documents (including the NPI of the physician who ordered the home health services and the NPI of the physician or the eligible professional who ordered or referred the DMEPOS, laboratory, imaging, or specialist services) relating to written orders or requests for payments for items of DMEPOS and home health, laboratory, imaging, and specialist services.

■ 5. Section 424.535 is amended by revising (a)(10) to read as follows:

§ 424.535 Revocation of enrollment and billing privileges in the Medicare program.

(a) * * *

(10) *Failure to document or provide CMS access to documentation.* (i) The provider or supplier (as described in section 1866(j) of the Act) did not comply with the documentation or CMS access requirements specified in § 424.516(f) of this subpart.

(ii) A provider or supplier that meets the revocation criteria specified in paragraph (a)(10)(i) of this section, is subject to revocation for a period of not more than 1 year for each act of noncompliance.

* * * * *

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

■ 6. The authority citation for part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302).

■ 7. Section 431.107 is amended by adding a new paragraph (b)(5) to read as follows:

§ 431.107 Required provider agreement.

* * * * *

(b) * * *

(5)(i) Furnish to the State agency its National Provider Identifier (NPI) (if eligible for an NPI); and

(ii) Include its NPI on all claims submitted under the Medicaid program.

Dated: April 28, 2010.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: April 29, 2010.

Kathleen Sebelius,

Secretary.

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program, and Program No. 93.778, Medical Assistance Program.

[FR Doc. 2010–10505 Filed 4–30–10; 4:15 pm]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

News Flash – In September 2012, the Centers for Medicare & Medicaid Services (CMS) announced the availability of a new electronic mailing list for those who refer Medicare beneficiaries for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Referral agents play a critical role in providing information and services to Medicare beneficiaries. To ensure you give Medicare patients the most current DMEPOS Competitive Bidding Program information, CMS strongly encourages you to review the information sent from this new electronic mailing list. In addition, please share the information you receive from the mailing list and the link to the "mailing list for referral agents" subscriber webpage with others who refer Medicare beneficiaries for DMEPOS. Thank you for signing up!

MLN Matters® Number: SE1305

Related Change Request (CR) #: 6421, 6417, 6696, 6856

Related CR Release Date: N/A

Effective Date: May 1, 2013

Related CR Transmittal #: R642OTN, R643OTN, R328PI, and R7810TN

Implementation Date: May 1, 2013

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)

Note: This Special Edition MLN Matters® Article is a consolidation and update of prior articles SE1011, SE1201, SE1208, and SE1221. Effective May 1, 2013, the Centers for Medicare & Medicaid Services (CMS) will turn on the Phase 2 denial edits. This means that Medicare will deny claims for services or supplies that require an ordering/referring provider to be identified and that provider is not identified, is not in Medicare's enrollment records, or is not of a specialty type that may order/refer the service/item being billed.

Provider Types Affected

This MLN Matters® Special Edition Article is intended for:

- Physicians and non-physician practitioners (including interns, residents, fellows, and those who are employed by the Department of Veterans Affairs (DVA), the Department of Defense (DoD), or the Public Health Service (PHS)) who order or refer items or services for Medicare beneficiaries,

- Part B providers and suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) who submit claims to carriers, Part A/B Medicare Administrative Contractors (MACs), and DME MACs for items or services that they furnished as the result of an order or a referral, and
- Part A Home Health Agency (HHA) services who submit claims to Regional Home Health Intermediaries (RHHIs), Fiscal Intermediaries (FIs, who still maintain an HHA workload), and Part A/B MACs.
- Optometrists may only order and refer DMEPOS products/services and laboratory and X-Ray services payable under Medicare Part B.

Provider Action Needed

If you order or refer items or services for Medicare beneficiaries and you do not have a Medicare enrollment record, you need to submit an enrollment application to Medicare. You can do this using the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) or by completing the paper enrollment application (CMS-855O). Review the background and additional information below and make sure that your billing staff is aware of these updates.

What Providers Need to Know

Phase 1: Informational messaging: Began October 5, 2009, to alert the billing provider that the identification of the ordering/referring provider is missing, incomplete, or invalid, or that the ordering/referring provider is not eligible to order or refer. The informational message on an adjustment claim that did not pass the edits indicated the claim/service lacked information that was needed for adjudication. Phase 2: Effective May 1, 2013, CMS will turn on the edits to deny Part B, DME, and Part A HHA claims that fail the ordering/referring provider edits. Physicians and others who are eligible to order and refer items or services need to establish their Medicare enrollment record and must be of a specialty that is eligible to order and refer.

All enrollment applications, including those submitted over the Internet, require verification of the information reported. Sometimes, Medicare enrollment contractors may request additional information in order to process the enrollment application.

Waiting too long to begin this process could mean that your enrollment application may not be processed prior to the May 1, 2013 implementation date of the ordering/referring Phase 2 provider edits.

Background

The Affordable Care Act, Section 6405, "Physicians Who Order Items or Services are Required to be Medicare Enrolled Physicians or Eligible Professionals," requires physicians or other eligible professionals to be enrolled in the Medicare Program to order or refer items or services for Medicare beneficiaries. Some physicians or other eligible professionals do not and will not send claims to a

Medicare contractor for the services they furnish and therefore may not be enrolled in the Medicare program. Also, effective January 1, 1992, a physician or supplier that bills Medicare for a service or item must show the name and unique identifier of the attending physician on the claim if that service or item was the result of an order or referral. Effective May 23, 2008, the unique identifier was determined to be the National Provider Identifier (NPI). The Centers for Medicare & Medicaid Services (CMS) has implemented edits on ordering and referring providers when they are required to be identified in Part B, DME, and Part A HHA claims from Medicare providers or suppliers who furnished items or services as a result of orders or referrals.

Below are examples of some of these types of claims:

- Claims from laboratories for ordered tests;
- Claims from imaging centers for ordered imaging procedures; and
- Claims from suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) for ordered DMEPOS.

Only physicians and certain types of non-physician practitioners are eligible to order or refer items or services for Medicare beneficiaries. They are as follows:

- Physicians (doctor of medicine or osteopathy, doctor of dental medicine, doctor of dental surgery, doctor of podiatric medicine, doctor of optometry, optometrists may only order and refer DMEPOS products/services and laboratory and X-Ray services payable under Medicare Part B.)
- Physician Assistants,
- Clinical Nurse Specialists,
- Nurse Practitioners,
- Clinical Psychologists,
- Interns, Residents, and Fellows,
- Certified Nurse Midwives, and
- Clinical Social Workers.

CMS emphasizes that generally Medicare will only reimburse for specific items or services when those items or services are ordered or referred by providers or suppliers authorized by Medicare statute and regulation to do so. Claims that a billing provider or supplier submits in which the ordering/referring provider or supplier is not authorized by statute and regulation will be denied as a non-covered service. The denial will be based on the fact that neither statute nor regulation allows coverage of certain services when ordered or referred by the identified supplier or provider specialty.

CMS would like to highlight the following limitations:

- Chiropractors are not eligible to order or refer supplies or services for Medicare beneficiaries. All services ordered or referred by a chiropractor will be denied.

- Home Health Agency (HHA) services may only be ordered or referred by a Doctor of Medicine (M.D.), Doctor of Osteopathy (D.O.), or Doctor of Podiatric Medicine (DPM). Claims for HHA services ordered by any other practitioner specialty will be denied.
- Optometrists may only order and refer DMEPOS products/services, and laboratory and X-Ray services payable under Medicare Part B.

Questions and Answers Relating to the Edits

1. What are the ordering and referring edits?

The edits will determine if the Ordering/Referring Provider (when required to be identified in Part B, DME, and Part A HHA claims) (1) has a current Medicare enrollment record and contains a valid National Provider Identifier (NPI) (the name and NPI must match), and (2) is of a provider type that is eligible to order or refer for Medicare beneficiaries (see list above).

2. Why did Medicare implement these edits?

These edits help protect Medicare beneficiaries and the integrity of the Medicare program.

3. How and when will these edits be implemented?

These edits were implemented in two phases:

Phase 1 -Informational messaging: Began October 5, 2009, to alert the billing provider that the identification of the ordering/referring provider is missing, incomplete, or invalid, or that the ordering/referring provider is not eligible to order or refer. The informational message on an adjustment claim that did not pass the edits indicated the claim/service lacked information that was needed for adjudication. The informational messages used are identified below:

For Part B providers and suppliers who submit claims to carriers:

N264	Missing/incomplete/invalid ordering provider name
N265	Missing/incomplete/invalid ordering provider primary identifier

For adjusted claims, the Claims Adjustment Reason Code (CARC) code 16 (Claim/service lacks information which is needed for adjudication.) is used.

DME suppliers who submit claims to carriers (applicable to 5010 edits):

N544	Alert: Although this was paid, you have billed with a referring/ordering provider that does not match our system record. Unless, corrected, this will not be paid in the future

For Part A HHA providers who order and refer, the claims system initially processed the claim and added the following remark message:

N272	Missing/incomplete/invalid other payer attending provider identifier

For adjusted claims the CARC code 16 and/or the RARC code N272 was used.

CMS has taken actions to reduce the number of informational messages.

In December 2009, CMS added the NPIs to more than 200,000 PECOS enrollment records of physicians and non-physician practitioners who are eligible to order and refer but who had not updated their PECOS enrollment records with their NPIs.[1]

On January 28, 2010, CMS made available to the public, via the Downloads section of the "Ordering Referring Report" page on the Medicare provider/supplier enrollment website, a file containing the NPIs and the names of physicians and non-physician practitioners who have current enrollment records in PECOS and are of a type/specialty that is eligible to order and refer. The file, called the Ordering Referring Report, lists, in alphabetical order based on last name, the NPI and the name (last name, first name) of the physician or non-physician practitioner. To keep the available information up to date, CMS will replace the Report on a weekly basis. At any given time, only one Report (the most current) will be available for downloading. To learn more about the Report and to download it, go to http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html; click on "Ordering & Referring Information" (on the left). Information about the Report will be displayed.

Phase 2: Effective May 1, 2013, 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. Below are the denial edits for Part B providers and suppliers who submit claims to carriers and/or MACs, including DME MACs:

254D	Referring/Ordering Provider Not Allowed To Refer
255D	Referring/Ordering Provider Mismatch
289D	Referring/Ordering Provider NPI Required

CARC code 16 and/or the RARC code N264 and N265 shall be used for denied or adjusted claims.

[1] NPIs were added only when the matching criteria verified the NPI.

Below are the denial edits for Part A HHA providers who submit claims:

37236 This reason code will assign when:	• The statement "From" date on the claim is on or after the date the phase 2 edits are turned on • The type of bill is '32' or '33' • Covered charges or provider reimbursement is greater than zero but the attending physician NPI on the claim is not present in the eligible attending physician file from PECOS or the attending physician NPI on the claim is present in the eligible attending physician files from PECOS but the name does not match the NPI record in the eligible attending physician files from EPCOS or the specialty code is not a valid eligible code
37237 This reason code will assign when:	• The statement "From" date on the claim is on or after the date the phase 2 edits are turned on • The type of bill is '32' or '33' • The type of bill frequency code is '7' or 'F-P' • Covered charges or provider reimbursement is greater than zero but the attending physician NPI on the claim is not present in the eligible attending physician file from PECOS or the attending physician NPI on the claims is present in the eligible attending physician files from PECOS but the name does not match the NPI record in the eligible attending physician files from PECOS or the specialty code is not a valid eligible code

Effect of Edits on Providers

I order and refer. How will I know if I need to take any sort of action with respect to these two edits?

In order for the claim from the billing provider (the provider who furnished the item or service) to be paid by Medicare for furnishing the item or service that you ordered or referred, you, the ordering/referring provider, need to ensure that:

a. You have a current Medicare enrollment record.

- If you are not sure you are enrolled in Medicare, you may:
  - i. Check the Ordering Referring Report and if you are on that report, you have a current enrollment record in Medicare and it contains your NPI;
  - ii. Contact your designated Medicare enrollment contractor and ask if you have an enrollment record in Medicare and it contains the NPI; or

iii. Use Internet-based PECOS to look for your Medicare enrollment record (if no record is displayed, you do not have an enrollment record in Medicare).
iv. If you choose iii, please read the information on the Medicare provider/supplier enrollment web page about Internet-based PECOS before you begin.

b. If you do not have an enrollment record in Medicare.

- You need to submit either an electronic application through the use of internet-based PECOS or a paper enrollment application to Medicare.

i. For paper applications - fill it out, sign and date it, and mail it, along with any required supporting paper documentation, to your designated Medicare enrollment contractor.
ii. For electronic applications – complete the online submittal process and either e-sign or mail a printed, signed, and dated Certification Statement and digitally submit any required supporting paper documentation to your designated Medicare enrollment contractor.
iii. In either case, the designated enrollment contractor cannot begin working on your application until it has received the signed and dated Certification Statement.
iv. If you will be using Internet-based PECOS, please visit the Medicare provider/supplier enrollment web page to learn more about the web-based system before you attempt to use it. Go to http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html, click on "Internet-based PECOS" on the left-hand side, and read the information that has been posted there. Download and read the documents in the Downloads Section on that page that relate to physicians and non-physician practitioners. A link to Internet-based PECOS is included on that web page.
v. If you order or refer items or services for Medicare beneficiaries and you do not have a Medicare enrollment record, you need to submit an enrollment application to Medicare. You can do this using Internet-based PECOS or by completing the paper enrollment application (CMS-855O). Enrollment applications are available via internet-based PECOS or .pdf for downloading from the CMS forms page (http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/index.html).

c. You are an opt-out physician and would like to order and refer services. What should you do?

If you are a physician who has opted out of Medicare, you may order items or services for Medicare beneficiaries by submitting an opt-out affidavit to a Medicare contractor within your specific jurisdiction. Your opt-out information must be current (an affidavit must be completed every 2 years, and the NPI is required on the affidavit).

d. You are of a type/specialty that can order or refer items or services for Medicare beneficiaries.
When you enrolled in Medicare, you indicated your Medicare specialty. Any physician specialty (Chiropractors are excluded) and only the non-physician practitioner specialties listed above in this article are eligible to order or refer in the Medicare program.

e. I bill Medicare for items and services that were ordered or referred. How can I be sure that my claims for these items and services will pass the Ordering/Referring Provider edits?

- You need to ensure that the physicians and non-physician practitioners from whom you accept orders and referrals have current Medicare enrollment records and are of a type/specialty that is eligible to order or refer in the Medicare program. If you are not sure that the physician or non-physician practitioner who is ordering or referring items or services meets those criteria, it is recommended that you check the Ordering Referring Report described earlier in this article.
- Ensure you are correctly spelling the Ordering/Referring Provider's name.
- If you furnished items or services from an order or referral from someone on the Ordering Referring Report, your claim should pass the Ordering/Referring Provider edits.
- The Ordering Referring Report will be replaced weekly to ensure it is current. It is possible that you may receive an order or a referral from a physician or non-physician practitioner who is not listed in the Ordering Referring Report but who may be listed on the next Report.

f. Make sure your claims are properly completed.

- Do not use "nicknames" on the claim, as their use could cause the claim to fail the edits.
- Do not enter a credential (e.g., "Dr.") in a name field.
- On paper claims (CMS-1500), in item 17, you should enter the Ordering/Referring Provider's first name first, and last name second (e.g., John Smith).
- Ensure that the name and the NPI you enter for the Ordering/Referring Provider belong to a physician or non-physician practitioner and not to an organization, such as a group practice that employs the physician or non-physician practitioner who generated the order or referral.
- Make sure that the qualifier in the electronic claim (X12N 837P 4010A1) 2310A NM102 loop is a 1 (person). Organizations (qualifier 2) cannot order and refer.

If there are additional questions about the informational messages, Billing Providers should contact their local carrier, A/B MAC, or DME MAC.

Billing Providers should be aware that claims that are denied because they failed the Ordering/Referring Provider would not expose the Medicare beneficiary to liability. Therefore, an Advance Beneficiary Notice is not appropriate.

g. What if my claim is denied inappropriately?

If your claim did not initially pass the Ordering/Referring provider edits, you may file an appeal through the standard claims appeals process.

Additional Guidance

1. Terminology: Part B claims use the term "ordering/referring provider" to denote the person who ordered, referred, or certified an item or service reported in that claim. The final rule uses technically

correct terms: 1) a provider "orders" non-physician items or services for the beneficiary, such as DMEPOS, clinical laboratory services, or imaging services and 2) a provider "certifies" home health services to a beneficiary. The terms "ordered" "referred" and "certified" are often used interchangeably within the health care industry. Since it would be cumbersome to be technically correct, CMS will continue to use the term "ordered/referred" in materials directed to a broad provider audience.

2. Orders or referrals by interns or residents: The IFC mandated that all interns and residents who order and refer specify the name and NPI of a teaching physician (i.e., the name and NPI of the teaching physician would have been required on the claim for service(s)). The final rule states that State-licensed residents may enroll to order and/or refer and may be listed on claims. Claims for covered items and services from un-licensed interns and residents must still specify the name and NPI of the teaching physician. However, if States provide provisional licenses or otherwise permit residents to order and refer services, CMS will allow interns and residents to enroll to order and refer, consistent with State law.

3. Orders or referrals by physicians and non-physician practitioners who are of a type/specialty that is eligible to order and refer who work for the Department of Veterans Affairs (DVA), the Public Health Service (PHS), or the Department of Defense(DoD)/Tricare: These physicians and non-physician practitioners will need to enroll in Medicare in order to continue to order or refer items or services for Medicare beneficiaries. They may do so by filling out the paper CMS-855O or they may use Internet-based PECOS. They will not be submitting claims to Medicare for services they furnish to Medicare beneficiaries.

4. Orders or referrals by dentists: Most dental services are not covered by Medicare; therefore, most dentists do not enroll in Medicare. Dentists are a specialty that is eligible to order and refer items or services for Medicare beneficiaries (e.g., to send specimens to a laboratory for testing). To do so, they must be enrolled in Medicare. They may enroll by filling out the paper CMS-855O or they may use Internet-based PECOS. They will not be submitting claims to Medicare for services they furnish to Medicare beneficiaries.

Additional Information

For more information about the Medicare enrollment process, visit http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html or contact the designated Medicare contractor for your State. Medicare provider enrollment contact information for each State can be found at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/Contact_list.pdf on the CMS website.

The Medicare Learning Network® (MLN) fact sheet titled, "Medicare Enrollment Guidelines for Ordering/Referring Provider," is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-

MLN/MLNProducts/downloads/MedEnroll_OrderReferProv_factSheet_ICN906223.pdf on the CMS website.

Note: You must obtain a National Provider Identifier (NPI) prior to enrolling in Medicare. Your NPI is a required field on your enrollment application. Applying for the NPI is a separate process from Medicare enrollment. To obtain an NPI, you may apply online at https://nppes.cms.hhs.gov/NPPES/Welcome.do on the CMS website. For more information about NPI enumeration, visit http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvIdentStand/index.html on the CMS website.

MLN Matters® Article MM7097, "Eligible Physicians and Non-Physician Practitioners Who Need to Enroll in the Medicare Program for the Sole Purpose of Ordering and Referring Items and Services for Medicare Beneficiaries," is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7097.pdf on the CMS website.

MLN Matters® Article MM6417, "Expansion of the Current Scope of Editing for Ordering/Referring Providers for Claims Processed by Medicare Carriers and Part B Medicare Administrative Contractors (MACs)," is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6417.pdf on the CMS website.

MLN Matters® Article MM6421, "Expansion of the Current Scope of Editing for Ordering/Referring Providers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers' Claims Processed by Durable Medical Equipment Medicare Administrative Contractors (DME MACs)," is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6421.pdf on the CMS website;

MLN Matters® Article MM6129, "New Requirement for Ordering/Referring Information on Ambulatory Surgical Center (ASC) Claims for Diagnostic Services," is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6129.pdf on the CMS website.

MLN Matters Article, MM6856, "Expansion of the Current Scope for Attending Physician Providers for free-standing and provider-based Home Health Agency (HHA) Claims processed by Medicare Regional Home Health Intermediaries (RHHIs), is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6856.pdf on the CMS website.

If you have questions, please contact your Medicare Carrier, Part A/B MAC, or DME MAC, at their toll-free numbers, which may be found at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html on the CMS website.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC., 1601 N. Tucson Boulevard, Suite 9 Tucson, AZ 85716, and, ALLIANCE FOR NATURAL HEALTH USA, 1350 Connecticut Avenue, NW, 5th Floor Washington, DC 20036, Plaintiffs, v. KATHLEEN G. SEBELIUS, SECRETARY OF HEALTH & HUMAN SERVICES, 200 Independence Avenue, SW Washington, DC 20201, *in her official capacity,* MICHAEL J. ASTRUE, COMMISSIONER, SOCIAL SECURITY ADMINISTRATION, 6401 Security Boulevard Baltimore, MD 21235, *in his official capacity,* TIMOTHY F. GEITHNER, SECRETARY OF THE TREASURY, 1500 Pennsylvania Avenue, NW, Washington, DC 20220, *in his official capacity,* and, UNITED STATES OF AMERICA, Defendants.	Civil Action No. 10-0499-RJL

SECOND AMENDED AND SUPPLEMENTAL
COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs Association of American Physicians and Surgeons, Inc. ("AAPS") and Alliance for Natural Health USA ("ANH-USA" and, collectively with AAPS, the "Plaintiffs") seek declaratory and injunctive relief based on the following allegations:

NATURE OF THE ACTION

1. AAPS and ANH-USA bring this action under the Medicare Act ("Medicare"), the Social Security Act ("Social Security"), the Administrative Procedure Act ("APA"), various restrictions on federal action in Article I of the U.S. Constitution, and the Fifth, Ninth, and Tenth Amendments to enjoin Defendants Sebelius, Astrue, and Geithner (collectively, the "Officer Defendants") and Defendant United States (collectively with the Officer Defendants, the "Defendants") from intruding into AAPS and ANH-USA members' medical and economic decisions that the Constitution and federal law reserve to the several states or to the people.

2. As set forth more fully in Paragraph 118, AAPS and ANH-USA seek the following injunctive and declaratory relief:

(a) Vacate the Social Security Program Operations Manual System ("POMS") on (a) *Waiver of Hospital Insurance Entitlement by Monthly Beneficiary,* POMS HI 00801.002, (b) *Withdrawal Considerations,* POMS HI 00801.034, and (c) *Withdrawal Considerations When Hospital Insurance is Involved,* POMS GN 00206.020, (i) as promulgated without the required notice-and-comment rulemaking, and (ii) for mandating (without authority) that AAPS and ANH-USA members and their patients participate in Medicare Part A as a condition to receiving Social Security benefits;

(b) Enjoin the re-promulgation of regulations similar to POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 as *ultra vires;*

(c) Enjoin and declare unlawful the Patient Protection & Affordable Care Act ("PPACA") mandate that businesses with 50 or more fulltime employees and individuals purchase health insurance or pay penalties (collectively, "PPACA insurance mandates") as outside the authority of Congress to enact and the federal government to enforce;

(d) Enjoin and declare unlawful the promulgation and enforcement of federal standards for health insurance as outside the authority of Congress to enact and the federal government to enforce;

(e) Enjoin and declare unlawful the enforcement of PPACA in its entirety because it lacks a severability clause and cannot be funded without the insurance mandates on businesses of 50 or more fulltime employees and individuals;

(f) Vacate the provisions of the Center for Medicare and Medicaid Services ("CMS") Manual System and the accompanying Charge Request 6417 and 6421 (collectively, "CR6417/6421") and Department of Health & Human Services ("HHS") Interim Final Rule with Comment Period ("IFC"), 75 Fed. Reg. 24,437 (2010), that purport to require physicians and other eligible professionals to have an HHS-approved enrollment or opt-out record in the Provider Enrollment, Chain and Ownership System ("PECOS") in order to refer under Medicare Part B, as *ultra vires* HHS authority under Medicare and adopted without APA's required notice and comment;

(g) Permanently and preliminarily enjoin HHS from requiring non-Medicare providers to enroll with Medicare, to appear in PECOS, or to obtain a National Provider Identifier ("NPI") absent another criterion – *e.g.,* engaging in HIPAA transactions or e-prescribing – that independently requires an NPI;

(h) Declare that nothing in Medicare or any other provision of law requires physicians to opt-out pursuant to 42 U.S.C. §1395(b)'s statutory safe harbor in order lawfully to treat Medicare beneficiaries for payment outside Medicare; and

(i) Order Defendants Sebelius and Astrue to submit an accounting on the solvency of Medicare and Social Security, respectively, to this Court.

The requested relief is necessary to preserve individual liberty from *ultra vires* federal dictates and to preserve individual liberty and choice under Medicare and Social Security.

PARTIES

3. Plaintiff AAPS is a not-for-profit membership organization incorporated under the laws of Indiana and headquartered in Tucson, Arizona. AAPS' members include thousands of physicians nationwide in all practices and specialties, many in small practices. AAPS was founded in 1943 to preserve the practice of private medicine, ethical medicine, and the patient-physician relationship. As set forth more fully in Paragraphs 13-34, AAPS members include without limitation medical caregivers – who also are consumers of medical care – as well as medical employers and owners and managers of medical businesses subject to the PPACA insurance mandates. AAPS members practice and reside in most (if not all) states in the Union, including without limitation the District of Columbia, Virginia, Idaho, Arizona, Georgia, Missouri, and Louisiana.

4. Plaintiff ANH-USA is a not-for-profit membership organization headquartered in the District of Columbia. ANH-USA was founded to promote sustainable health and freedom of choice in healthcare and to shift the medical paradigm from an exclusive focus on surgery, drugs, and other conventional techniques to an "integrative" approach incorporating food, dietary supplements, and lifestyle changes. Traditional "preventative" medicine is too often defined as taking more and more drugs at an earlier and earlier age, even in childhood. By contrast, ANH-USA's concept of sustainable health is real preventative medicine and dramatically reduces healthcare costs through diet, dietary supplements, exercise, and the avoidance of toxins. As set forth more fully in Paragraphs 13-34, ANH-USA members include without limitation medical caregivers – who also are consumers of medical care – as well as medical employers and owners

and managers of medical businesses, consumers of medical care who are not medical professionals, and manufacturers and marketers of dietary supplements subject to PPACA's insurance mandates. ANH-USA members practice or reside in most (if not all) states in the Union, including without limitation the District of Columbia, Virginia, Idaho, Arizona, Georgia, Missouri, and Louisiana.

5. Defendant Sebelius is the Secretary of Health and Human Services and the head of HHS, an executive department of the United States government.

6. Defendant Astrue is the Commissioner of the Social Security Administration ("SSA"), an independent agency within the executive branch of the United States government.

7. Defendant Geithner is the Secretary of the Treasury and the head of the Department of the Treasury, an executive department of the United States government.

8. Defendant United States is the federal sovereign. In forming the United States, the several states delegated to it only such authorities as are enumerated in the Constitution, with the balance reserved to themselves as individual State sovereigns or to the people.

JURISDICTION AND VENUE

9. This action arises out of Defendants' ongoing violations of Medicare, Social Security, the APA, various clauses in Article I of the U.S. Constitution, and the Fifth, Ninth, and Tenth Amendments. As such, this action raises federal questions over which this Court has jurisdiction pursuant to: 28 U.S.C. §1331; the Acts of March 3, 1863, 12 Stat. 762, and June 25, 1936, 49 Stat. 1921 (as amended); D.C. Code §11-501; and this Court's equity jurisdiction.

10. With certain exceptions applicable here, the Anti-Injunction Act, 26 U.S.C. §7421(a), denies federal district courts jurisdiction over pre-collection suits to enjoin the assessment or collection of federal taxes. The Declaratory Judgment Act includes similar

restrictions on declaratory relief under that Act, 28 U.S.C. §2201(a), but neither addresses declaratory relief under other acts nor denies jurisdiction for declaratory relief generally.

11. Pursuant to 28 U.S.C. §1391(e), venue is proper in the District of Columbia, where plaintiff ANH-USA resides and where defendants Sebelius and Geithner maintain offices. Pursuant to 5 U.S.C. §703, venue is proper in any court of competent jurisdiction.

12. An actual and justiciable controversy exists between Plaintiffs and Defendants.

PLAINTIFFS' STANDING

13. AAPS members include without limitation: practicing physicians and other medical caregivers; retired physicians and other retired medical caregivers on Social Security; and physicians and others who own or manage medical businesses subject to PPACA's insurance mandates. All individual AAPS members are consumers of medical services in addition to any capacity that they have as medical caregivers.

14. ANH-USA members include without limitation: practicing physicians and other medical caregivers; retired physicians, other retired medical caregivers, and retired consumers on Social Security; consumers of medical services who prefer to maintain high-deductible catastrophic medical insurance and procure their non-catastrophic medical care through the "integrative" approach advocated by ANH-USA and practiced by its members; and physicians and others who own or manage medical businesses subject to PPACA's insurance mandates, as well as dietary-supplement companies subject to PPACA's insurance mandates. All individual ANH-USA members are consumers of medical services in addition to any capacity that they have as medical caregivers.

15. To the extent that they relate to third parties (as distinct from AAPS, ANH-USA, and their members), the allegations of injury (Paragraphs 16-34) are made on the basis of

information and belief, formed after reasonable inquiry, which likely could be proved conclusively after a reasonable opportunity for discovery.

Ongoing Injuries from Compelled Participation in Medicare Part A

16. Some AAPS and ANH-USA members who are retired and receive Social Security would like to cease participation in Medicare Part A, but POMS HI 00801.002, POMS HI 00801.034, POMS GN 00206.020 prevent their doing so without losing eligibility for Social Security. These members do not wish to lose eligibility for Social Security.

17. AAPS and ANH-USA members who are practicing physicians and other medical caregivers who have opted out of Medicare, or never enrolled in Medicare, and own, operate, or practice at facilities outside Medicare Part A would like to compete with medical caregivers within Medicare and facilities within Medicare Part A in serving retired Americans, but the retired patients have greater difficulty retaining such AAPS and ANH-USA members because POMS HI 00801.002, POMS HI 00801.034, POMS GN 00206.020 compel their participation in Medicare Part A. As such, POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 give an advantage to these competitors vis-à-vis AAPS and ANH-USA members who have opted out of Medicare or never enrolled in Medicare.

18. Many patients (including both existing patients and prospective patients of AAPS and ANH-USA members) prefer to avoid Medicare Part A specifically and Medicare generally because the quality of care and treatment is better outside of these Medicare programs. Similarly, many physicians (including AAPS and ANH-USA members) prefer to operate outside Medicare Part A specifically and Medicare generally to avoid federal restrictions on the practice of medicine.

Ongoing Injuries from Health Insurance Legislation

19. AAPS and ANH-USA members include without limitation the owners of businesses with more than 50 fulltime employees, who are subject to a new PPACA requirement to purchase health insurance for employees or else pay a penalty, and the imposition of this requirement reduces the present value of such businesses. AAPS and ANH-USA members include without limitation owners of such businesses that currently use high-deductible catastrophic medical insurance coupled with health-savings accounts for employees. This approach does not comply with PPACA's health-insurance controls. The 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.

20. AAPS and ANH-USA members include without limitation physicians and other medical care providers who engage in economically viable "cash practices" that operate outside of insurance reimbursement and outside of Medicare. In many instances, these patients maintained high-deductible catastrophic medical insurance and pay for AAPS and ANH-USA members' services either from cash or from medical savings accounts. Because PPACA will increase insurance premiums considerably, thereby reducing these patients' available resources for paying directly for these services, PPACA will weaken these patients' ability to procure these services from AAPS and ANH-USA members and instead advantage AAPS and ANH-USA members' competitors whose services are covered by PPACA-eligible insurance regimes and Medicare.

21. PPACA's insurance mandates will render the "cash practice" business model of AAPS and ANH-USA members economically non-viable, such that these members will need to go out of business or invest in a different form of practice.

22. AAPS and ANH-USA members that own or are entities with 50 or more fulltime employees employ numerous employees who are single or married to spouses who do not work (and thus cannot rely on a spouse's employer-provided health insurance) and who earn less than 400 percent of the federal poverty level.

23. The current health insurance premiums for AAPS and ANH-USA members will rise or have risen, based on PPACA's requirements, including without limitation (a) prohibiting insurers from excluding pre-existing conditions (children immediately, and everyone in 2014), (b) prohibiting insurers from setting lifetime limits, (c) requiring insurers to cover preventive health services and to allow children to remain on their parents' plans through age 26, and (d) restricting insurers' use of annual limits on coverage.

24. In Massachusetts, insurance premiums have risen under the state program on which Congress based PPACA. PPACA's new insurance mandates forces up the insurance costs for most Americans, including most AAPS and ANH-USA members.

Ongoing Injuries from PECOS- and NPI-Related Requirements

25. The ability to refer Medicare-eligible patients for Medicare items and services enables non-enrolled members of AAPS and ANH-USA to treat patients who desire to pay directly for services from those members without relinquishing their entitlement to Medicare reimbursement for services or consultations referred by those members, but provided by a Medicare-enrolled provider or facility. Eliminating the ability to refer for Medicare items and services would increase the costs associated with obtaining services from non-Medicare members of AAPS and ANH-USA and would put those members at an economic and competitive disadvantage vis-à-vis Medicare providers.

26. Enrolling or registering in Medicare or PECOS and obtaining an NPI require up-front and ongoing paperwork and monitoring on the part of AAPS and ANH-USA members who do not wish to participate in Medicare. That paperwork and monitoring imposes non-trivial costs on these members.

27. Non-enrolled AAPS and ANH-USA members expect to lose significant portions of their practices due to the competitive disadvantage of losing the ability to refer for items and service under Medicare Part B. Significant percentages of patients will leave these AAPS and ANH-USA members if the patients cannot get reimbursed for such items and services.

28. The statutory safe harbor in 42 U.S.C. §1395(b) for opting out of Medicare is more restrictive than Medicare itself requires to avoid Medicare requirements. Non-enrolled physicians need only notify prospective patients of their non-enrollment in accordance with any general laws such as those on advertising and trade practices.

29. In addition to the foregoing economic harms to the practices of non-enrolled AAPS and ANH-USA members, CR6417/6421 and the IFC also injure AAPS and ANH-USA members' patients (as well as the AAPS and ANH-USA members in their capacity as patients) by limiting access to non-Medicare providers and thereby limiting the quality and choice in medical treatment available to those patients.

Physicians' Third-Party Standing to Assert Patients' Rights

30. In addition to the concrete, first-party injuries alleged in Paragraphs 16-29, AAPS and ANH-USA members who are physicians or vendors also have standing to protect the patient-physician and vendor-customer relationship both under principles of third-party standing and from their capacity as "vendors" under this Circuit's vendor-standing decisions.

Procedural Injuries

31. As explained in COUNT I and COUNT IV, Defendants have denied AAPS, ANH-USA, and their members the opportunity to participate in a rulemaking that the APA required Defendants to hold before adopting legislative rules that affect the interests of AAPS and ANH-USA members. If the Court grants the procedural relief requested in Paragraph 118, and Defendants initiate rulemakings on the linkage of Social Security benefits with Medicare Part A and the CR6417/6421 and IFC requirement to register with PECOS, AAPS, ANH-USA, and their members would comment in that rulemaking proceeding to protect their interests and those of their members. By taking the complained-of actions without the rulemaking proceedings required by the APA, Defendants denied the procedural rights conferred by Congress on AAPS, ANH-USA, and their members.

32. In addition to the procedural injuries in Paragraph 31, AAPS and ANH-USA members suffer concrete injuries, *see* Paragraphs 16 to 30, which fall within the zone of interests of the relevant statutes, *see* Paragraph 33. Accordingly, Plaintiffs have procedural standing, which relaxes the showings required for immediacy and redressability for substantive standing.

Zone of Interests

33. AAPS and ANH-USA and their members meet the prudential zone-of-interests test because the rights that AAPS and ANH-USA assert are within the relevant statutes' intended purposes (*e.g.,* individual and provider autonomy not to enroll or to opt out of Medicare; freedom from federal dictates outside the Constitution's authorization; state Freedom of Choice in Health Care Acts; and the APA's assurance of an opportunity to comment before agencies legislate via interpretation).

Associational Standing

34. AAPS and ANH-USA meet the requirements for associational standing because (a) each organization has members with standing, (b) the missions of AAPS and ANH-USA include autonomy for their members' medical practices and their members' own medical care, including the economic and liberty interests in both medical practice and medical care, and (c) nothing requires that AAPS or ANH-USA members participate as party plaintiffs.

RIPENESS

35. AAPS and ANH-USA members have ripe claims against the Defendants because their claims are sufficiently immediate for purposes of constitutional standing as set forth in Paragraphs 16-32, their claims are purely legal and thus fit for judicial review now without the need for future facts or implementation details, and they will suffer immediate and irreparable hardship if the Court defers review as set forth in Paragraphs 42-46.

36. The Defendants have no interest in deferring review and will suffer no hardship from immediate review. To the contrary, before the Defendants invest significant effort in implementing PPACA, they have a pressing interest in determining PPACA's validity.

37. With respect to the procedural claims, the Defendants' failure to provide the required notice-and-comment rulemaking are ripe for review and will not become more ripe with the passage of time.

SOVEREIGN IMMUNITY

38. Defendant United States has waived its sovereign immunity for actions against itself, its instrumentalities, and its officers for non-monetary injunctive and declaratory relief and for the entry of judgments and decrees against the United States in such actions. The United States has waived sovereign immunity for this action and for the relief sought in Paragraph 118.

39. With the Officer Defendants specifically named in their official capacities, sovereign immunity does not shield the Officer Defendants' *ultra vires* actions.

40. This Court possesses equity jurisdiction over federal officers derived both from the Court's enabling legislation and from the historic equity jurisdiction of Maryland courts over Maryland officers, prior to Maryland's ceding the District of Columbia as a federal enclave.

41. As a matter of historical fact, at the time that the states ratified the U.S. Constitution, the equitable, judge-made doctrine that allows use of the sovereign's courts in the name of the sovereign to order the sovereign's officers to account for their conduct (*i.e.,* the rule of law) was as least as firmly established and as much a part of the legal system as the judge-made doctrine of federal sovereign immunity. No act of Congress limits this Court's equity jurisdiction for an action against Defendants' *ultra vires* acts.

IRREPARABLE HARM AND INADEQUATE ALTERNATE REMEDIES

42. Plaintiffs' action is not barred by the APA's "adequate-remedy bar," 5 U.S.C. §704, or analogous equitable doctrines because no other provision of law provides an adequate alternate legal remedy for the injuries to AAPS's and ANH-USA's members.

43. Under equity jurisdiction, alternate legal actions that arise after the filing of an equity action do not displace the previously filed equity action, even if the subsequent alternate remedy is an adequate remedy.

44. Administrative remedies are not even available for AAPS and ANH-USA members who are practicing physicians, other medical caregivers, or vendors that have opted out of Medicare (or never enrolled in Medicare) and wish to enter professional relationships with retirees, but the POMS's requiring retirees to forgo Social Security as the cost of opting out of Medicare Part A interferes with the ability of such practicing AAPS and ANH-USA member

physicians, other medical caregivers, and vendors that have opted out of – or otherwise do not participate in – Medicare. The retirees do not wish to lose their eligibility for Social Security (and so continue to participate in Medicare Part A), and the AAPS and ANH-USA member physicians, other medical caregivers, and vendors could not initiate an administrative challenge to the retirees' benefits in any event.

45. If the penalties associated with PPACA's insurance mandates are civil penalties and not taxes, the law does not provide an alternate remedy to recoup the penalty.

46. With respect to payments under PPACA's individual insurance mandate, AAPS and ANH-USA members who are physicians lack a remedy to recoup their patients' and prospective patients' "tax" (if the individual mandate's penalty is a tax). Because these AAPS and ANH-USA members lack an alternate remedy, the Anti-Injunction Act does not preclude their challenging PPACA's individual mandate.

47. Because this Court has jurisdiction as a threshold matter, the Declaratory Judgment Act, 28 U.S.C. §§2201-2202, provides this Court the power to "declare the rights and other legal relations of any interested party…, whether or not further relief is or could be sought." 28 U.S.C. §2201; *accord* FED. R. CIV. P. 57 advisory committee note ("the fact that another remedy would be equally effective affords no ground for declining declaratory relief").

48. To the extent that Plaintiffs seek relief with respect to federal taxes, this Court's equity jurisdiction provides the basis for declaratory relief, even if the Declaratory Judgment Act does not. Nothing in the 1935 amendments to the Declaratory Judgment Act or any prior or subsequent act of Congress limited this Court's equity jurisdiction for declaratory relief related to federal taxes.

49. A plaintiff's irreparable injury and lack of an adequate legal remedy justify injunctive relief. In addition to the declaratory relief requested in Paragraph 118, Plaintiffs are entitled to injunctive relief because imminent and ongoing exposure to unlawful federal mandates under PPACA, denial of federal benefits under the POMS, and the imposition of non-compensable PECOS- and NPI-related compliance costs and loss of business constitute irreparable injury. As set forth in Paragraphs 42-46, Plaintiffs lack an adequate alternate legal remedy.

CONSTITUTIONAL, STATUTORY & REGULATORY BACKGROUND

50. The Constitution that created the United States from the several states embodies a form of federalism based on the dual sovereignties of the federal government on the one hand and the state governments on the other.

51. Article I, section 8, provides Congress the authority "to lay and collect taxes, duties, imposts and excises, to pay the debts and provide for the … general welfare," provided that "all duties, imposts and excises shall be uniform throughout the United States." Article I, section 8, also authorizes Congress to "regulate commerce … among the several states" and "[t]o make all laws which shall be necessary and proper for carrying into execution the foregoing powers."

52. Article I, section 2, and the Sixteenth Amendment require that direct taxes "shall be apportioned among the several states … according to their respective numbers," except that Congress may "lay and collect taxes on incomes, from whatever source derived, without apportionment among the several states, and without regard to any census or enumeration." Except as provided by the Sixteenth Amendment with respect to "taxes on income," Article I,

section 9, provides that "[n]o capitation, or other direct, tax shall be laid, unless in proportion to the census or enumeration herein before directed to be taken."

53. The Fifth Amendment prohibits the taking of private property for public use without just compensation and includes an equal-protection component against federal discrimination that parallels the Equal Protection Clause of the Fourteenth Amendment.

54. The Ninth Amendment provides that the "enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people," and the Tenth Amendment reserves to the states or to the people all powers not expressly provided to the federal government.

Medicare and the Social Security Act

55. Medicare Act is codified at 42 USC §§1395 *et seq.,* and Social Security is codified at 42 USC §§401 *et seq.* Together, these two statutes provide medical care (Medicare) and a pension (Social Security) for retired Americans and represent the principal government safety net for them.

56. Under 42 U.S.C. §1395l(q)(1), requests for payment for Medicare Part B items or services must include unique physician identification numbers for the referring physicians, if the entity submitting the request either knows or has reason to believe there has been a referral by a referring physician.

57. Defendants maintain the POMS, which includes (a) *Waiver of Hospital Insurance Entitlement by Monthly Beneficiary,* POMS HI 00801.002, (b) *Withdrawal Considerations,* POMS HI 00801.034, and (c) *Withdrawal Considerations When Hospital Insurance is Involved,* POMS GN 00206.020.

58. POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 represent Defendants' and SSA's established and considered views on the issue of eligibility for Social Security vis-à-vis participation in Medicare Part A. Because that connection is not present in the regulations or statutes, legal consequences flow from POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 (namely, non-participation in Medicare Part A denies eligibility for Social Security). POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 represent the Defendants "final agency action" on the subject.

Online Registration of "Health Care Providers"

59. The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") adopted the NPI as a standard unique health identifier for health care providers (*i.e.,* any provider of medical or other health services, and any other person or organization that furnishes, bills, or is paid for health care in the normal course of business) that transmit health information in electronic form in connection with a transaction for which HIPAA standards have been adopted.

60. HIPAA requires these "covered health care providers" to obtain an NPI and to use it in all HIPAA transactions. For other "health care providers" (*i.e.,* those that do not transmit information electronically under HIPAA), HIPAA *allows* but does not require obtaining an NPI. Similarly, HHS regulations require using NPIs in certain e-prescribing transactions not governed by HIPAA and require an NPI to qualify for incentive payments associated with e-prescribing.

61. Both before and after HIPAA, Medicare allowed the use of alternate identifying information for providers who referred for items or services under Medicare Part B. Nothing in Medicare or any other provision of law prohibits the continued use of such pre-HIPAA unique identifiers.

Patient Protection and Affordable Care Act

62. On March 23, 2010, PPACA became law after a party-line vote in the Senate and nearly a party-line vote in the House, with 34 Democrats opposing the bill and no Republicans supporting it. PPACA greatly expanded federal control over the medical industry, which represents approximately one sixth of the national economy. The United States has never adopted such major legislation on such a narrow, party-line vote.

63. The majority leadership in both houses of Congress, in coordination with the Executive Branch, exerted unusual control over the drafting of the Senate bill and the reconciliation bill that the House adopted to avoid the ability of members of the Senate to filibuster the final bill. Neither bill was vetted in congressional committees. Instead, the leadership made targeted changes and concessions to ensure support by groups of legislators or individual legislators to enable passage. The United States has never adopted such major legislation via the reconciliation process.

64. PPACA mandates that individuals maintain federally approved insurance or pay a penalty, 26 U.S.C. §5000A, and that "large employers" (*i.e.,* those employing 50 or more fulltime employees) provide federally approved insurance or pay a penalty, 26 U.S.C. §4980H.

65. PPACA prohibits insurers from excluding insureds with pre-existing conditions (children immediately, and everyone in 2014), §2704(a), prohibits insurers from setting lifetime limits, §2711(a)(2), requires insurers to cover preventive health services and to allow children to remain on their parents' plans through age 26, §2714(a), and restricts insurers' use of annual limits on coverage, §2711(a)(2).

66. By design, PPACA's federal criteria for acceptable health insurance subsidize PPACA policy on acceptable insurance terms (*e.g.,* exclusion of pre-existing conditions, annual

and lifetime limits on coverage, and extended coverage) by spreading costs to private parties, without relying on the Spending Clause or the Taxing Power.

67. Because the Democratic congressional majorities and president had campaigned in 2008 *against* raising taxes on those earning less than $250,000 and *against* a Republican proposal to tax health insurance benefits, the Democratic leadership was adamant that the penalties associated with PPACA's insurance mandates are not taxes. PPACA justifies the insurance mandates solely with respect to the Commerce Clause, PPACA identifies various taxes in areas other than the insurance mandates (*e.g.,* excise taxes on tanning salons), and PPACA §§9001-9017 collects PPACA's revenue provisions without listing the penalties associated with the insurance mandates.

68. By forcing up premiums generally for those who are young, solvent, and/or healthy to subsidize lower premiums for those who are elderly, poor, and/or sick, the federal requirement to obtain federally acceptable insurance and the corresponding imposition of criteria for acceptable insurance represents a regulatory taking, without just compensation, in violation of the Fifth Amendment. Alternatively, PPACA's insurance mandates violate the Due Process Clause as compelled contracts, undue burdens on privacy and liberty, and denials of equal protection, and violate the Tenth Amendment by commandeering the people, in violation of their reserved rights.

69. If a tax, the penalties associated with PPACA'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.

70. The Supreme Court has never upheld the ability of Congress to regulate lawful inactivity – here the failure to purchase PPACA-approved health insurance – under either the Commerce Clause or the Taxing Power.

71. A penalty for not securing PPACA-approved health insurance is not an impost, duty, or excise on anything. Instead, a penalty for not securing PPACA-approved health insurance is a capitation or direct tax on a subset of individuals, as opposed to a capitation or direct tax on all individuals.

72. PPACA §6402(a) amended Medicare to require, among other things, that all health care providers eligible for an NPI must include an NPI on claims for payment submitted under Medicare. 42 U.S.C. §1128J(e). Neither PPACA nor any other provision of law requires that providers who merely *refer* for Medicare items or services obtain or use an NPI.

73. Because PPACA's insurance mandates are central to PPACA's economic viability and because PPACA contains no severability clause, Congress intended the entire PPACA to be unenforceable if the employer insurance mandate is held invalid.

Administrative Procedure Act

74. The APA requires executive agencies to conduct notice-and-comment rulemaking when promulgating or amending substantive or legislative rules, unless the agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest and incorporates that finding and a brief statement of reasons in its *Federal Register* notice. 5 U.S.C. §553(b)-(c).

75. Although initial regulatory or statutory interpretations can be exempt from notice-and-comment requirements, 5 U.S.C. §553(b)(A), the APA nonetheless requires agencies to

undergo notice-and-comment rulemaking when amending a prior interpretation or when the purported interpretation in fact creates or destroys new rights or obligations.

IFC Requirement to Enroll or Opt Out via PECOS

76. CMS is the division within HHS that administers the Medicare program and monitors the Medicaid programs offered by each state. CMS maintains its Online Manual System for use by itself and its Medicare partners and contractors to administer CMS programs and to provide operating instructions, policies, and procedures. CMS updates its Online Manual System via "Change Requests."

77. On or about September 28, 2009, CMS issued CR6417/6421 to announce new rules to deny Medicare Part B payments unless ordering and referring physicians were enrolled in PECOS. Although CMS initially announced that the new policy would take effect January 4, 2010, CMS extended the effective date (on or about November 25, 2009) until April 5, 2010, and then (on or about February 17, 2010) until January 3, 2011.

78. In its IFC issued after the filing of the initial complaint in this action, 75 Fed. Reg. 24,448-49, HHS purports to require an NPI and an approved enrollment record or opt-out record in PECOS as a condition for referring items or services under Medicare Part B. HHS elected not to undergo notice-and-comment rulemaking based on the good-cause exception and, in part, on 42 USC §1395hh(b)(1)(B)'s exemption for Medicare rules required to take effect within less than 150 days of the authorizing statute's enactment.

79. In conjunction with the IFC, CMS revised CR6417/6421 to provide that CMS would announce a firm enforcement date coordinated with the IFC's enforcement date.

80. Although some IFC aspects are within 42 USC §1395hh(b)(1)(B)'s 150-day period, requiring Medicare providers to provide an NPI on claims for payment does not because

PPACA requires the rulemaking by January 1, 2011 (*i.e.,* more than 150 days after PPACA's enactment). No provision of law requires HHS to require medical providers to enroll or otherwise appear in PECOS to refer for Medicare items or services.

State Laws on Health Insurance

81. Various states – including without limitation Virginia, Idaho, Arizona, Georgia, Missouri, and Louisiana – have versions of the Freedom of Choice in Health Care Act or similar laws that protect AAPS and ANH-USA members and their patients from PPACA requirements, including without limitation PPACA insurance mandates. In addition, most states – including without limitation Virginia, Idaho, Arizona, Georgia, Missouri, and Louisiana – have laws that regulate the terms and flexibility of what insurers can offer as health insurance. The foregoing state laws confer rights on AAPS and ANH-USA members and their patients.

82. Although duly enacted and constitutionally valid federal laws preempt state laws that expressly or impliedly conflict with federal law, federal laws that exceed the federal government's constitutional powers – such as PPACA generally and its insurance mandates particularly – do not preempt the foregoing state laws or their protections of AAPS and ANH-USA members and their patients

FACTUAL BACKGROUND

83. Although millions of Americans rely on Medicare and Social Security in their retirement planning, both programs are unsustainable in the long run under the status quo because their incoming funds will cease to cover their outgoing obligations. Because it can barely (if at all) afford to continue Medicare and Social Security, the United States cannot afford another major entitlement program like PPACA without first addressing the insolvency of Medicare and Social Security.

84. PPACA's supporters in Congress intentionally and misleadingly claimed that PPACA would reduce the federal deficit by approximately $138 billion over the first ten years, based on scoring from the Congressional Budget Office ("CBO"). With CBO scoring, however, the assumptions that Congress imposes bind CBO, even if the assumptions are not realistic.

85. All informed stakeholders know the limitations of CBO scoring, such as counting ten years of revenues (including approximately $500 billion from Medicare) to pay for six years of PPACA coverage, double counting revenues from other programs such as Social Security (approximately $50 billion) and the Community Living Assistance Services and Supports ("CLASS") Act (approximately $70 billion), and moving related expenses into stand-alone bills solely to avoid including their totals in the PPACA score (*e.g.,* the approximately $210 billion "doc fix" to stop a scheduled 21-percent cut in Medicare payments to doctors).

86. On or about March 17, 2010, Defendant Sebelius published an op-ed piece on the PPACA bill entitled "Patient's plea makes the best case for health care reform," which cited CBO for the proposition that "the president's plan will lower the federal deficit by about $100 billion over the next 10 years." Defendant Sebelius knew the foregoing limitations of CBO's analysis but intentionally did not disclose them in her op-ed with the intent to sway her readers.

87. On or about March 24, 2010, CBO reported that Social Security would pay out more than it took in revenue for 2010, something that has not occurred in decades and that SSA had not predicted to occur until 2016. The current economic downturn exacerbated Social Security's balance sheet by providing less income from employment taxes and increased claims for eligibility because of the sluggish economy.

88. In the most recent trust fund report released in early August, 2010, the Officer Defendants (who, along with the Secretary of Labor, are Medicare and Social Security trustees)

issued a self-serving report on the Medicare and Social Security trust funds. These reports rely on the same budget gimmickry that the Officer Defendants and their legislative allies used to claim that PPACA would lower the federal deficit.

89. The majorities in both houses of Congress also wish to maintain that storyline, regardless of actual solvency. The statutory reports to Congress are inadequate to protect the interests of those who rely on Medicare and Social Security, including AAPS and ANH-USA members and their patients.

COUNT I
POMS'S TYING OF MEDICARE AND SOCIAL SECURITY

90. Plaintiff incorporates Paragraphs 1-89 and 94-118 as if fully set forth herein.

91. POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 require the acceptance of Medicare Part A as a condition to receipt of Social Security benefits. That requirement is *ultra vires* Medicare, Social Security, and the implementing regulations because the statutes allow participating in Social Security without participating in Medicare Part A.

92. POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 are substantive rules, which therefore required notice-and-comment rulemaking as the means of promulgating them. Defendants did not conduct notice-and-comment rulemaking to implement POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020.

93. For the foregoing reasons, the issuance of POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 was arbitrary, capricious, an abuse of discretion, without observance of procedure required by law, not otherwise in accordance with the law, in excess of authority granted by law, *ultra vires,* and without observance of procedure required by law.

COUNT II
UNLAWFUL EMPLOYER INSURANCE MANDATE

94. Plaintiff incorporates Paragraphs 1-93 and 97-118 as if fully set forth herein.

95. Nothing in Article I or elsewhere in the U.S. Constitution authorizes the federal government to require private employers, with no direct connection to, or contract with, the federal government to purchase federally approved health insurance for employees or pay a penalty, and nothing in Article I or elsewhere in the U.S. Constitution authorizes the federal government to set the acceptable terms of health insurance.

96. For the foregoing reasons, PPACA's uncompensated mandate for employers with 50 or more fulltime employees to purchase federally approved health insurance is in excess of authority granted by law, not in accordance with the law, and *ultra vires.*

COUNT III
UNLAWFUL INDIVIDUAL MANDATE

97. Plaintiff incorporates Paragraphs 1-96 and 106-118 as if fully set forth herein.

98. Nothing in Article I or elsewhere in the U.S. Constitution authorizes the federal government to require individual citizens, with no direct connection to or contract with the federal government, to purchase federally approved health insurance or pay a penalty, and nothing in Article I or elsewhere in the U.S. Constitution authorizes the federal government to set the acceptable terms of health insurance for such individuals.

99. For the foregoing reasons, PPACA's uncompensated mandate for individuals to purchase federally approved health insurance is in excess of authority granted by law, not in accordance with the law, and *ultra vires.*

COUNT IV
UNLAWFUL REQUIREMENTS FOR PECOS AND MEDICARE ENROLLMENT, MEDICARE OPT-OUT, AND NPIS

100. Plaintiff incorporates Paragraphs 1-99 and 106-118 as if fully set forth herein.

101. With respect to its PECOS-related requirements, neither CR6417/6421 nor the HHS ICF qualify for 5 U.S.C. §553(b)(B)'s or 42 USC §1395hh(b)(1)(B)'s exemptions from notice-and-comment rulemaking. With respect to those referring for items and services under Medicare Part B, CR6417/6421 and the IFC promulgate substantive rules that required notice-and-comment rulemaking.

102. HHS lacks authority to make filing an enrollment or opt-out record in PECOS a prerequisite to refer items or services under Medicare.

103. Nothing in Medicare or any other provision of law requires non-Medicare providers to comply with 42 U.S.C. §1395(b)'s statutory safe harbor before treating and obtaining payment from Medicare-eligible beneficiaries outside the Medicare system.

104. Nothing in PPACA 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).

105. For the foregoing reasons, CR6417/6421 and the IFC are arbitrary, capricious, an abuse of discretion, without observance of procedure required by law, not otherwise in accordance with the law, in excess of authority granted by law, and *ultra vires.*

COUNT V
ACCOUNTING FOR MEDICARE

106. Plaintiff incorporates Paragraphs 1-105 and 112-118 as if fully set forth herein.

107. Federal executive officers such as Defendant Sebelius owe a fiduciary duty to the American people to properly implement important federal programs such as Medicare. Notwithstanding that millions of Americans rely on Medicare, Medicare faces insolvency because of federal mismanagement.

108. In the face of Medicare's prospective insolvency, politicians try to avoid the issue, and the Congress (through PPACA specifically but also generally) relies on budget gimmickry to avoid the difficult budgetary issues presented. Indeed, Congress in PPACA purports to cut half a trillion dollars from Medicare to pay for new entitlements that the United States cannot afford.

109. Defendant Sebelius knowingly stated that CBO's scorings showed that PPACA would reduce the federal deficit, when she knows that the opposite is true in reality, without the unrealistic and narrowing assumptions that CBO was compelled to make.

110. Congress and the American public need an honest accounting on Medicare's solvency to address the urgent situation facing Medicare.

111. For the foregoing reasons, Defendant Sebelius' conduct violates her fiduciary and equitable duties.

COUNT VI
ACCOUNTING FOR SOCIAL SECURITY

112. Plaintiff incorporates Paragraphs 1-111 and Paragraph 118 as if fully set forth herein.

113. Federal executive officers such as Defendant Astrue owe a fiduciary duty to the American people to properly implement important federal programs such as Social Security. Notwithstanding that millions of Americans rely on Social Security, Social Security faces insolvency because of federal mismanagement.

114. In the face of Social Security's prospective insolvency, politicians try to avoid the issue, and the Congress (through PPACA specifically but also generally) relies on budget gimmickry to avoid the difficult budgetary issues presented.

115. Defendant Astrue knows that PPACA'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 PPACA on behalf of those who rely on him and Social Security for their retirement planning.

116. Congress and the American public need an honest accounting on Social Security's solvency to address the urgent situation facing Social Security.

117. For the foregoing reasons, Defendant Astrue's conduct violates his fiduciary and equitable duties.

PRAYER FOR RELIEF

118. Wherefore, Plaintiffs AAPS and ANH-USA respectfully ask this Court to grant the following relief:

A. Pursuant to 5 U.S.C. §706, 28 U.S.C. §§1331, 2201-2202, the Acts of March 3, 1863, 12 Stat. 762, and June 25, 1936, 49 Stat. 1921 (as amended), D.C. Code §11-501, FED. R. CIV. PROC. 57, and this Court's equitable powers, a Declaratory Judgment that:

(i) Defendants adopted POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 without the required notice-and-comment rulemaking;

(ii) In conditioning eligibility for Social Security on participation in Medicare Part A, POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 are *ultra vires* Medicare, Social Security, and HHS' other authority;

(iii) The federal government lacks authority under the Commerce Clause to compel

businesses or individuals to purchase PPACA-compliant health insurance or pay an offsetting penalty;

(iv) Congress enacted PPACA's requirements for businesses or individuals to purchase health insurance or pay an offsetting penalty exclusively under the Commerce Clause, and not under the Taxing Power;

(v) The federal government lacks authority under the Commerce Clause and the Necessary and Proper Clause to compel businesses or individuals to purchase health insurance or pay an offsetting penalty;

(vi) Requiring the private purchase – by individuals or businesses – of insurance with greater coverage than the purchaser desires and for which the premiums of the healthy, solvent, and young subsidize the sick, poor, and elderly constitutes a regulatory taking;

(vii) If the PPACA insurance mandates' penalties are taxes, requiring the payment of a penalty for failure to comply with PPACA's insurance mandates constitutes either an un-apportioned capitation or direct tax or non-uniform duty, impost or excise;

(viii) Defendants adopted CR6417/6421 and the HHS IFC without the required notice-and-comment rulemaking

(ix) HHS lacks the authority to compel non-Medicare providers to enroll or otherwise appear in PECOS as a prerequisite to referring for items or services under Medicare Part B;

(x) HHS lacks the authority to compel non-Medicare providers to obtain an NPI absent some independent event that lawfully requires obtaining an NPI;

(xi) Non-Medicare providers lawfully may see Medicare-eligible patients and charge

those patients a fee that is lawful under applicable state laws, without complying with 42 U.S.C. §1395(b)'s safe harbor, and Medicare imposes no obligations on such providers beyond any applicable requirements of state law; and

(xii) The Officer Defendants have breached their fiduciary duties to the American people by allowing Social Security and Medicare to face insolvency.

B. Pursuant to 5 U.S.C. §706, 28 U.S.C. §§1331, 2202, the Acts of March 3, 1863, 12 Stat. 762, and June 25, 1936, 49 Stat. 1921 (as amended), D.C. Code §11-501, and this Court's equitable powers, an Order providing that

(i) POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020 are vacated; and

(ii) Defendants are enjoined from re-promulgating by rulemaking the substantive requirements of POMS HI 00801.002, POMS HI 00801.034, and POMS GN 00206.020, except to the extent that those substantive requirements are fully consistent with the declaratory relief in Paragraph 118(A);

(iii) Defendant Sebelius and HHS are enjoined from promulgating federal criteria for acceptable health insurance policies for private individuals or businesses;

(iv) Defendants and any and all federal officers acting independently or in concert with them are enjoined from promulgating or enforcing any mandate that individuals or businesses purchase or carry health insurance;

(v) CR6417/6421 and HHS's IFC (to the extent that it addresses rulemakings that PPACA either required to take effect 150 or more days after PPACA's enactment or that PPACA did not require) are vacated;

(vi) Defendant Sebelius shall prepare and submit to this Court an accounting on

Medicare's solvency; and

(vii) Defendant Astrue shall prepare and submit to this Court an accounting on Social Securities' solvency.

C. Pursuant to FED. R. CIV. P. 65, 5 U.S.C. §706, 28 U.S.C. §§1331, 2202, the Acts of March 3, 1863, 12 Stat. 762, and June 25, 1936, 49 Stat. 1921 (as amended), D.C. Code §11-501, and this Court's equitable powers, an Order preliminarily enjoining HHS from requiring non-Medicare providers to enroll with Medicare, to appear in PECOS, or to obtain an NPI absent another criterion – *e.g.,* engaging in HIPAA transactions or e-prescribing – that independently requires an NPI and from denying Medicare reimbursement to patients for Medicare-covered services solely because they were referred by a physician who is not enrolled in Medicare or PECOS or who lacks an NPI.

D. Pursuant to 28 U.S.C. §2412 and any other applicable provisions of law or equity, award AAPS and ANH-USA their costs and reasonable attorneys fees.

E. Such other relief as may be just and proper.

Dated: September 8, 2010

Respectfully submitted,

/s/ Lawrence J. Joseph

Lawrence J. Joseph, D.C. Bar No. 464777

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Counsel for Plaintiffs Association of American Physicians and Surgeons, Inc. and Alliance for Natural Health USA

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC. *et al.*, Plaintiffs, v. KATHLEEN G. SEBELIUS, Secretary of Health & Human Services, in her official capacity, *et al.*, Defendants.	)	Civil Action No. 1:10-0499-RJL

DECLARATION OF LAURA T. HAMMONS, M.D.

I, Laura T. Hammons, M.D., hereby declare and state as follows:

1. I am over 18 years of age, and I am not a party to this action. I am a resident of New Mexico and a member of the Association of American Physicians and Surgeons, Inc. ("AAPS"). I plan to remain an AAPS member and to remain in New Mexico.

2. I graduated from East Tennessee University Medical School in 1986, and I have a private medical practice in Gallup, New Mexico.

3. There is a shortage of physicians in my area. Because not all physicians see Medicare and Medicaid patients, the shortage is exacerbated for Medicare and Medicaid patients.

4. In addition to my private, for-profit practice, I have served *pro bono* (without charge) as the Medical Director of the Little Sisters of the Poor Home for the Aged. For over twenty years, I have referred these patients out for needed services – such as bloodwork, x-rays, oxygen, physical therapy orders, and the similar services – for which their Medicare eligibility qualified them.

5. I have not enrolled in the Provider Enrollment, Chain and Ownership System ("PECOS"), and I would prefer not to enroll in PECOS, which I regard as an administrative burden, an unwarranted risk of unauthorized disclosure of information about me and my practice,

and an economic risk that the Medicare system will erroneously debit my business banking account. As a result of the Medicare system's new policy to require PECOS enrollment for referrers, I no longer can successfully refer services for Medicare-eligible patients at the Little Sisters of the Poor Home for the Aged.

6. I am busy in my private practice, and the PECOS changes will not affect my income, but those changes cause severe inconvenience to my patients. For example, on or about January 4, 2011, an elderly man with bilateral lung cancer and respiratory distress was admitted to the Little Sisters of the Poor Home for the Aged. He cannot afford medical care and, for all practical purposes, has almost no money. His only medical coverage is Medicare, and he is too weak to go out to see a Medicare physician. According to the local medical supplier in Gallup, Medicare will not honor my order for oxygen. As a result, I was unable to refer this patient for oxygen under Medicare. Our only hope for him, at this point, is to wait until hospice enrolls him to see whether that different way of ordering the oxygen will allow this patient some relief.

7. The situation with this lung-cancer patient with respiratory distress is not unique. Based on my experience, similar episodes will continue to arise. These rejections of service and the toll that they take on my patients are physically and emotionally painful for my patients. They would prefer a return to the prior status quo, under which I could refer them for these services under Medicare. For humanitarian and professional reasons, I too would prefer a return to that prior status quo so that I could alleviate their pain.

8. I have personal knowledge of the foregoing declarations and am competent to testify thereto at trial.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 7th day of January, 2011, at Gallup, New Mexico.

Laura T. Hammons, M.D.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC. *et al.*, Plaintiffs, v. KATHLEEN G. SEBELIUS, Secretary of Health & Human Services, in her official capacity, *et al.*, Defendants.	)	Civil Action No. 1:10-0499-RJL

DECLARATION OF GEORGE KEITH SMITH, M.D.

I, George Keith Smith, M.D., hereby declare and state as follows:

1. I am over 18 years of age and not a party to this action. I reside in Oklahoma, work in Oklahoma City, Oklahoma, and plan to continue both to reside and work there.

2. I am the Medical Director of the Surgery Center of Oklahoma ("Surgery Center"), which is a partnership of Metro Surgery Center, LLP ("Metro Surgery"), and SHC Oklahoma City, Inc. ("SHCOC"). I am the President of SHCOC's Board of Directors and Metro Surgery's Managing Partner. In these positions, I am authorized to speak for Surgery Center, Metro Surgery, and SHCOC. In addition to my capacities with these entities, I am an anesthesiologist with a private practice at Surgery Center.

3. I am a member of the Association of American Physicians and Surgeons, Inc. ("AAPS"), and I intend to remain an AAPS member. In addition, the Surgery Center is an AAPS member, and – in my capacity with the Surgery Center – I intend for the Surgery Center to remain an AAPS member.

4. To enable it to charge its deeply-discounted prices to cash-based patients, the Surgery Center has a payment policy that requires payment in full when services are rendered,

with alternate payment arrangements available for human resource departments or divisions of self-insured companies. The Surgery Center does not see Medicare-eligible patients.

5. Because it offers quality care at low prices, without the rationing that goes with insurance and government health programs, the Surgery Center often sees patients from Canada, notwithstanding that Canada has a comprehensive national health-care program.

6. If the Surgery Center could treat Medicare-eligible patients wholly outside of Medicare on the Surgery Center's payment terms, without any of the burdens or requirements imposed by the Medicare statute, 42 U.S.C. §§1395-1395kkk-1, and any implementing regulations or policies, the Surgery Center would be willing to treat such patients, just like it treats their Canadian counterparts. This arrangement would benefit the patients, the Surgery Center, and the physicians who practice there, including me.

7. The opportunity to treat such Medicare-eligible patients on the Surgery Center's terms would put the Surgery Center on an equal footing with its hospital competitors, with respect to competition for such patients. Similarly, that opportunity would put physicians and surgeons – including me – affiliated with the Surgery Center on an equal footing with their competitors at other medical facilities, with respect to competition for such patients.

8. By coercing Americans generally and Oklahomans specifically to procure expensive, comprehensive health insurance – notwithstanding that many prefer either to remain uninsured or to insure only against catastrophic injury or illness – the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) ("PPACA") will put my cash-based practice on an unequal footing with my competitors at other medical facilities, with respect to competition for such patients. First, these patients will have comprehensive coverage that they did not heretofore have, making my low prices seem high compared to having the patients'

surgery covered by comprehensive insurance. Second, by virtue of paying the significantly higher premiums that PPACA will require, these patients will simply have fewer funds to devote to "cash" practices like mine, even if they would prefer to have their surgery at our facility for other reasons (*e.g.*, the quality of care, the speed of scheduling, convenience, or prior professional relationships).

9. I have not enrolled in the Provider Enrollment, Chain and Ownership System ("PECOS"), and I object to enrolling in PECOS, which I regard as an administrative burden, an unwarranted risk of unauthorized disclosure of information about me and my practice, and an economic risk that the Medicare system will erroneously debit my business banking account.

10. Currently, I do not see Medicare-eligible patients, but I would consider doing so if I could see them on the Surgery Center's payment terms, without any of the burdens or requirements imposed by the federal Medicare system as cited in Paragraph 6. The ability to refer Medicare-eligible patients for services would put me on an equal footing with my competitors at other medical facilities, with respect to competition for such patients.

11. I have been, and expect to remain, able to pay any health-related expenses as they arise through use of a health savings account, income and, if necessary, savings, and investments. In addition, I use and plan to continue to use a high-deductible insurance ($10,000) insurance policy, which covers me and my three children aged fourteen, nineteen, and twenty two for approximately $200 per month. Neither I nor my children are covered by any other health insurance.

12. I do not qualify for Medicare, Medicaid, or Social Security, and I do not receive any benefits from those programs. Based on my age and income, I do not expect to qualify for

any of the foregoing three programs in or before 2014, under PPACA or otherwise. Accordingly, I will be subject to PPACA's individual insurance mandate in 2014.

13. I object to the PPACA's unconstitutional overreaching and to being forced to obtain and maintain qualifying health care insurance for myself and my dependents, or to pay a penalty for failing to have such insurance. I do not wish to have such insurance and do not believe that the cost of health insurance is a wise or acceptable use of my financial resources.

14. I wish to have autonomy over my medical care and want physicians to have their autonomy to recommend treatments for me, without the third-party oversight that such insurance entails.

15. I will be harmed financially if I am compelled to purchase health care insurance coverage, which I neither want nor need, to comply with PPACA, or to pay the prescribed penalties for non-compliance. In either case, I will be forced to divert financial resources from my own priorities, which I consider to be the best and most advantageous use of my resources.

16. Litigating this issue myself, before or after having paid the penalty for failing to procure PPACA-mandated insurance, would be prohibitively expensive because the likely costs of the litigation would exceed the penalty that PPACA would impose for non-compliance.

17. I have been advised by AAPS counsel that the presiding judge in the above-captioned action indicated during a status conference that cases in the U.S. District Court for the District of Columbia take approximately three years to complete. Based on that timeline, and the reported likelihood that this litigation – or the issues that it presents – will reach the U.S. Supreme Court, this litigation is necessary now, to ensure that I avoid diverting funds to PPACA penalties circa April 2015 or to increased health insurance premiums circa January 2014.

18. I have personal knowledge of the foregoing and am competent to testify thereto at trial.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this __th day of January, 2011, at Oklahoma City, Oklahoma.

GKSmith MD

George Keith Smith, M.D.

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS, INC. *et al.*, Plaintiffs-Appellants, v. KATHLEEN G. SEBELIUS, Secretary of Health & Human Services, in her official capacity, *et al.*, Defendants-Appellees.	)	No. 13-5003

SECOND DECLARATION OF LAWRENCE J. JOSEPH

I, Lawrence J. Joseph, hereby declare and state as follows:

1. I am over 18 years of age and not a party to this action. I reside in McLean, Virginia, and represent the Plaintiffs-Appellants in the above-captioned action.

2. In preparing to file the Plaintiffs-Appellants' emergency motion for interim relief on Count IV in the above-captioned appeal, I reviewed with the declarants the material declarations made in opposition to the Defendants-Appellees' motion to dismiss.

3. Other than the impact of the challenge "PECOS" changes' becoming more severe in the Gallup, New Mexico, area due to retiring physicians and announced retirements, the facts declared circa January 2011 have not changed materially in the intervening two years and two months.

4. If requested or required by the Court or the Defendants-Appellees, the Plaintiffs-Appellants' declarants can provide renewed declarations to the same material effect as the declarations that they provided circa January 2011.

5. I have personal knowledge of the foregoing and am competent to testify thereto at trial.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 13th day of March, 2013, at McLean, Virginia.

/s/ Lawrence J. Joseph
Lawrence J. Joseph

U.S. Department of Justice
Civil Division, Federal Programs Branch

Via U.S. Mail:
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June 27, 2011

VIA U.S. MAIL

The Honorable Amy Berman Jackson
U.S. District Court for the District of Columbia
333 Constitution Avenue N.W.
Washington, D.C. 20001

Re: Association of American Physicians and Surgeons v. Sebelius, No. 10-499 (ABJ)

Dear Judge Jackson:

Pursuant to Judge Leon's suggestion during the in-chambers conference on October 7, 2010, the parties jointly write to update the Court on the potential for Plaintiffs to move for a preliminary injunction with respect to Count IV of the Second Amendment and Supplemental Complaint. Defendants' motion to dismiss that Complaint is fully briefed.

In Count IV, Plaintiffs challenge new regulations addressing the conditions under which the Medicare program will pay for certain "ordered or referred" Part B items or services. 75 Fed. Reg. 24,437 (May 5, 2010). These regulations took effect on July 6, 2010. Id. The Department of Health and Human Services ("HHS") is not willing to suspend the effect of these regulations. However, in June 2010, HHS issued a press release explaining that, for the time being, it had delayed the implementation of claims edits that would automatically reject claims for failure to comply with these regulations. See HHS, Press Release, CMS to Review PECOS Enrollment Process (June 30, 2010). Moreover, in August 2010, HHS advised several members of Congress that it would provide notice to providers before implementing claims edits that would reject claims automatically. See, e.g., Letter from Donald M. Berwick, M.D., Administrator, Centers for Medicare & Medicaid Services, to Rep. Michael Arcuri, U.S. House of Representatives (Aug. 19, 2010). And while HHS announced in December 2010 a placeholder date of July 5, 2011, for implementation of claims edits that would reject claims automatically, see CMS Manual System, Pub. 100-20, Transmittals 823 & 825 (Dec. 16, 2010), HHS does not currently plan to implement the claims edits on July 5, 2011.

HHS has represented to Plaintiffs that, before implementing claims edits that would automatically reject claims for failure to comply with the new regulations, it will provide them with sufficient notice to move the Court for preliminary relief. Accordingly, the parties agree that there is

no need to brief a motion for a preliminary injunction with respect to Count IV at this time. However, Plaintiffs reserve the right to file such a motion upon notice that the claims edits will be implemented. If Plaintiffs so move, Defendants of course reserve the right to assert any available defenses, including lack of jurisdiction. Defendants will not, however, argue that Plaintiffs unduly delayed in seeking preliminary relief by waiting until the claims edits were implemented instead of seeking such relief at this time.

The parties appreciate the Court's attention to this matter.

Sincerely yours,

/s/ Lawrence J. Joseph
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN ASSOCIATION OF PHYSICIANS AND SURGEONS, *et al.*, Plaintiffs, v. KATHLEEN G. SEBELIUS, Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 10-499 (ABJ)

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO STAY CASE PENDING RESOLUTION OF APPEALS RAISING IDENTICAL ISSUES

In response to Defendants' motion to stay, Plaintiffs ask the Court to expedite its ruling on Defendants' motion to dismiss — indeed, to summarily enter a judgment that is almost entirely adverse to them — so that they may petition the D.C. Circuit to consolidate this case with the related appeals in *Seven Sky v. Holder* and *Hall v. Sebelius*. Pls.' Opp'n at 4 [Doc. No. 49]. Plaintiffs thus effectively concede that this case is closely intertwined with *Seven Sky* and *Hall*, and that the D.C. Circuit's resolution of those cases will control here. But because *Seven Sky* and *Hall* have already been fully briefed and argued, consolidation would only complicate the appellate proceedings and slow the issuance of controlling decisions — in the unlikely event the D.C. Circuit were to permit consolidation at all, given the late stage of those proceedings. Moreover, given the prospect of Supreme Court review, Plaintiffs agree that this Court should defer resolution of their substantive challenge to Medicare enrollment requirements explicitly authorized by the Affordable Care Act. Accordingly, litigation costs and judicial resources would best be conserved by a stay of proceedings in this Court.

A. *Florida*, *Seven Sky*, and *Hall* Will Control the Resolution of the Central Issues in this Case

To speed an appeal and facilitate potential consolidation in the D.C. Circuit, Plaintiffs propose that this Court summarily resolve their principal challenges as follows:

- Their Article I challenges to the Affordable Care Act's "individual and employer mandates" should be rejected for the reasons set forth by Judge Kessler in *Mead v. Holder*, 766 F. Supp. 2d 16 (D.D.C. 2011), *appeal pending sub nom. Seven Sky v. Holder*, No. 11-5047 (D.C. Cir. argued Sept. 23, 2011), *see* Pls.' Opp'n at 4 & Prop. Order at 2;[1]

- Their challenges to provisions of a Social Security Administration handbook that explain the connection between the receipt of old-age benefits under the Social Security Act and the statutory entitlement to Medicare Part A benefits should be rejected for the reasons set forth by Judge Collyer in *Hall v. Sebelius*, 770 F. Supp. 2d 61 (D.D.C. 2011), *appeal pending*, No. 11-5076 (D.C. Cir. argued Oct. 13, 2011), *see* Pls.' Opp'n at 4 & Prop. Order at 1;

- Their claims for an equitable accounting of the Medicare and Social Security trust funds should be "dismissed without prejudice" because "it is premature to order an equitable accounting [before] the pending challenges to [the Affordable Care Act] have become final in both the Supreme Court and the [D.C.] Circuit," Prop. Order at 2; and

- With respect to their substantive challenge to enrollment requirements for physicians who refer beneficiaries for Medicare Part B items or services, "the prospect [of] the Supreme Court's resolution of [the Affordable Care Act's] lawfulness and the absence of a severability clause counsel for deferring resolution of the issue," Prop. Order at 3.

Thus, Plaintiffs' own proposal confirms that the resolution of the central issues in this case either will be directly controlled by the Supreme Court's resolution of *Florida v. U.S. Department of Health and Human Services* , 648 F.3d 1235 (11th Cir. 2011), *petitions for cert. filed*, -- U.S.L.W. -- (U.S. Sept. 27-28, 2011) (Nos. 11-393, 11-398, 1140), or the D.C. Circuit's resolution of *Seven Sky* and *Hall*, or should be deferred pending a decision in those cases.

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[1] Defendants note that Judge Kessler's decision in *Mead* does not actually address the constitutionality of the employer responsibility provision (referred to by Plaintiffs as the "employer mandate"), nor is that issue presented on appeal in *Seven Sky*. However, that question is raised in two pending cert. petitions. *See* Petition for Writ of Certiorari at 29, *Florida* (No. 11-400); Petition for Writ of Certiorari at 38-42, *Liberty University v. Geithner* (No. 11-438).

Plaintiffs' suggestion that accelerating the resolution of this matter will "serve judicial economy" is faulty. Faster work does not mean less work. The Court cannot simply take Plaintiffs' word for how the case should be resolved; it must work to determine the correct resolution of each claim. This effort is precisely what would be spared by a stay. Plaintiffs' only response is that if this Court hurries, then this case can catch up with *Seven Sky* and *Hall* in the D.C. Circuit and be heard by judges already familiar with the issues. Pls.' Opp'n at 5. But *Seven Sky* and *Hall* have already been fully briefed, argued, and submitted for decision. Do Plaintiffs propose asking the D.C. Circuit to stay decision in both of those cases while the appeal in this case is briefed and argued — a process that would take months? Moreover, *Seven Sky* and *Hall* are pending before two *separate* panels. Do Plaintiffs propose asking the D.C. Circuit to split this case in two for new hearings by those two panels? Even if procedurally possible — a dubious proposition — this would hardly be an efficient maneuver, because two separate panels would be forced to consider threshold issues that cut across both "cases." Efficiency would be a casualty of Plaintiffs' proposal, not a beneficiary.

Plaintiffs identify only a handful of subsidiary issues that, in their view, would not be resolved or informed by *Florida*, *Seven Sky*, and *Hall*, or should not be deferred. These issues do not counsel against a stay.

First, Plaintiffs oppose deferring their *procedural* challenge to an interim final rule (and related provisions of an internal claims processing manual) setting forth enrollment requirements for physicians who refer beneficiaries for Medicare Part B items or services. Pls.' Opp'n at 5. Yet, as noted above, they affirmatively suggest deferring resolution of their *substantive* challenge to the same interim final rule based in part on "the prospect [of] the Supreme Court's resolution of [the Affordable Care Act's] lawfulness and the absence of a severability clause."

Prop. Order at 3. The same considerations justify deferring their procedural claim.

The interim final rule that Plaintiffs challenge directly "implements several provisions of the . . . Affordable Care Act." 75 Fed. Reg. 24437 (May 5, 2010). Defendants have argued that Plaintiffs' procedural challenge fails because, among other reasons, the Affordable Care Act explicitly required the Secretary to issue certain implementing regulations (requiring referring physicians to enroll in Medicare) on an expedited basis — thus exempting those regulations from the Administrative Procedure Act's notice and comment requirements — and there was good cause to issue other, interlocking regulations (requiring referring physicians to use a standard provider number when they enroll) at the same time. *See* Defs.' Mot. to Dism. at 71-74 [Doc. No. 32].[2] Plaintiffs have argued that these Affordable Care Act provisions cannot be severed from the minimum coverage provision. Although the government disagrees, if the D.C. Circuit or the Supreme Court were to invalidate the minimum coverage provision and hold it inseverable from the balance of the Affordable Care Act, the statutory basis for expedited issuance of the interim final rule would be less clear. Thus, a severability ruling from the Supreme Court or the D.C. Circuit may influence not only Plaintiffs' substantive challenge to the interim final rule, as Plaintiffs concede, but also their procedural claim.

Second, Plaintiffs hypothesize that if the Supreme Court reviews the constitutionality of the employer responsibility provision, it could reject the *Florida* plaintiffs' argument that the provision infringes on state sovereignty under the Tenth Amendment — and thus decline to reconsider *Garcia v. San Antonio Metropolitan Transit Authority*, 469 U.S. 528 (1985) —

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[2] Defendants have also argued that the enrollment requirements are rules of agency procedure that are exempt from notice and comment, Defs.' Mot. to Dism. at 70-71, and that the challenged provisions of the internal claims processing manual are similarly exempt because they do not constitute final agency action, *id.* at 74.

without addressing whether that provision falls within Congress's Article I authority to regulate *private* employers. Pls.' Opp'n at 5. But *Garcia* also establishes that "a privately owned and operated enterprise . . . could not credibly argue that Congress exceeded the bounds of its Commerce Clause powers in prescribing minimum wage and overtime rates for . . . employees." 469 U.S. at 537. By prescribing minimum levels of insurance coverage, the employer responsibility provision similarly regulates the terms and conditions of employment. Defs.' Mot. to Dism. at 42-43. Thus, the extent to which the Supreme Court reconsiders *Garcia* may also inform this Court's resolution of Plaintiffs' challenge to the employer responsibility provision. And if, contrary to the government's arguments, the Supreme Court or the D.C. Circuit were to invalidate the minimum coverage provision and hold it inseverable from the balance of the Affordable Care Act, it would be unnecessary to address this question.

Third, Plaintiffs note that this case raises Fifth Amendment (equal protection and takings) challenges to the minimum coverage provision that are not presented in *Florida* or *Seven Sky*. It is unclear how Plaintiffs propose that this Court resolve these claims: Their proposed order does not mention them, and Plaintiffs seem to suggest that the D.C. Circuit should resolve them in the first instance. Pls.' Opp'n at 4. Indeed, Plaintiffs' amicus brief in *Seven Sky* urges the D.C. Circuit (i) to exercise its "discretion to address these issues in [*Seven Sky*], in the interest of judicial economy" and, regardless, (ii) to "address the impact of its decision in [*Seven Sky*] on the AAPS/ANH-USA litigation." Br. for AAPS and ANH-USA as Amici Curiae at 4, 5 (*Seven Sky*, D.C. Cir. No. 11-5047). It would make little sense for this Court to summarily resolve Plaintiffs' Fifth Amendment claims based on their speculation that the D.C. Circuit might grant a petition for consolidation to address claims that, in Plaintiffs' view, that court already has the discretion to address. In any event, Plaintiffs' Fifth Amendment claims — which are

insubstantial, as Defendants have explained, *see* Defs.' Mot. to Dism. at 52-55 & n.38; Defs.' Reply at 21-26 — would be mooted if the Supreme Court or the D.C. Circuit were to invalidate the minimum coverage provision on Article I grounds.

B. No Jurisdictional Issues Counsel Against a Stay

Plaintiffs appear to agree that no jurisdictional issues in *Hall* counsel against a stay here. *See* Pls.' Opp'n at 3 & n.2. They contend, however, that a stay is unwarranted because of the prospect that *Florida* and *Seven Sky* will be resolved on a jurisdictional basis inapplicable in this case: the Anti-Injunction Act. *Id.* But Defendants' motion to stay explained that "the government's position is that both *Florida* and *Seven Sky* should be decided on the merits," and noted that "the government has affirmatively argued that the Anti-Injunction Act does not bar [the individual] plaintiffs' challenges" in those cases. Defs.' Mot. to Stay at 6-7. Plaintiffs respond that these statements are "misinformed at best" — if not "disingenuously semantic" — because the government suggested in its *Florida* cert. petition that the Court "direct the parties to address the applicability of the Anti-Injunction Act." Pls.' Opp'n at 3 & n.2. These arguments seriously mischaracterize the government's petition for certiorari in *Florida*.

It is true that the government's cert. petition suggested that the Court address whether an individual plaintiff's challenge to the minimum coverage provision is barred by the Anti-Injunction Act. *See* Petition for Writ of Certiorari at 32, *Florida* (No. 11-398). Specifically, it explained that the courts of appeals have reached conflicting conclusions on the question and suggested that, because the Court has stated that Anti-Injunction Act operates to "'withdraw jurisdiction from the state and federal courts,'" it would be appropriate for the Court to consider the question as a threshold matter. *Id.* at 33 (quoting *Enochs v. Williams Packing & Navigation Co.*, 370 U.S. 1, 5 (1962)). However, the government's petition explicitly stated that "the United

States continues to believe that the Anti-Injunction Act does not bar these challenges to the minimum coverage provision." *Id.* Accordingly, it suggested that "the Court should also consider appointing an amicus to file a brief defending the position that the Anti-Injunction Act does bar this suit," *id.*; otherwise, that position would be left undefended by the parties. Thus, Plaintiffs' suggestion that Defendants have misled the Court about the government's position on the applicability of the Anti-Injunction Act is mistaken.

Plaintiffs offer one scenario where, in their view, they are differently situated from the individual plaintiffs in *Florida* and *Seven Sky* with respect to the Anti-Injunction Act: Because the Plaintiff associations assert *double* third-party standing to challenge the minimum coverage provision — that is, they assert claims on behalf of their member physicians to sue on behalf of unnamed patients — the Anti-Injunction Act would not bar their claims even if the Supreme Court or D.C. Circuit were to hold that it bars the individual plaintiffs' challenges in *Florida* or *Seven Sky*. But as Defendants have explained, the Plaintiff associations lack such super-attenuated third-party standing to invoke the rights of their member physicians to bring claims on behalf of unnamed patients — who are perfectly able to bring their *own* challenges to the minimum coverage provision, as many have. *See* Defs.' Mot. to Dism. at 12 n.8. Only if this Court first determined that the Plaintiff associations have third-party standing would it have to address the question whether the Anti-Injunction Act bars third-party challenges to the minimum coverage provision. That question has not been fully briefed here, *see* Defs.' Reply at 14 n.12, and its resolution is likely to be informed by *Florida* and *Seven Sky*. Regardless, "a stay of the proceedings in one case is justifiable even where the parallel proceedings 'may not settle every question of fact and law,' but would settle some outstanding issues and simplify others." *Bridgeport Hosp. v. Sebelius*, No. 09-1344, 2011 WL 862250, at *1 (D.D.C. Mar. 10, 2011)

(quoting *Landis v. North American Co.*, 299 U.S. 248, 256 (1936)).

C. Plaintiffs Would Not Be Harmed by a Stay

Finally, Plaintiffs contend that a stay would harm them because it would "'compel[ ] [them] to stand aside while a litigant in another [case] settles the rule of law that will define the rights of both.'" Pls.' Opp'n at 6 (quoting *Landis*, 299 U.S. at 255). They also assert that they would be harmed by a stay because (i) a cloud of uncertainty looms over the insurance and medical markets and (ii) requiring physicians who refer beneficiaries for Medicare Part B items and services to enroll in Medicare using a standard provider number causes irreparable harm to both Plaintiff associations' members and their unnamed patients. These assertions do not withstand scrutiny.

As a practical matter, regardless of whether the Court stays this case, other cases will settle the rules of law simply because they are further along in the courts. That is a simple fact of litigation: Some cases move faster than others. Declining to stay this case will not change the relative positions of these cases, but a stay will conserve resources. In any case, Plaintiffs have availed themselves of the opportunity to file an amicus brief in *Seven Sky*, so their voices have not gone unheard. Moreover, even if Plaintiffs could show any concrete harm from the nebulous "cloud of uncertainty" they claim the Affordable Care Act created in the insurance and medical markets, that uncertainty will be resolved by *Florida* and *Seven Sky*; this case need not be used as a vehicle for that purpose. Finally, Plaintiffs' claim of irreparable harm from Medicare enrollment requirements for referring physicians rings hollow. As the parties explained in a joint letter to the Court on June 27, 2011, although Defendants are not willing to suspend the effect of the new regulations, they have delayed the implementation of claims edits that would automatically reject Medicare claims for failure to comply with them. Accordingly, Plaintiffs

agreed that there was no need to seek immediate injunctive relief, which one would expect were Plaintiffs suffering irreparable harm. Because these concerns are illusory and the benefits of a stay are real, a stay is warranted.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court stay this case pending the resolution of *Florida*, *Seven Sky*, and *Hall*.

Dated: November 3, 2011

Respectfully submitted,

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INTRODUCTION

Plaintiffs Association of American Physicians & Surgeons, Inc. ("AAPS") and Alliance for Natural Health-USA ("ANH-USA") challenge actions by the United States as federal sovereign and three federal officers – associated with the Social Security Administration and the Departments of Health & Human Services ("HHS") and of the Treasury – who implement the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), as amended by Pub. L. No. 111-152, 124 Stat. 1029 (2010) ("PPACA"), the Medicare statute, 42 USC §§1395-1395kkk-l ("Medicare"), and the Medicare and the Social Security trust funds. The Court has allowed each side ten pages to brief the impact of *Hall v. Sebelius*, 667 F.3d 1293 (D.C. Cir. 2012), and *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S.Ct. 2566 (2012) ("*NFIB*").

Before outlining how *Hall* and *NFIB* affect this litigation, Plaintiffs first emphasize three key points: (1) issue preclusion is not binding on those who did not participate in the litigation in question, *Baker v. General Motors Corp.*, 522 U.S. 222, 237-38 & n.11 (1998) ("[i]n no event… can issue preclusion be invoked against one who did not participate in the prior adjudication"); (2) *stare decicis* does not extend to issues that were not conclusively settled:

> Questions which merely lurk in the record, neither brought to the attention of the court nor ruled upon, are not to be considered as having been so decided as to constitute precedents.

Cooper Indus., Inc. v. Aviall Serv., Inc., 543 U.S. 157, 170 (2004) (interior quotations omitted); *Waters v. Churchill*, 511 U.S. 661, 678 (1994) ("cases cannot be read as foreclosing an argument that they never dealt with"); and (3) even *stare decisis* can be applied so conclusively that it violates due process, *S. Cent. Bell Tel. Co. v. Alabama*, 526 U.S. 160, 167-68 (1999). Given their incontrovertible due-process right to distinguish their claims from third parties' claims, Plaintiffs submit that *Hall* and *NFIB* (a) do not resolve Count I; (b) require judgment for Plaintiffs on Counts II, III, and IV; and (c) have no impact on the accounting requested by Counts V and VI.

I. *HALL* DOES NOT RESOLVE COUNT I

Count I challenges Defendants' action to condition receipt of Social Security benefits on acceptance of Medicare Part A as *ultra vires* Medicare, Social Security, and the implementing regulations, which allow participating in Social Security without participating in Medicare Part A. In *Hall*, a split panel resolved similar *substantive* claims raised by third parties, without addressing the alternative procedural claims that Plaintiffs have raised. Nothing in *Hall* would preclude a different (or even the same) administrator from exercising discretion differently, even if *Hall* correctly decided that Medicare does not *require* the substantive relief sought in *Hall.* At the outset, therefore, *Hall* does not foreclose Count I's procedural claims, which could strike the agency action, leaving a future administrator free to reach a different regulatory conclusion. In addition, a future panel in the D.C. Circuit may well agree with Judge Henderson's vigorous dissent that the majority failed to address the key issue that the *Hall* plaintiffs raised, *Hall*, 667 F.3d at 1297 (Henderson, J., dissenting), thereby reaching a different result for Plaintiffs here.

But even if *Hall* resolved all of Plaintiffs' claims, this Court would still need to find its jurisdiction before entering a merits judgment against Plaintiffs based on *Hall.* In this litigation but not in *Hall*, the federal defendants have argued that 42 U.S.C. §405(g)-(h) bars litigation under federal-question jurisdiction, Defs.' Reply Br. at 5-8 [Doc. 45], which – if true – would preclude this Court's reaching the merits of Count I. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 93-94 (1998) (federal courts may not rely on hypothetical jurisdiction to reach merits). Accordingly, Plaintiffs make two alternative arguments. First, if 42 U.S.C. §405(g)-(h) denies subject-matter jurisdiction, this Court must dismiss for lack of jurisdiction, without reaching the substantive or procedural merits. Second, Defendants are wrong about 42 U.S.C. §405(g)-(h), and this Court can reach the substantive and procedural merits of Count I under this Court's unique equity jurisdiction for suits over federal actors, *Kendall v. U.S. ex rel. Stokes*, 37 U.S. (12

Pet.) 524, 580-81 (1838); *Stark v. Wickard*, 321 U.S. 288, 290 n.1 (1944); *Peoples v. Dep't of Agriculture*, 427 F.2d 561, 564 (D.C. Cir. 1970), without resort to the federal-question jurisdiction statute, 28 U.S.C. §1331, that Defendants argue is barred by 42 U.S.C. §405(g)-(h).

Defendants proffer an alternate jurisdictional flaw, based on the D.C. Circuit's reaching the substantive merits in *Hall* contrary to Plaintiffs' merits position. Joint Status Rpt. at 8-9 [Doc. 53]. Under Defendants' argument, *Hall* renders Plaintiffs' merits position so insubstantial as to deny federal jurisdiction, even without 42 U.S.C. §405(g)-(h)'s bar to federal-question jurisdiction.

Of course, the Supreme Court has long held that "federal courts are without power to entertain claims otherwise within their jurisdiction if they are so attenuated and unsubstantial as to be absolutely devoid of merit," where a claim is "plainly unsubstantial … either because it is obviously without merit or because its unsoundness so clearly results from the previous decisions of *this court* as to foreclose the subject and leave no room for the inference that the question sought to be raised can be the subject of controversy." *Hagans v. Lavine*, 415 U.S. 528, 537 (1974) (interior quotations omitted, emphasis added); *Goosby v. Osser*, 409 U.S. 512, 518 (1973) ("[a] claim is insubstantial *only* if its unsoundness so clearly results from the previous decisions of *this court* as to foreclose the subject and leave no room for the inference that the questions sought to be raised can be the subject of controversy") (interior quotations omitted, emphasis added). *Hall*, of course, is not a decision *of the Supreme Court*, and this Court cannot hold now that the Supreme Court will both grant a writ of *certiorari* and rule against the *Hall* plaintiffs.

Although counsel typically would research issues in *this* Circuit first, Defendants rely on extra-circuit decisions (primarily from the Fourth Circuit) to argue that even a *circuit court's* contrary ruling will render an argument insubstantial. Joint Status Rpt. at 8-9 [Doc. 53]. This

argument has two flaws. First, even the Fourth Circuit would counsel other circuits to resolve such issues for themselves: *Va. Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 393 (4th Cir. 2001). Second, this Circuit indeed has resolved the issue, consistent with the Supreme Court's plain language, to require a controlling *Supreme Court* decision, not merely a Circuit decision. *Tuck v. Pan Am. Health Org.*, 668 F.2d 547, 549 n.3 (D.C. Cir. 1981); *cf. LaRouche v. Fowler*, 152 F.3d 974, 982 (D.C. Cir. 1998) (*Goosby* "made clear just how minimal a showing is required to establish substantiality"). Defendants' contrary argument is wholly unfounded in this Circuit.

II. *NFIB* AND THE ORIGINATION CLAUSE NOT ONLY FURTHER ESTABLISH THIS COURT'S JURISDICTION OVER THIS LITIGATION BUT ALSO REQUIRE JUDGMENT FOR THE PLAINTIFFS ON COUNTS II, III, AND IV

NFIB rejected most of Defendants' jurisdictional and merits arguments, but upheld the individual mandate as a tax vis-à-vis the *NFIB* plaintiffs' facial challenge. Specifically, different five-justice majorities rejected PPACA's "individual mandate" as a valid exercise of the Commerce Clause or the Necessary and Proper Clause, but upheld it as an unspecified form of taxation (albeit not a direct tax). Notwithstanding the Taxing Power's breadth, "any tax must still comply with other requirements in the Constitution." *NFIB*, 132 S.Ct. at 2598. This section addresses the relevance of *NFIB* to Counts II, III, and IV under two constitutional doctrines.

First, *NFIB* did not consider the Fifth Amendment issues that Plaintiffs raise here and *a fortiori* did not consider them *as applied* to Plaintiff members who suffer Fifth Amendment injuries. Second Am. Compl. ¶¶23-24, 53, 65-66, 68 [Doc. 26]; Christman Decl. ¶¶5, 9; Smith Decl. ¶¶11, 15 [Doc. 38-1]. Thus, Plaintiffs could prevail against PPACA, *as applied to them*, even if *NFIB* had facially raised issues under the Fifth Amendment: "That the regulation may be invalid as applied … does not mean that the regulation is facially invalid," and vice versa. *I.N.S. v. Nat'l Ctr. for Immigrants' Rights*, 502 U.S. 183, 188 (1991).

Second, *NFIB* did not consider – and thus did not decide – whether the *NFIB* tax originating in a Senate amendment is invalid under the Origination Clause: "All bills for raising revenue shall originate in the House of Representatives; but the Senate may propose and concur with amendments as on other bills." U.S. CONST. art. 1, §7, cl. 1. PPACA's mandate taxes originated *as taxes* in a Supreme Court decision interpreting PPACA contrary to the legislative intent that those mandates *were not taxes;* as such, institutional and separation-of-powers concerns that otherwise might counsel against looking past PPACA's enrolled bill number (H.R. 3590), *see, e.g., U.S. v. Munoz-Flores*, 495 U.S. 385, 408-10 (1990) (Scalia, J., concurring), simply do not apply. Instead, this Court should recognize that PPACA (as rewritten by *NFIB*) would not have passed either legislative body. If the House wishes to re-enact PPACA with its tax mandates, the House remains free to do so. Until then, this Court should hold that PPACA's employer and individual mandates violated the Origination Clause by originating in the Senate.

A. PPACA's Mandates Violate the Origination Clause as Revenue Measures that Originated in the Senate

Although the Supreme Court has declined definitively to outline the contours of what qualifies as a revenue-raising bill under the Origination Clause, *Twin City Bank v. Nebeker*, 167 U.S. 196, 202 (1897), the Court's decisions have outlined the key terms sufficiently for this purpose. First, "revenue bills are those that levy taxes in the strict sense of the word, and are not bills for other purposes which may incidentally create revenue." *Id.* (*citing* 1 J. Story, COMMENTARIES ON THE CONSTITUTION §880, pp. 610-611 (3d ed. 1858)). Under "this general rule … a statute that creates a particular governmental program and that raises revenue to support that program, as opposed to a statute that raises revenue to support Government generally, is not a 'Bil[l] for raising Revenue' within the meaning of the Origination Clause." *Munoz-Flores*, 495

U.S. at 397-98. As justified by *NFIB* under the Taxing Power, however, the individual mandate does not qualify as part of PPACA's governmental program. It survives solely as a tax.

The "general rule" in *Munoz-Flores* applies to governmental programs that raise revenue via targeted provisions such as the "special assessment provision at issue in th[at] case." *Id.* at 398; *accord Nebeker*, 167 U.S. at 202-03; *Millard v. Roberts*, 202 U.S. 429, 436-37 (1906). Here, however, the individual mandate can avoid other constitutional infirmities (*e.g.*, non-uniform excise taxation), *see* Section II.C.1, *infra*, only as an income tax under the Sixteenth Amendment. Unlike special-purpose taxes, income taxes go to the general funds of the U.S. Treasury. 44 Cong. Rec. 4420 (1909) (Mr. Heflin); *Haskin v. Secretary of the Dep't of Health & Human Serv.*, 565 F.Supp. 984, 986-87 (E.D.N.Y. 1983) (*citing* 2 H. McCormick, SOCIAL SECURITY CLAIMS AND PROCEDURES 418 (3d ed. 1983)).

Thus unlike *Munoz-Flores*, "*Nebeker* and *Millard* [where] the special assessment provision was passed as part of a particular program to provide money for that program" and where "[a]ny revenue for the general Treasury … create[d] is thus 'incidenta[l]' to that provision's primary purpose," *Munoz-Flores*, 495 U.S. at 399, *NFIB* justifies the tax here solely for its revenue-raising purpose by providing funds into the general Treasury. Indeed, while PPACA as a whole included a governmental program for health insurance, it also focused on deficit reduction. Second Am. Compl. ¶¶84, 86 [Doc. 26]. For the PPACA components at issue here – the employer and individual mandates – *NFIB* justifies them solely as taxes to raise revenue.

Significantly, the Origination Clause applies not only to whole bills but also to discrete sections and amendments, *Nebecker*, 167 U.S. at 202-03 (looking to whether the "act, or by *any of its provisions"* had the purpose of "rais[ing] revenue to be applied in meeting the expenses or

obligations of the government") (emphasis added), subject to a germaneness test. *Flint v. Stone Tracy Co.*, 220 U.S. 107, 142-43 (1911), *abrogated in part on other grounds, Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 540-43 (1985). The D.C. Circuit has cited *Flint* for the proposition that the "Senate may propose any amendment 'germane to the subject-matter of the bill.'" *Moore v. U.S. House of Representatives*, 733 F.2d 946, 949 n.8 (D.C. Cir. 1984), *abrogated in part on other grounds, Raines v. Byrd*, 521 U.S. 811 (1997). In *Flint*, the Senate substituted a corporation tax for a House-originated inheritance tax in a "general bill for the collection of revenue." *Flint*, 220 U.S. at 142-43. Here, by contrast, the House-originated version of H.R. 3590 concerned minor amendments related to members of the Armed Forces and other federal employees,[1] *See* Service Members Home Ownership Tax Act of 2009, H.R. 3590, 111th Cong., 1st Sess. (Oct. 8, 2009) (Ex. 1) ("SMHOTA"), not a "general bill for the collection of revenue" as in *Flint*. As such, the Senate Majority Leader's wholesale substitution of PPACA for SMHOTA was in no way "germane" to SMHOTA's limited scope.

In summary, to the extent that they could be constitutional at all, PPACA's mandates qualify as income taxes that supply revenue to the Treasury. As income taxes, PPACA's mandates therefore "levy taxes in the strict sense of the word," rather than "incidentally create revenue." *Nebeker*, 167 U.S. at 202. Even while deeming special assessments levied against

[1] The Senate's authority to attach revenue-raising amendments to House bills applies only to House revenue bills. 2 HINDS' PRECEDENTS OF THE HOUSE OF REPRESENTATIVES OF THE UNITED STATES §1489 (1907); *cf. Armstrong v. U.S.*, 759 F.2d 1378, 1382 (9th Cir. 1985) ("once a revenue bill has been initiated in the House, the Senate is fully empowered to propose amendments"). In addition to the inquiry into whether the Senate PPACA amendments constitute a revenue bill – as distinct from a regulatory program – this Court also must determine whether H.R. 3590 qualifies as a "revenue bill" into which the Senate Majority Leader could import his PPACA amendments by stripping all of H.R. 3590's text after the enacting clause (*i.e.*, "Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled") and inserting PPACA into the gutted shell.

criminals to compensate victims to fall outside the Origination Clause's reach, *Munoz-Flores* acknowledged that "[a] different case might be presented if the program funded were entirely unrelated to the persons paying for the program." *Munoz-Flores*, 495 U.S. at 401 n.7. As applied to individuals like Dr. Smith with adequate – but PPACA-noncompliant – insurance, PPACA's mandates are "entirely unrelated to the persons paying for the program," *id.*, with no "element of contract" to justify the exchange. *Roberts,* 202 U.S. at 437. For all of the foregoing reasons, the PPACA mandates challenged in Counts II and III fall within the Origination Clause's scope and thus are void because they did not originate in the House.

B. *NFIB* Reinforces this Court's Jurisdiction

NFIB rejects the jurisdictional bar (if any) in the Anti-Injunction Act, *NFIB*, 132 S.Ct. at 2584, thereby removing one of Defendants' jurisdictional arguments. Defs.' Memo at 28-29 [Doc. 32]. In addition, *NFIB* reinforces Plaintiffs' standing for Counts II and III in two ways.

First, Plaintiffs' members' allegations here are similar to the members' allegations that sufficed in *NFIB*. *Compare* Ex. 2 (*NFIB* plaintiffs'exhibits Ex. 25-31 on standing) *with* Pls.' Memo Ex. 1-3, 5-6 (Plaintiffs' exhibits on standing) [Doc. 38-1]. Under *NFIB*, Defendants' arguments on standing are baseless.

Second, by violating the Origination Clause of the Constitution – which the Founders intended to protect the People from over-reaching taxation by placing the Taxing Power initially in the hands of those most directly subject to removal via the ballot box, *Munoz-Flores*, 495 U.S. at 395 (*citing* THE FEDERALIST No. 58)[2] – the combination of PPACA and *NFIB* inflict

[2] *See also* Randy E. Barnett, *Commandeering the People: Why the Individual Health Insurance Mandate is Unconstitutional*, 5 N.Y.U. J.L. & LIBERTY 581, 632–33 (2010) ("The public is acutely aware of tax increases").

procedural injury on Plaintiffs' members, thereby reducing Plaintiffs' required showings to establish redressability and immediacy. *Nat'l Treasury Employees Union v. U.S.*, 101 F.3d 1423, 1428-29 (D.C. Cir. 1996); *Florida Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664-65 (D.C. Cir. 1996) (*en banc*); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 571-72 & n.7 (1992). These injuries fall in the dead center of the interests that the Origination Clause protects, posing no prudential obstacles to Plaintiffs' standing. *Nat'l Credit Union Admin. v. First Nat'l Bank & Trust, Co.*, 522 U.S. 479, 492 (1998). By undermining Defendants' arguments on immediacy, this procedural injury defeats Defendants' primary arguments against Plaintiffs' standing for Counts II and III.

C. *NFIB* Requires Judgment for the Plaintiffs on All PPACA-Related Counts

The following two sections explain the merits impact of *NFIB* on Counts II, III, and IV. For the first two, nullifying PPACA's two tax mandates flows directly from nullifying PPACA. For the third, PPACA's nullification denies Defendants' authority to adopt the rules in question.

1. *NFIB* Requires Judgment for the Plaintiffs on the PPACA Mandates

Whatever taxing power Congress may have, Congress cannot tax the failure voluntarily to surrender the Fifth Amendment rights that Plaintiffs claim here. Pls.' Memo. at 49-54 [Doc. 38]. Further, to the extent that PPACA's mandates are excise taxes, the excise is not uniform across the country and thus unconstitutional. Pls.' Memo. at 46 (individual mandate), 55 (employer mandate) [Doc. 38]. *NFIB* expressly rejected direct taxation, *NFIB*, 132 S.Ct. at 2599, the only other form of non-income taxation available under the Taxing Power. Thus, PPACA's mandates can fall within the Taxing Power only as income taxation, which falls squarely within the Origination Clause, rendering PPACA void in its entirety because PPACA's mandates originated in the Senate. *See* Section II.A, *supra.*

2. *NFIB* Requires Judgment for the Plaintiffs on Count IV Because PPACA

Supplies the Substantive Authority on Which HHS Replies for the Challenged Agency Actions

If the Origination Clause or the Fifth Amendment renders PPACA a nullity, the defendants lack authority for the agency actions challenged in Count IV. *See* Pls.' Memo. at 62-63 [Doc. 38]. But even if PPACA could survive and provide *substantive* authority, Count IV's *procedural* claims would remain unsettled. *See id.* at 60-62. Thus, *NFIB* does not dispose of Count IV, even if this Court rejects Plaintiffs' arguments against PPACA.

III. NEITHER *HALL* NOR *NFIB* AFFECTS COUNTS V AND VI

Counts V and VI seek an accounting from federal officers responsible for the Medicare and Social Security trust funds. Neither *Hall* nor *NFIB* relate to the issues in Counts V or VI.

CONCLUSION

WHEREFORE, this Court should deny the Defendants' motion to dismiss.

Dated: July 27, 2012

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

MEMORANDUM OPINION

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

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

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

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

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

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

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

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

FACTUAL BACKGROUND

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

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

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

STANDARD OF REVIEW

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

I. Subject Matter Jurisdiction

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

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

II. Failure to State a Claim

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

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

ANALYSIS

I. Plaintiffs lack standing to assert Count I.

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

A. Statutory Background

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

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

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

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

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

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

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

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

its members are in every practical sense identical." *United Food and Commercial Workers Union Local 751*, 517 U.S. at 552 (citations and internal quotation marks omitted). To qualify for associational standing, a plaintiff must satisfy a three-prong test: (a) the organization's members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *Id.* at 553.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Id. at 113–14 (citations omitted).

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

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

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

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

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

A. Statutory Background

1. *ACA Employer Insurance Mandate*

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

2. *ACA Individual Insurance Mandate*

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

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

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

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

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

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

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

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

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

C. Counts II and III are ripe for decision.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A. Statutory and Regulatory Background

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

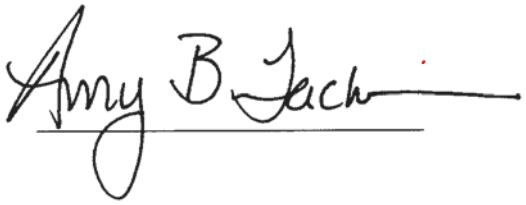
Finally, plaintiffs claim that defendants Sebelius and Astrue have violated their fiduciary and equitable duties to the American people by allowing the Medicare and Social Security programs to face insolvency, Compl. ¶¶ 106–117, 118(A)(xii), and the complaint demands an honest accounting of both programs,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

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

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

CONCLUSION

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



AMY BERMAN JACKSON
United States District Judge

DATE: October 31, 2012

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

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of March 2013, I have caused the foregoing document, together with its addendum, to be served on the following counsel via the Court's CM/ECF System:

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