IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, et al.,	)	
Plaintiffs,	)	
v.	)	Case No. 1:10-CV-0499 (RJL)
KATHLEEN G. SEBELIUS, Secretary of the United States Department of Health and Human Services, et al.,	)	
Defendants.	)	

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

Plaintiffs have essentially folded three separate lawsuits into a single complaint. Each is fatally flawed.

To begin, the Court plainly lacks jurisdiction over plaintiffs' Social Security claims, which challenge provisions of a Social Security Administration manual (the "POMS" manual) describing the statutory link between entitlement to Social Security benefits and Medicare Part A benefits. Despite attaching seven declarations to their opposition brief, plaintiffs identify no one entitled to either benefit, and thus no one actually harmed by the challenged provisions. Nor could they: Although plaintiffs complain that the POMS provisions impermissibly provide for an automatic entitlement to Part A benefits, those provisions merely explain the operation of the underlying statutes and regulations, which plaintiffs do not challenge; moreover, plaintiffs offer no alternative reading of the statutory and regulatory scheme. And in any event, the mere entitlement to Medicare Part A benefits — which need not be used, and do not preclude a beneficiary from visiting whatever doctor or hospital he chooses — causes no cognizable injury. Indeed, plaintiffs concede that they "may have no dispute with Defendants." Pls.' Opp'n at 60. Accordingly, the Court need not reach the merits, as there is no case or controversy to resolve.

Plaintiffs' challenge to the Affordable Care Act also fails. Again, the plaintiff associations identify no member who is harmed now by the minimum coverage provision, which could not affect them until at least 2014, and perhaps not even then; any prediction today of potential harm four years from now is too speculative to support standing. Plaintiffs' challenge to the ACA fares no better on the merits. Their challenge centers on whether Congress had the power to enact the minimum coverage provision. It did. The provision is a quintessential exercise of Congress's power to regulate commerce: It prevents substantial cost-shifting in the health care services market, and is key to the viability of the Act's insurance reforms (such as the

elimination of pre-existing condition exclusions). What is more, the provision is also justified as an exercise of Congress's broad powers under the Necessary and Proper Clause. Plaintiffs' arguments to the contrary distort the meaning of United States v. Comstock, 130 S. Ct. 1939 (2010), the Takings Clause, and equal protection principles. And plaintiffs' taxing argument fails because whether a statute is an exercise of the taxing power turns on its practical operation, not on the label that Congress employed. The minimum coverage provision operates like a tax: it is codified in the Internal Revenue Code; it is administered by the IRS; it is calculated based on household income; it is reported on tax returns; and it is inapplicable to those who fall below the filing threshold.

The Court likewise lacks jurisdiction over plaintiffs' Medicare claims, which challenge an interim final rule (and two administrative "change requests") providing that a billing supplier will not receive payment for "ordered or referred" Part B items or services unless the claim (1) identifies the referring physician by his National Provider Identifier ("NPI"); and (2) the referring physician has enrolled in (or opted out of) Medicare, thus generating a record in the Medicare's PECOS database. Here again, however, plaintiffs fail to identify any member affected by these changes: the member physicians they identify either do not participate in Medicare, and are not required to comply, or were already required to comply by prior regulations that plaintiffs do not challenge here. Even if the Court were to address the merits, however, each of these requirement is fully supported by statutory authority, including the ACA — and, yet again, plaintiffs offer no alternative reading of the statutory and regulatory scheme. Instead, they insist that their member physicians can refer beneficiaries for Part B services — which are subsidized by taxpayers — without complying with these minimal administrative steps. They are mistaken.

For these reasons, and those that follow, defendants' motion to dismiss should be granted and this case should be dismissed in its entirety.

ARGUMENT

I. PLAINTIFFS' SOCIAL SECURITY CLAIMS SHOULD BE DISMISSED

A. The Court Lacks Jurisdiction over Plaintiffs' Social Security Claims

To begin, plaintiffs fail to address defendants' causation and redressability arguments, which should be treated as conceded. See LCvR 7.1; see, e.g., Phrasavang v. Deutsche Bank, 656 F. Supp. 2d 196, 201 (2009). As defendants have explained, because the POMS merely explain the effect of the governing statute and regulations, any "injury" is caused not by the POMS, but by the underlying statute and regulations. For the same reason, invalidating the POMS would not redress any "injury" because the controlling statute and regulations — which plaintiffs do not challenge — would remain in effect. Defs.' MTD at 10-11.

Moreover, plaintiffs do not dispute that neither AAPS nor ANH-USA asserts any injury to its own interests as an organization from the POMS. Defs.' MTD at 10. Rather, they sue only in their representative capacity on behalf of their members. See, e.g., Orient Decl. ¶ 4 (AAPS Exec. Dir., describing suit as "on behalf of members, in a representative capacity"); Dubeau Decl. ¶ 4 (ANH-USA Exec. Dir., describing mission "to defend its members' . . . rights in court"). Yet despite having amended their complaint twice, and having attached several declarations to their opposition brief, plaintiffs still fail to name any particular member allegedly harmed by the POMS. See Summers v. Earth Island Inst., 129 S. Ct. 1142, 1151-52 (2009); Am. Chem. Council v. Dep't of Transp., 468 F.3d 810, 820 (D.C. Cir. 2006).[1] This dooms this claim.

[1] Plaintiffs argue that the requirement to actually name a specific member with standing does not apply at the pleading stage, arguing that for now the Court may "simply assume" that such a member exists. Pls.' Opp'n at 8 n.2. But "[t]hat is not how standing works. No court can simply assume it has jurisdiction." Friends of the Earth v. U.S. Dep't of Interior, 478 F. Supp.

Plaintiffs' complaint asserts harm to two headless categories of members. First, they allege that some members "would like to cease participation in Medicare Part A" but, because of the POMS, cannot do so "without losing eligibility for Social Security." Second Amended and Supplemental Complaint ("SAC"), ¶ 16. But they identify no member who qualifies for either program. In fact, only two of their declarants address entitlement at all, and both explicitly state that they "do not qualify for Medicare . . . or Social Security, and . . . do not expect to . . . in or before 2014." Christman Decl. ¶ 6; Smith Decl. ¶ 12. What is more, even if plaintiffs had named a specific member, their allegations do not describe a cognizable injury. Even if an individual could not opt out of entitlement to Medicare Part A, he need not actually "participate" in the program. Defs.' MTD at 7-8, 13-14. The mere entitlement to benefits that need not be used does not constitute a cognizable injury. Plaintiffs do not respond to this argument, and it, too, should be treated as conceded.

Second, plaintiffs allege that the POMS put physicians who have opted out of Medicare at a competitive disadvantage vis-à-vis other physicians, SAC ¶ 17, presumably on the theory that patients with Medicare coverage might prefer to see doctors who accept Medicare payments. But as defendants have explained, there is no causal link between this alleged injury and the POMS provisions plaintiffs challenge, which involve entitlement to Part A benefits (for inpatient hospital services) not Part B benefits (for physician services). This Part A entitlement does not affect a beneficiary's ability to see whatever physician he chooses, and does not affect a physician's ability to contract for Part B covered services. Defs.' MTD at 11. It is not surprising, then, that plaintiffs submit no declarations asserting any such harm, and in fact

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2d 11, 17 (D.D.C. 2007) (granting motion to dismiss where association failed to identify a particular member with standing). Otherwise, associations could freely circumvent the core standing requirements applicable to individuals, and such cases would proceed to summary judgment before courts could ensure that any particular person was actually harmed.

acknowledge that "Plaintiffs may have no dispute with Defendants" with respect to the POMS. Pls.' Opp'n 60.[2]

B. Plaintiffs' Social Security Claims Should Be Dismissed for Failure to Exhaust Administrative Remedies

In their Second Amended Complaint, plaintiffs argue that the POMS violates the APA because it (the POMS) is inconsistent with the law and was adopted without notice and comment. SAC ¶¶ 16-18, 90-93. Plaintiffs' POMS-related claims arise under the Social Security Act. SAC ¶¶ 16-18, 90-93; Defs.' MTD at 4-5. Thus, they must be brought under 42 U.S.C. §405, which forecloses reliance on other jurisdictional statutes and imposes exhaustion requirements.[3] Shalala v. Ill. Council on Long Term Care, 529 U.S. 1, 5 (2000); Weinberger v. Salfi, 422 U.S. 749, 766-67 (1975).

Plaintiffs have not exhausted their remedies, but seek to circumvent the exhaustion requirement by way of two separate arguments. First, they contend that their action falls outside of § 405 because it arises under this Court's unique equity jurisdiction. Pls' Opp'n at 25-26, 27.

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[2] The plaintiff associations fail to establish third-party standing to raise claims on behalf of unnamed patients. They concede that, to do so, a member doctor would have to establish (1) his own Article III standing, as well as (2) a "close relationship" with a patient possessing the right and (3) a "hindrance" to the patient's ability to protect his own interests. Pls.' Opp'n at 15; see Kowalski v. Tesmer, 543 U.S. 125, 129-30 (2004) (citing Powers v. Ohio, 499 U.S. 400, 411 (1991)). They also do not seriously dispute that the "close relationship" prong cannot be satisfied by hypothetical "prospective patients," rather than identified "existing clients"; rather, they argue that, standing alone, neither prong of the Powers test is dispositive. Pls.' Opp'n at 15. But controlling precedent dictates that these "two additional showings" are "required," Kowalski, 543 U.S. at 130, and that "[both] requirements must be met," Am. Immig. Lawyers Ass'n v. Reno, 199 F.3d 1352, 1362 n.15 (D.C. Cir. 2000). And the notion that these unnamed patients face a "hindrance" because the government has argued that they lack standing is meritless. Pls.' Opp'n at 16. A "hindrance" must be something other than the "normal burdens of litigation" that interferes with a rightholder's ability to bring suit. Am. Immig. Lawyers Ass'n, 199 F.3d at 1363-64. If the unnamed patients lack standing, there is no right for their doctors to enforce. Moreover, any hindrance is "disproved" where individuals have actually brought suit to enforce the asserted right, Kowalski, 543 U.S. at 132, as several have in other ACA challenges.

[3] 42 U.S.C. § 1395ii imposes analogous restrictions for Medicare-related suits.

Second, plaintiffs contend, that they are unable to avail themselves of administrative remedies and so must be allowed to sue, notwithstanding that they have not presented their claim to the agency (much less exhausted). Id. at 27. Both of plaintiffs' arguments fail.

1. Unique Jurisdiction

This Court possesses no jurisdiction unique to the District of Columbia federal district court ("D.D.C."). At one time, D.D.C. did have state-court-like general jurisdiction, but that ended about 40 years ago, with the passage of the District of Columbia Court Reorganization Act of 1970 ("DCCRA"), codified in relevant part at D.C. Code Ann. §§ 11-501 to 11-921 (1973). Both the Supreme Court and the D.C. Circuit have recognized that the DCCRA transferred such jurisdiction to the Superior Court for the District of Columbia, bringing this Court's jurisdiction into line with other federal district courts. Palmore v. United States, 411 U.S. 389, 408-409 (1973); JMM Corp. v. District of Columbia, 378 F.3d 1117, 1123-24 (D.C. Cir. 2004) ("The DCCRA transferred all local jurisdiction . . . from the Federal courts to a new Superior Court of the District of Columbia and the District of Columbia Court of Appeals.").[4]

2. Indirect Review

Plaintiffs allege that their member physicians who have "opted out of Medicare" are hurt by coupling Medicare and Social Security entitlements because patients who would otherwise use these doctors' services apparently do not do so for fear of losing their Social Security

[4] Plaintiffs' citation to Ganem v. Heckler, 746 F.2d 844, 851 (D.C. Cir. 1984), is unavailing. Pls.' Opp'n at 25. Ganem held that a court may exercise mandamus jurisdiction over a Social Security claim. 746 F.2d at 850. But the availability of mandamus jurisdiction over Social Security claims (and, by logical extension, Medicare claims) is "subject to the standard rule that the existence of an alternative remedy precludes mandamus." Action Alliance of Senior Citizens v. Leavitt, 483 F.3d 852, 858 (D.C. Cir. 2007). Plaintiffs have alternate remedies available to them in the form of administrative review and, if necessary, federal court review under § 405(g). See Action Alliance, 483 F.3d 858; Defs.' MTD at 15. Thus, mandamus jurisdiction is unavailable. But even if it were available, plaintiffs' claims would fail because plaintiffs do not have a clear right to relief, and defendants do not have a clear duty to act. Baptist Mem. Hosp. v. Sebelius, 603 F.3d 57, 62 (D.C. Cir. 2010); see Defs.' MTD at 9-20.

benefits.[5] SAC ¶ 44. And what is more, plaintiffs insist, their member doctors could not "initiate an administrative challenge to the retirees' [loss of] benefits" and so are excepted from exhaustion requirements.[6] Id. Defendants explained in their opening brief that doctors who are members of the plaintiff associations can seek review of their Social Security–related claims through administrative actions brought by their patients, and that the availability of such review suffices to require such claims to be brought under § 405. See, e.g., Am. Chiropractic Ass'n v. Leavitt, 431 F.3d 812, 816-18 (D.C. Cir. 2005); Colo. Heart Inst., LLC v. Johnson, 609 F. Supp. 2d 30, 34-38 (D.D.C. 2009).

Plaintiffs respond that indirect review of their claims is not available because "th[e] Defendants' policies put their members on an unlawfully unequal footing vis-à-vis their competitors" and that, "[f]or that reason, they will never get the customers they seek, so they cannot avail themselves of the indirect path through [the] channeling provisions envisioned by Am. Chiropractic Ass'n v. Leavitt." Pls.' Opp'n at 27. This argument fares no better than plaintiffs' misbegotten "unique jurisdiction" argument. The argument depends on the factual inference that, due to this alleged unequal footing, plaintiffs "will never get the customers they seek." Id. When ruling on a motion to dismiss, a Court will not accept inferences "unsupported by the facts set out in the complaint." Browning v. Clinton, 292 F.3d 235, 242 (D.C. Cir. 2002) (citations and quotation marks omitted). The facts set out in the SAC do not support the inference suggested by plaintiffs. In the section of the complaint detailing the alleged injuries

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[5] This allegation is nonsensical. See Defs.' MTD at 11. Plaintiffs' members patients need not elect to enroll in and pay for Medicare Part B insurance, and even if they do, they are in no sense required to visit only those doctors who accept Medicare Part B. Their choice of physician has no connection to entitlement to Social Security old-age benefits.

[6] Plaintiffs' argument, even if accepted, pertains only to a subset of their POMS claims (i.e., those brought on behalf of physicians as physicians).

caused by the connection between old-age payments and Medicare Part A entitlement, plaintiffs contend that patients have a "greater difficulty retaining" member doctors, but not that patients will never retain member doctors.[7] SAC. ¶ 17. And the complaint does not allege that the circumstances will deteriorate for the doctors such that in the future they will "never get the customers they seek." Pls.' Opp'n at 27. Indeed, even if the Complaint alleged this, the Court would not need to accept plaintiffs' inference because it is unreasonable — given the presence of the modifier "never" — and Courts need only accept reasonable inferences. Gilvin v. Fire, 259 F.3d 749, 756 (D.C. Cir. 2001). Thus, plaintiffs offer no basis to question the feasibility of indirect review.

In short, § 405 applies to plaintiffs' Social-Security-related claim, which must be dismissed for lack of exhaustion. See Lower Counties Cmty. Health Servs. v. U.S. Dep't of Health and Human Servs., 317 Fed. App'x 1 (D.C. Cir. 2009) (dismissing case for lack of jurisdiction because plaintiff did not exhaust administrative remedies under § 405).

C. The Challenged POMS Provisions Need Not Have Been Submitted for Notice and Comment

[7] Plaintiffs cite paragraph 20 of the complaint in support of their argument that administrative review will be unavailable. Pls.' Opp'n at 27. Paragraph 20 details the alleged harms caused by the ACA — not the POMS. SAC ¶ 20. This citation bears no fruit for plaintiffs. For one thing, if plaintiffs allege only harm caused by the ACA, then invalidation of the POMS will do nothing to redress the harm. Thus, this alleged harm provides no basis on which to upend the POMS. See County of Delaware v. Dept. of Transp., 554 F.3d 143, 148-150 (D.C. Cir. 2009) (concluding plaintiffs lacked standing because invalidation of government action would not redress alleged injury). For another, this paragraph, in any case, does not allege that member doctors "will never get the customers they seek." Rather, it alleges that the ACA will make it less likely that patients will retain member doctors — because those doctors operate "cash practices" and patients will have less disposable income due to insurance premium increases allegedly caused by the ACA — not that they never will. See SAC ¶ 20. Plaintiffs also cite a declaration in support of their argument, Smith Decl. ¶¶ 7-8, 10. But the declaration does not support the allegation that member doctors will never secure patients, and it complains of harms from the ACA, not the POMS. Id.

The challenged POMS provisions merely explain the effect of the existing statutory and regulatory scheme. Thus, they are at most interpretive rules, which are exempt from notice and comment, as Judge Collyer held in Hall v. Sebelius, 689 F. Supp. 2d 10, 20 (D.D.C. 2009). See also Defs.' MTD 16-18; Cent. Tex. Tel. Coop. v. FCC, 402 F.3d 205, 212, 214 (D.C. Cir. 2005) (interpretive rules "must derive a proposition from an existing document whose meaning compels or logically justifies the proposition," but need not "parrot statutory or regulatory language" and "may have the effect of creating new duties") (internal quotations omitted). Plaintiffs offer two theories to avoid this conclusion. Neither is correct.[8]

First, plaintiffs argue that the POMS "invented a duty" that does not appear in the Social Security Act — namely, that to "terminat[e] Social Security benefits" an individual must "repay past benefits received." Pls.' Opp'n at 59-60. But the POMS did not "invent" this requirement; rather, it is contained in SSA's withdrawal regulation, which allows an individual to withdraw a Social Security application if "[a]ll benefits already paid based on the application being withdrawn are repaid or [SSA is] satisfied that they will be repaid." 20 C.F.R. 404.640(b)(3).[9] Plaintiffs do not challenge this underlying regulation, and it would remain in effect even if the POMS were invalidated.

Second, plaintiffs argue that because the challenged POMS provisions were not issued as "free-standing" rules but, instead, were placed in the POMS manual, they effectively "amended

[8] As defendants have explained, as an initial matter plaintiffs also lack standing to raise their procedural claims: they fail to identify any particular member with a particularized injury to a concrete interest (as distinct from the abstract interest in adherence to procedure), or a causal connection between the challenged agency action and that alleged injury. Defs.' MTD at 12.

[9] Since defendants' opening brief was filed, 20 C.F.R. § 404.640 was modified by a final rule with request for comments to limit requests to withdraw an application for old-age benefits to one per lifetime, within twelve months of the first month of entitlement. 75 Fed. Reg. 76256 (Dec. 8, 2010). The requirement in subsection (b)(3) to repay all benefits is unchanged.

the POMS, a prior interpretation," and thus required notice and comment. Pls.' Opp'n at 59. That is nonsense. It is true, of course, that "[w]hen an agency has given its regulation a definitive interpretation, and later significantly revises that interpretation, the agency has in effect amended that rule, something it may not accomplish without notice and comment." Alaska Prof'l Hunters v. FAA, 177 F.3d 1030, 1034 (D.C. Cir. 1999). But here, plaintiffs identify no prior interpretation of 20 C.F.R. § 404.640(b)(3), or any substantive regulation, that is inconsistent with the challenged POMS provisions. Instead, they appear to argue that the POMS manual, as a whole, represents SSA's definitive interpretation of the entire Social Security Act, and thus cannot be modified without notice and comment. That contention is at odds with both precedent and common sense. See Schweiker v. Hansen, 450 U.S. 785, 789 (1981) (predecessor manual to POMS "has no legal force, and . . . does not bind the SSA"). Where a new interpretive rule does not conflict with an earlier, authoritative interpretation of a particular regulation, notice and comment is simply not required. See, e.g., Paralyzed Veterans of Am. v. D.C. Arena L.P., 117 F.3d 579, 587 (D.C. Cir. 1997). The fact that the new interpretive rule is placed in an administrative manual, together with thousands of other provisions interpreting different regulations, does not change that.

D. The Challenged POMS Provisions Are Consistent with the Statutory and Regulatory Framework

Entitlement to Medicare Part A benefits arises automatically for individuals who turn 65 and are entitled to monthly Social Security benefits. 42 U.S.C. § 426(a); 42 C.F.R. § 406.6(b). Neither the statute nor the regulations sets forth any mechanism that a qualifying individual can use to "avoid" automatic Medicare Part A entitlement, other than by declining to apply for monthly Social Security benefits. See 42 U.S.C. § 426(a). Nor is there a mechanism enabling an individual to "extinguish" automatic entitlement to Medicare Part A benefits, other than

withdrawal of an application for Social Security benefits. 20 C.F.R. § 404.640. Thus, as defendants have explained, the challenged POMS provisions merely explain the effect of this statutory and regulatory scheme — that is, the absence of a mechanism permitting an individual to forgo entitlement to Medicare Part A while retaining entitlement to monthly Social Security benefits. Simply put, the POMS do not conflict with the governing law.

Plaintiffs contest none of this in their opposition. Critically, they offer no alternative reading of the governing statute or regulations — which alone dooms this claim. In fact, they appear to question whether their members are harmed by the POMS provisions at all, suggesting that, in fact, "Plaintiffs may have no dispute with Defendants." Pls.' Opp'n at 60 (citing Moore v. Charlotte-Mecklenburg Bd. of Educ., 402 U.S. 47, 47-48 (1971) (dismissing appeal for lack of a case or controversy)). This concession underscores the lack of a case or controversy here.

First, plaintiffs suggest that "it appears that Part A [entitlement] seriously erodes the freedom of choice available to the Medicare-eligible patient, given Defendants' attaching Medicare strings to mere [entitlement]." Id. But as defendants have explained, see Defs.' MTD at 7-8, the mere entitlement to Medicare Part A benefits does not limit an individual's freedom of choice. Nothing in Medicare Part A requires beneficiaries to actually use the benefits to which they are entitled. Nothing requires them to see particular providers of hospital services. Nothing precludes them from visiting hospitals or doctors who do not participate in Medicare. And nothing bars them from spending their own money on medical care or other insurance, 42 U.S.C. § 1395f(a)(1); indeed, a beneficiary can refuse to authorize a hospital to seek Medicare payment for his care, in which case "the provider may charge the beneficiary for all services furnished to him." 42 C.F.R. § 489.21(b)(4). Plaintiffs dispute none of this and, at bottom, identify no concrete way that mere entitlement to Part A benefits harms any beneficiary.

Second, plaintiffs appear to seek confirmation that, in defendants' view, "a patient's Medicare Part A [entitlement] does not prevent a non-Medicare physician or facility from seeing that patient, wholly outside of Medicare, without complying with 42 U.S.C. § 1395a(b)." Pls.' Opp'n at 60. That is correct. Section 1395a(b) governs the use of private contracts between physicians and Medicare beneficiaries, including opt-out requirements. That section defines "Medicare beneficiary" to include individuals "entitled to benefits under part A of this subchapter or enrolled under part B." 42 U.S.C. § 1395a(b)(5). However, because physician services are provided under Part B, the opt-out regulations define "beneficiary" to mean "an individual who is enrolled in Part B of Medicare." 42 C.F.R. § 405.400; see also id. §§ 405.405, 405.410, 405.420. Thus, by regulation, the requirements of 42 U.S.C. § 1395a(b) apply only to physicians who choose to provide Part B beneficiaries with a covered service outside of Medicare. The mere fact that a prospective patient is entitled to Part A benefits does not trigger the requirements of 42 U.S.C. § 1395a(b). Accordingly, an entitlement to Part A benefits alone does not burden a physician's ability to contract for Part B covered services.

II. PLAINTIFFS' ACA-RELATED CLAIMS SHOULD BE DISMISSED

A. The Court Lacks Jurisdiction over Plaintiffs' ACA Claims

Plaintiffs attempt to identify two AAPS member physicians, Dr. Christman and Dr. Smith, who could potentially be subject to the minimum coverage provision when it takes effect in 2014. But they offer no response to the argument that, if these individuals are in fact subject to the provision and elect not to comply, any penalty would not be due until April 2015 — more than four years from now, which is "too remote temporally" to support standing. Defs.' MTD at 26 (citing McConnell v. FEC, 540 U.S. 93, 226 (2003)).[10]

[10] Plaintiffs are mistaken to argue that state laws purporting to exempt individuals from the minimum coverage provision give those individuals standing to challenge it. Pls.' Opp'n at 9.

Moreover, neither Dr. Christman nor Dr. Smith alleges any current harm from the minimum coverage provision; rather, each vaguely states that he "will be harmed financially" if he is ultimately subject to it. Christman Decl. ¶ 9; Smith Decl. ¶ 15 (emphasis added). But, as previously explained, much can change between now and 2014, and any future harm is highly uncertain. Although both predict (based on their current income, which they do not provide) that they "do not expect" to be eligible for Medicaid in 2014, fortunes can change rapidly. They cannot possibly know they will not be eligible for Medicaid four years from now. Their incomes could fall, making the provision inapplicable. They could take a job offering qualifying coverage. Or they could fall ill and decide that obtaining coverage is a sensible choice. Thus, these speculative injuries are too uncertain to support standing.[11]

With respect to the employer responsibility provision, plaintiffs' attempt to identify members with standing falls even further short. Rather than naming particular members, as Summers and American Chemistry Council require, plaintiffs state that they have "confidential information" about four anonymous "ANH-USA corporate members" that "employ 100, 110, 250, and 550 employees." DuBeau Decl. ¶ 9. This is plainly insufficient. Moreover, as previously explained, any potential assessments apply only to large employers that do not offer a minimum level of coverage to full-time employees. Defs.' MTD at 26 & n.16. Plaintiffs say nothing about the coverage these "corporate members" currently offer, and thus fail to

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The issue is whether the minimum coverage provision harms them and, if so, when. Even if those state laws did create enforceable rights, their existence could not accelerate any such harm. The same is true of their attempt to invoke "equal protection standing." See Pls.' Opp'n at 13.

[11] Plaintiffs do not respond to defendants' argument that a speculative increase in health insurance premiums — or the effect of such an increase on the associations' members' profits — is too speculative to support standing, and it should be treated as conceded. Defs.' MTD at 25.

demonstrate that any potential assessments could apply to them even today, let alone in 2014 when the provision takes effect — indeed, because that is impossible to know now.[12]

B. Plaintiffs' Challenges to the Minimum Coverage and Employer Responsibility Provisions Are Unripe

With respect to ripeness, plaintiffs principally insist — as defendants have acknowledged — that where the operation of a statute against certain individuals is inevitable, "it is irrelevant to the existence of a justiciable controversy that there will be a time delay before the disputed provisions will come into effect. Defs.' MTD at 27 (quoting Blanchette v. Conn. Gen. Ins. Corp., 419 U.S. 102, 143 (1974)); Pls.' Opp'n at 21. But contrary to plaintiffs' assertion that "no facts remain to develop," Pls.' Opp'n at 22, any potential injury here is not inevitable, but highly speculative, as numerous contingencies affect whether any particular individual would be injured by the minimum coverage provision. See supra Part II.A. Because this case involves "contingent future events that may not occur as anticipated, or indeed may not occur at all," Thomas v. Union Carbide Agric. Prods. Corp., 473 U.S. 568, 580-81 (1985), it is not ripe for review. Indeed, given these contingencies, postponing review here "would permit better review of the issues while . . . causing no significant hardship to the parties." NIPSCO v. FECR, 954 F.2d 736, 738 (D.C. Cir. 1992).

C. The ACA Falls within Congress's Article I Powers

1. The Minimum Coverage Provision Regulates Activity that Substantially Affects Interstate Commerce

The requirement that health care consumers have insurance to pay for the health care services they consume is a quintessential exercise of Congress's power to regulate interstate

[12] Defendants do not, for purposes of this motion to dismiss, intend to pursue the arguments in Part II.B.1.c of their opening brief, in which defendants contended that the Anti-Injunction Act bars plaintiffs' challenges to the minimum coverage and employer responsibility provisions.

commerce. Defs.' MTD at 35-42; Liberty Univ. v. Geithner, 2010 WL 4860299, at *14-15 (W.D. Va. Nov. 30, 2010); Thomas More Law Ctr. v. Obama, 720 F. Supp. 2d 882, 892-94 (E.D. Mich. 2010). The minimum coverage provision furthers two principal economic goals. First, it prevents the substantial cost-shifting in the interstate health care market that results from the practice of consuming health care without insurance. Defs.' MTD at 38-42. Second, the minimum coverage requirement is key to the viability of the Act's requirement that insurers provide coverage to all persons without regard to their medical condition or history and without charging more based on that condition or history. Id. at 35-38.

Plaintiffs disagree with the conclusion that the Commerce Clause justifies Congress's enactment of the minimum coverage provision. They offer two arguments in support of their position.[13] The first is that "[c]ommerce entails voluntary activity and purposeful exchange, not mere inactivity," and the minimum coverage provision regulates the "mere inactivity of not purchasing PPACA-compliant health insurance." Pls.' Opp'n at 38 (emphasis omitted). The second is that upholding the minimum coverage provision under the Commerce Clause "would undermine our constitutional structure by creating an unlimited power indistinguishable from a national police power." Id. at 41.

These arguments fail. Plaintiffs members are "inactive" only in the sense that they say they do not intend to buy ACA-compliant health insurance come 2014. Pls.' Opp'n at 38. But insurance requirements are not imposed because an individual has entered the insurance market. They are imposed because of costs and risks incurred in a broader market — here, the interstate market for health care services. See Summit Health Ltd. v. Pinhas, 500 U.S. 322, 329 (1991). Plaintiffs' attempt to divorce their members' participation in the national health care market —

[13] Plaintiffs separately address whether the Necessary and Proper Clause supports the minimum coverage provision. These arguments are addressed in the next section of this brief.

in which they in no sense claim to be inactive — from their means of paying for services in that market disregards the teachings of the Supreme Court, which has rejected such artificial distinctions in favor of "broad principles of economic practicality." United States v. Lopez, 514 U.S. 549, 571 (1995) (Kennedy, J., concurring); see also Gonzales v. Raich, 545 U.S. 1, 22 (2005); Wickard v. Filburn, 317 U.S. 111, 119, 129 (1942) (sustaining exercise of the commerce power even though the regulation "forc[ed] some farmers into the market to buy what they could provide for themselves"); Swift Co. v. United States, 196 U.S. 375, 398 (1905); cf. Brown Shoe Co. v. United States, 370 U.S. 294, 336-337 (1962).

Plaintiffs ignore the fundamental feature of health insurance — its function as the principal and practical means of payment for health care services in the United States. Buying insurance reflects a choice of one method of dealing with the cost of potential medical expenses. M.M. Porat, et al., Market Insurance versus Self Insurance: The Tax-Differential Treatment and Its Social Cost, 58 J. Risk & Ins. 657, 668 (1991) (buying insurance is an economic substitute for other "competing pre-loss risk-financing methods"). See also J.P. Ruger, The Moral Foundations of Health Insurance, 100 Q.J. Med. 53, 55 (2006); Mark V. Pauly, Risks and Benefits in Health Care: The View From Economics, 26 Health Aff. 653, 658 (2007).[14] And from both the societal and the individual perspective, "[t]he decision whether to purchase

[14] Professor Pauly notes that some consumers value more highly insurance that pays for medical costs that are likely to be incurred than insurance that provides inferior coverage for likely costs but superior coverage for catastrophic events. Pauly, supra, at 658. This reflects a significant distinction between health insurance and other types of insurance. The sole purpose of many types of insurance is to provide protection "against events that are highly unlikely to occur but involve large losses if they do occur." Milton Friedman, How To Cure Health Care, The Public Interest, Winter 2001, at 10. With regard to medical services, in contrast, "it has become common to rely on insurance to pay for regular medical examinations and often for prescriptions." Id.; see also Martin S. Feldstein, The Welfare Loss of Excess Health Insurance, 81 J. Pol. Econ. 251, 253 (1973) ("Health insurance is purchased not as a final consumption good but as a means of paying for the future stochastic purchases of health services.").

insurance or to attempt to pay for health care out of pocket, is plainly economic." Thomas More Law Ctr., 720 F. Supp. 2d at 893. "Regardless of whether one relies on an insurance policy, one's savings, or the backstop of free or reduced-cost emergency room services, one has made a choice regarding the method of payment for the health care services one expects to receive." Liberty, 2010 WL 4860299 at *15. Congress acted well within its Commerce Clause power in regulating this economic decision that has profound economic effects on interstate commerce.

Plaintiffs' national police power argument is similarly unavailing. The Supreme Court in Lopez and United States v. Morrison, 529 U.S. 598 (2000), established limits on the Commerce Clause and warned against the clause becoming a national police power. The minimum coverage provision falls well within the limits established in Lopez and Morrison. According to these cases, Congress may not use the Commerce Clause to regulate a purely non-economic subject matter, if that subject matter bears no more than an "attenuated" connection to interstate commerce, and if the regulation does not form part of a broader scheme of economic regulation. Morrison, 529 U.S. at 615; Lopez, 514 U.S. at 567. But the ACA does not depend on "attenuated" links between its subject matter and interstate commerce. It instead directly regulates an economic subject matter of national proportions, the financing of payments in the $2.7 trillion national market for health services. See supra at 15-17; Sara Rosenbaum, Can States Pick Up the Health Reform Torch?, 362 New Engl. J. Med. e29, at 3 (2010) ("Affordable health care is a national problem that demands a national solution."); State Coverage Initiatives: Hearing Before the Subcomm. on Health of the H. Comm. on Ways & Means, 110th Cong. 7 (2008) (statement of Alan R. Weil, Exec. Dir., Nat'l Acad. of State Health Policy) ("Expecting states to address the many vexing health policy issues on their own is unrealistic, and constrains the number of states that can even make such an effort.").

2. The Minimum Coverage Provision Is an Integral Part of the Larger Regulatory Scheme and Is Necessary and Proper to Congress's Regulation of Interstate Commerce

The Supreme Court has long held that courts must accord great deference to the regulatory means that Congress selects to accomplish its legitimate regulatory objectives. That deference reflects both a proper allocation of authority to the democratically-elected branches of government, and a recognition of the greater capacity of those branches to make such operational choices. Thus, Justice Scalia observed in his concurring opinion in Raich that "where Congress has the authority to enact a regulation of interstate commerce, 'it possesses every power needed to make that regulation effective.'" 545 U.S. at 36 (quoting United States v. Wrightwood Dairy Co., 315 U.S. 110, 118-19 (1942)). "[T]he relevant inquiry is simply 'whether the means chosen are "reasonably adapted" to the attainment of a legitimate end under the commerce power' or under other powers that the Constitution grants Congress the authority to implement." United States v. Comstock, 130 S. Ct. 1949, 1957 (2010) (quoting Raich, 545 U.S. at 37 (Scalia, J., concurring in the judgment)). The Act's reforms of the insurance market — particularly the guaranteed issue requirement — are, unquestionably, exercises of the commerce power.[15] The minimum coverage provision is not only rationally related, but is "essential," to the implementation of these reforms. Congress found that, absent the minimum coverage provision, these insurance reforms would encourage more individuals to forgo or drop insurance until they needed care, increasing insurance prices and threatening the viability of the health care insurance market.[16] ACA §§ 1501(a)(2)(H), (I), 10106(a); Defs.' MTD at 36-37.

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[15] In the complaint, plaintiffs challenged Congress's power to enact such reforms. SAC ¶¶ 95, 98. Sensibly, plaintiffs appear to have dropped those challenges, as they go unmentioned in their opposition brief.

[16] Plaintiffs contend that the "obvious solution" to the problem posed by "market timers" is to deny them access to insurance. Pls.' Opp'n at 41. But this "solution" would leave intact the pre-

Plaintiffs argue that the Necessary and Proper Clause does not support the minimum coverage provision for three reasons: (1) the minimum coverage provision does not satisfy the five-part test for applying the Clause set out in Comstock; (2) the minimum coverage provision violates the Takings Clause of the Fifth Amendment, and (3) the minimum coverage provision transgresses the equal protection component of the Fifth Amendment's due process clause. Plaintiffs' arguments miss their mark.

a. Comstock

Contrary to plaintiffs' assertion, Comstock reaffirmed the Supreme Court's well-established deference to Congress's exercise of power under the Necessary and Proper Clause. Indeed, the Court emphasized the "breadth" of that clause, reciting the long line of cases since M'Culloch v. Maryland, 17 U.S. (4 Wheat.) 316 (1819), establishing that Congress gets to choose how to implement its enumerated powers, so long as its choices have a rational basis. See Comstock, 130 S. Ct. at 1957. The remainder of what plaintiffs inflate into a "five part test," Pls.' Opp'n at 47-48, consisted of the reasons establishing why, in Comstock, the system of civil commitment procedures at issue there was rationally connected to the implementation of congressional powers, even though — unlike Raich and unlike this case — those procedures did not directly further a scheme authorized by a specific enumerated power.

In any event, plaintiffs misapply the purported five-part test. Plaintiffs argue that "the rationality of the ends-means fit is weak" because "compelled private transactions are disfavored in our political and legal tradition." Pls.' Opp'n at 48. Whether a practice is favored or disfavored, contemporarily or historically, is not the constitutional measure of Congress's legislative choices. By importing this question of policy preferences, plaintiffs misread the

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existing condition exclusions that Congress intended to eliminate, and as Congress's choice comports with the constitution, plaintiffs cannot displace it with their own policy preference.

rational basis test under the Commerce Clause and under the Necessary and Proper Clause. Plaintiffs also ignore, among other things, the long-established authority of Congress to exercise eminent domain — that is, the power to compel a transaction — in furtherance of Commerce Clause regulations, see Luxton v. N. River Bridge Co., 153 U.S. 525, 529-30 (1894); the long list of insurance-purchase requirements in the United States Code; and the 30-year-old Superfund Act, which compels property owners to enter into transactions to remedy contamination on their properties, see Nurad, Inc. v. William E. Hooper & Sons Co., 966 F.2d 837, 845 (4th Cir. 1992).

Plaintiffs also argue that the minimum coverage provision is invalid because "[t]he federal government has no history of involvement — outside of Spending-Clause programs for which the government itself pays — in health insurance," and "[t]he Individual Mandate does not reasonably extend the federal government's pre-existing practices with respect to public health." Pls.' Opp'n at 48. These arguments, again, are irrelevant under the governing law, which looks only to whether the provision is rationally connected to the implementation of the commerce power — a standard that the minimum coverage provision plainly meets. The arguments are also factually wrong. The federal government has regulated the field of health insurance for decades, see Defs.' MTD at 33, indeed, for the entire period the national health care and health insurance markets have existed in their current form.[17]

Plaintiffs next assert that the minimum coverage provision is not valid because it "competes directly with [the] states' police power." Pls.' Opp'n at 48. There is no such competition. As Comstock itself makes clear, "[t]he powers 'delegated to the United States by the Constitution' include those specifically enumerated powers listed in Article I along with the implementation authority granted by the Necessary and Proper Clause. Virtually by definition,

[17] See, e.g., Paul Starr, The Social Transformation of American Medicine 320-27 (1982) (describing growth of national commercial health insurance market after World War II).

these powers are not powers that the Constitution 'reserved to the States.'" 130 S. Ct. at 1962 (quoting U.S. Const. amend. X). If a measure is rationally related to the implementation of other enumerated powers, it is valid under the Necessary and Proper Clause, and the Tenth Amendment is not implicated at all.

Last, plaintiffs argue that the minimum coverage provision cannot be valid because it rests on a claim of a federal police power that lacks any limiting principle. As explained earlier, see supra Part II.C.1 , this argument is meritless.

b. Takings Claim

Plaintiffs argue that the minimum coverage provision cannot be justified by the Necessary and Proper Clause because it violates the Takings Clause of the Fifth Amendment. Pls.' Opp'n at 49-53. Plaintiffs allege that the ACA — by establishing minimum coverage requirements and minimum requirements for the terms of insurance policies (e.g., by prohibiting insurance companies from refusing coverage based on a pre-existing medical condition) — forces up premiums charged by private insurance companies and, in doing so, effects a taking.[18] SAC ¶ 68. Defendants explained that plaintiffs' allegation founders for three primary reasons: (1) the claim is not ripe because they have not sought compensation in the Court of Federal Claims under the Tucker Act, 28 U.S.C. § 1491; (2) even if the ACA does cause an increase in insurance premiums for some persons, that increase cannot be legally attributed to the government; and (3) an obligation to pay money does not constitute a taking.

[18] Defendants assume for purposes of this argument only that the ACA has resulted, or will result, in increased premiums. However, the CBO has predicted that the minimum coverage provision will, in fact, lower premiums by bringing relatively healthy individuals into the insurance market. See Letter from Douglas W. Elmendorf, Director, CBO, to Senator Evan Bayh, U.S. Senate, at 6 (Nov. 30, 2009). Thus, as the provision will not cause an increase in premiums, it will not effect a taking, and plaintiffs' argument fails. Correlatively, even if the reforms regarding policy terms could cause premiums to increase, this, of course, would not establish that the minimum coverage provision — a separate provision — effects a taking. Thus, plaintiffs' necessary-and-proper argument with respect to that provision would fail.

None of plaintiffs' responses is persuasive. The Takings Clause "is designed not to limit the governmental interference with property rights per se, but rather to secure compensation in the event of otherwise proper interference amounting to a taking." First English Evangelical Lutheran Church of Glendale v. County of Los Angeles, 482 U.S. 304, 314-15 (1987) (emphasis omitted). Plaintiffs have not sought such compensation. Indeed, relying on Duke Power Co. v. Carolina Envtl. Study Group, 438 U.S. 59, 71 n.15 (1978), plaintiffs argue that they need not sue first in the Court of Claims under the Tucker Act to recover on a takings claim. Duke Power does not help them. In this case, the Supreme Court held that a court has the power to determine whether Congress has withdrawn Tucker Act remedies with respect to a particular takings claim. Id.; CBS Outdoor, Inc. v. New Jersey Transit Corp., 2007 WL 2509633, at *11 (D.N.J. 2007); Richard H. Seamon, An Analysis of Jurisdictional Issues Arising from Eastern Enterprises v. Apfel, 51 Ala. L. Rev. 1239, 1243-44 (Spring 2000). But it also concluded that, if a court concludes that Tucker Act remedies are available, the case must be dismissed, as a takings claim would be premature.[19] See Duke Power, 438 U.S. at 94 n.39; CBS Outdoor, 2007 WL 2509633, at *11; Seamon, 51 Ala. L. Rev. at 1243-44. If there is any ambiguity in Duke Power, the Court clarified its position twelve years later in Preseault v. ICC, 494 U.S. 1, 11(1990), concluding that "taking claims against the Federal Government are premature until the property owner has availed itself of the process provided by the Tucker Act." Plaintiffs do not and cannot allege that the ACA withdraws Tucker Act remedies. Thus, the takings allegation is unripe.

Plaintiffs' response to defendants' argument that the alleged increase in premiums does not constitute a taking because any requirement to pay higher premiums would be imposed by a private party, rather than defendants, is no more persuasive. Defs.' MTD at 53-54**.** Plaintiffs

[19] This conclusion is subject to the exception, noted in footnote 36 of defendants' opening brief, Defs.' MTD at 53 n.36, which is inapplicable on the facts of this case.

assert that defendants are responsible for the actions of private insurers because those insurers have increased, or will increase, their premiums in response to the ACA. Pls.' Opp'n at 50-51. This argument is a non-sequitur. The insurance reforms do not require premium increases. If insurance companies increase premiums, it will be a result of their own free choice. The most that could be argued, then, is that the government was aware that insurance premiums could rise. But awareness of a third party's actions does not suffice to support a takings claim. Shewfelt v. United States, 104 F.3d 1333, 1337 (Fed. Cir. 1997).

Plaintiffs' citation of Turney v. United States, 115 F. Supp. 457 (Ct. Cl. 1953), does not rescue this argument. Turney is the only case in which the Federal Circuit or its predecessor (the court that entertains takings claims against the federal government under the Tucker Act) has concluded that "the government's action towards a third-party . . . [had] a direct and substantial enough effect on the plaintiff to require compensation under the Takings Clause," Casa de Cambio Comdiv v. United States, 291 F.3d 1356, 1361 (Fed. Cir. 2002). But the facts of that case bear no resemblance whatsoever to the facts here. In Turney, the U.S. government encouraged the third party (the Philippines), to act, in contrast to this case, where the government would merely be aware of actions by a private party. What is more, the factual circumstances of Turney suggest a unique closeness between the United States and the third party: The United States had just liberated the Philippines from Japan in World War II and had given tens of millions of dollars to the Philippines from the sale of surplus military equipment. Casa de Cambio Comdiv, 291 F.3d at 1362-63 (discussing the unique facts of Turney). Indeed, the Federal Circuit has underscored the singular nature of Turney — and the extent to which it turned on the special historical circumstances — by declining to recognize takings in more recent cases in which the United States has encouraged sovereigns to undertake actions which could be considered takings. See B&G Enters., Ltd. v. United States, 220 F.3d 1318, 1321 (Fed. Cir.

2000), cert. denied, 531 U.S. 1144 (2001); Langenegger v. United States, 756 F.2d 1565, 1572 (Fed. Cir. 1985). Here, plaintiffs can identify no special relationship between the government and the private insurers. In sum, the United States cannot be held responsible under the Takings Clause for the voluntary actions of insurance companies.

Plaintiffs also try unsuccessfully to undercut defendants' argument that "[t]he mere imposition of an obligation to pay money, as here, does not give rise to a claim under the Takings Clause of the Fifth Amendment." Commonwealth Edison Co. v. United States, 271 F.3d 1327, 1340 (Fed. Cir. 2001). Plaintiffs argue that this position, adopted by five members of the Supreme Court in Eastern Enterprises v. Apfel, 524 U.S. 498, 540 (1998) (Kennedy, J., concurring); id. at 554 (Breyer, J., dissenting), is not part of the holding, given the disparate views in the case. Pls.' Opp'n at 52-53. Plaintiffs also maintain that the Supreme Court in Railroad Retirement Board v. Alton R. Co. 295 U.S. 330, 357 (1935), did allow that money can be the subject of a taking. Defendants did not cite Eastern Enterprises as binding precedent, but rather as persuasive authority for the position that an obligation to pay money does not constitute a taking.[20] The contrary position would stretch the takings doctrine beyond all recognition by charging federal courts with redistributing the economic costs of virtually every regulatory action, a function inconsistent with the proper role of courts in our constitutional system. Defs.' MTD at 54-55. And Railroad Retirement Board boots plaintiffs nothing. That decision did not hold that the challenged law violated the Takings Clause. Rather, it held that the law violated the Due Process Clause. Railroad Retirement Board, 295 U.S. at 360. (This fact explains why no justice in Eastern Enterprises cited the case in the back-and-forth about whether a bare obligation

[20] There is other such authority. Swisher Int'l v. Schafer, 550 F.3d 1046, 1054-55 (11th Cir. 2008), cert. denied, 130 S. Ct. 71 (2009); Commonwealth Edison Co., 271 F.3d at 1340 (Fed. Cir. 2001); SRM Chem. Ltd. v. Fed. Mediation & Conciliation Serv., 355 F. Supp. 2d 373, 377 (D.D.C. 2005).

to pay money can constitute a taking.) Its reference to the taking of money is dictum. Without Railroad Retirement Board, plaintiffs have no argument. And for the reasons discussed in defendants' opening brief and the raft of precedent cited there (and above), the Court should conclude that an obligation to pay money cannot constitute a taking.

c. Equal Protection

Plaintiffs also contend that the minimum coverage provision cannot be justified by the Necessary and Proper Clause because it violates the equal protection component of the Fifth Amendment's due process clause. Pls.' Opp'n at 12-14, 53-54. The alleged violation is that provision unlawfully discriminates against people who desire "high-deductible, catastrophic-risk insurance" policies (which do not satisfy the ACA's minimum coverage requirement) and can make their deductible payments. This is because they allegedly will not be able to purchase these policies in 2014, and therefore, if not exempted from the minimum coverage provision, will face a penalty for not having minimum essential coverage — as opposed to others with minimum essential coverage who will not have to pay a penalty.[21] Id. at 13.

This argument fails. Economic legislation is subject to a deferential rational-basis review standard, Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 15 (1976), and "equal protection is not a license for courts to judge the wisdom, fairness, or logic of legislative choices," F.C.C. v. Beach Commc'ns Inc., 508 U.S. 307, 313 (1993). Congress had a rational basis for

[21] In fact, the ACA provides that purchase of a catastrophic care plan will meet the essential health benefits package requirements if an individual is under 30 years of age or meets the tests of 26 U.S.C. § 5000A(e) with respect to affordable coverage or financial hardship. ACA § 1302(e)(2), 124 Stat. 168. Plaintiffs also do not define the specific components of a "high-deductible, catastrophic-risk insurance." In 2014, exchanges will offer individuals, families, and small businesses a wide range of plans, including lower-cost consumer-driven health plans and those coupled with Health Savings Accounts ("HSAs") that tend to have higher deductibles and higher cost sharing. Exchanges will also offer health plans at the "bronze" or basic level, which will expand availability of consumer-driven plans and HSA-eligible plans to new consumers.

distinguishing between certain high-deductible, catastrophic risk policies and plans that will be offered in the individual market. See ACA § 1302. It could conclude that certain high-deductible, catastrophic risk policies would not well serve the statue's purpose of reducing cost-shifting in the interstate health care market because the risk that a person would not be able meet the high deductible payment is greater than for a lower deductible payment, thus increasing the risk of shifting costs to other participants in the health care system. While plaintiffs argue that they can make the payment, financial circumstances can change quickly, and Congress could rationally conclude that the more prudent course is to require non-exempted individuals purchasing coverage in the individual market to have insurance policies with lower deductibles. Plaintiffs might disagree with this policy choice, but it is a rational one, and that dooms their claim.

3. The Minimum Coverage and Employer Responsibility Provisions Are Valid Exercises of Congress's Independent Power under the General Welfare Clause

The minimum coverage provision is also a valid exercise of the taxing power. In "passing on the constitutionality of a tax law," a court is "concerned only with its practical operation, not its definition or the precise form of descriptive words which may be applied to it." Nelson v. Sears, Roebuck & Co., 312 U.S. 359, 363 (1941). The minimum coverage provision is in the Tax Code, and it operates as a tax. See Defs.' MTD at 45-46.

Plaintiff argues that Congress did not intend to exercise its General Welfare Clause authority at all, because it denominated the minimum coverage provision as a "penalty" and not as a "tax."[22] Pls.' Opp'n at 42. But when determining whether Congress has exercised its taxing

[22] Plaintiffs cite declarations in support of this argument and other merits arguments. See Pls.' Opp'n at 42, 51, and 53. These declarations are outside of the pleadings and should be ignored for purposes of resolving defendants' Rule 12(b)(6) motion. See, e.g., Winston v. Clough, 712 F. Supp. 2d 1, 5 (D.D.C. 2010).

power, the substance of the provision controls over any labels.[23] Nelson, 312 U.S. at 363; see also United States v. Sotelo, 436 U.S. 268, 275 (1978); Woods v. Cloyd W. Miller Co., 333 U.S. 138, 144 (1948).[24] Thus, a provision may qualify as an exercise of the taxing power even where Congress has made findings under the Commerce Clause in support of that provision. See Adventure Res., Inc. v. Holland, 137 F.3d 786, 794 (4th Cir. 1998) (Coal Act premiums are taxes); Energy Policy Act of 1992, Pub. L. No. 102-486, § 19142(a)(1) (1992). And as explained in defendants' opening brief, the penalty for failing to satisfy the provision operates as a tax (e.g., the penalty is collected through an individual's tax return and it is calculated based on taxable income). See Defs.' MTD at 46 n.28.

Plaintiffs expend great effort attempting to explain away the legislative history of the ACA reflecting Congress's intention to exercise its taxing power. Specifically, they argue that: (1) a report from the Joint Committee on Taxation — specifically, See Joint Comm. on Taxation, 111th Cong., Technical Explanation of the Revenue Provisions of the "Reconciliation Act of 2010," as amended, in Combination with the "Patient Protection and Affordable Care Act" 33 (Mar. 21, 2010) — is invalid legislative history because it post-dates the Senate's passage of the ACA and does not reflect the views of the chamber of Congress that drafted the legislation, and (2) floor statements "warrant little if any deference." Pls.' Opp'n at 42-43.

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[23] Numerous provisions in the Internal Revenue Code impose assessments that are described as "penalties." See, e.g., 26 U.S.C. §§ 138(c)(2); 5731(c); 6684; 6720C. The constitutionality of these exercises of the General Welfare Clause power is not in doubt.

[24] Plaintiffs try to overcome this firmly established legal rule by citing Bd. of Trs. of Univ. of Ill. v. United States, 289 U.S. 48, 58 (1933). But that case held merely that a statute that could be valid under both the commerce power and the taxing power was not subject to constitutional limits on one of those powers — there, the since-overturned prohibition of federal taxes on state instrumentalities. Id.

The Court need not resort to the legislative history because, as discussed above, the minimum coverage provision operates as a tax. If the Court chooses to review the legislative history, however, it should reject plaintiffs' arguments. The March 21, 2010, report from the Joint Committee on Taxation is pre-enactment legislative history: It discusses the revenue provisions of the Reconciliation Act, which amended the ACA and did not pass either house of Congress until March 25, 2010, and those provisions specifically dealt with the measures at issue here. Plaintiffs also contend that the report is irrelevant because it did not "come from the chamber that drafted [the] PPACA (i.e., the Senate)." Pls' Opp'n at 42. This argument, too, is DOA. The Reconciliation Act was drafted by the House, not the Senate; the Health Care and Education Reconciliation Act of 2010 ("HCERA"), Pub. L. No. 111-152, 124 Stat. 1029, (Mar. 30, 2010), began life as H.R. 4872. And the joint committee that issued the report on the Reconciliation Act includes five House Members.

Finally, while floor statements may not be dispositive evidence of legislative intent, they are relevant. See, e.g., United States v. Hayes, 129 S. Ct. 1079, 1088 (2009) (considering floor statement when assessing statutory meaning). And the statements cited by defendants in the motion to dismiss treat the minimum coverage provision as tax. See Defs.' MTD at 45.

Plaintiffs pivot from their discussion of legislative history to a discussion of canons of statutory construction. They argue that earlier versions of the bill that became the ACA described the levy imposed for not securing sufficient insurance as a "tax" not a "penalty," but that the "tax" language was scrapped to secure votes. Pls.' Opp'n at 43. To plaintiffs, "[t]hat change [from use of "tax" to "penalty"] triggers two powerful canons of statutory construction." Id. The first is that the language of the statute should be slavishly followed, insofar as the ACA uses the term "penalty" rather than "tax," because the statute was the result of a compromise. Id. The second is that Congress does not intend to enact sub silentio language that had previously

been discarded. Id. Plaintiffs' "powerful canons" are off target. Use of the word "penalty" does not foreclose the conclusion that Congress has exercised its taxing power, especially as there is no independent "penalty power" in the Constitution. When it comes to determining whether Congress has exercised its taxing power, labels do not matter — effects matter. See Nelson, 312 U.S. at 363 (1941). And this levy is in effect a tax. See Defs.' MTD at 45-46.

Next, plaintiffs take issue, though not directly, with defendants' argument that the regulatory purpose of the minimum coverage provision does not place it beyond Congress's taxing power. Pls.' Opp'n at 44. The qualifier "not directly" is used in the previous sentence because plaintiffs do not challenge the proposition that a tax may have a regulatory purpose — for good reason, they could not do so in the face of Supreme Court precedent. See, e.g., United States v. Sanchez, 340 U.S. 42, 44 (1950). Rather, they contend that defendants have ignored a limitation, namely, that the proposition is true only if the law, "on its face[,] purports to be an exercise of the taxing power." Pls.' Opp'n at 44 (internal quotation omitted). Even if plaintiffs were right about this, they would gain nothing. The minimum coverage penalty is, on its face, a product of the taxing power: The levy is codified in the Internal Revenue Code in a subtitle labeled "Miscellaneous Excise Taxes"; the income threshold for the penalty to apply is based on the statutory threshold requiring individuals to file income tax returns, 26 U.S.C. § 5000A(e)(2); it is reported on an individual's tax return, 26 U.S.C. § 5000A(b)(2); it is calculated based on an individual's household income for federal tax purposes, 26 U.S.C. § 5000A(c)(1), (2); and, a taxpayer's responsibility for family members turns on their status as dependents under the Internal Revenue Code, 26 U.S.C. § 5000A(a), (b)(3).

Plaintiffs next contend that the penalty, if it is a tax, may be unlawful as a capitation tax and is impermissible because it is a non-uniform tax. These arguments are unpersuasive.

They insist that the definition of capitation endorsed by defendants stems from dicta — not holdings — of Supreme Court cases. Pls.' Opp'n at 45; See Hylton v. United States, 3 U.S. (3 Dall.) 171, 175 (1796) (opinion of Chase, J.); see also Pac. Ins. Co. v. Soule, 74 U.S. (7 Wall.) 433, 444 (1868). Plaintiffs are wrong: The definition of capitation was a necessary part of the holding in Pacific Insurance Company. The Court in that case had to determine whether a tax fell into the category of direct taxes — which include capitations — and, therefore, had to define capitations. Pac. Ins. Co., 74 U.S. 443-46. In any case, the definition is not wrong because it derives from dicta. Damningly, plaintiffs do not offer an alternative definition. And as a result, plaintiffs do not even take a definitive stance on whether the penalty is a capitation. They say the penalty "may qualify as an unlawful" capitation and that it is unlawful to "the extent . . . it is a capitation." Pls.' Opp'n at 45-46. In the end, then, plaintiffs make a suggestion, not an argument. The Court should deem plaintiffs to have waived any argument that the penalty constitutes an unlawful capitation.

Plaintiffs' uniformity argument can be dispatched in short order. Taxes must be "uniform" under Article 1, Section 8, Clause 1. An indirect tax is uniform when the tax "operates with the same force and effect in every place where the subject of it is found." Head Money Cases, 112 U.S. 580, 594 (1884); see also United States v. Ptasynski, 462 U.S. 74, 82 (1983). Plaintiffs seem to argue that the penalty is not a uniform tax because the amount collected would not be the same in each state. Pls.' Opp'n at 46**.** But variance, if any, would be due to different factual circumstances, not the application of different principles. That the principles are the same suffices to establish uniformity. See Ptasynski, 462 U.S. at 86.

4. The Employer Responsibility Provision Regulates Interstate Commerce in the National Labor Market

Plaintiffs essentially abandon the argument that the employer responsibility provision is unconstitutional in and of itself, arguing simply that "the Employer Mandate is unconstitutional for substantially the same reason as the Individual Mandate" and that, if it is assessed under the taxing power, it fails for being non-uniform. Pls.' Opp'n at 54. Plaintiffs are wrong about both. Supreme Court precedent firmly establishes that, under the Commerce Clause, Congress can regulate the terms and conditions of employment in the national labor market, United States v. Darby, 312 U.S. 100, 118 (1941); NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 49 (1937), as it has through the employer responsibility provision. See Defs.' MTD at 42-43. The Court need not even consider the provision under the taxing power. But if it were to do so, the provision would pass muster as a uniform tax: The same provision applies irrespective of state boundaries. See Ptasynski, 462 U.S. at 82.

Instead, plaintiffs argue primarily that the employer responsibility provision should be invalidated because the minimum coverage provision is unconstitutional and, as the ACA lacks a severability clause, the employer responsibility provision must go down with the rest of the act. Pls.' Opp'n at 54. The minimum coverage provision, however, is constitutional, so this argument fails.[25]

5. Plaintiffs' Claims for an Accounting Should Be Dismissed

Plaintiffs lack standing to raise their accounting claims. While they insist that their members "obviously have a financial interest in the solvency" of Medicare and Social Security, Pls.' Opp'n at 66 n.34 (emphasis added), they identify no particular member eligible for either program. See Summers, 129 S. Ct. at 1151-52. Even if they had, no such member could

[25] Defendants can brief the question of severability at a later date, if necessary. Suffice it to say that plaintiffs' call for the invalidation of the entire statute inverts the governing principles of severability analysis, which is guided by the general presumption that a court should invalidate no more of a statute than necessary to remedy a constitutional violation. See, e.g., Free Enterprise Fund v. Pub. Co. Accounting Oversight Bd., 130 S. Ct. 3138, 3161 (2010).

plausibly identify a concrete injury that is actual or imminent — say, for example, an impending reduction in benefits. See Lujan, 504 U.S. at 560. Rather, the allegations in the complaint make clear that plaintiffs seek to ensure that defendants "properly implement important federal programs." SAC ¶¶ 107, 113. But this is the prototypical generalized grievance that is too abstract to support Article III standing. See, e.g., Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, 454 U.S. 464, 482-83 (1982) ("This Court repeatedly has rejected claims of standing predicated on the right, possessed by every citizen, to require that the Government be administered according to law.") (internal quotation omitted).

Moreover, plaintiffs do not dispute that defendants already provide lengthy annual reports to Congress detailing the well-known fiscal challenges of Medicare and Social Security. Defs.' MTD at 56-57. Plaintiffs insist those reports are inadequate, but do not say why. They do not assert that the reports are incomplete or incorrect, or that they deviate from generally accepted accounting principles. And they do not explain how the court-ordered "equitable accounting" they seek would be any better, or would remedy any ill. Pls.' Opp'n at 66-67. Because defendants already do what plaintiffs ask the Court to order them to do, there is no live case or controversy with respect to these claims. See Rhodes v. Stewart, 488 U.S. 1, 4 (1988).

III. PLAINTIFFS' MEDICARE ENROLLMENT AND NPI CLAIMS SHOULD BE DISMISSED

A. The Court Lacks Jurisdiction over Plaintiffs' Medicare Physician Enrollment and NPI Claims

Despite attaching several declarations to their opposition brief, the plaintiff associations still identify no member who has standing to challenge the interim final rule (or change requests) that are the focus of this claim. Again, plaintiffs do not allege that the new regulations harm their members directly, nor could they, as the penalty for failing to meet those requirements falls not on the referring physician, but on the billing supplier, whose claim for reimbursement will be

denied. Rather, plaintiffs' theory of harm is that if they decline to enroll in or to opt out of Medicare (and thus establish a PECOS record) or decline to obtain an NPI, they will be put "at an economic and competitive disadvantage" because their patients may instead choose to see compliant doctors to ensure that their claims from suppliers (who do participate in Medicare) will be properly reimbursed. SAC ¶ 25. They attempt to identify three AAPS member physicians with standing. None, however, has an injury that was caused by the interim final rule (or change requests) or that would be redressed by the invalidation of those provisions.

Two AAPS member physicians, Dr. Orient and Dr. Smith, indicate that they do not currently treat Part B beneficiaries or refer them for covered services. See Orient Decl. ¶¶ 24-25; Smith Decl. ¶ 10. Thus, the interim final rule (and change requests) impose no burden on them whatsoever: Because they do not participate in Medicare, they do not need to enroll or to opt out (which would establish a record in PECOS), and they are not required by Medicare to obtain an NPI. Accordingly, if the interim final rule (or change requests) were invalidated, nothing would change for them, and no injury would be redressed: They still would not treat or refer Part B beneficiaries. Their declarations make this clear. Both state that they are unwilling to treat Part B beneficiaries, or to refer Part B beneficiaries for covered services (which are subsidized by taxpayers), unless they can do so without any federal oversight. For example, Dr. Smith would "consider" treating Part B beneficiaries only if he could do so on his own terms, "without any of the burdens or requirements imposed by the Medicare statute, 42 U.S.C. §§ 1395—1395kkk-1." Smith Decl. ¶¶ 6, 10 (emphasis added). Likewise, Dr. Orient would do so only if "the barrier of federal oversight and coercion" were removed and she could see and refer Part B beneficiaries "without any Medicare-related conditions' applying." Orient Decl. ¶ 25 (emphasis added). Thus, invalidation of the interim final rule (or change requests), with which they currently need

not comply, would provide Dr. Orient and Dr. Smith no relief, as the many regulations that have been attached for decades to physician participation in Medicare would remain in effect.[26]

A third AAPS member physician, Dr. Hammons, although differently situated, also lacks standing. She alleges that she has seen and referred Part B beneficiaries for more than 20 years, but does not have an enrollment record in PECOS and would prefer not to have one. Hammons Decl. ¶¶ 4-5. But prior regulations — which plaintiffs do not challenge — already require a physician in her position who has not opted out of Medicare to file an enrollment application, 42 C.F.R. § 424.505, and to revalidate that enrollment information every five years, id. § 424.515, either of which would generate a record in PECOS.[27] Thus, the interim final rule (and change requests) do not require her to do anything that was not already required of her, and invalidation of them would provide no relief. Moreover, rather than providing evidence of competitive disadvantage or lost income — plaintiffs' theories of harm, see Pls.' Opp'n at 9-10 — Dr. Hammons explains that "I am busy in my private practice, and the PECOS changes will not affect my income." Hammons Decl. ¶ 6 (emphasis added). Thus, she, too, lacks standing.

B. Plaintiffs' Medicare Enrollment and NPI Claims Are Meritless

1. The Requirement to Enroll or to Opt Out is Valid

Plaintiffs assert that, as a matter of statutory interpretation, "nothing in Medicare or any other provision of law requires physicians to opt-out pursuant to 42 U.S.C. § 1395a(b)'s statutory safe harbor in order to lawfully treat Medicare beneficiaries for payment outside of Medicare." SAC ¶ 2(h); see also id. ¶ 103. They elaborate: "The statutory safe harbor in 42 U.S.C.

[26] Dr. Orient, who is the only declarant to assert that she does not have an NPI, lacks standing to challenge that requirement for an additional reason: This requirement is contained in the ACA itself, the pertinent provisions of which plaintiffs do not challenge.

[27] Although Dr. Hammons indicates that she does not collect a salary as medical director of a nursing home, she does not state that Medicare is not billed for services she provides to Part B beneficiaries. Hammond Decl. ¶ 4.

§ 1395a(b) for opting out of Medicare is more restrictive than Medicare itself requires to avoid Medicare requirements." Id. ¶ 28. Thus, they ask the Court to declare that non-enrolled physicians "may see Medicare-eligible patients and charge those patients a fee that is lawful under applicable state laws, without complying with . . . § 1395a(b)." Id. ¶ 118(xi). As defendants have explained, that reading of the Medicare Act is flatly incorrect and refuted by controlling precedent. Defs.' MTD at 66-67 (citing United Seniors Ass'n v. Shalala, 182 F.3d 965, 968-70 (D.C. Cir. 1999) (for "services that Medicare would reimburse" "[a] doctor who enters into a . . . private contract with even a single patient is barred from submitting a claim to Medicare on behalf of any patient for a two-year period") (emphasis added).

Plaintiffs' confused response is that the 1997 enactment of 42 U.S.C. § 1395a(b) somehow conflicts with two earlier, more general provisions of the Medicare Act. Pls.' Opp'n at 64. The first of these, 42 U.S.C. § 1395a(a), which provides "freedom of choice" to Medicare beneficiaries, not physicians, states that a beneficiary "may obtain health services from any . . . person qualified to participate under this subchapter if such . . . person undertakes to provide him such services." But while § 1395a(b) regulates the use of private contracts, it does nothing to prevent a beneficiary from seeing any doctor who "undertakes to provide him . . . services." 42 U.S.C. § 1395a(a). The second, 42 U.S.C. § 1395, provides in part that "[n]othing in [the Medicare Act] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." But § 1395a(b) does not regulate the actual "practice" of medicine or the "manner" of service delivery; it regulates administrative details, such as enrollment, the content of contracts, and the submission of claims — much like numerous other provisions of the Medicare

Act. At bottom, § 1395a(b) conflicts with neither of these provisions, and the D.C. Circuit's proper construction of the provision in United Seniors controls here.[28]

2. The PECOS and NPI Requirements Are Supported By Statute and Regulation

As defendants have explained, there is no general requirement that physicians practicing entirely outside of Medicare either submit an enrollment application or obtain an NPI. But there is ample authority to require physicians either to enroll in or to opt out of Medicare (and thus generate a PECOS record) and to obtain an NPI in order to refer beneficiaries for covered Part B items or services. Defs.' MTD at 67-69.

Plaintiffs concede that defendants have "cited authority [to] require PECOS and NPIs . . . for Medicare[-enrolled] providers." Pls.' Opp'n at 62. They insist, however, that this authority does not apply to "non-Medicare[-enrolled] physicians who, in seeing Medicare-eligible patients, refer those patients for Medicare orders and services." Id. Notably, plaintiffs cite no authority in support of their position, and offer no alternative reading of the statutory and regulatory scheme. In effect, they stick their heads in the sand. Rather than reiterate the authorizing provisions here, defendants respectfully refer the Court to their opening brief. Defs.' MTD at 67-69.

Plaintiffs also appear to attack the PECOS, NPI, and opt-out requirements as arbitrary and capricious, asserting that defendants "have not identified a rationale to compel [physicians

[28] Plaintiffs' belated attempt to bring a constitutional challenge to § 1395a(b) — raised for the first time in their opposition brief — should be summarily rejected. See Pls.' Opp'n at 65 (asserting "a constitutional right to ignore Medicare altogether"); id. at 64 n.33. Plaintiffs' complaint — which has already been amended twice — nowhere states such a constitutional claim. See SAC ¶¶ 2(h), 28, 101-05, 118(xi); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (complaint must "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests") (emphasis added). And plaintiffs may not amend their complaint to add a new claim by way of an opposition brief. See, e.g., College Sports Council v. GAO, 421 F. Supp. 2d 59, 71 n.16 (D.D.C. 2006). In any event, this claim should be rejected for the reasons stated by the district court in United Seniors Ass'n v. Shalala, 2 F. Supp. 2d 39 (D.D.C. 1998) (Hogan, J.) (rejecting constitutional challenge to 42 U.S.C. § 1395a(b)), aff'd on other grounds, 182 F.3d 965 (D.C. Cir. 1999).

who treat and refer Part B beneficiaries] — who are only nominally connected with the Medicare system — to file a formal opt-out pursuant to 42 U.S.C. § 1395a(b), to enroll in PECOS, or to obtain an NPI." Pls.' Opp'n at 66. That is simply incorrect. As demonstrated in defendants' opening brief, the purpose of § 1395a(b) is to prevent doctors from charging more for Medicare-covered services than Medicare fee schedules would permit, unless the patient clearly consents to receive the services outside of Medicare. Defs.' MTD at 59; see also United Seniors, 182 F.3d at 967 (noting Secretary's explanation of § 1395a(b)'s purpose). Moreover, requiring physicians who treat Part B beneficiaries either to enroll or to opt-out (which generates a PECOS record) helps curb improper payments to unqualified physicians and suppliers. Defs.' MTD at 61 (citing 71 Fed. Reg. at 20754-55). And the use of standardized, unique physician identification numbers, such as the NPI, helps to avoid billing confusion and to combat fraud. Defs.' MTD 60 (citing 69 Fed. Reg. at 3434; 75 Fed. Reg. at 24441-42). Given the deferential standard of review applied to arbitrary and capricious claims under the APA, plaintiffs' arguments must be rejected. See, e.g., Stilwell v. Office of Thrift Supervision, 569 F.3d 514, 519 (D.C. Cir. 2009) (agency action must be upheld "so long as it is reasonable and reasonably explained").

C. Plaintiffs' Notice and Comment Claims with Respect to the Interim Final Rule and Change Requests Should Be Dismissed

1. HHS Had No Duty to Provide Notice and an Opportunity for Comment prior to Issuing the Interim Final Rule or Change Requests

Because the enrollment and NPI requirements simply reflect "judgment[s] about what mechanics and processes are most efficient," they are rules of agency procedure that are exempt from notice and comment requirements. Public Citizen v. Dep't of State, 276 F.3d 634, 640 (D.C. Cir. 2002) (citing 5 U.S.C. § 553(b)(3)(A)); see Defs.' MTD at 70. Plaintiffs' single-sentence response to this argument — that this exception does not apply because the challenged requirements "determine the availability of, or entitlement to, a benefit," Pls.' Opp'n at 62 n.29

— is misplaced, for that is not the correct test. On the contrary, the D.C. Circuit has recognized that rules may operate to deny someone a benefit yet remain unambiguously procedural. See Public Citizen, 276 F.3d at 640 (citing JEM Broad. Co. v. FCC, 22 F.3d 320, 327-28 (D.C. Cir. 1994) (rule rejecting flawed license applications without leave to amend, resulting in denial of license)). The proper inquiry focuses not on the injury to the party, but on the nature of the value judgment involved. Here, the challenged requirements do not change the substantive criteria determining which physicians may participate in Medicare; they simply reflect an administrative judgment about the most efficient way to identify eligible physicians during the claims process.

2. HHS Had Good Cause To Forgo Pre-issuance Notice and Comment

HHS also had good cause to determine, with respect to the interim final rule, that notice and comment procedures would be "impracticable [and] unnecessary" given (1) the need for prompt regulatory guidance; (2) the lack of new burdens on physicians; and (3) the interim nature of the rule. Defs.' MTD 71-73 (citing 75 Fed. Reg. at 24446). Plaintiffs do not dispute the existence of these circumstances. Rather, relying on Chamber of Commerce v. SEC, 443 F.3d 890 (D.C. Cir. 2006), they argue that the circumstances here were not sufficiently "exigent" to justify invocation of the good cause exception. Pls.' Opp'n at 61. In that case, the SEC attempted to justify dispensing with notice and comment because an imminent change in the composition of the Commission would result in delays. Chamber of Commerce, 443 F.3d at 908. The D.C. Circuit rejected this rationale, reasoning that because delays associated with commission membership changes are "hardly atypical," accepting the SEC's justification would effectively swallow the "narrow" good cause exception. Id.

The good cause inquiry, however, is "inevitably fact- or context- dependent," Mid-Tex Elec. Coop. v. FERC, 822 F.2d 1123, 1132 (D.C. Cir. 1987), and the circumstances here are a far cry from Chamber of Commerce. Under the Medicare Act, a rule is exempt from notice and

comment when it implements a statutory provision that must take effect within 150 days, or about 5 months, after the statute's enactment. 42 U.S.C. § 1395hh(b)(2). Here, Congress required HHS to issue a rule concerning enrollment requirements for physicians ordering home health services or durable medical equipment within about 3 months of the ACA's enactment. ACA § 6405.[29] It likewise required HHS to issue a rule directing NPIs to be included on enrollment applications within about 9 months of the ACA's enactment. Id. § 6402. Although the latter provision falls outside § 1395hh(b)(2)'s statutory exemption, it would have made little sense for HHS to create regulatory guidance to implement § 6405's enrollment requirements, only to modify it several months later for one that included § 6402's NPI requirement. Moreover, courts have found good cause where similarly short lengths of time were at issue. See, e.g., Universal Health Services v. Sullivan, 770 F. Supp. 704, 720 (D.D.C. 1991) (7 months considered "short order" where statute "imposed numerous and complex administrative duties upon the Secretary"); NWICGA v. Food & Nutrition Serv., 416 F. Supp. 2d 92, 106 (D.D.C. 2006) (18 months, where agency was "also attending to other demanding obligations"). And exigency is but one factor to be considered in the good cause inquiry, which considers the "totality of the circumstances." Coalition for Parity v. Sebelius, 709 F. Supp. 2d 10, 24 (D.D.C. 2009). Given the scope of the ACA and its demands on HHS, the complexity of the Medicare Act and its payment systems, the need for prompt regulatory guidance, the lack of new burdens on physicians, and the interim nature of the rule, there was good cause for HHS to waive ordinary notice and comment procedures.

[29] Accordingly, plaintiffs concede that notice and comment were not required with respect to the interim final rule insofar as it addresses durable medical equipment and home health services. Pls.' Opp'n at 61 (citing SAC ¶ 80).

3. HHS Had No Obligation To Provide Notice and Comment before Issuing the Change Requests Because They Do Not Constitute Final Agency Actions

Finally, nothing obligated HHS to provide notice and comment before issuing the change requests because they did not alter plaintiffs' legal obligations with respect to enrollment or the use of NPIs; they merely restated existing requirements. Defs.' MTD at 74 (citing Indep. Dealers Ass'n v. EPA, 372 F.3d 420, 428 (D.C. Cir. 2004)). Plaintiffs' response — that the change requests are not interpretive rules because they supposedly "narrowed HHS discretion" by declining to "accept[] referrers without PECOS enrollment or NPIs," Pls.' Opp'n at 61-62 — misses the point.

Since 1992, the Medicare Act has required that suppliers of referred items or services (such as wheelchairs or X-rays) identify the referring physician by name and provider number; otherwise, the supplier may be denied payment for the claim. 42 U.S.C. § 1395*l*(q). Since at least 2006, referring physicians (unless they accept no payment) have been required to enroll in Medicare or to opt out, id. § 1395a(b), which since 2003 has generated a record in PECOS. And since 2008, the Medicare program has required that the NPI be used on all claims, to identify both the billing provider and supplier and, where required, the referring physician. 75 Fed. Reg. at 24440. Thus, the change requests "tread no new ground": They simply automate the enforcement of requirements that were already in existence. See Indep. Dealers Ass'n v. EPA, 372 F.3d at 428.

CONCLUSION

For the foregoing reasons, the Court should grant defendants' motion and dismiss this action in its entirety.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 10, 2011, the foregoing document was filed with the Clerk of Court via the CM/ECF system, causing it to be served on plaintiffs' counsel of record.

/s/ Justin Sandberg
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