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.	

MOTION TO DISMISS

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), defendants Kathleen G. Sebelius, Secretary of the Department of Health and Human Services, Michael J. Astrue, Commissioner of the Social Security Administration, Timothy F. Geithner, Secretary of the Treasury, and the United States of America respectfully move the Court to dismiss this action. The accompanying memorandum sets forth the grounds for this motion.

Dated: November 22, 2010

Respectfully submitted,

TONY WEST
Assistant Attorney General

RONALD C. MACHEN JR
United States Attorney

SHEILA M. LIEBER
Deputy Director, Federal Programs Branch, Civil Division

/s/ Justin M. Sandberg
JUSTIN M. SANDBERG
(Ill. Bar No. 6278377)
ERIC B. BECKENHAUER
(Cal. Bar No. 237526)
U.S. Dept. of Justice, Civil Division,
20 Mass. Ave., NW, Rm. 7302
Washington, DC 20001
(202) 514-5838 phone
(202) 616-8202 fax
justin.sandberg@usdoj.gov

Attorneys for Defendants

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Defendants.	)	

PROPOSED ORDER

Upon consideration of Defendants' Motion to Dismiss, Plaintiffs' opposition thereto, and Defendants' reply, it is hereby

ORDERED that the motion is GRANTED; and it is

FURTHER ORDERED that the action is hereby DISMISSED.

SO ORDERED.

Dated: _____

_____
RICHARD J. LEON
United States District Judge

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MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

TONY WEST
Assistant Attorney General

RONALD C. MACHEN JR
United States Attorney

SHEILA M. LIEBER
Deputy Director, Federal Programs Branch, Civil Division

JUSTIN M. SANDBERG
Trial Attorney
ERIC B. BECKENHAUER
Trial Attorney
U.S. Dept. of Justice, Civil Division,
Federal Programs Branch
20 Mass. Ave., NW, Rm. 7302
Washington, DC 20001
(202) 514-5838 phone
(202) 616-8202 fax
justin.sandberg@usdoj.gov
Attorneys for Defendants

TABLE OF CONTENTS

TABLE OF AUTHORITIES v

INTRODUCTION 1

I. PLAINTIFFS' SOCIAL SECURITY CLAIMS SHOULD BE DISMISSED 6

A. The Statutory and Regulatory Background of the POMS 6

1. Medicare Provisions.....6

2. Social Security Provisions 8

3. The Challenged POMS Provisions 8

4. Exhaustion under the Social Security Act 9

B. Argument 9

1. The Court Lacks Jurisdiction over Plaintiffs' Social Security Claims 9

2. The Social Security Claims Should Be Dismissed for Failure To Exhaust Administrative Remedies 14

3. Plaintiff's Social Security Claims Are Not Cognizable.....16

a. The Challenged POMS Provisions Need Not Have Been Submitted for Notice and Comment 16

b. The Challenged POMS Provisions Are Consistent with the Statutory and Regulatory Framework.....18

II. PLAINTIFFS' ACA-RELATED CLAIMS SHOULD BE DISMISSED 21

A. ACA's Statutory Background.....21

B. Argument 24

1. The Court Lacks Jurisdiction over Plaintiffs' ACA Claims 24

a. Plaintiffs Lack Standing to Challenge the Minimum Coverage and Employer Responsibility Provisions.....24

b. Plaintiffs' Challenges to the Minimum Coverage and Employer Responsibility Provisions Are Unripe 27

c. The Anti-Injunction Act Bars Plaintiffs' Challenges to the Minimum Coverage and Employer Responsibility Provisions 28

2. The Comprehensive Regulatory Measures of the ACA Fall within Congress's Article I Powers 30

a. Congress's Authority To Regulate Interstate Commerce Is Broad 30

b. The ACA Regulates the Interstate Markets in Health Insurance, Health Care Services, and Employment 32

c. 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 35

d. The Minimum Coverage Provision Regulates Activity that Substantially Affects Interstate Commerce 39

e. The Employer Responsibility Provision Regulates Interstate Commerce in the National Labor Market 43

f. The Minimum Coverage Provision and Employer Responsibility Provisions Are Valid Exercises of Congress's Independent Power under the General Welfare Clause 44

3. The Minimum Coverage Provision is Not a Direct Tax that Would Require Apportionment among the States 47

a. As a Valid Exercise of Congress's Commerce Clause Powers, the Minimum Coverage Provision Is Not Subject to Apportionment 48

b. The Minimum Coverage Provision Is Not a "Direct Tax" 49

4. Plaintiffs' Takings Claim is Unripe and Meritless 52

5. Plaintiffs' Claims for an Accounting Should Be Dismissed 56

III. PLAINTIFFS' MEDICARE ENROLLMENT AND NPI CLAIMS SHOULD BE DISMISSED 57

A. Statutory and Regulatory Background of Medicare Part B 58

1. Provider Numbers 60

2. Enrollment as a Medicare Provider.....61

3. Change Requests 62

4. The Affordable Care Act 62

5. Interim Final Rules 63

B. Argument 64

1. The Court Lacks Jurisdiction over Plaintiffs' Medicare Physician Enrollment and NPI Claims 65

2. Plaintiffs' Medicare Enrollment and NPI Claims Are Meritless 66

a. The Requirement To Enroll or To Opt Out Is Valid.....66

b. The PECOS Requirement Is Supported by Statute and Regulation 67

c. The NPI Requirement Is Supported by Statute and Regulation 68

3. Plaintiffs' Notice and Comment Claims with Respect to the Interim Final Rule and Change Requests Should Be Dismissed.....69

a. HHS Had No Duty to Provide Notice and an Opportunity for Comment prior to Issuing the Interim Final Rule or Change Requests. 70

b. HHS Had Good Cause To Forgo Pre-Issuance Notice and Comment.....71

c. The Medicare Act Eliminated Any Duty To Provide Notice and Comment with Respect to the Interim Final Rule insofar as it Addresses Durable Medical Equipment and Home Health Services 73

d. HHS Had No Obligation To Provide Notice and Comment before Issuing the Change Requests Because They Do Not Constitute Final Agency Actions 74

CONCLUSION 74

TABLE OF AUTHORITIES

Federal Cases

Abbott Labs. v. Gardner,
387 U.S. 136 (1967) 27

Allen v. Wright,
468 U.S. 737 (1984) 57

Am. Chemistry Council v. Dep't of Transp.,
468 F.3d 810 (D.C. Cir. 2006) 10

Am. Chiropractic Ass'n v. Leavitt,
431 F.3d 812 (D.C. Cir. 2005) 16

Amgen Inc. v. Smith,
357 F.3d 103 (D.C. Cir. 2004) 6

Ashcroft v. Iqbal,
129 S. Ct. 1937 (2009) 1

Asiana Airlines v. FAA,
134 F.3d 393 (D.C. Cir. 1998) 73

Atlantic Urological Assocs v. Leavitt,
549 F. Supp. 2d 20 (D.D.C. 2008) 11

B&G Enter. Ltd. v. United States,
220 F.3d 1318 (Fed. Cir. 2000), cert. denied, 531 U.S. 1144 (2001) 54

Baldwin v. Sebelius,
No. 10-1033, 2010 WL. 3418436 (S.D. Cal. Aug. 27, 2010) 26, 28

Barr v. United States,
736 F.2d 1134 (7th Cir. 1984) 29

Bartley v. United States,
123 F.3d 466 (7th Cir. 1997) 29

Blanchette v. Conn. Gen. Ins. Corp.,
419 U.S. 102 (1974) 27

Bd of Trustees v. United States,
289 U.S. 48 (1933) 49

Bob Jones Univ. v. Simon,
416 U.S. 725 (1974) 29, 46

Brushaber v. Union Pac. R.R.,
240 U.S. 1 (1916) 50

CTIA-Wireless Assoc. v. FCC,
530 F.3d 984 (D.C. Cir. 2008) 27

Casa de Cambio Comdiv v. United States,
291 F.3d 1356 (Fed. Cir. 2002) 53

Cement Kiln Recycling Coal. v. EPA,
493 F.3d 207 (D.C. Cir. 2007) 2, 17

Cent. Texas Telegraph Cooperative v. FCC,
402 F.3d 205 (D.C. Cir. 2005) 17, 18

Charles C. Steward Machine Co. v. Davis,
301 U.S. 548 (1937) 44

Citizens United v. FEC,
130 S. Ct. 876 (2010) 3, 26

Coal. for Parity v. Sebelius,
709 F. Supp. 2d 10, 2010 WL. 2484269 (D.D.C. June 21, 2010) 71, 73

Colo. Heart Inst., LLC v. Johnson,
609 F. Supp. 2d 30 (D.D.C. 2009) 16

Colo. Springs Prod. Credit Ass'n v. Farm Credit Admin.,
967 F.2d 648 (D.C. Cir. 1992) 55

Commonwealth Edison Co. v. United States,
271 F.3d 1327 (Fed. Cir. 2001) 54

Connolly v. Pension Benefit Guaranty Corp.,
475 U.S. 211 (1986) 55

Covenant Media of S.C. v. City of North Charleston,
493 F.3d 421 (4th Cir. 2007) 25

Cruzan v. Missouri Dep't of Health,
497 U.S. 261 (1990) 34

Ctr. for Automobile Safety v. Nat'l Highway Traffic Safety Admin.,
452 F.3d 798 (D.C. Cir. 2006) 70

Ctr. for Biological Diversity v. U.S. Dep't of Interior,
563 F.3d 466 (D.C. Cir. 2009) 25

Daniel v. Paul,
395 U.S. 298 (1969) 42

E. Enterprises v. Apfel,
524 U.S. 498 (1998) 54

FW/PBS, Inc. v. Dallas,
493 U.S. 215 (1990) 25

Fertilizer Inst. v. EPA,
935 F.2d 1303 (D.C. Cir. 1991) 17

First English Evangelical Lutheran Church of Glendale v. County of Los Angeles,
482 U.S. 304 (1987) 52

Fla. Audubon Social v. Bentsen,
94 F.3d 658 (D.C. Cir. 1996) 12

Florida v. U.S. Dep't of Health & Human Servs.,
No 10-91, 2010 WL. 4010119, XX (N.D. Fla. Oct. 14, 2010) ..... passim

Foodservice & Lodging Inst. v. Regan,
809 F.2d 842 (D.C. Cir. 1987) 29-30

Garcia v. San Antonio Metro. Transit Authority,
469 U.S. 528 (1985) 43

Gibson v. Matthews,
926 F.2d 532 (6th Cir. 1991) 56

Goetz v. Glickman,
149 F.3d 1131 (10th Cir. 1998) 49

Gonzales v. Raich,
545 U.S. 1 (2005) ..... passim

Grand Lodge of Fraternal Order of Police v. Ashcroft,
185 F. Supp. 2d 9 (D.D.C. 2001) 27

Hall v. Sebelius,
689 F. Supp. 2d 10 (D.D.C. 2009) 13, 18, 20

Head Money Cases (Edye v. Robertson),
112 U.S. 580 (1884) 48, 49, 52

Heart of Atlanta Motel v. United States,
379 U.S. 241 (1964) 42

Heckler v. Ringer,
466 U.S. 602 (1984) 15

Heller v. Doe,
509 U.S. 312 (1993) 56

Helvering v. Davis,
301 U.S. 619 (1937) 44

Hodel v. Va. Surface Mining & Reclamation Ass'n,
452 U.S. 264 (1981) 38

Hosp.Building Co. v. Trustees of Rex Hospital,
425 U.S. 738 (1976) 33

Hunt v. Wash. State Apple Adver.Comm'n,
432 U.S. 333 (1977) 10

Hylton v. United States,
3 U.S. (3 Dall.) 171 (1796) 50, 51

Independent Dealers Ass'n v. EPA,
372 F.3d 420 (D.C. Cir. 2004) 74

Interstate Natural Gas Ass'n of Am. v. FERC,
494 F.3d 1092 (D.C. Cir. 2007) 10

Inves. Annuity, Inc. v. Blumenthal,
609 F.2d 1 (D.C. Cir. 1979) 30

JEM Broadcasting v. FCC,
22 F.3d 320 (D.C. Cir. 1994) 70

Jordan Hospital v. Leavitt,
571 F. Supp. 2d 108 (D.D.C. 2008) 19

Kimel v. Fla. Board of Regents,
528 U.S. 62 (2000) 56

Knowlton v. Moore,
178 U.S. 41 (1900) 50

Kowalski v. Tesmer,
543 U.S. 125 (2004) 13

Leedom v. Kyne,
358 U.S. 184 (1958) 18

Levin v. Commerce Energy, Inc.,
130 S. Ct. 2323 (2010) 55

Lewis v. Casey,
518 U.S. 343 (1996) 25

License Tax Cases,
72 U.S. (5 Wall.) 462 (1867) 5, 44

Lingle v. Chevron U.S.A., Inc.,
544 U.S. 528 (2005) 52

Lujan v. Defenders of Wildlife,
504 U.S. 555 (1992) 10, 12, 13, 26

M'Culloch v. Maryland,
17 U.S. (4 Wheat.) 316 (1819) 38

Maryland v. Wirtz,
392 U.S. 183 (1968) 43

McConnell v. FEC,
540 U.S. 93 (2003) 3, 26

In re Medicare Reimbursement Litigation,
414 F.3d 7 (D.C. Cir. 2005) 18

Methodist Hospital v. Shalala,
38 F.3d 1225 (D.C. Cir. 1994) 20

Mid-Tex Electric Cooperative v. FERC,
822 F.2d 1123 (D.C. Cir. 1987) 71, 73

Monmouth Med. Ctr. v. Thompson,
257 F.3d 807 (D.C. Cir. 2001) 74

Moon v. Freeman,
379 F.2d 382 (9th Cir. 1967) 49

Murphy v. IRS,
493 F.3d 170 (D.C. Cir. 2007) 50, 51, 52

NLRB v. Jones & Laughlin Steel Corp.,
301 U.S. 1 (1937) 35, 43

NRDC v. Pena,
147 F.3d 1012 (D.C. Cir. 1998) 25

Nat'l Air Traffic Controllers Ass'n v. Federal Serv. Impasses Panel,
437 F.3d 1256 (D.C. Cir. 2006) 18

Nat'l Athletic Trainers Ass'n, v. U.S. Dep't of Health
& Human Services,
455 F.3d 500 (5th Cir. 2006) 16

Nat'l Board of YMCA v. United States,
395 U.S. 85 (1969) 53

Nat'l Family Planning & Reproduction Health
Ass'n v. Gonzales,
468 F.3d 826 (D.C. Cir. 2006) 12, 65-66

Nat'l Kidney Patients Ass'n v. Sullivan,
958 F.2d 1127 (D.C. Cir. 1992) 16

Nat'l Women, Infants, and Children Grocers Ass'n v.
Food and Nutrition Service,
416 F. Supp. 2d 92 (D.D.C. 2006) 72

Nat'l League of Cities v. Usery,
426 U.S. 833 (1976) 43

Nebraska v. EPA,
331 F.3d 995 (D.C. Cir. 2003) 47

Nelson v. Sears, Roebuck & Co.,
312 U.S. 359 (1941) 46

New York v. United States,
505 U.S. 144 (1992) 56

Newdow v. Roberts,
603 F.3d 1002 (D.C. Cir. 2010) 10, 66

Noble State Bank v. Haskell,
219 U.S. 104 (1911) 55

Ortwein v. Schwab,
410 U.S. 656 (1973) 56

Pac. Insurance Co. v. Soule,
74 U.S. 443 (1868) 51

Pollock v. Farmers' Land & Trust Co.,
158 U.S. 601 (1895) 50

Preseault v. Interstate Commerce Comm'n,
494 U.S. 1 (1990) 53

Public Citizen v. Dep'tt of State,
276 F.3d 634 (D.C. Cir. 2002) 70

Reich v. Dep't of Conservation & Nat'l Resources,
28 F.3d 1076 (11th Cir. 1994) 43

Rhodes v. Stewart,
488 U.S. 1 (1988) 57

Rodgers v. United States,
138 F.2d 992 (6th Cir. 1943) 49

SRM Chemical Ltd. v. Fed.Mediation & Conciliation Serv.,
355 F. Supp. 2d 373 (D.D.C. 2005) 54

Sabri v. United States,
541 U.S. 600 (2004) 38

Shalala v. Ill. Council on Long Term Care,
529 U.S. 1 (2000) 14, 15, 16

Shewfelt v. United States,
104 F.3d 1333 (Fed. Cir. 1997) 54

Simmons v. United States,
308 F.2d 160 (4th Cir. 1962) 46

Sonzinsky v. United States,
300 U.S. 506 (1937) 47

South Carolina ex rel. Tindal v. Block,
717 F.2d 874 (4th Cir. 1983) 49

South Dakota v. Dole,
483 U.S. 203 (1987) 44

Springer v. United States,
102 U.S. 586 (1881) 50

Steel Co. v. Citizens for Better Environment,
523 U.S. 83 (1998) 1

Student Loan Marketing Association v. Riley,
104 F.3d 397 (D.C. Cir. 1997) 53

Summers v. Earth Island Institute,
129 S. Ct. 1142 (2009) ..... passim

Summit Health Ltd. v. Pinhas,
500 U.S. 322 (1991) 33

Swisher International v. Schafer,
550 F.3d 1046 (11th Cir. 2008) cert. denied, 130 S. Ct. 71 (2009) 54

Thomas Jefferson University v. Shalala,
512 U.S. 504 (1994) 20

Thomas More Law Ctr. v. Obama,
No. 02-11156, 2010 WL. 3952805 (E.D. Mich. Oct. 7, 2010) ..... passim

Thomas v. Union Carbide Agriculture Products Co.,
473 U.S. 568 (1985) 27, 28

Toilet Goods Ass'n v. Gardner,
387 U.S. 158 (1967) 28

Tyler v. United States,
281 U.S. 497 (1930) 5, 51

U.S. Department of Treasury v. Fabe,
508 U.S. 491 (1993) 33

Union Electric Co. v. United States,
363 F.3d 1292 (Fed. Cir. 2004) 50

United Seniors Ass'n v. Shalala,
182 F.3d 965 (D.C. Cir. 1999) 11, 59, 67

United States v. Clintwood Elkhorn Mining Co.,
553 U.S. 1 (2008) 29, 30

United States v. Comstock,
130 S. Ct. 1949 (2010) 38, 47

United States v. Darby,
312 U.S. 100 (1941) 5, 35, 43

United States v. Kahriger,
345 U.S. 22 (1953) 46

United States v. Lopez,
514 U.S. 549 (1995) 31, 32

United States v. Mfrs. National Bank of Detroit,
363 U.S. 194 (1960) 5, 51

United States v. Morrison,
529 U.S. 598 (2000) 32

United States v. Ptasynski,
462 U.S. 74 (1983) 52

United States v. Sanchez,
340 U.S. 42 (1950) 44, 46

United States v. South-Eastern Underwriters Ass'n,
322 U.S. 533 (1944) 33, 36

United States v. Sperry Corp.,
493 U.S. 52 (1989) 55

United States v. Stangland,
242 F.2d 843 (7th Cir. 1957) 49

United States v. Stewart,
451 F.3d 1071 (9th Cir. 2006) 31

United States v. Wrightwood Dairy Co.,
315 U.S. 110 (1942)..... 38

Usery v. Turner Elkhorn Mining Co.,
428 U.S. 1 (1976)..... 55

Veazie Bank v. Fenno,
75 U.S. (8 Wall.)533 (1869) 50

Wash. State Dep't of Social & Health Services v.
Guardianship Estate of Keffeler,
537 U.S. 371 (2003)..... 19

Weinberger v. Salfi,
422 U.S. 749 (1975)..... 2, 14, 15

Wickard v. Filburn,
317 U.S. 111 (1942)..... passim

Williamson Cnty. Regional Planning Comm'n v.
Hamilton Bank of Johnson City,
473 U.S. 172 (1985).....53

Woods v. Cloyd W. Miller Co.,
333 U.S. 138 (1948)..... 45

Federal Constitution, Statutes and Regulations

U.S. Const. art. I, § 2, cl. 3..... 48

U.S. Const. art. I, § 8, cl. 1. .....44, 47

U.S. Const. art. I, § 8, cl. 3..... 30

U.S. Const. art. I, § 8, cl. 18..... 30, 38

U.S. Const art I, § 9, cl. 4..... 48

U.S. Const. amend. XIV 48

U.S. Const. amend. XVI 48, 51

20 C.F.R. § 404.640 ..... passim

20 C.F.R. § 404.900(a)(1)-(6) 15

42 C.F.R. § 405.405 ..... passim

42 C.F.R. § 405.410 ..... passim

42 C.F.R. § 405.420 ..... 59, 68

42 C.F.R. § 405.904(a) 15

42 C.F.R. § 406.6 ..... passim

42 C.F.R. § 406.6(b) 7, 9, 19

42 C.F.R. § 406.10(b) 19

42 C.F.R. § 407.27 7

42 C.F.R. § 424.505 ..... passim

42 C.F.R. § 424.506 63

42 C.F.R. § 424.506(b)(1) 64

42 C.F.R. § 424.506(b)(2) 64

42 C.F.R. § 424.506(b)(3) 64

42 C.F.R. § 424.506(c)(1) 64

42 C.F.R. § 424.507 64

42 C.F.R. § 424.507(a)(1) 64

42 C.F.R. § 424.507(a)(2) 64

42 C.F.R. § 424.507(b) 64

42 C.F.R. § 424.510 ..... passim

42 C.F.R. § 424.510(d)(2)(ii) 61

42 C.F.R. § 424.515 ..... 61, 62

42 C.F.R. § 489.21(b)(4) 8, 11

45 C.F.R. § 162.406 ..... 60, 69, 71

45 C.F.R. § 162.408 61

45 C.F.R. § 162.410 ..... 61, 66

42 C.F.R. § 162.410(b) 61

45 C.F.R. § 162.412(a) 61, 69

5 U.S.C. § 551(4) 74

5 U.S.C. § 553 ..... passim

5 U.S.C. § 553(b) 17

5 U.S.C. § 553(b)(B) 71, 72

5 U.S.C. § 553(b)(3)(A) 6, 70

5 U.S.C. § 559 73

5 U.S.C. § 704 70

5 U.S.C. § 706(2)(A) 18

5 U.S.C. § 706(2)(c) 18

28 U.S.C. § 1331 14

28 U.S.C. § 1346(a)(2) 53

28 U.S.C. § 1491 ..... 5, 52

28 U.S.C. § 1491(a)(1) 53

28 U.S.C. § 2201(a) 29

29 U.S.C. § 206 43

29 U.S.C. § 651 43

29 U.S.C. § 1181(a) 33

29 U.S.C. § 1182 33

42 U.S.C. § 300gg 33

42 U.S.C. § 300gg-1 33

42 U.S.C. § 402 ..... 7, 9

42 U.S.C. § 402(a) 7

42 U.S.C. § 405 ..... 2, 10, 14

42 U.S.C. § 405(g) ..... passim

42 U.S.C. § 405(h) ..... passim

42 U.S.C. § 413(a)(2)(A) 7

42 U.S.C. § 413(d)(1) 7

42 U.S.C. § 414(a) 7

42 U.S.C. § 426 ..... passim

42 U.S.C. § 426(a) ..... passim

42 U.S.C. § 1302 69

42 U.S.C. 1320a-7 59

42 U.S.C. § 1320c-5 59

42 U.S.C. § 1395 ..... passim

42 U.S.C. § 1395a(b) ..... passim

42 U.S.C. § 1395a(b)(2)(B) 66

42 U.S.C. § 1395a(b)(3)(B)(ii)-(iii) 67

42 U.S.C. § 1395c 6

42 U.S.C. § 1395cc 59

42 U.S.C. § 1395cc(j)(1) 66, 67

42 U.S.C. § 1395dd 39

42 U.S.C. § 1395f(a)(1) 8

42 U.S.C. § 1395hh ..... passim

42 U.S.C. § 1395hh(b) 70, 73

42 U.S.C. § 1395hh(b)(2) 73

42 U.S.C. § 1395hh(b)(2)(B) 64, 71

42 U.S.C. § 1395i-2a 20

42 U.S.C. § 1395i-4 6

42 U.S.C. § 1395ii 15

42 U.S.C. § 1395j 7

42 U.S.C. § 1395k 59

42 U.S.C. § 1395k(a)(2)(B) 66

42 U.S.C. § 1395*l*(q)(1) 59, 69, 71

42 U.S.C. § 1395*l*(q)(2) 59

42 U.S.C. § 1395n 59

42 U.S.C. § 1395o 7, 17

42 U.S.C. §§ 1395o-1395s 7, 20

42 U.S.C. §§ 1395u(r) 71

42 U.S.C. § 1395w-4 ..... 7, 59

42 U.S.C. § 1395w-4(g)(4) 66

42 U.S.C. § 1395x(d) 70

42 U.S.C. § 1395x(r) 70

42 U.S.C. § 1395x(s) 59

42 U.S.C. § 1395y(a)(1)(A) 67

42 U.S.C. § 1395y(e) 59

69 Fed. Reg. 3434 60

71 Fed. Reg. 20,754 61

75 Fed. Reg. 24,437 ..... passim

I.R.C. § 36B(c)(2)(C)(i) 26

I.R.C. § 36B(c)(2)(C)(ii) 26

I.R.C. § 4980B 46

I.R.C. § 4980D 46

I.R.C. § 4980H(a) 28

I.R.C. § 4980H(b) 28

I.R.C. § 4980H(d) 3

I.R.S. § 4980H(d)(1) 29

I.R.C. § 5000A(a) 45, 51

I.R.C. § 5000A(b) 28

I.R.C. § 5000A(b)(1) 45, 51

I.R.C. § 5000A(b)(2) 46

I.R.C. § 5000A(c)(1) 46, 52

I.R.C. § 5000A(c)(1)(B) 51

I.R.C. § 5000A(c)(2) 46, 51

I.R.C. § 5000A(e)(1) 51

I.R.C. § 5000A(e)(2) 45, 51

I.R.C. § 5000A(f)(1)(A)(1) 26

I.R.C. § 5000A(g)(1) 3, 29

I.R.C. § 5000A(g)(2) 46

I.R.C. § 6656 29

I.R.C. § 6671(a) 3, 29

I.R.C. § 7421(a) 28

I.R.C. §§ 9801-03 ..... 33, 46

Pub. L. No. 93-406, 88 Stat. 829 (1974) 33

Pub. L. No. 99-272, 100 Stat.82 (1985) 33

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§ 1001 23
§ 1201 ..... 23, 35
§ 1311 22
§ 1401-02 23
§ 1421 22
§ 1501 23
§ 1501(a)(2)(A) 22, 34
§ 1501(a)(2)(B) 21
§ 1501(a)(2)(E) 21
§ 1501(a)(2)(F) 21, 23
§ 1501(a)(2)(G) 21
§ 1501(a)(2)(H) 23, 36, 37
§ 1501(a)(2)(I) ..... passim
§ 1501(a)(2)(J) 37
§ 1501(b) 46, 51
§ 1513 ..... 22, 34, 43
§ 2001 23
§ 6402(a) 63, 69
§ 6405 64

§ 6405(b)(1) 63, 68, 69, 73
§ 6405(b)(2) 63, 68, 69, 73
§ 6405(c) 63, 68, 69
§ 6405(d) 74
§ 10101(a) 23, 35
§ 10103(e) 35
§ 10106 23
§ 10106(a) ..... passim

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§ 1002 ..... 23, 46
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INTRODUCTION

Plaintiffs — the Association of American Physicians and Surgeons ("AAPS") and the Alliance for Natural Health USA ("ANH-USA") — have essentially combined three disconnected lawsuits in a single complaint. None of their claims is within the jurisdiction of this Court, and none, in any event, has merit. The complaint should be dismissed under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).[1]

The first "suit," brought by the two associations on behalf of their members, purports to challenge explanatory guidance contained in a Social Security Administration ("SSA") handbook, the Program Operations Manual System ("POMS"). The Social Security Act states that an individual aged 65 or older who is "entitled to monthly [old-age] insurance benefits" under Social Security "shall be entitled to hospital insurance benefits under Part A" of Medicare. 42 U.S.C. § 426(a). SSA, through the POMS, sensibly interprets this statutory language to provide that an individual receiving Social Security old-age benefits cannot relinquish his entitlement to Medicare Part A without also relinquishing his entitlement to old-age benefits. Plaintiffs attack this interpretation as a violation of the Administrative Procedure Act ("APA"), claiming that the POMS are inconsistent with the law and were adopted without notice and comment. 2d Am. Compl. ("SAC") ¶¶ 8-50.

The Social Security claims should be dismissed. First, plaintiffs do not satisfy the Article III requirements for standing to sue, because, among other reasons, they do not name a specific member who has standing to bring each claim (as they must to sue in an associational capacity),

[1] Plaintiffs bear the burden to show subject matter jurisdiction under Rule 12(b)(1), and the Court must determine whether it has subject matter jurisdiction before addressing the merits of the complaint. See Steel Co. v. Citizens for Better Env't, 523 U.S. 83, 94-95 (1998). Under Rule 12(b)(6), "[t]o survive a 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, 129 S. Ct. 1937, 1949 (2009) (internal quotation marks omitted).

Summers v. Earth Island Inst., 129 S. Ct. 1142, 1151-52 (2009), and they do not identify any concrete harm that has been suffered. Second, plaintiff associations and their members have failed to exhaust statutorily mandated administrative remedies. See 42 U.S.C. § 405. With exceptions not relevant here, a federal court cannot exercise jurisdiction over a Social Security claim unless a plaintiff has presented it to the agency first. Weinberger v. Salfi, 422 U.S. 749, 766-67 (1975). Plaintiffs have not identified a member who has presented such claims to the agency; this dooms the claims.[2] Finally, as to the merits, plaintiffs' Social Security claims fall flat. If the challenged POMS provisions are reviewable at all, they are interpretive rules, and interpretive rules need not be submitted for notice and comment. Cement Kiln Recycling Coal. v. EPA, 493 F.3d 207, 226 (D.C. Cir. 2007). And because these provisions reasonably interpret, 42 U.S.C. § 426, they do not violate the APA.

The second "suit" — related to the first only in that it pertains to health care — targets the new health care reform legislation, the Patient Protection and Affordable Care Act ("ACA" or "Act"), Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010), as amended by Health Care and Education Reconciliation Act of 2010 ("HCERA"), Pub. L. No. 111-152, 124 Stat. 1029 (Mar. 30, 2010). Plaintiffs, who again sue on behalf of their members, focus on two aspects of the ACA's regulation of the multi-trillion dollar interstate health care market: (i) a requirement that individuals maintain a minimum level of insurance coverage or pay a penalty on their tax return (beginning in tax year 2014), and (ii) a requirement that large employers provide a minimum level of coverage to employees or, in some circumstances, face an assessment. Plaintiffs allege that these provisions exceed Congress's powers under Article I of the U.S. Constitution, create an unapportioned "direct tax" in violation of Article I, §§ 2 and 9, effect unconstitutional takings,

[2] Nor, in any case, have plaintiffs satisfied the accompanying non-jurisdictional exhaustion requirements.

deny equal protection, violate due process, and run afoul of the Ninth and Tenth Amendments. SAC ¶¶ 62-73, 94-99. Finally, plaintiffs claim that this Court should order an accounting of the Medicare and Social Security trust funds because the Secretary of Health and Human Services and the Commissioner of SSA have violated their fiduciary duties. Id. ¶¶ 83-89, 112-17.

These claims should also be dismissed. They do not come close to satisfying the basic prerequisites of jurisdiction under Article III. Plaintiffs again fail to identify a specific member who has standing to bring each claim. Summers, 129 S. Ct. at 1151-52. Also, neither the associations nor any of their members has standing to challenge the minimum coverage provision because plaintiffs identify no imminent harm flowing from that provision: The minimum coverage provision does not take effect until 2014, so any conceivable injury flowing from it is too remote temporally to support standing. McConnell v. FEC, 540 U.S. 93, 226 (2003) overruled in part on other grounds by Citizens United v. FEC, 130 S. Ct. 876 (2010). Plaintiffs do not, in any case, identify any harm flowing from the challenged provision, as opposed to other elements of the ACA. And just as any alleged injury caused by the minimum coverage provision is too remote and uncertain to support standing, so too the claims against the employer responsibility and minimum coverage provision are unripe. Much can happen between now and 2014 that would render any judicial pronouncements here purely advisory.

These impediments aside, the Anti-Injunction Act bars jurisdiction over these claims. Any penalty under the employer responsibility or minimum coverage provisions of the ACA would be assessed and paid like a tax. 26 U.S.C. (I.R.C.) §§ 4980H(d), 5000A(g)(1). The Anti-Injunction Act prevents a plaintiff from filing a pre-payment action to abate collection of such a penalty. I.R.C. § 6671(a). To challenge the penalty, a plaintiff must pay it and seek a refund.

Finally, as to their novel fiduciary duty claims, plaintiffs cannot base standing on a

generalized grievance — a vague perception that defendants' conduct is unlawful — rather than a cognizable injury in fact. In any event, the information plaintiffs seek regarding the fiscal soundness of the Social Security and Medicare trust funds is already publicly available.

Plaintiffs' challenge to the ACA fares no better on the merits. In enacting the minimum coverage and employer responsibility provisions, Congress acted well within its authority under the Commerce Clause. Congress determined that, without the minimum coverage provision, the reforms in the Act, such as the ban on denying coverage and setting premiums based on pre-existing conditions, would not work, as they would amplify existing incentives for individuals to "wait to purchase health insurance until they needed care," shifting even greater costs onto third parties. ACA §§ 1501(a)(2)(I), 10106(a). Congress thus found that the minimum coverage provision "is essential to creating effective health insurance markets in which improved health insurance products that are guaranteed issue and do not exclude coverage of pre-existing conditions can be sold." Id. Also, Congress understood, and plaintiffs do not deny, that virtually everyone at some point needs medical services, which cost money. The ACA regulates economic decisions about how to pay for those services — whether to pay in advance through insurance or to attempt to do so later out of pocket (often unsuccessfully) — that, "in the aggregate," without question substantially affect the vast, interstate health care market. Gonzales v. Raich, 545 U.S. 1, 22 (2005); see Thomas More Law Ctr. v. Obama, No. 02-11156, 2010 WL 3952805 (E.D. Mich. Oct. 7, 2010). Congress has authority under the Commerce Clause and the Necessary and Proper Clause to adopt the minimum coverage provision. And plaintiffs' challenge to the employer responsibility provision is spurious. Congress has long regulated the terms and conditions of employment, including the terms on which an employer sponsors health insurance for its employees, and it has been settled for decades that such regulations are within

the commerce power. See, e.g., United States v. Darby, 312 U.S. 100, 118 (1941).

In addition, Congress has independent authority to enact these provisions as an exercise of its power under Article I, Section 8, to lay taxes and make expenditures to promote the general welfare. License Tax Cases, 72 U.S. (5 Wall.) 462, 471 (1867). The employer responsibility provision and the minimum coverage provision will raise substantial revenues, and both are therefore valid under longstanding precedent, even though Congress also had a regulatory purpose in enacting the provisions. It is equally well-established that a tax predicated on a volitional event — such as a decision not to purchase health insurance — is not a "direct tax" subject to apportionment under Article I, Sections 2 and 9. United States v. Mfrs. Nat'l Bank of Detroit, 363 U.S. 194, 197-98 (1960); Tyler v. United States, 281 U.S. 497, 502 (1930).

Plaintiffs also contend that the ACA, by allegedly driving up insurance premiums, effects an unconstitutional taking. This claim founders for three reasons: (1) the claim is not ripe because plaintiffs have not sought compensation under the Tucker Act, 28 U.S.C. § 1491; (2) any increase in insurance premiums cannot legally be attributed to the government; and (3) an obligation to pay money does not constitute a taking. And to the extent plaintiffs attempt to state due process or equal protection claims, those too are meritless. Their asserted due process right to a "freedom of contract" has been rejected for at least 70 years, and the courts now consistently recognize that Congress may undertake economic regulation so long as it has a rational basis to do so. Congress not only had a rational basis to act, it had compelling reasons to do so.

The third "suit" challenges the Department of Health and Human Service's ("HHS") issuance of an interim final rule 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), and two corresponding changes to its internal claims processing manual (known as

"change requests") that implement these requirements. Plaintiffs raise two basic challenges. First, plaintiffs claim that the provisions exceed HHS's authority by requiring physicians who refer Medicare beneficiaries to other providers of items or services paid for by Medicare (1) to enroll in or opt out of Medicare, and (2) to obtain a standard provider number, the National Provider Identifier ("NPI"), for use on claim forms. Second, plaintiffs maintain that, under the APA, 5 U.S.C. § 553, and Medicare Act, 42 U.S.C. § 1395hh, the rule and change requests should have been preceded by notice and comment. Plaintiffs' assault on HHS's interim final rule and change requests fails as well. Plaintiffs face an insurmountable threshold obstacle, namely, they lack standing to raise these claims for the reasons discussed above. The claims also come up short on the merits. HHS had clear authority to establish the enrollment and NPI rules, and it did not need to first provide notice and an opportunity to comment because these are "rules of agency organization, procedure, or practice" to which no notice-and-comment obligation attaches, see 5 U.S.C. § 553(b)(3)(A).[3] The Court should dismiss plaintiffs' complaint under Rules 12(b)(1) and 12(b)(6).

I. PLAINTIFFS' SOCIAL SECURITY CLAIMS SHOULD BE DISMISSED.

A. The Statutory and Regulatory Background of the POMS

1. Medicare Provisions

Title XVIII of the Social Security Act established Medicare to provide health insurance to the elderly and disabled. Amgen Inc. v. Smith, 357 F.3d 103, 105 (D.C. Cir. 2004). Medicare Part A, or "hospital insurance," covers services furnished by hospitals and other institutional providers. 42 U.S.C. §§ 1395c–1395i-4. By operation of statute, entitlement to Medicare Part A benefits occurs automatically for individuals who turn 65 and are entitled to monthly Social Security benefits. 42 U.S.C. § 426(a) ("Every individual who — (1) has attained age 65, and

[3] HHS did accept post-issuance comments.

(2)(A) is entitled to monthly [Social Security] benefits under [42 U.S.C. § 402] . . . shall be entitled to hospital insurance benefits under part A of subchapter XVIII . . . .").[4] Because entitlement to Medicare Part A is automatic, these individuals need take no further steps to "enroll" in or to "apply" for hospital insurance coverage under Medicare Part A. 42 C.F.R. § 406.6(b).

In this respect, Medicare Part A stands in contrast to Medicare Part B, which provides supplemental medical insurance benefits for certain services not covered under Part A, including physician services. While Part A is often referred to as "mandatory," Part B is an optional program to which individuals are not automatically entitled. 42 U.S.C. §§ 1395j–1395w-4. Under Part B, individuals "elect to enroll," must pay insurance premiums, and may choose to "disenroll." See 42 U.S.C. §§ 1395o-1395s; 42 C.F.R. 407.27.

An individual determined to avoid entitlement to Medicare Part A can do so. One could choose not to file an application for monthly Social Security benefits. See 42 U.S.C. § 426(a). Or, one could "withdraw" a previously submitted application. 20 C.F.R. § 404.640. That said, because entitlement to Medicare part A is a consequence of entitlement to Social Security benefits, no mechanism exists to extinguish the entitlement to Medicare Part A benefits while retaining the entitlement to monthly Social Security benefits.

Benefits of Medicare Part A entitlement are not forced upon unwilling beneficiaries. Nothing in Medicare Part A requires individuals to actually use the benefits to which they are entitled. Beneficiaries are not forced to seek out any particular hospital services. And nothing

[4] Entitlement to monthly Social Security old-age benefits, in turn, generally arises when an individual: (1) has turned 62; (2) has filed an application for those benefits; and (3) is "fully insured." See 42 U.S.C. § 402(a). An individual is "fully insured" if he has a sufficient number of "quarters of coverage," id. § 414(a); that is, quarters in which he has been paid "wages" above a certain amount, id. § 413(a)(2)(A), (d)(1).

precludes them from spending their own money on medical care or other insurance, 42 U.S.C. § 1395f(a)(1); a beneficiary can simply refuse to authorize the hospital to request payment for care, in which case "the provider may charge the beneficiary for all services furnished to him." 42 C.F.R. § 489.21(b)(4).

2. Social Security Provisions

As noted above, Social Security regulations provide a means of avoiding entitlement to monthly Social Security benefits and thereby avoiding entitlement to Medicare Part A. Under 20 C.F.R. § 404.640, an individual may "withdraw" an application for monthly Social Security benefits by submitting a written request. Moreover, an individual may withdraw an application even after he has begun receiving monthly Social Security benefits, provided that the benefits are repaid or the agency is satisfied that they will be. 20 C.F.R. § 404.640. Although plaintiffs complain that their members cannot opt out of Medicare Part A without surrendering their monthly Social Security benefits, they challenge neither the withdrawal regulation, 20 C.F.R. § 404.640, nor the statute that establishes automatic Part A entitlement, 42 U.S.C. § 426(a).

3. The Challenged POMS Provisions

Plaintiffs focus on three provisions of POMS, an internal handbook designed to explain the operation of statutes and regulations to agency employees, particularly those who process claims. See https://secure.ssa.gov/apps10/poms.nsf/aboutpoms (last visited Nov. 22, 2010) ("The POMS states only internal SSA guidance.") Consistent with this purpose, the three POMS provisions that plaintiffs challenge explain the effect of the statutes and regulations discussed above.[5] For example, HI 00801.002 states that a person entitled to monthly Social Security

[5] The POMS provisions are available online at http:/policy.ssa.gov/poms.nsf/links/0600801002 (HI 00801.002); http:/policy.ssa.gov/poms.nsf/links/0600801034 (HI 00801.034); and http:/policy.ssa.gov/poms.nsf/links/0200206020 (GN 00206.020) (last visited Nov. 22, 2010).

benefits may not "waive" Medicare Part A "entitlement," and that the only way to avoid such "entitlement" is by withdrawing the application for those Social Security benefits, which "requires repayment" of the amounts previously received. The first part of this statement explains that, as discussed above, statutory "entitlement" to Medicare Part A follows automatically from entitlement to monthly Social Security benefits — a proposition plaintiffs do not contest. See 42 U.S.C. § 426(a); 42 C.F.R. § 406.6(b). The second part explains SSA's unchallenged withdrawal regulation, also discussed above, which allows an individual to withdraw an application for monthly Social Security benefits so long as he repays any benefits already received. 20 C.F.R. § 404.640. The other two challenged POMS provisions essentially repeat these ideas (and, indeed, refer back to HI 00801.002). See HI 00801.034; GN 00206.020.

4. Exhaustion under the Social Security Act

Under 42 U.S.C. § 405(h), claims that arise under the Social Security Act must be brought pursuant to the Act's special channeling provision, which is codified at 42 U.S.C. § 405(g). Section 405(h) specifically states, in relevant part:

> No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter [Title II].[6]

42 U.S.C. § 405(h). Section 405(g) requires claimants to exhaust their administrative remedies, by obtaining a final decision from SSA, before filing a suit in federal court: "Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party . . . may obtain a review of such decision by a civil action . . . ." (emphasis added).

B. Argument

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

Plaintiffs lack standing to raise any Social Security claim. Neither AAPS nor ANH-USA

[6] Title II includes the old-age insurance program. See 42 U.S.C. § 402.

asserts any cognizable injury to itself as an organization, or to its members, from the POMS. See SAC ¶¶ 16-17. Indeed, they fail to identify even one member with standing to raise any particular claim. That fact alone dooms plaintiffs' claim of associational standing.

To establish Article III standing, a plaintiff suing on his or her own behalf must demonstrate an injury in fact, causation, and redressability. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-561 (1992). The associational standing test is more rigorous. An organization invoking such standing must show that (1) at least one of its members has standing to sue in her own right; (2) the interests the association seeks to protect are germane to its purpose; and (3) neither litigation over the claim asserted nor the relief sought requires the participation of an individual member. Interstate Natural Gas Ass'n of Am. v. FERC, 494 F.3d 1092, 1095 (D.C. Cir. 2007). To satisfy the first of these prongs, an association must name a specific member with standing for each claim it asserts. Summers, 129 S. Ct. at 1151-52; Am. Chemistry Council v. Dep't of Transp., 468 F.3d 810, 820 (D.C. Cir. 2006). Plaintiffs make no attempt to name any member allegedly harmed by the POMS. Thus, the Court should dismiss their Social Security claims for lack of jurisdiction.[7]

Even if plaintiffs had named particular members, however, none could have standing to challenge the POMS. No hypothetical plaintiff could either trace any harm to the POMS or establish that the relief sought would redress their injuries. See generally Newdow v. Roberts, 603 F.3d 1002, 1012 n.6 (D.C. Cir. 2010) (causation and redressability "can be viewed as two facets of a single requirement") (citation omitted). Because the POMS merely explain the effect

[7] Moreover, plaintiffs do not satisfy the third prong of this test with respect to the Social Security claims because "the claim asserted . . . requires the participation of individual members in the lawsuit." Hunt v. Wash. State Apple Advertising Comm'n, 432 U.S. 333, 343 (1977). The Social Security claims must be channeled through 42 U.S.C. § 405 and the attendant administrative procedures, and the participation of individual members is needed to bring claims through this process. See Shalala v. Ill. Council on Long Term Care, 529 U.S. 1, 24 (2000).

of the governing statute and regulations, see supra Part I.A.1-3, any "injury" is caused not by the POMS, but by the unchallenegd statute and regulations. And as a corollary, invalidating the POMS would not redress any injury because the controlling statutes and regulations, which the POMS merely explain, would remain in effect. See, e.g., Atl. Urological Assocs. v. Leavitt, 549 F. Supp. 2d 20, 27-28 (D.D.C. 2008).

Nevertheless, plaintiffs attempt to allege harm to two categories of their 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." SAC ¶ 16. Plaintiffs do not explain, however, how the mere entitlement to Medicare Part A benefits supposedly harms these members. See id. Those benefits are premium-free, need not actually be used, and do not prevent individuals from seeking hospital services from whatever provider they choose, see 42 C.F.R. § 489.21(b)(4), regardless of whether the hospital participates in Medicare (although almost all do). 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 because patients with Medicare coverage might prefer to see doctors who accept Medicare payments. But this concern has no logical link to the issues in this case, which involve the benefits for inpatient hospital services under Medicare Part A, not physician services under Medicare Part B. See United Seniors Ass'n v. Shalala, 182 F.3d 965, 967 (D.C. Cir. 1999). And whether or not patients are entitled to hospital insurance under Medicare Part A, they may choose to see a physician who accepts Medicare Part B payments, or one who does not. Even if plaintiffs' theory were at all logical, any competitive disadvantage befalling a physician who opted out of Medicare would be a self-inflicted harm that cannot constitute a cognizable injury. Nat'l Family Planning & Reprod. Health Ass'n v. Gonzales, 468 F.3d 826, 831 (D.C. Cir. 2006).

Plaintiffs' assertion of "procedural standing" to bring Count I, based on the deprivation of an alleged right to comment on the challenged POMS, see SAC ¶¶ 31-32, 92, is likewise unavailing. It is true that one "who has been accorded a procedural right to protect his concrete interests can assert that right without meeting all the normal standards for redressability and immediacy." Lujan, 504 U.S. at 572 n.7. But this doctrine does not relieve plaintiffs of the obligation to name a member with standing to vindicate the asserted procedural right. See Summers, 129 S. Ct. at 1151-52. Nor does it excuse a plaintiff from demonstrating the other elements of Article III standing: a particularized injury to a concrete interest (as distinct from the abstract interest in adherence to procedure), and a causal connection between the challenged agency action and that injury. See Fla. Audubon Soc. v. Bentsen, 94 F.3d 658, 664-69 (D.C. Cir. 1996) (en banc). Thus, it is not enough to assert, as plaintiffs do, that the associations or their members "would comment" if given the opportunity. SAC ¶ 31; see Summers, 129 S. Ct. at 1151 (alleged loss of "ability to file comments" alone is "insufficient to create Article III standing"). No member could satisfy the injury and causation requirements because the mere entitlement to Medicare Part A benefits, which need not be used, is not a cognizable harm, and even if it were, its source is not the POMS, but the statute that confers the automatic entitlement. And to the extent that the associations bring this procedural claim on their own, rather than on their members' behalf — the only claim for which this is arguably the case — they fail to identify any concrete injury to their own interests as organizations that the POMS affects.[8]

[8] The plaintiff associations' assertion that they can establish their own standing by relying on the rights of their unnamed member physicians to bring claims on behalf of their unnamed patients is even more tenuous. See SAC ¶ 30. To establish standing under this theory, plaintiffs would have to establish that they have associational standing to sue on behalf of at least one member doctor with respect to each claim and that their member doctors have third-party standing to assert the rights of their patients. As explained, the associations lack standing to sue on behalf of their members. Summers, 129 S. Ct. at 1151-52. Nor would their member doctors have third-party standing to sue on behalf of their patients. To do so, a member doctor would

This Court should not follow Hall v. Sebelius, No. 08-1715, a pending case in which Judge Collyer found, at the motion to dismiss stage, that several plaintiffs have standing to challenge these sections of the POMS. In Hall, there are two categories of individual named plaintiffs: (1) those suing to avoid having to "enroll" in Medicare Part A upon applying for Social Security benefits; and (2) those suing to "disenroll" from Part A benefits to which they have already become entitled. The Court dismissed the claims of the first category of plaintiffs, properly finding that they lacked standing because they had not yet applied for Social Security benefits, and therefore had not yet become entitled to Medicare Part A. 689 F. Supp. 2d 10, 18 (D.D.C. 2009). The Court doubly erred, however, in finding that the second category of plaintiffs had standing because it simply "assum[ed] that the POMS prevent them from declining Medicare Part A while receiving the monthly [Social Security] benefits to which they are entitled." Id. at 19. First, the assumption skirts the relevant issues, namely, whether it is the POMS, as opposed to the unchallenged statute and regulations, that cause the alleged injury, and whether invalidating the POMS would redress that injury. The Court in Hall thus relieved plaintiffs of their burden to demonstrate that they had satisfied the irreducible constitutional requirements of standing. See Lujan, 504 U.S. at 560-61. Second, the assumption ignores the lack of an actual injury. Even if an individual cannot decline or opt out of the entitlement to Medicare Part A while receiving Social Security benefits, he need not actually "participate" in

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have to establish not only (1) his own Article III standing, but also (2) that he "has a 'close' relationship with the [patient] who possesses the right" and (3) that "there is a 'hindrance' to the [patient's] ability to protect his own interests." Kowalski v. Tesmer, 543 U.S. 125, 129-30 (2004) (citations omitted). But here, no doctors or patients are identified, and a "hypothetical" doctor-patient relationship is insufficient to establish the requisite "close" relationship. Id. at 131. Moreover, plaintiffs identify no "hindrance" to any patient's ability to vindicate his own interests, because there is none: Individuals in other lawsuits have challenged both the POMS, see Hall v. Sebelius, 689 F. Supp. 2d 10 (D.D.C. 2009), and the minimum coverage provision, see, e.g., Florida v. U.S. Dep't of Health & Human Servs., No. 10-91, 2010 WL 4010119, at *3 (S.D. Fla. Oct. 14, 2010). This argument founders.

Medicare Part A, see SAC ¶ 16 — that is, he need not actually use the Medicare Part A benefits to which he is entitled. The mere entitlement to benefits causes no cognizable injury, and that critical distinction cannot be assumed away.

2. The Social Security Claims Should Be Dismissed for Failure To Exhaust Administrative Remedies.

The Court should dismiss plaintiffs' Social Security claims (Count I) because plaintiffs have not exhausted their administrative remedies. Plaintiffs purport to raise these claims under the general federal question statute, 28 U.S.C. § 1331, SAC ¶ 9, but such claims must be brought pursuant 42 U.S.C. § 405. Section 405 imposes administrative exhaustion requirements which plaintiffs have not met.

Under § 405(h), claims that arise under the Social Security Act must be brought pursuant to §405(g), and cannot be brought pursuant to § 1331 (or any other statute). "[Section] 405(h) . . . bars federal-question [i.e., § 1331] jurisdiction here. The association or its members must proceed instead through the special review channel [i.e., § 405(g)] that the statutes create." Illinois Council, 529 U.S. at 5; Salfi, 422 U.S. at 757-64 .

The POMS-related claims arise under Title II of the Social Security Act. A claim arises under the Social Security Act if the Act provides "both the standing and the substantive basis" for the claims. Salfi, 422 U.S. at 761; Illinois Council, 529 U.S. at 11-12. Plaintiffs' POMS-related claims arise under the Social Security Act: They both spring from the basic contention that the government is wrongfully depriving some unidentified individuals of Social Security benefits because an individual cannot receive these benefits if he renounces his entitlement to Medicare Part A. SAC ¶¶ 16-18, 90-93; see Salfi, 422 U.S. at 761. And under Supreme Court precedent, that the claims could also be said to arise under the APA does not undercut the conclusion that they arise under the Social Security Act and so must be channeled through the

Act's special review provisions. See SAC ¶¶ 92, 118; Salfi, 422 U.S. at 760-61; Heckler v. Ringer, 466 U.S. 602, 614 (1984); Illinois Council, 529 U.S. at 5, 7.[9]

Section 405(g) requires a plaintiff to exhaust administrative remedies for Social Security Act claims before suing in federal court. It does so by requiring that a "final decision" from the Commissioner precede the filing of a civil action. See 42 U.S.C. § 405(g); Salfi, 422 U.S. at 765. Under SSA regulations, to obtain a final decision (i.e., to exhaust), an individual ordinarily must (1) present a claim to SSA and receive an "initial determination," (2) request "reconsideration" of the initial determination, (3) request and obtain a hearing from an administrative law judge ("ALJ"), and (4) request that the Appeals Council review the ALJ's decision.[10] 20 C.F.R. § 404.900(a)(1)-(6).

The four steps to exhaustion outlined in SSA regulations include a non-waivable element as well as waivable elements. Step one — the presentment requirement — is non-waivable. "Section 405(g) contains the nonwaivable and nonexcusable requirement that an individual present a claim to the agency before raising it in court," Illinois Council, 529 U.S. at 15, unless agency review is not available.

The court cannot review plaintiffs' Social Security claims because plaintiffs have not alleged that any member of AAPS or ANH-USA has presented the claims to the SSA. See Illinois Council, 529 U.S. at 24; Salfi, 422 U.S. at 765. Such presentment is an "absolute

[9] Nor does it matter that plaintiffs could portray the Social Security claims as being Medicare claims; the Medicare Act incorporates the Social Security Act's channeling provision. 42 U.S.C. § 1395ii; Illinois Council, 529 U.S. at 5-14.

[10] SSA would transfer a claim regarding the connection between Social Security entitlement and Medicare entitlement to HHS for a hearing by an ALJ and administrative appellate review (by the Medicare Appeals Council), if that claim were deemed a challenge to a determination of entitlement to Medicare Part A. See 42 C.F.R. § 405.904(a). Even if this process were employed, SSA would issue the initial determination and handle a request for reconsideration of that determination prior to transferring the matter to HHS. Id. The elements of exhaustion under HHS regulations are nearly identical to those imposed by SSA regulations. Id.

prerequisite" to judicial review. Nat'l Kidney Patients Ass'n v. Sullivan, 958 F.2d 1127, 1129-30 (D.C. Cir. 1992); see also Illinois Council, 529 U.S. at 15. Plaintiffs' Social Security claims should be dismissed.

Plaintiffs claim that this presentment requirement does not apply to their members in their capacities as practicing doctors because "[a]dministrative remedies are not even available" to them.[11] SAC ¶ 44. The associations maintain that member physicians who have "opt[ed] 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 benefits.[12] Id. Moreover, the associations continue, their member doctors could not "initiate an administrative challenge to the retirees' [loss of] benefits." Id.

This allegation runs aground on D.C. Circuit precedent. See Am. Chiropractic Ass'n v. Leavitt, 431 F.3d 812, 816-18 (D.C. Cir. 2005). Member doctors could secure judicial review of this claim through administrative actions by their patients, i.e., patients could bring administrative claims and, following exhaustion, sue in federal court. Such review, though indirect, suffices to require a member doctor to work through § 405. Id. at 816-17; Nat'l Athletic Trainers Ass'n, Inc. v. HHS, 455 F.3d 500, 503-08 (5th Cir. 2006); Colo. Heart Inst., LLC v. Johnson, 609 F. Supp. 2d 30, 34-38 (D.D.C. 2009).

3. Plaintiffs' Social Security Claims Are Not Cognizable.

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

Plaintiffs allege that the challenged statements from the POMS (HI 801.002, 801.034 and GN 206.020) violate the APA because they are substantive rules that should have been preceded

[11] This allegation highlights a standing problem identified earlier in the brief: Plaintiffs have not, as they must, specifically identified injured members. See Part I.B.1 supra.

[12] This allegation is nonsensical. See Part I.B.1 supra.

by notice and comment. SAC ¶ 92. Even if plaintiffs could overcome the standing and exhaustion hurdles, this allegation would fail. If reviewable at all under the APA, the POMS provisions would be treated as interpretive rules, which are not subject to notice and comment. 5 U.S.C. § 553(b); Cement Kiln Recycling Coalition, 493 F.3d at 226.

To qualify as interpretive, a rule "must derive a proposition from an existing document whose meaning compels or logically justifies the proposition." Cent. Tex. Tel. Coop. v. FCC, 402 F.3d 205, 212 (D.C. Cir. 2005). But an interpretive rule need not "parrot statutory or regulatory language" and "may have the effect of creating new duties." Id. at 214 (quotation marks omitted); see also Fertilizer Inst. v. EPA, 935 F.2d 1303, 1308 (D.C. Cir. 1991).

The challenged statements in the POMS interpret the Social Security Act and its implementing regulations. Section 426 (of Title 42 of the United States Code) states that "[e]very individual who . . . has attained the age of 65, and is entitled to monthly insurance benefits [i.e., monthly Social Security old-age benefits] under section 402 of this title . . . shall be entitled to hospital insurance benefits under part A of subchapter XVIII of this chapter." The POMS statements interpret this provision to mean precisely what it says — that entitlement to Medicare Part A follows automatically from entitlement to Social Security benefits. The POMS statements further recognize the absence of any procedure in the Social Security Act or regulations to sever that entitlement from the receipt of Social Security Benefits. See POMS HI 801.002, HI 800.034, and GN 206.020.

As used in 42 U.S.C. § 426, the word "entitled" means that an individual can claim benefits without taking an additional step. This contrasts with the use of the word "eligible" in the Act to describe an individual who must take an additional step, such as submitting an application, to claim benefits. Compare 42 U.S.C. § 426 with 42 U.S.C. § 1395o (addressing

Medicare Part B, and stating that "[e]very individual who . . . is entitled to hospital insurance benefits under part A of this subchapter . . . is eligible to enroll in the insurance program established by this part"). Thus, the use of the word "entitled" in § 426 properly leads to the parallel statement in the POMS provisions that an individual entitled to Social Security benefits automatically may claim Medicare Part A benefits, such as reimbursement for hospital visits. And the use of the mandatory word "shall" in § 426, see In re Medicare Reimbursement Litig., 414 F.3d 7, 10 (D.C. Cir. 2005) (noting that "shall" is a mandatory term), yields the conclusion that this entitlement to Medicare Part A necessarily follows from entitlement to Social Security benefits; if one becomes entitled to Social Security benefits, then he or she "shall" be entitled to Medicare Part A. Since the POMS articulate a straightforward interpretation of the statute, they are interpretive rules exempt from notice and comment. Texas Tel. Coop., 402 F.3d at 212; Hall, 689 F. Supp. 2d at 20.

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

Plaintiffs allege that the Medicare Act and the Social Security Act "allow participating in Social Security without participating in Medicare Part A," SAC ¶ 91, and that the POMS conflict with those statutes because they "condition[] eligibility for Social Security on participation in Medicare Part A," id. ¶ 118(A)(ii). Accordingly, they assert that the POMS violate the APA because they are conflict with the Medicare and Social Security Acts. Id. ¶ 93; see 5 U.S.C. § 706(2)(A), (C).[13] This claim is premised on a misreading of the statutory scheme (as well as the

[13] Plaintiffs' further assertion that the POMS should be invalidated as "ultra vires," SAC ¶ 93, should be summarily rejected. A district court's assertion of jurisdiction to undertake nonstatutory review of agency action under the ultra vires doctrine, which predates the APA, see Leedom v. Kyne, 358 U.S. 184 (1958), is "extraordinary" and "extremely narrow in scope." Nat'l Air Traffic Controllers Ass'n v. Fed. Serv. Impasses Panel, 437 F.3d 1256, 1263 (D.C. Cir. 2006). Where, as here, there are "compelling arguments regarding the proper interpretation of the disputed statutory provisions," Nat'l Air Traffic Controllers, 437 F.3d at 1264, or the

POMS) and should be rejected.

Nothing in the statutory or regulatory scheme conditions entitlement to Social Security on "participation" in Medicare Part A, as plaintiffs claim, see SAC ¶ 16. As relevant to this case, 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 set 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.

The challenged POMS provisions are fully consistent with this statutory and regulatory scheme, and merely explain one consequence of its design — that is, the absence of a statutory or regulatory provision 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. At the very least, the POMS represent the SSA's reasonable interpretation of the Social Security Act and its implementing regulations. As such, they warrant deference from the Court. See Wash. State Dep't of Soc. & Health Servs. v. Guardianship Estate of Keffeler, 537 U.S. 371, 385 (2003) (while the "administrative interpretations [in POMS] are not the products of formal rulemaking, they nevertheless warrant respect") (citations omitted from parenthetical). Indeed, to the extent that the POMS interpret the governing regulations, see 42 C.F.R. § 406.6; id. § 406.10(b); 20 C.F.R. § 404.640, they "must be given controlling weight unless . . . plainly erroneous or inconsistent" with those regulations. Thomas Jefferson Univ. v.

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plaintiffs may vindicate their rights "through . . . administrative proceedings and through subsequent judicial review of any final agency action," Jordan Hosp. v. Leavitt, 571 F. Supp. 2d 108, 118 (D.D.C. 2008), nonstatutory review under the ultra vires doctrine is inappropriate.

Shalala, 512 U.S. 504, 512 (1994) (citation omitted). Such deference is "all the more warranted" where the provisions concern "complex and highly technical regulatory program[s]" such as Medicare and Social Security. Id.; Methodist Hosp. v. Shalala, 38 F.3d 1225, 1229 (D.C. Cir. 1994).

The Court in Hall misunderstood this consequence of the existing statutory and regulatory scheme. It observed that "the POMS, and not the Social Security Act or the accompanying regulations, created the condition that [p]laintiffs challenge here" because "neither the statute nor the regulation specifies that [p]laintiffs must withdraw from and repay [Social Security] retirement benefits in order to withdraw from Medicare Part A." 689 F. Supp. 2d 10, 20-21 (D.D.C. 2009). To be sure, the statute and regulations may not use those precise words, but that is inescapably their practical effect: There is simply no other statutory or regulatory mechanism to extinguish the automatic (and harmless) entitlement to Medicare Part A benefits. As individuals already entitled to Social Security benefits do not "apply" for or "enroll" in Medicare Part A, it is not surprising that neither the statute nor any regulation provides them with a right to "disenroll" or "withdraw." The Hall Court is mistaken, and plaintiffs claims should be denied.[14]

[14] Moreover, as discussed in Part I.B.1, striking down the POMS would not redress the alleged "injury" of automatic entitlement to Medicare Part A benefits because the statutory and regulatory scheme conferring this entitlement would remain intact. To give effect to the apparent desire of some AAPS and ANH-USA members to extinguish their Medicare Part A entitlement while retaining their Social Security entitlement, the Court would have to create a "waiver" or "disenrollment" procedure that the governing statute and regulations neither set forth nor require defendants to create. Congress knows how to create such procedures, but it did not do so here. See 42 U.S.C. §§ 1395i-2a, 1395o-1395s. The Court should not require procedures that Congress saw no need to prescribe. What is more, the scheme that Congress chose has an obvious salutary effect: For every person who does not want entitlement to hospital insurance, there are many more who do want that insurance but would fall through the cracks if some additional enrollment or application process were required.

II. PLAINTIFFS' ACA-RELATED CLAIMS SHOULD BE DISMISSED.

A. ACA's Statutory Background

In 2009, the United States spent more than 17 percent of its gross domestic product on health care, in a $2.5 trillion interstate market. ACA §§ 1501(a)(2)(B), 10106(a). Notwithstanding this extraordinary expenditure, more than 50 million people — an estimated 16.7 percent of the population — went without health insurance in 2009, and, absent the new legislation, that number would have climbed to more than 54 million by 2019. U.S. Census Bureau, Income, Poverty, and Health Insurance Coverage in the United States: 2009, at 22 (Sept. 2010); see also Cong. Budget Office ("CBO"), Key Issues in Analyzing Major Health Insurance Proposals 11 (Dec. 2008) [hereinafter Key Issues]; CBO, The Long-Term Budget Outlook 21-22 (June 2009).

The record before Congress documented the staggering costs that a broken health care system visits on individual Americans and the nation as a whole. The millions who lack health insurance coverage still receive medical care, but often cannot pay for it. The costs of that uncompensated care, $43 billion in 2008 alone, are shifted to providers, the insured population (in the form of higher premiums), governments, and taxpayers. ACA §§ 1501(a)(2)(F), 10106(a). But cost shifting is not the only economic harm imposed by the lack of insurance. Congress found that the "economy loses up to $207,000,000,000 a year because of the poorer health and shorter lifespan of the uninsured," id. §§ 1501(a)(2)(E), 10106(a), and concluded that 62 percent of all personal bankruptcies result in part from medical expenses, id. §§ 1501(a)(2)(G), 10106(a). All these costs, Congress determined, substantially affect interstate commerce. Id. §§ 1501(a)(2)(F), 10106(a).

In order to remedy this enormous problem in a critical sector of the American economy,

the Act comprehensively "regulates activity that is commercial and economic in nature: economic and financial decisions about how and when health care is paid for, and when health insurance is purchased." Id. §§ 1501(a)(2)(A), 10106(a). First, to address inflated fees and premiums in the individual and small-business insurance market, Congress established health insurance exchanges "as an organized and transparent marketplace for the purchase of health insurance where individuals and employees (phased-in over time) can shop and compare health insurance options." H.R. Rep. No. 111-443, pt. II, at 976 (2010) (internal quotation omitted). The exchanges will regulate premiums, implement procedures to certify qualified health plans, coordinate participation and enrollment in health plans, and provide consumers with needed information. ACA § 1311.

Second, the Act builds on the existing system of health insurance, in which most individuals receive coverage as part of their compensation. See CBO, Key Issues, at 4-5. It creates a system of tax incentives for small businesses to encourage the purchase of health insurance for their employees, and through the employer responsibility provision, imposes assessments, in certain circumstances, on large businesses that do not provide their employees adequate coverage. ACA §§ 1421, 1513. The employer responsibility provision will (i) create incentives for large employers to provide a minimum level of coverage, alleviating the "job lock" that occurs when workers decline to take better jobs because they must give up their current health plan and may be unable to obtain a comparable one, see CBO, Key Issues, at 8, and (ii) prevent "employers who do not offer health insurance to their workers" from gaining "an unfair economic advantage" over those who do offer it. H.R. Rep. No. 111-443, pt. II, at 984-85.

Third, the Act will subsidize insurance coverage for much of the uninsured population. As Congress understood, nearly two-thirds of the uninsured are in families earning below 200

percent of the federal poverty level, H.R. Rep. No. 111-443, pt. II, at 978 (2010); see also CBO, Key Issues, at 27, while 4 percent of those with income greater than 400 percent of the poverty level are uninsured, CBO, Key Issues, at 11. The Act will plug this gap by providing health insurance tax credits and reduced cost-sharing for those with income between 100 and 400 percent of the federal poverty level, ACA §§ 1401-02, and expanding eligibility for Medicaid to those below 133 percent of the federal poverty level beginning in 2014, id. § 2001.

Fourth, the Act will remove barriers to insurance coverage. It will prohibit widespread insurance industry practices that increase premiums — or deny coverage entirely — to those with the greatest need for health care. For example, the Act will bar insurers from refusing to cover individuals with pre-existing medical conditions and prohibit insurers from setting lifetime limits on the dollar value of coverage. Id. §§ 1001, 1201, 10101(a). It will also prevent insurers from rescinding coverage for any reason other than fraud or misrepresentation, or declining to renew coverage based on health status. Id. §§ 1001, 1201.

Finally, the Act will require that all Americans, with specified exceptions, maintain a minimum level of health insurance coverage, or pay a penalty on their tax returns starting with tax year 2014. Id. §§ 1501, 10106, as amended by HCERA § 1002. Congress found that this provision "is an essential part of this larger regulation of economic activity," and that its absence "would undercut Federal regulation of the health insurance market." ACA §§1501(a)(2)(H), 10106(a). That judgment rested on detailed congressional findings. Congress 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). Conversely, Congress also found that, without the minimum coverage provision, the reforms in the Act, such as the ban on denying coverage based on pre-existing conditions, would amplify

existing incentives for individuals to "wait to purchase health insurance until they needed care," thereby further shifting costs onto third parties. Id. §§ 1501(a)(2)(I), 10106(a). Congress thus found that the minimum coverage provision "is essential to creating effective health insurance markets in which improved health insurance products that are guaranteed issue and do not exclude coverage of pre-existing conditions can be sold." Id.

The CBO projects that by 2019, the reforms in the Act will reduce the number of uninsured Americans by 32 million. Letter from Douglas W. Elmendorf, Director, CBO, to the Hon. Nancy Pelosi, Speaker, U.S. House of Representatives 9 (Mar. 20, 2010) [hereinafter CBO Letter]. It further projects that the Act's combination of reforms, subsidies, and tax credits will reduce the average premium paid by individuals and families in the individual and small-group markets. Id. at 15; CBO, An Analysis of Health Insurance Premiums Under the Patient Protection and Affordable Care Act 23-25 (Nov. 30, 2009). And the CBO estimates that the interrelated revenue and spending provisions in the Act — specifically including revenue from the employer responsibility and minimum coverage provisions — will yield net savings to the federal government of more than $100 billion over ten years. CBO Letter at 2.

B. Argument

1. The Court Lacks Jurisdiction over Plaintiffs' ACA Claims.

a. Plaintiffs Lack Standing to Challenge the Minimum Coverage and Employer Responsibility Provisions.

Plaintiffs challenge two provisions of the ACA: the minimum coverage provision, and the employer responsibility provision. But when those provisions take effect in 2014, they will operate on individuals and certain large businesses, not on the plaintiff associations. And just as they neglected to name any of their members subject to the POMS, plaintiffs neglect to name any member subject to either of these provisions. That failure is fatal to their assertion of standing.

Summers, 129 S. Ct. at 1151-52; see Part I.B.1 supra.

No member of either association, in any case, would have standing to challenge the minimum coverage provision, because plaintiffs identify no concrete harm traceable to that provision. Notably, plaintiffs do not allege that the provision will compel their members to buy coverage they otherwise would not purchase. Rather, they allege that the "current health insurance premiums for AAPS and ANH-USA members" — that is, for those who already have insurance — "will rise or have risen." SAC ¶ 23 (emphasis added). Similarly, plaintiffs speculate that increased premiums will affect unnamed physicians who take cash payments for their services. SAC ¶¶ 20-21. Plaintiffs' attenuated chain of causation — that the ACA will cause premiums to rise, which in turn will affect patients' decisions which physicians to visit, and which in turn will affect the associations' members' profit margins — is far too speculative to meet their burden to show standing. See Ctr. for Biological Diversity v. U.S. Dep't of Interior, 563 F.3d 466 (D.C. Cir. 2009) (speculation about behavior of third parties cannot form basis for standing). Further, plaintiffs connect the alleged potential increase in insurance premiums not to the provisions of the ACA that they challenge, but instead to ACA provisions regarding preexisting conditions, lifetime coverage limits, and the coverage of young adults. SAC ¶ 23. The law is clear, however, that "standing is not dispensed in gross," Lewis v. Casey, 518 U.S. 343, 358 n.6 (1996). Plaintiffs cannot mix and match, challenging one provision of the statute (i.e., the minimum coverage provision) based on injuries allegedly caused by other provisions (i.e., the health insurance industry reforms). FW/PBS, Inc. v. Dallas, 493 U.S. 215, 230-33 (1990); Covenant Media of S.C. v. City of North Charleston, 493 F.3d 421, 430 (4th Cir. 2007); NRDC v. Pena, 147 F.3d 1012, 1024 n.4 (D.C. Cir. 1998).

The minimum coverage provision itself causes no imminent, concrete harm. It will not

take effect until 2014. Even then, if an individual member is subject to the provision and elects not to comply, any penalty would not be payable until his tax return for that year is due (i.e., April 2015). This supposed injury is "too remote temporally" to support standing. McConnell, 540 U.S. at 226 (no standing where law regulating the cost of campaign ads would not affect Senator for more than four years), overruled in part on other grounds by Citizens United, 130 S. Ct. 876. Moreover, much can change between now and 2014, making any attempt to predict harm to a particular member highly uncertain. An individual may become eligible for Medicare or Medicaid, and thus satisfy the minimum coverage provision.[15] His income could fall, making the provision inapplicable. He may take a job offering qualifying coverage. Or he could discover a pre-existing condition or suffer an illness, and decide that buying coverage is a sensible choice. Thus, as of now, any harm that an individual member might suffer is remote rather than imminent, speculative rather than concrete, and "at least partly within [his] own control." Lujan, 504 U.S. at 564 n.2; see Baldwin v. Sebelius, No. 10-1033, 2010 WL 3418436, at *3 (S.D. Cal. Aug. 27, 2010), cert. denied, 2010 WL 3617248.

For similar reasons, no member of either association would have standing to challenge the employer responsibility provision. That provision as well will not take effect until 2014, and is too temporally remote to support standing. Further, the potential assessments it establishes would apply only if, at that time, an employer has more than 50 full-time equivalent employees; only if the employer does not offer a minimum level of coverage;[16] and, even then, only if one of

[15] Notably, any AAPS or ANH-USA member who is covered by Medicare Part A in 2014 will not run afoul of the minimum coverage provision. I.R.C. § 5000A(f)(1)(A)(1).

[16] The assessments do not apply to employers offering "affordable" coverage (i.e., an employee's required contribution does not exceed 9.5 percent of household income) that provides "minimum value" (i.e., at least 60 percent of the "total allowed costs of benefits are covered"). I.R.C. § 36B(c)(2)(C)(i), (ii).

its employees buys coverage on an exchange and receives a premium tax credit, which is hardly inevitable.[17]

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

For similar reasons, plaintiffs' challenges to the minimum coverage provision and the employer responsibility provision are not ripe for review. The ripeness inquiry "evaluate[s] both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." Abbott Labs. v. Gardner, 387 U.S. 136, 149 (1967). Plaintiffs satisfy neither prong of the inquiry because, to begin, they name no member subject to either provision. Even if they had, no injury could occur before 2014, and plaintiffs has not shown one will occur even then. See Thomas v. Union Carbide Agric. Prods. Co., 473 U.S. 568, 580-81 (1985) (claim not ripe if it rests upon "contingent future events that may not occur as anticipated, or indeed may not occur at all") (citation and internal quotation marks omitted); Grand Lodge of Fraternal Order of Police v. Ashcroft, 185 F. Supp. 2d 9, 17-18 (D.D.C. 2001). Moreover, that a party may incur "preparation costs" before a rule takes effect does not establish a sufficient hardship to warrant review of a claim predicated upon future contingencies. See CTIA–Wireless Ass'n v. FCC, 530 F.3d 984, 988-89 (D.C. Cir. 2008).

To be sure, 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." Blanchette v. Conn. Gen. Ins. Corp., 419 U.S. 102, 143 (1974). However, as explained above, in contrast to Blanchette, any injury to plaintiffs or

[17] Thus, even an employer that offers no coverage at all may not be subject to an assessment. For example, its employees could opt to purchase insurance outside of an exchange. They could purchase insurance within an exchange, but not be eligible for a premium tax credit because their income exceeds 400 percent of the federal poverty level. They could be covered by the plans of a parent or spouse. Or they could elect to forgo coverage entirely.

their members here is far from "inevitabl[e]." Nor is this a case like Abbott Laboratories, where the plaintiffs demonstrated an "immediate" and "direct effect on [their] day-to-day business." 387 U.S. at 152. This case instead involves "contingent future events that may not occur as anticipated, or indeed may not occur at all." Thomas, 473 U.S. at 580-81. Even where only "a purely legal question" is presented, uncertainty as to whether a statute will harm the plaintiffs renders the controversy unripe. Toilet Goods Ass'n v. Gardner, 387 U.S. 158, 163-64 (1967). If this Court were to rule, developments between now and 2014 could render its opinion purely advisory. That is precisely what the ripeness doctrine seeks to avoid.[18]

c. The Anti-Injunction Act Bars Plaintiffs' Challenges to the Minimum Coverage and Employer Responsibility Provisions.

The Court also lacks jurisdiction over plaintiffs' challenges to the minimum coverage and employer responsibility provisions because they seek to restrain the federal government from collecting the penalties specified under those provisions. The Anti-Injunction Act ("AIA") provides, with exceptions inapplicable here, that "no suit for the purpose of restraining the assessment or collection of any tax shall be maintained in any court by any person, whether or not such person is the person against whom such tax was assessed." I.R.C. § 7421(a). It does not matter whether the payment sought to be enjoined is labeled a "penalty" or "assessable payment" rather than a "tax." Cf. I.R.C. § 5000A(b) (imposing a "penalty"); id. § 4980H(a), (b) ("assessable payment"). With exceptions immaterial here, these payments are "assessed and

[18] The courts in Thomas More and Florida found that the plaintiffs in those cases had standing because they needed to plan now for the possibility that they would be subject to the Act in 2014, and found the case to be ripe because the Act was certain to go into effect. Thomas More, No. 10-11156, 2010 WL 3952805, at *5; Florida, 2010 WL 4010119, at *21-22 n.11. Those courts erred. As the court correctly reasoned in Baldwin, it cannot be known now whether the plaintiffs will be subject to the Act in 2014, or whether the Act would operate to the plaintiffs' detriment. 2010 WL 3418436, at *3. Further, whether the Act itself is certain to go into effect is irrelevant; this case is unripe because the effect of the Act on these plaintiffs' unnamed members remains unknown.

collected in the same manner" as other penalties under the Internal Revenue Code, I.R.C. §§ 5000A(g)(1), 4980H(d)(1), and, like these other penalties, fall within the bar of the AIA. I.R.C. § 6671(a); see Barr v. United States, 736 F.2d 1134, 1135 (7th Cir. 1984) ("Section 6671 provides that the penalty at issue here is a tax for purposes of the Anti-Injunction Act.").[19] Applying the AIA here serves its purpose, to preserve the government's ability to collect such assessments expeditiously with "a minimum of preenforcement judicial interference and to require that the legal right to the disputed sums be determined in a suit for refund." Bob Jones Univ. v. Simon, 416 U.S. 725, 736 (1974) (internal quotation omitted).

District courts accordingly lack jurisdiction to order the abatement of any liability for a tax or a penalty, apart from their power to consider validly filed claims for refunds. Bartley v. United States, 123 F.3d 466, 467-68 (7th Cir. 1997). These jurisdictional limitations apply even where, as here, a plaintiff raises a constitutional challenge to a statute that imposes a penalty. United States v. Clintwood Elkhorn Mining Co., 553 U.S. 1, 10 (2008). The AIA therefore bars plaintiffs' effort to enjoin collection of the minimum coverage penalty.

The same is true for the employer responsibility provision. Even if an assessment ultimately were imposed, an employer could challenge it at that time, just as it can challenge other penalties assessed under the Internal Revenue Code, such as for failing to deposit taxes, including employment taxes, see I.R.C. § 6656. See, e.g., Foodservice & Lodging Inst. v. Regan, 809 F.2d 842, 844-45 (D.C. Cir. 1987). The AIA thus also bars plaintiffs' premature attempt to enjoin the employer responsibility provision.[20]

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[19] For this reason, the Florida court erred in finding that the AIA would not apply because Congress characterized the minimum coverage provision as a "penalty." Florida, 2010 WL 4010119, at *4-16.

[20] The Declaratory Judgment Act, 28 U.S.C. § 2201(a), similarly bars declaratory relief here, providing jurisdiction to the district courts to grant such relief "except with respect to Federal taxes." As the Supreme Court noted in Bob Jones University, 416 U.S. at 732 n.7, the tax

2. The Comprehensive Regulatory Measures of the ACA Fall within Congress's Article I Powers.

Even if this Court had subject matter jurisdiction and could reach the merits of plaintiffs' constitutional challenges to the minimum coverage and employer responsibility provisions of the Act, those claims would still fail.[21]

a. Congress's Authority To Regulate Interstate Commerce Is Broad.

The Constitution grants Congress power to "regulate Commerce . . . among the several States," U.S. Const. art. I, § 8, cl. 3, and to "make all Laws which shall be necessary and proper" to the execution of that power, id. cl. 18. This grant of authority is expansive. Congress may "regulate the channels of interstate commerce"; it may "regulate and protect the instrumentalities of interstate commerce, and persons or things in interstate commerce"; and it may "regulate activities that substantially affect interstate commerce." Raich, 545 U.S. at 16-17. The question is not whether any one person's conduct affects interstate commerce, but whether Congress rationally concluded that the class of activities, "taken in the aggregate," substantially affects interstate commerce. Raich, 545 U.S. at 22; see also Wickard v. Filburn, 317 U.S. 111, 127-28 (1942). In other words, "[w]here the class of activities is regulated and that class is within the reach of federal power, the courts have no power to excise, as trivial, individual instances of the class." Raich, 545 U.S. at 23 (citation and quotation omitted).

In exercising its Commerce Clause power, Congress may reach even wholly intrastate, non-commercial matters when it concludes that doing so is necessary to a larger program regulating interstate commerce. Raich, 545 U.S. at 18. Thus, when "a general regulatory statute

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exception to the Declaratory Judgment Act demonstrates the "congressional antipathy for premature interference with the assessment or collection of any federal tax."

[21] Plaintiffs contend that the entire ACA is unconstitutional because minimum coverage and employer responsibility provisions are invalid and nonseverable. SAC ¶ 73. This contention fails because, as explained below, the provisions are constitutional.

bears a substantial relation to commerce, the de minimis character of individual instances arising under that statute is of no consequence." Id. at 17 (internal quotation omitted); see also id. at 37 (Scalia, J., concurring in the judgment) (noting that Congress's authority to make its regulation of commerce effective is "distinct" from its authority to regulate matters that substantially affect interstate commerce); United States v. Stewart, 451 F.3d 1071, 1076-77 (9th Cir. 2006). In assessing congressional judgments on these issues, the Court's task "is a modest one." Raich, 545 U.S. at 22. The Court need not itself measure the impact on interstate commerce of the subject of Congress's regulation, nor need the Court itself calculate how integral a particular provision is to a larger regulatory program. The Court's task instead is simply to determine "whether a 'rational basis' exists" for Congress's conclusions. Id. (quoting United States v. Lopez, 514 U.S. 549, 557 (1995)). Under rational basis review, this Court may not second-guess the factual record upon which Congress relied.

Raich and Wickard illustrate the breadth of the Commerce power and the deference accorded Congress's judgments. In Raich, the Court sustained Congress's authority to prohibit possession of home-grown marijuana intended solely for personal use; it was sufficient that the Controlled Substances Act "regulates the production, distribution, and consumption of commodities for which there is an established, and lucrative, interstate market." Raich, 545 U.S. at 26. Similarly, in Wickard, the Court upheld a penalty on wheat grown for home consumption despite the farmer's protests that he did not intend to sell the commodity. It was sufficient that the existence of homegrown wheat, in the aggregate, could "suppl[y] a need of the man who grew it which would otherwise be reflected by purchases in the open market," thus undermining the efficacy of the federal price stabilization scheme. Wickard, 317 U.S. at 128. Thus, in each case, the Court sustained Congress's power to regulate even individuals who claimed not to

participate in interstate commerce, because these regulations were components of broad schemes regulating interstate commerce.

Raich came after the Court's decisions in United States v. Lopez, 514 U.S. 549 (1995), and United States v. Morrison, 529 U.S. 598 (2000), and thus it highlights the central focus and limited scope of those decisions. Unlike Raich, and unlike this case, neither Lopez nor Morrison involved regulation of economic activity. And neither case addressed a measure that was integral to a comprehensive scheme to regulate activities in interstate commerce. Lopez was a challenge to the Gun-Free School Zones Act of 1990, "a brief, single-subject statute making it a crime for an individual to possess a gun in a school zone." Raich, 545 U.S. at 23. Possessing a gun in a school zone is not an economic activity. Nor was the prohibition against possessing a gun "'an essential part of a larger regulation of economic activity, in which the regulatory scheme could be undercut unless the intrastate activity were regulated.'" Id. at 24 (quoting Lopez, 514 U.S. at 561). Likewise, the statute at issue in Morrison simply created a civil remedy for victims of gender-motivated violent crimes. Id. at 25. Gender-motivated violent crimes are not an economic activity either, and the statute at issue focused on violence against women, unlike the ACA, which focuses on broader regulation of economic activity in the health care services and health insurance markets.

b. The ACA Regulates the Interstate Markets in Health Insurance, Health Care Services, and Employment.

Contrary to plaintiffs' assertion that "[n]othing in Article I or elsewhere in the U.S. Constitution authorizes the federal government to set the acceptable terms of health insurance," SAC ¶¶ 95, 98, regulation of the $2.5 trillion interstate health care market that consumes more than 17.5 percent of the annual gross domestic product is well within the compass of congressional authority under the Commerce Clause. ACA §§ 1501(a)(2)(B), 10106(a). It has

long been established that Congress has power to regulate the markets for insurance, see United States v. South-Eastern Underwriters Ass'n, 322 U.S. 533, 553 (1944), and health care services, see Summit Health Ltd. v. Pinhas, 500 U.S. 322, 328-29 (1991); Hosp. Bldg. Co. v. Trs. of Rex Hosp., 425 U.S. 738, 743-44 (1976).

In South-Eastern Underwriters, the Supreme Court concluded, in light of the "emergence of an interconnected and interdependent national economy," U.S. Dep't of Treasury v. Fabe, 508 U.S. 491, 499 (1993), that the "business of insurance" is "not wholly beyond the regulatory power of Congress under the Commerce Clause," but rather is subject to Commerce Clause regulation to the same extent as any other commercial endeavor. South-Eastern Underwriters, 322 U.S. at 553. In accord with this decision, Congress has repeatedly exercised its power over health insurance by, among other measures, adopting numerous statutes regulating the content of policies offered by private insurers. In 1974, Congress enacted the Employee Retirement and Income Security Act, Pub. L. No. 93-406, 88 Stat. 829 ("ERISA"), which establishes federal requirements for health insurance plans offered by private employers. A decade later, Congress passed the Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, 100 Stat. 82 ("COBRA"), which allows workers and their families who lose their health benefits under certain circumstances the right to continue receiving certain benefits from their group health plans for a time. In 1996, Congress enacted the Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 ("HIPAA"), to improve access to health insurance by, among other things, generally prohibiting group plans from discriminating against individual participants and beneficiaries based on health status, requiring insurers to offer coverage to small businesses, and limiting the pre-existing condition exclusion period for group plans. I.R.C. §§ 9801-03; 29 U.S.C. §§ 1181(a), 1182; 42 U.S.C. §§ 300gg, 300gg-1.

The ACA builds on many federal laws regulating health insurance, which are undoubtedly constitutional. Congress's power to regulate the contents of insurance policies has withstood the 35-plus year test of time since ERISA was enacted. This fact refutes plaintiffs' argument denying Congress's power to set limits on the terms of health insurance, as "the Constitution carries the gloss of history." Cruzan v. Missouri Dep't of Health, 497 U.S. 261, 305 (1990) (Scalia, J., concurring).

Plaintiffs' challenge has no more force when it focuses specifically on the minimum coverage provision. That provision regulates decisions about how to pay for services in the interstate health care market. Regulating these decisions is essential to the insurance market reforms enacted by the Act. The decisions, in any case, are quintessentially economic. As Congress recognized, "decisions about how and when health care is paid for, and when health insurance is purchased" are "economic and financial" and therefore "commercial and economic in nature." ACA §§ 1501(a)(2)(A), 10106(a).[22] This provision thus falls within the traditional scope of the Commerce Clause.

Plaintiffs' challenge to the employer responsibility provision is likewise spurious. ACA § 1513; HCERA § 1003. A law that regulates the terms of employment, including the terms by which an employer sponsors health insurance for its employees, on its face regulates interstate economic matters. For that reason, it has been settled for decades that such regulation is within Congress's Commerce Clause authority. See, e.g., Darby, 312 U.S. at 118 (upholding Fair Labor Standards Act); NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1, 57 (1937) (upholding National Labor Relations Act); Florida, 2010 WL 4010119, at *24-26 (rejecting claim that the employer responsibility provision violates Article I or the Ninth or Tenth Amendments).

[22] Although Congress is not required to set forth particularized findings in support of an invocation of its commerce power, when, as here, it does so, courts "will consider congressional findings in [their] analysis." Raich, 545 U.S. at 21.

c. 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 ACA's reforms of the interstate insurance market — particularly its requirement that insurers guarantee coverage for all individuals, even those individuals with pre-existing medical conditions — could not function effectively without the minimum coverage provision. The provision is an essential part of a larger regulation of interstate commerce, and thus, under Raich, is well within Congress's Commerce Clause authority. Raich, 545 U.S. at 18. Analyzing the minimum coverage provision under the Necessary and Proper Clause leads to the same conclusion for fundamentally the same reason. See id. at 37 (Scalia, J. concurring). The provision is a reasonable means to accomplish Congress's goal of ensuring access to affordable coverage for all Americans.

The Act adopts a series of measures to increase the availability and affordability of health insurance, including, in particular, measures to prohibit insurance industry practices that have denied coverage, terminated coverage, or increased premiums for those with the greatest health care needs. Effective for plan years beginning on or after September 23, 2010, the ACA prohibits insurers from placing lifetime limits on the dollar value of coverage, rescinding coverage except in cases of fraud, and imposing pre-existing exclusion conditions on children. ACA §§ 10101(a), 10103(e). Beginning in 2014, the Act will bar insurers from refusing to cover individuals with pre-existing medical conditions and from setting eligibility rules or premiums based on health status, medical condition, claims experience, or medical history. Id. § 1201. These provisions, which directly regulate the content of insurance policies sold nationwide, are clearly within the Commerce Clause power. See, e.g., South-Eastern Underwriters, 322 U.S. at 553.

The minimum coverage provision is an "essential" part of this larger regulatory scheme for the interstate health care market. ACA §§ 1501(a)(2)(H), 10106(a). Congress found that, absent the minimum coverage provision, the insurance reforms would encourage more individuals to forgo or drop insurance, increasing insurance prices and threatening the viability of the health care insurance market. The new insurance regulations would allow individuals to "wait to purchase health insurance until they needed care" — at which point the ACA would obligate insurers to provide them with health insurance, subject to no coverage limits or premium adjustments, despite the pre-existing conditions they may have. Id. §§ 1501(a)(2)(I), 10106(a). Market timers, taking advantage of the absence of exclusions for pre-existing conditions, would purchase insurance only when their health care needs were substantial. Premiums would increase because fewer healthy people would participate in the insurance market. In turn, many individuals with relatively less substantial health care needs still in the market could well choose to become market timers themselves, dropping their insurance until they needed to use it (i.e., after a significant illness or accident occurs). A "death spiral" of rising costs and premiums and market defections would result, creating pressures that would "inexorably drive [the health insurance] market into extinction." Health Reform in the 21st Century: Insurance Market Reforms: Hearing Before the H. Comm. on Ways and Means, 111th Cong. 13 (2009) (statement of Professor Uwe Reinhardt, Princeton University); see Alan C. Monheit et al., Community Rating and Sustainable Individual Health Insurance Markets in New Jersey: Trends in New Jersey's Individual Health Coverage Program Reveal Troubled Time for the Program, Health Affairs, 167, 168 (July/Aug. 2004) (describing the mechanics of an "adverse-selection death spiral" in a market with no exclusions, no individual premium adjustments, and no minimum coverage requirement) (cited in statement of Dr. Reinhardt at 13 n.4).[23] The minimum coverage

[23] See also id. at 101-02 (testimony of Dr. Reinhardt); id. at 123-24 (submission of National

provision, designed to prevent this result, is thus indispensable to Congress's broader effort to regulate the underwriting practices that prevented many from obtaining health insurance. ACA §§ 1501(a)(2)(H), (I), 10106(a); see Thomas More, 2010 WL 3952805, at *9-10.

In other respects as well, the minimum coverage provision is essential to the Act's comprehensive regulatory scheme to ensure that health insurance is available and affordable. The provision works in tandem with the Act's reforms to reduce the upward pressure on premiums caused by the practice of medical underwriting. This process of individualized review of an applicant's health status results in administrative fees that are responsible for 26 to 30 percent of the cost of premiums in the individual and small group markets. Id. §§ 1501(a)(2)(J), 10106(a). And medical underwriting yields substantially higher risk-adjusted premiums or outright denial of insurance coverage for an estimated one-fifth of applicants. CBO, Key Issues, at 81. The minimum coverage requirement helps to counteract these pressures by significantly increasing health insurance coverage and the size of purchasing pools, and thereby increasing economies of scale. ACA §§ 1501(a)(2)(J), 10106(a).

Congress thus found that the minimum coverage provision is an integral part of the ACA's "comprehensive framework for regulating" health care services and health insurance markets. Raich, 545 U.S. at 24. Congress had ample basis to conclude that not regulating this "class of activity" would "undercut the regulation of the interstate market" in health care and health insurance. Raich, 545 U.S. at 18; see id. at 37 (Scalia, J., concurring in the judgment) ("Congress may regulate even noneconomic local activity if that regulation is a necessary part of a more general regulation of interstate commerce."); see Thomas More, 2010 WL 3952805, at

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Association of Health Underwriters) (observing, based on the experience of "states that already require guaranteed issue of individual policies, but do not require universal coverage," that "[w]ithout near universal participation, a guaranteed-issue requirement . . . would have the perverse effect of encouraging individuals to forgo buying coverage until they are sick or require sudden and significant medical care").

*9-10.

Because the minimum coverage provision is essential to Congress's overall regulatory reform of the interstate health care and health insurance markets, it is also a valid exercise of Congress's authority under the Necessary and Proper Clause, U.S. Const. art. I, § 8, cl. 18, to accomplish that goal. "[T]he Necessary and Proper Clause grants Congress broad authority to enact federal legislation." United States v. Comstock, 130 S. Ct. 1949, 1956 (2010). It has been settled since M'Culloch v. Maryland, 17 U.S. (4 Wheat.) 316 (1819), that this clause affords Congress the power to employ any means "reasonably adapted to the end permitted by the Constitution." Hodel v. Va. Surface Mining & Reclamation Ass'n, 452 U.S. 264, 276 (1981) (internal quotation omitted). And when Congress legislates in furtherance of a legitimate end, its choice of means is accorded broad deference. See Sabri v. United States, 541 U.S. 600, 605 (2004); see also Comstock, 130 S. Ct. at 1956-57. "[W]here Congress has the authority to enact a regulation of interstate commerce, 'it possesses every power needed to make that regulation effective.'" Raich, 545 U.S. at 36 (Scalia, J., concurring in the judgment) (quoting United States v. Wrightwood Dairy Co., 315 U.S. 110, 118-19 (1942)). As demonstrated above, see Part II.B.2.c, Congress reasonably found that the minimum coverage provision not only is adapted to, but is "essential" to, achieving key reforms of the interstate health care and health insurance markets.

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

The minimum coverage provision is a valid exercise of Congress's powers for a second reason: Decisions about whether to obtain health insurance or to attempt (often unsuccessfully) to pay for health care out of pocket, in the aggregate, substantially affect the interstate health care market. Individuals who forgo health insurance coverage do not thereby forgo health care. This

country guarantees emergency health care, regardless of insurance coverage or the ability to pay, under the Emergency Medical Treatment and Active Labor Act, 42 U.S.C. § 1395dd. CBO, Key Issues, at 13. In addition, most hospitals are nonprofit organizations that "have some obligation to provide care for free or for a minimal charge to members of their community who could not afford it otherwise." Id. For-profit hospitals "also provide such charity or reduced-price care." Id. In other words, many of the uninsured will "receive treatments from traditional providers for which they either do not pay or pay very little, which is known as 'uncompensated care.'" CBO, Key Issues, at 13; see also Council of Economic Advisers ("CEA"), The Economic Case for Health Care Reform 8 (June 2009) (in The Economic Case for Health Reform: Hearing Before the H. Comm. on the Budget, 111th Cong. 5 (2009)) [hereinafter The Economic Case].

Uncompensated care, however, is not free. In the aggregate, that uncompensated cost amounted to $43 billion in 2008, about five percent of overall hospital revenues. CBO, Key Issues, at 114. Public funds subsidize these costs. Through programs such as Disproportionate Share Hospital payments, the federal government paid tens of billions of dollars for such uncompensated care in 2008 alone. H.R. Rep. No. 111-443, pt. II, at 983 (2010); see also CEA, The Economic Case, at 8. The remaining costs fall in the first instance on health care providers, which in turn "pass on the cost to private insurers, which pass on the cost to families." ACA §§ 1501(a)(2)(F), 10106(a). This cost-shifting effectively creates a "hidden tax" reflected in fees charged by providers (to the uninsured and the insured alike) and in premiums charged by insurers. CEA, Economic Report of the President 187 (Feb. 2010); see also H.R. Rep. No. 111-443, pt. II, at 985 (2010); S. Rep. No. 111-89, at 2 (2009). As premiums increase, more people decide not to buy coverage, further narrowing the risk pool and forcing upwards even more the price of coverage for the insured. The result is a self-reinforcing "premium spiral." Health

Reform in the 21st Century, supra, at 118-19 (submission of American Academy of Actuaries); see also H.R. Rep. No. 111-443, pt. II, at 985 (2010). Small employers particularly suffer from this premium spiral, due to their relative lack of bargaining power. See H.R. Rep. No. 111-443, pt. II, at 986-88 (2010); Statement of Raymond Arth, Nat'l Small Business Ass'n at 5 (June 10, 2008) (in 47 Million and Counting: Why the Health Care Market Is Broken: Hearing Before the S. Comm. on Finance, 110th Cong. (2008)) (noting the need for insurance reform and a minimum coverage provision to limit the growth of small business premiums).

The putative right to forgo health insurance that plaintiffs champion includes decisions by some to engage in market timing like that discussed above. These individuals will purchase insurance in later years, but choose in the short term to incur out-of-pocket costs with the backup of emergency room services that hospitals must provide whether or not the patient can pay. See CBO, Key Issues, at 12. By making the economic calculation to opt out of the health insurance pool during these years, these individuals skew premiums upward for the insured population. Yet, when they later need care, many of these uninsured will opt back into a system maintained in the interim by the insured. In the aggregate, these economic decisions by the uninsured substantially affect the interstate health care market. Congress may employ its Commerce Clause authority to address these substantial, aggregate effects. See Raich, 545 U.S. at 16-17; Wickard, 317 U.S. at 127-28.

Individuals who make the "economic and financial" choice to try to pay for health care services without insurance, ACA §§ 1501(a)(2)(A), 10106(a), are not passive bystanders divorced from the health care market. To the contrary, as was recognized by the first court to reach a decision on the merits of a challenge to the ACA, the health care market is unique, because "[n]o one can guarantee his or her health, or ensure that he or she will never participate

in the health care market." Thomas More, 2010 WL 3952805, at *9. Indeed, far from being passive bystanders, the vast majority of uninsured population actively use health care services. See, e.g., Kaiser Family Found., Uninsured and Untreated: A Look at Uninsured Adults Who Received No Medical Care for Two Years 1 (2010) (62 percent of the uninsured below 133 percent of the federal poverty level have used some medical care in the last two years), available at http://www.kff.org/uninsured/upload/8083.pdf; Centers for Disease Control & Prevention, Summary Health Statistics for U.S. Children: National Health Interview Survey 2008, at 37 tbl. 13 (2009) (nearly half of uninsured children had seen a doctor in the last six months and 85 percent had seen a doctor in the last two years), available at http://www.cdc.gov/nchs/data/series/sr_10/sr10_244.pdf. Nor do these persons sit passively even in relation to insurance coverage. Instead, movement in and out of insured status is "highly fluid." CBO, How Many People Lack Health Insurance and for How Long? 4 (May 2003) (for those uninsured at a given point in the year, 63 percent had coverage at some other point in the same year). These persons make the decisions to add or drop coverage with the knowledge that they will not bear the full cost if they attempt to pay for their health needs out of pocket. The Economic Case at 17; see also Bradley Herring, The Effect of the Availability of Charity Care to the Uninsured on the Demand for Private Health Insurance, 24 J. Health Econ. 225, 226 (2005). Notwithstanding plaintiffs' attempt to characterize these economic decisions as "inactivity," they have a direct and substantial effect on the interstate health care market in which the uninsured and insured alike participate, and thus are subject to federal regulation.

The ACA in fact regulates economic activity far more directly than provisions the Supreme Court has previously sustained. In Wickard, for example, the Court upheld a system of production quotas, despite the plaintiff farmer's claim that the statute "forc[ed] some farmers

into the market to buy what they could provide for themselves." 317 U.S. at 129. The Court reasoned that "[h]ome-grown wheat . . . competes with wheat in commerce. The stimulation of commerce is a use of the regulatory function quite as definitely as prohibitions or restrictions thereon." Id. at 128; see also id. at 127 ("The effect of the statute before us is to restrict the amount which may be produced for market and the extent as well to which one may forestall resort to the market by producing to meet his own needs.") (emphasis added); see also Heart of Atlanta Motel v. United States, 379 U.S. 241, 258-59 (1964) (Commerce Clause reaches decisions not to engage in transactions with persons with whom plaintiff did not wish to deal); Daniel v. Paul, 395 U.S. 298 (1969) (same). And in Raich, the Court likewise rejected plaintiffs' claim that their home-grown marijuana was "entirely separated from the market" and thus not subject to regulation under the Commerce Clause. 545 U.S. at 30. These cases show that the Court "has consistently rejected claims that individuals who choose not to engage in commerce thereby place themselves beyond the reach of the Commerce Clause." Thomas More, 2010 WL 3952805, at *9. The ACA likewise regulates the conduct of a class of individuals who almost certainly will participate in the health care market, who have decided to finance that participation in one particular way, and whose decisions impose substantial costs on other participants in that market. Given the substantial effects of these economic decisions on interstate commerce, Congress has authority to regulate.

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

Plaintiffs contend that Congress lacks the constitutional authority to require large employers to offer their employees a minimum level of insurance coverage, or face potential assessments. SAC ¶¶ 94-96; ACA § 1513; HCERA § 1003. The Commerce Clause clearly provides such authority. Supreme Court precedent firmly establishes that Congress can regulate

the terms and conditions of employment in the national labor market. See, e.g., Darby, 312 U.S. at 113-14 (upholding Fair Labor Standards Act ("FLSA") of 1938); Jones & Laughlin Steel Co., 301 U.S. at 49.**;** Garcia v. San Antonio Metro. Transit Auth., 469 U.S. 528, 537 (1985) ("Were [the transit authority] a privately owned and operated enterprise, it could not credibly argue that Congress exceeded the bounds of its Commerce Clause powers in prescribing minimum wage and overtime rates for [transit authority] employees."); Maryland v. Wirtz, 392 U.S. 183, 191-93 (1968).[24] The employer responsibility provision merely supplies an additional term to the employment relationship. Time-worn federal statutes regulate fundamental aspects of the employment relationship, such as compensation and occupational safety and health. See, e.g., FLSA, 29 U.S.C. § 206; OSHA, 29 U.S.C. § 651 et seq. In like fashion, the employer responsibility provision establishes how large employers should handle another important facet of the employment relationship related to both worker compensation and health, namely, health insurance benefits. It does so by addressing a covered employer's responsibility regarding health insurance, much as the FLSA sets a minimum wage. ACA § 1513; HCERA § 1003. Congress drew on ample experience to conclude that quintessential and wide-spread economic activity such as employment by large employers "substantially affect[s] interstate commerce," and so could be regulated.[25] Raich, 545 U.S. at 16-17.

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[24] Wirtz was overruled by National League of Cities v. Usery, 426 U.S. 833, 854 (1976), which in turn was overruled by Garcia, 469 U.S. at 557. See also Reich v. Dep't of Conservation & Nat'l Resources, 28 F.3d 1076, 1079 (11th Cir. 1994) (Garcia "established the constitutionality of the extension of the federal wage and hour provisions to state employees").

[25] The provision serves important purposes related to interstate commerce. First, the record before Congress showed that interstate commerce is inhibited, and economic progress stymied, when workers decline to take better jobs because, to do so, they must give up their current health plan and may be unable to obtain a comparable one. See CBO, Key Issues, at 8. By creating incentives for large employers to provide a minimum level of coverage, the Act addresses this "job lock" and facilitates interstate commerce. Second, the employer responsibility provision will prevent "employers who do not offer health insurance to their workers" from gaining "an

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

Plaintiffs' challenge to the ACA also fails because, independent of its Commerce Clause authority, Congress also acted within its "Power To lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States[.]" U.S. Const. art. I, § 8, cl. 1. Congress's taxing and spending power under the General Welfare Clause has long been recognized as "extensive." License Tax Cases, 72 U.S. (5 Wall.) 462, 471 (1867); see also Charles C. Steward Mach. Co. v. Davis, 301 U.S. 548, 581 (1937). Congress may use its power under this Clause even for purposes that would exceed its powers under the other provisions of Article I. See United States v. Sanchez, 340 U.S. 42, 44 (1950). To be sure, Congress must use this power under Article I, Section 8, Clause 1 to "provide for the . . . general Welfare." But, as the Supreme Court held 75 years ago with regard to the Social Security Act, decisions of how best to provide for the general welfare are for the representative branches, not for the courts. Helvering v. Davis, 301 U.S. 619, 640, 645 & n.10 (1937); see also South Dakota v. Dole, 483 U.S. 203, 207 (1987).

Plaintiffs suggest that the General Welfare Clause cannot support the ACA because it was not explicitly invoked by Congress. SAC ¶ 67. Similarly, the Florida court held that the ACA was not an exercise of the taxing power because Congress did not express an intention to rely on that power. Florida, 2010 WL 4010119, at *7-16. Both contentions are incorrect. The Florida court based its conclusion almost entirely on the use of the word "tax" with regard to the minimum coverage provision in the House bill, and the use of the word "penalty" in the Senate bill ultimately adopted. But not one shred of legislative history suggests that Congress intended

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unfair economic advantage relative to those employers who do provide coverage." H.R. Rep. No. 111-443, pt. II, at 985-86.

by this shift in terminology to abjure use of its taxing power. Moreover, in debating the Act, congressional leaders explicitly defended the minimum coverage provision as an exercise of the taxing power as well as an exercise of the commerce power. See, e.g., 156 Cong. Rec. H1854, H1882 (daily ed. Mar. 21, 2010) (statement of Rep. Miller); 156 Cong. Rec. H1824, H1826 (daily ed. Mar. 21, 2010) (statement of Rep. Slaughter); 155 Cong. Rec. S13,751, S13,753 (daily ed. Dec. 22, 2009) (statement of Sen. Leahy); 155 Cong. Rec. S13,558, S13,581-82 (daily ed. Dec. 20, 2009) (statement of Sen. Baucus). In addition, the bipartisan Joint Committee on Taxation in its report detailing the revenue provisions of the final bill, expressly noted that the penalty under the minimum coverage provision is "assessed through the [Internal Revenue] Code and accounted for as an additional amount of Federal tax owed." 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). In any event, "[t]he question of the constitutionality of action taken by Congress does not depend on recitals of the power which it undertakes to exercise." Woods v. Cloyd W. Miller Co., 333 U.S. 138, 144 (1948).

The employer responsibility and minimum coverage provisions fall within Congress's "extensive" General Welfare authority. Employers who are subject to ACA, and who fail to provide a minimum level of coverage to their employees, are subject to potential assessments. The Act similarly requires individuals not otherwise exempt to obtain "minimum essential coverage" or pay a penalty. Id. § 1501(b), as amended by HCERA § 1002 (adding I.R.C. § 5000A(a), (b)(1)). Congress placed these provisions in the Internal Revenue Code. With respect to the latter provision, individuals who are not required to file income tax returns for a given year are not subject to this provision. I.R.C. § 5000A(e)(2). In general, the penalty is

calculated as the greater of a fixed amount or a percentage of the individual's household income, but cannot exceed the national average premium for the lowest-tier plans offered through health insurance exchanges for the taxpayer's family size. I.R.C. § 5000A(c)(1), (2). The individual must report the penalty on his return for the taxable year, as an addition to his income tax liability. I.R.C. § 5000A(b)(2). The penalty is assessed and collected in the same manner as other assessable penalties imposed under the Internal Revenue Code.[26]

That these provisions have regulatory purposes does not place them beyond Congress's taxing power.[27] Sanchez, 340 U.S. at 44; see also United States v. Kahriger, 345 U.S. 22, 27-28 (1953); cf. Bob Jones Univ., 416 U.S. at 741 n.12.[28] So long as a statute is "productive of some revenue," the courts will not second-guess Congress's exercise of its General Welfare Clause powers, and "will not undertake, by collateral inquiry as to the measure of the regulatory effect of a tax, to ascribe to Congress an attempt, under the guise of taxation, to exercise another power denied by the Federal Constitution." Sonzinsky v. United States, 300 U.S. 506, 514 (1937).

The minimum coverage provision, like the employer responsibility provision, easily

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[26] The Secretary of the Treasury may not collect the penalty by means of notices of federal liens or levies, or bring a criminal prosecution for a failure to pay the penalty. I.R.C. § 5000A(g)(2).

[27] Congress has long used the taxing power as a regulatory tool, and in particular as a tool to regulate how health care is paid for in the national market. HIPAA, for example, limits the ability of group health plans to exclude or terminate applicants with pre-existing conditions, and imposes a tax on any such plan that fails to comply with these requirements. I.R.C. §§ 4980D, 9801-03. In addition, the Internal Revenue Code requires group health plans to offer COBRA continuing coverage to terminated employees, and similarly imposes a tax on any plan that fails to comply with this mandate. I.R.C. § 4980B.

[28] Nor does the statutory label of the minimum coverage provision as a "penalty" matter. "[In] passing on the constitutionality of a tax law [the 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) (internal quotation omitted); see also Simmons v. United States, 308 F.2d 160, 166 n.21 (4th Cir. 1962).

meets this standard. The nonpartisan Joint Committee on Taxation included these provisions in its review of the "Revenue Provisions" of the Act and the Reconciliation Act, analyzing them as a "tax," an "excise tax," and a "penalty." 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" 31, 37 (Mar. 21, 2010); see also Joint Comm. on Taxation, Report JCX-47-09 (Nov. 5, 2009). Moreover, the Joint Committee, along with the CBO, repeatedly predicted how much revenue the provisions would raise and considered those amounts in determining the impact of the bill on the deficit. The CBO estimated that the provisions together would produce about $14 billion in annual revenue. CBO Letter at tbl. 4 at 2. Thus, as Congress recognized, these provisions produce revenue alongside their regulatory purposes, which is all that Article I, Section 8, Clause 1 requires.[29]

3. The Minimum Coverage Provision is Not a Direct Tax that Would Require Apportionment among the States.

Plaintiffs also challenge the minimum coverage provision as a "direct tax" that is not apportioned among the States, allegedly in violation of Article I, Sections 2 and 9 of the Constitution. SAC ¶ 69. That argument is doubly incorrect. Measures enacted in aid of Congress's Commerce Clause powers are not subject to the apportionment requirement that can apply — but very rarely does — when Congress relies exclusively on its taxing powers. Moreover, if analyzed as an exercise only of Congress's taxing authority, the minimum coverage provision is not a "direct tax" — historically, an exceedingly narrow category.

[29] Because these provisions fall within Congress's Article I powers for the reasons explained above, plaintiffs' claim that they violate the Tenth Amendment, SAC ¶ 68, is without merit. Absent any claim that a state has been commandeered to administer a federal regulatory scheme — and there is no such claim here — Congress cannot violate the Tenth Amendment by enacting a statute otherwise within its enumerated powers. See Comstock, 130 S. Ct. at 1962; Nebraska v. EPA, 331 F.3d 995, 999 (D.C. Cir. 2003).

a. As a Valid Exercise of Congress's Commerce Clause Powers, the Minimum Coverage Provision Is Not Subject to Apportionment.

Article I, Section 8 grants Congress the "Power To lay and collect Taxes, Duties, Imposts and Excises," but requires that "all Duties, Imposts and Excises shall be uniform throughout the United States." Article I, Section 2 provides that "direct Taxes shall be apportioned among the several States which may be included within this Union, according to their respective Numbers." Article I, Section 9 similarly 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." U.S. Const. art. I, § 2, cl. 3 (amended by U.S. Const. amends. XIV, XVI); id. art. I, § 9, cl. 4 (amended by U.S. Const. amend. XVI).

These requirements apply only to statutes enacted exclusively in the exercise of Congress's taxing power, and not to statutory penalties in aid of other constitutional authorities — including the Commerce Clause. In the Head Money Cases (Edye v. Robertson), 112 U.S. 580, 595-96 (1884), the Supreme Court considered whether a fee levied on non-citizen passengers brought into a U.S. port complied with the uniformity requirement of Article I, Section 8. Although the fee appeared to satisfy the requirements of uniformity and "general welfare" applicable when Congress exercises its taxing power, the Court explained that such issues were beside the point because the fee was a "mere incident of the regulation of commerce." Id. at 595. The dispositive question was whether the fee was valid under the Commerce Clause, regardless of the limits of Congress's taxing authority. Id. at 596.

In accord with the Head Money Cases, the courts of appeals have repeatedly emphasized that "direct tax" claims offer no cause to set aside a statutory penalty enacted in aid of Congress's regulatory powers under the Commerce Clause. Thus, after the Supreme Court upheld the Agricultural Adjustment Act's quota provisions under the Commerce Clause in

Wickard, various plaintiffs argued that the penalties enforcing the quotas were "in reality a direct tax not levied in proportion to the census or enumeration as required under Article 1, Sections 2 and 9 and Clauses 3 and 4 of the Constitution." Rodgers v. United States, 138 F.2d 992, 994 (6th Cir. 1943). The Rodgers court disagreed, because the penalty was "a method adopted by the Congress for the express purpose of regulating the production of cotton affecting interstate commerce" as well as "the fostering, protecting and conserving of interstate commerce and the prevention of harm to the people from its flow." The incidental effect of raising revenue therefore did "not divest the regulation of its commerce character," and Article I, Sections 2 and 9 had "no application." Id. at 995 (citing Head Money Cases, 112 U.S. at 595).[30] Congress's Commerce Clause authority is not cabined by Congress's taxing power. See, e.g., Bd. of Trustees v. United States, 289 U.S. 48, 58 (1933). Plaintiffs' attempt to conflate these authorities, and their respective limits, fails. See Thomas More, 2010 WL 3952805, at *10.

b. The Minimum Coverage Provision Is Not a "Direct Tax."

Even if the taxing power alone justifies the minimum coverage provision, the direct tax clause still would not be implicated here. From the beginning of the Republic, the Court has treated only a very narrow category of taxes as subject to apportionment. The minimum coverage provision does not fall within that category.

The rule of apportionment was part of the compromise that counted slaves as three-fifths of a person. See Bruce Ackerman, Taxation and the Constitution, 99 Colum. L. Rev. 1, 8-13 (Jan. 1999). Any effort, for example, to impose a tax on slaves would fall disproportionately on non-slaveholding states, as it would have to be apportioned by population, with the slave-holding

[30] Other circuits agree. United States v. Stangland, 242 F.2d 843, 848 (7th Cir. 1957); Moon v. Freeman, 379 F.2d 382, 390-93 (9th Cir. 1967); see also South Carolina ex rel. Tindal v. Block, 717 F.2d 874 (4th Cir. 1983); Goetz v. Glickman, 149 F.3d 1131 (10th Cir. 1998).

states paying less per capita because of the three-fifths rule. As Justice Paterson explained in one of the Court's first landmark opinions, the "rule of apportionment" was "the work of [a] compromise" that "cannot be supported by any solid reasoning" and that "therefore, ought not to be extended by construction." Hylton v. United States, 3 U.S. (3 Dall.) 171, 178 (1796) (opinion of Paterson, J.); Murphy v. IRS, 493 F.3d 170, 183 (D.C. Cir. 2007) (quoting Hylton). Accordingly, courts have construed capitation or other direct taxes narrowly to mean only head or poll taxes and taxes on property.[31]

The Supreme Court briefly expanded the definition of a "direct tax" to include a tax on personal property, as well as on income derived from real or personal property. Pollock v. Farmers' Land & Trust Co., 158 U.S. 601 (1895). The Sixteenth Amendment, however, repudiated the latter aspect of that holding. See Brushaber v. Union Pac. R.R., 240 U.S. 1, 19 (1916). The continued validity of the first aspect of Pollock's holding — that taxes imposed on the ownership of personal property are "direct" — is also in doubt. See Ackerman, 99 Colum. L. Rev. at 50-51. At most, Pollock stands for the proposition that a general tax on the whole of an individual's personal property would be direct. See Union Elec. Co. v. United States, 363 F.3d 1292, 1300 (Fed. Cir. 2004). In sum, whether or not any part of Pollock survives, the Court has since made clear that only a tax imposed on property, "solely by reason of its ownership," is a "direct tax." Knowlton v. Moore, 178 U.S. 41, 81 (1900).

There is no sensible basis to claim that the minimum coverage provision imposes taxes on property, real or personal. It is not tied to the value of the individual's property. It instead imposes a tax on the choice of a method to finance the future costs of one's health care, a decision made against the backdrop of a regulatory scheme that guarantees emergency care and

[31] See Springer v. United States, 102 U.S. 586, 602 (1881); Veazie Bank v. Fenno, 75 U.S. (8 Wall.) 533, 543 (1869); Hylton v. United States, 3 U.S. (3 Dall.) 171 (1796).

requires insurance companies to allow people to purchase insurance after they are already sick. The penalty is imposed monthly, ACA § 1501(b) (adding I.R.C. § 5000A(c)(2)), and each month is predicated on a new taxable event: the individual's decision whether to obtain qualifying health insurance coverage. A tax predicated on a decision, as opposed to a tax on property, has always been understood to be indirect. Mfrs. Nat'l Bank of Detroit, 363 U.S. at 197-98; Tyler, 281 U.S. at 502. Under any plausible interpretation, the penalty is not a direct tax. See Murphy, 493 F.3d at 185.

Nor is the requirement a "capitation tax." Justice Chase explained that a capitation (or poll, or head) tax is one imposed "simply, without regard to property, profession, or any other circumstance." Hylton, 3 U.S. at 175 (opinion of Chase, J.); see also Pac. Ins. Co. v. Soule, 74 U.S. 433, 444 (1868) (adopting Justice Chase's definition). The minimum coverage provision is not a flat tax imposed without regard to the taxpayer's circumstances. To the contrary, among other exemptions, the Act excuses persons with incomes below the threshold for filing a return, as well as persons for whom the cost of coverage would exceed 8 percent of household income. I.R.C. § 5000A(e)(1), (2).[32] The payment required by the Act further varies with the taxpayer's income, subject to a floor of a particular dollar amount, and to a cap equal to the cost of qualifying coverage. I.R.C. § 5000A(c)(1), (2). And, of course, the penalty does not apply at all if individuals obtain coverage. I.R.C. § 5000A(a), (b)(1). The minimum coverage provision thus

[32] Thus, even if the minimum coverage provision would have been viewed as a direct tax prior to the Sixteenth Amendment, given that Congress designed the minimum coverage provision penalty to vary in proportion to the individual's income, I.R.C. § 5000A(c)(1)(B), (c)(2), it would fall within Congress's authority to "to lay and collect taxes on incomes, from whatever source derived, without apportionment among the several States, and without regard to any census or enumeration." U.S. Const. amend. XVI.

is tailored to the individual's circumstances and is not a capitation tax.[33]

4. Plaintiffs' Takings Claim Is Unripe and Meritless.

Plaintiffs allege that the ACA, by establishing minimum requirements for insurance policies (e.g., prohibiting exclusion on the basis of pre-existing conditions), forces up premiums charged by private insurance companies and, in doing so, effects a taking.[34] SAC ¶ 68. They ask the court to enjoin the operation of the statute on this ground. Id. ¶ 118(A)(vi), (B)(iii). While regulatory actions can result in compensable takings, see, e.g., Lingle v. Chevron U.S.A., Inc., 544 U.S. 528, 537-40 (2005), plaintiffs' arguments miss the mark for at least three 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.

Plaintiffs' takings claim is not ripe because they have not alleged that they — or anyone on whose behalf they sue — have sought compensation under the Tucker Act in the United States Court of Federal Claims. 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). Moreover, the

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[33] Plaintiffs also suggest that the minimum coverage provision imposes a "non-uniform" tax. SAC ¶ 69. 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). The minimum coverage provision applies nationally, and so poses no uniformity issue. See Ptasynski, 462 U.S. at 86; Murphy, 493 F.3d at 186.

[34] Defendants assume for purposes of this argument only that the ACA has resulted, or will result, in increased premiums.

government need not provide the compensation in advance or contemporaneously with the taking. All that is required is a "reasonable, certain and adequate provision for obtaining compensation." Preseault v. Interstate Commerce Comm'n, 494 U.S. 1, 11-12 (1990) (quotation marks omitted). The Tucker Act provides jurisdiction in the Court of Federal Claims for actions to recover damages against the government based on the Constitution. 28 U.S.C. § 1491(a)(1). This jurisdiction includes takings claims.[35] See Preseault, 494 U.S. at 12. "For this reason, taking claims against the Federal Government are premature until the property owner has availed itself of the process provided by the Tucker Act." Preseault, 494 U.S. at 11 (citing Williamson Cnty. Reg'l Planning Comm'n v. Hamilton Bank of Johnson City, 473 U.S. 172, 195 (1985)). Plaintiffs have not alleged that they have sought relief under the Tucker Act.[36] Thus, this claim is not ripe and cannot be entertained by this Court.

Even if the Court could entertain this claim, it fails. The alleged increase in insurance premiums does not constitute a taking because any requirement to pay higher premiums would be imposed by a private party, rather than the defendants. "[A] compensable taking does not occur unless the government's actions on the intermediate third party have a 'direct and substantial' impact on the plaintiff asserting the takings claim." Casa de Cambio Comdiv v. United States, 291 F.3d 1356, 1361 (Fed. Cir. 2002). In National Board of YMCA v. United States, 395 U.S. 85, 93 (1969), the Supreme Court concluded that the United States was not

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[35] Federal district courts have concurrent jurisdiction to hear cases involving damage claims of under $10,000. 28 U.S.C. § 1346(a)(2). Given the nature of plaintiffs' claims, defendants presume that plaintiffs contend that more than $10,000 is at stake.

[36] None of the limited exceptions to the Tucker-Act-first rule applies here. The ACA has not unambiguously withdrawn Tucker Act jurisdiction to hear a suit involving the statute that is alleged to have effected the taking. Preseault, 494 U.S. at 12. Nor does plaintiffs' claim involve "straightforward mandates of cash payment to the government." Student Loan Mktg. Ass'n v. Riley, 104 F.3d 397, 402 (D.C. Cir. 1997). The alleged increased premium payments, even if they were to arise, would not go to the government.

liable for damage done by rioters to a YMCA in the Panama Canal Zone, which was being temporarily occupied by U.S. troops, because there was not "direct and substantial enough government involvement to warrant compensation under the Fifth Amendment." It is not enough if the government is alleged merely to have been aware of the third party's actions, see, e.g., Shewfelt v. United States, 104 F.3d 1333, 1337 (Fed. Cir. 1997), or to have encouraged — but not required — the action, see, e.g., B&G Enters., Ltd. v. United States, 220 F.3d 1318, 1321 (Fed. Cir. 2000), cert. denied, 531 U.S. 1144 (2001). Plaintiffs' claim thus fails: The ACA does not require insurers to raise premiums, and plaintiffs do not allege otherwise. SAC ¶ 68.

Moreover, their claim fails even if one assumes (counterfactually) that the claim is ripe and that the ACA does require the payment of money: "The 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); Swisher Int'l v. Schafer, 550 F.3d 1046, 1054-55 (11th Cir. 2008), cert. denied, 130 S. Ct. 71 (2009); SRM Chem. Ltd. v. Fed. Mediation & Conciliation Serv., 355 F. Supp. 2d 373, 377 (D.D.C. 2005). This position was adopted by five members of the Supreme Court in Eastern Enterprises v. Apfel, 524 U.S. 498, 540 (1998) (Kennedy, J., concurring) (concluding that the "obligation to perform an act, the payment of benefits," is not a taking); id. at 554 (Breyer, J., dissenting) (explaining that an "ordinary liability to pay money" does not constitute a taking).

To constitute a taking, the government's action must — as is not the case here — target specific "physical or intellectual property" or a "specific, separately identifiable fund of money." Id. at 554-555 (Breyer, J., dissenting); see also id. at 541-42 (Kennedy, J., concurring); Swisher, 550 F.3d at 1056. A broader view of the Takings Clause — one that recognized a taking on the basis of a general monetary obligation — would deviate from precedent and hamstring

governments by potentially requiring compensation for all legislation adjusting the benefits and burdens of economic life.[37] Cf. Connolly v. Pension Benefit Guar. Corp., 475 U.S. 211, 222-23 (1986).

Plaintiffs' position would stretch the takings doctrine beyond all recognition, expanding it to include any government-inspired action with an economic effect. Many regulations increase the cost of goods. FDA regulations make drugs safer, but impose costs that manufacturers doubtless pass on to consumers. EPA regulation of the environment makes air and water cleaner, but also imposes costs that ultimately may be reflected in the cost of goods sold. If plaintiffs were correct, federal courts would be in the business of redistributing the economic costs of virtually every regulatory action, a function inconsistent with the proper role of courts in our constitutional system. Levin v. Commerce Energy, Inc., 130 S. Ct. 2323, 2333 (2010) (noting that Courts take a largely hands-off role in reviewing constitutional challenges to economic legislation because of the respect owed to legislative judgments in that area).[38]

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[37] Plaintiffs' claim fails for another reason: A "long line of Supreme Court decisions emphasizes that the government may compel a private party to surrender its funds without providing compensation if the government's use of those funds confers a significant, concrete, and disproportionate benefit." Colo. Springs Prod. Credit Ass'n v. Farm Credit Admin., 967 F.2d 648, 654 (D.C. Cir. 1992); see United States v. Sperry Corp., 493 U.S. 52, 60 (1989). More comprehensive insurance coverage is clearly a "significant, concrete" benefit. It is also a "disproportionate" benefit in that the recipient of the expanded coverage receives greater worth from it than does the public at large. See id.; Noble State Bank v. Haskell, 219 U.S. 104, 110-11 (1911).

[38] Although plaintiffs assert in passing that the minimum coverage provision also violates due process and equal protection, see SAC ¶ 68, they do not appear to attempt to state a claim for relief based on either theory, see id. ¶¶ 98,118. In any event, the Court would lack jurisdiction over any such claim for the reasons already stated. See supra Part II.B.1. Moreover, with respect to due process, the liberty interest that plaintiffs assert — an alleged right not to contract, id. ¶ 68 — is a not a fundamental interest, but a purely economic one. Florida, 2010 WL 4010119, at *32. Economic legislation is subject to a deferential rational-basis review standard. Usery v. Turner Elkhorn Mining Co., 428 U.S. 1, 15 (1976). Here, Congress's conclusion "that the individual mandate was 'essential' to the insurance market reforms contained in the statute . . . is a 'rational basis' justifying the individual mandate." Florida, 2010 WL 4010119, at *33.

5. Plaintiffs' Claims for an Accounting Should Be Dismissed.

In Counts V and VI, plaintiffs assert that Secretary Sebelius and Commissioner Astrue have mismanaged Medicare and Social Security to the point of insolvency, and they ask the Court to direct the defendants to perform an accounting of those programs on the basis of their alleged "fiduciary duty" as "[f]ederal executive officers." SAC ¶¶ 107, 113. These claims should be rejected.

First, plaintiffs lack standing to raise these claims. Plaintiffs identify no concrete injury that they (or any member) has suffered because of defendants' alleged failure to fulfill fiduciary duties. The crux of their claims is that defendants and Congress relied on "budget gimmickry" to enact the ACA, and that an "honest accounting" of Medicare and Social Security is needed to impose fiscal discipline on the federal government. SAC ¶¶ 88, 110, 116. But absent an individualized, concrete injury, plaintiffs are left to assert injury from their vague perception that defendants' conduct is unlawful. This objection, without more, is at best a generalized

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Any equal protection claim would fail for the same reason. Plaintiffs do not contend that the ACA draws distinctions on the basis of any suspect class. And even if the ACA did discriminate on the bases that plaintiffs allege (age, health, and wealth), see SAC ¶ 68, the statute must still be sustained, as there is a rational basis for the regulation. See Kimel v. Fla. Bd. of Regents, 528 U.S. 62, 83-84 (2000) (age-based classifications are subject to rational basis review); Heller v. Doe, 509 U.S. 312, 320-21 (1993) (same for health-based classifications); Ortwein v. Schwab, 410 U.S. 656, 660 (1973) (same for wealth-based classifications).

Plaintiffs also assert in passing that the minimum coverage provision violates the Ninth and Tenth Amendments, see SAC ¶ 68, but, again, do not appear to attempt to state a claim for relief on these grounds, see id. ¶¶ 98, 118. In any event, these assertions add no force to plaintiffs' claim. The Ninth Amendment has been interpreted as a "rule of construction" that "does not confer substantive rights." Gibson v. Matthews, 926 F.2d 532, 537 (6th Cir. 1991) (citation omitted). And the Supreme Court has explained that the Tenth Amendment "states but a truism" that "[i]f a power is delegated to Congress in the Constitution, the Tenth Amendment expressly disclaims any reservation of that power to the States." New York v. United States, 505 U.S. 144, 156 (1992). The sole question presented by Count III, then, is whether the minimum coverage provision is a proper exercise of Congress's Article I powers. It is.

grievance, and the Supreme Court has "repeatedly held that an asserted right to have the Government act in accordance with law is not sufficient, standing alone, to confer jurisdiction on a federal court." Allen v. Wright, 468 U.S. 737, 754 (1984).

Second, defendants already provide annual reports to Congress describing the financial status of these funds, and they have done so for more than 40 years. These 200-page reports provide detailed information about both current operations and future actuarial projections. In fact, the most recent reports acknowledge the well-known fiscal challenges facing both Medicare and Social Security that plaintiffs accuse defendants of whitewashing. See Bds. of Trustees of Fed. Hosp. Ins. & Fed. Supp. Med. Ins. Trust Funds, 2010 Annual Report, at 5 (Aug. 5, 2010) (Medicare Part A fund projected to become exhausted in 2029, twelve years later than otherwise projected if ACA had not passed); Bd. of Trustees, Fed. Old-Age & Survivors Ins. & Fed. Disability Ins. Trust Funds, 2010 Annual Report, H.R. Doc. No. 111-137, at 3 (Aug. 5, 2010) (combined Social Security funds projected to become exhausted in 2037).[39] These reports obviate any need for an accounting. Indeed, because defendants already do what plaintiffs ask the Court to order them to do, there is simply no live case or controversy with respect to these claims and thus no jurisdiction to entertain them. See Rhodes v. Stewart, 488 U.S. 1, 4 (1988). Plaintiffs' claims for an accounting should be dismissed.

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

The Medicare Act has long required physicians who provide Medicare Part B beneficiaries with services that would be covered by Medicare either to enroll in Medicare, or to opt out of the Medicare program. The Act has also long required suppliers who bill Medicare for certain items or services that require a physician order or referral to identify the referring

[39] Available at https://www.cms.gov/ReportsTrustFunds/downloads/tr2010.pdf and http://www.ssa.gov/OACT/TR/2010/tr10.pdf (last visited Nov. 22, 2010).

physician by name and provider number. These requirements not only facilitate the administration of the Medicare program — including the payment of hundreds of millions of claims per year — but allow HHS to monitor Medicare spending and to combat waste and fraud.

The ACA reinforces these longstanding requirements, explicitly requiring (or expressly authorizing the Secretary to require) that physicians referring beneficiaries for Part B items and services be enrolled in Medicare and use a standard provider number, the National Provider Identifier ("NPI"). Contrary to these provisions, plaintiffs 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 wrong. But the Court need not even reach this issue because plaintiffs lack standing to raise these claims.

Plaintiffs also contend that HHS erred by issuing an interim final rule and two internal administrative documents (known as "change requests") without first providing notice and an opportunity for comment. Plaintiffs are wrong for several reasons, but the most basic one is this: The interim final rule and change requests announce procedural rules designed to help HHS more efficiently identify those physicians who may (among other things) refer patients for services covered by Medicare, and procedural rules are exempted from notice and comment requirements under the APA and the Medicare Act. These claims should be dismissed.

A. Statutory and Regulatory Background of Medicare Part B

Medicare Part B covers medical services, including physician services. Nothing in the Medicare Act requires a physician to treat Medicare Part B beneficiaries or to accept Medicare Part B payments. However, if a physician chooses to provide a Medicare Part B beneficiary with a service that would be covered by Medicare, he has two options. The physician may enroll in Medicare, submit a claim, and obtain payment in accordance with Medicare fee schedules. 42

U.S.C. §§ 1395cc, 1395n, 1395w-4. This option requires the submission of an enrollment application containing the physician's provider number, as explained below. 42 C.F.R. §§ 424.505, 424.510. Or the physician may enter into a private contract with the beneficiary outside of Medicare and without its fee limitations. 42 U.S.C. § 1395a(b). This option requires the physician to opt out of Medicare for a two-year period by submitting an affidavit stating that he will not submit any claim to, or receive payment from, Medicare during that time. Id.; 42 C.F.R. §§ 405.405, 405.410, 405.420. The purpose of the opt-out provision 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. See United Seniors Ass'n, 182 F. 3d at 967.

In addition to physician services, Medicare Part B covers other medical items or services, such as wheelchairs or X-rays, when ordered or referred by an eligible professional. See 42 U.S.C. §§ 1395k, 1395x(s). Suppliers of such items or services must comply with the requirements of the Medicare Act and its implementing regulations to obtain payment. Since 1992, one such requirement has been to identify the referring physician by name and provider number. Id. § 1395*l*(q)(1). Otherwise, the supplier may be denied payment for the claim. Id. § 1395*l*(q)(2).

This requirement complements — and helps enforce — the Medicare Act's other requirements. For example, the Act generally precludes payment for items or services prescribed by a physician who has been excluded from the Medicare program for fraud or abuse, 42 U.S.C. §§ 1395y(e), 1320a-7, or for providing uneconomical, unnecessary, or substandard care, id. § 1320c-5. Thus, the provider-number requirement enables HHS to ensure that referring physicians and professionals are of a specialty eligible to refer, and that they have not been

excluded from the program. The requirement also enables HHS to combat waste and fraud. See 75 Fed. Reg. at 24444.

1. Provider Numbers

Both public and private health plans have long used provider numbers of one form or another to identify physicians for administrative purposes. Historically, these numbers were not standardized, meaning that a single physician might have different provider numbers for various plans, and the same provider number might be assigned to different physicians by different plans. 69 Fed. Reg. 3434, 3434 (Jan. 23, 2004). The lack of unique provider numbers caused confusion and facilitated fraud. For example, in the Medicare program, referring physicians were initially identified on claims forms by a Unique Physician Identification Number ("UPIN"). Over time, however, suppliers increasingly exploited weaknesses in the UPIN system to obtain improper payments — for example, by using UPINs assigned to a physician other than the referring physician; by overusing generic UPINs intended for temporary use; or by using fictitious UPINs. See 75 Fed. Reg. at 24441-42.

Under the Health Insurance Portability and Accountability Act ("HIPAA"), § 262, Pub. L. No. 104-191, 110 Stat. 1936 (1996), provider numbers were standardized in three ways. First, the National Provider Identifier ("NPI") was adopted as the "standard unique health identifier" for health care providers, meaning that eligible physicians could obtain a unique NPI that would be universally recognized by all health plans, including Medicare. 45 C.F.R. § 162.406. Second, physicians who conduct standard electronic transactions — such as submitting claims to insurers in electronic form — were required to obtain an NPI and to use it in those transactions. Id. § 162.410. And third, insurers, including Medicare, were required to use the NPI for standard electronic transactions, id. § 162.412(a), and were permitted to use the NPI for any other lawful

purpose — for example, to require it on paper claims, see id. § 162.410(b). Accordingly, in 2008, the Medicare program required that the NPI be used on all claims, to identify both the billing provider or supplier and, where required, the referring physician. 75 Fed. Reg. at 24440. Thus, if a physician were enrolled in Medicare, he was required to have an NPI. And even if a physician had opted out of Medicare, he was required under HIPAA to have an NPI unless he billed private insurers in paper form only and those insurers did not require an NPI (or he did not accept insurance at all).

A physician may obtain an NPI by submitting an application, in paper form or online, containing basic information about himself, his practice, and his specialty. See 45 C.F.R. § 162.408. There is no charge to obtain an NPI. The Office of Management and Budget ("OMB") estimates that the application takes 20 minutes to complete. See NPI Application/ Update Form, CMS-10114, at 3 (Nov. 2008), available at http://www.cms.gov/cmsforms/ downloads/CMS10114.pdf.

2. Enrollment as a Medicare Provider

To curb improper payments to unqualified physicians and suppliers, in 2006 HHS established more stringent Medicare enrollment requirements. 71 Fed. Reg. 20754, 20754-55 (Apr. 21, 2006). Under those regulations, physicians and suppliers who have not opted out of Medicare are required to submit an enrollment application (paper or electronic) to obtain Medicare billing privileges, 42 C.F.R. §§ 424.505, 424.510, and to recertify the accuracy of their enrollment information every five years, id. § 424.515. Moreover, NPIs must be reported on enrollment applications. 75 Fed. Reg. at 24440; see 42 C.F.R. § 424.510(d)(2)(ii).

The Provider Enrollment, Chain, and Ownership System ("PECOS") is an electronic data repository that contains the information furnished by physicians and suppliers in their Medicare

enrollment applications (and, for physicians who have validly opted out of Medicare, their opt-out affidavits). 75 Fed. Reg. 24440. An internet-based interface with PECOS also enables — but does not require — physicians and suppliers to submit enrollment applications and to change enrollment information online. See http://www.cms.gov/MedicareProviderSupEnroll/04_InternetbasedPECOS.asp#TopOfPage. PECOS became available for use in 2003 and contains enrollment records for physicians and suppliers who have submitted an enrollment application since then. However, if a physician or supplier obtained Medicare billing privileges before 2003, but has not submitted an enrollment application since, cf. 42 C.F.R. §§ 424.505, 424.510, 424.515, he may not have an enrollment record in PECOS. Likewise, a physician or supplier who obtained billing privileges after 2003 but before 2006, when NPIs were required on enrollment applications, may have a PECOS record that does not contain his NPI.

3. Change Requests

To process the hundreds of millions of claims submitted each year, the Medicare program relies on automated claims processing systems, typically administered by contractors in accordance with HHS specifications. In 2009, to improve the administrative enforcement of the program requirements outlined above, HHS issued two changes to its internal claims processing manual: Change Requests 6417 and 6421. These changes expanded the automated "claims editing" process to ensure that, where required, the referring physician's name and NPI are provided on a claim; that the referring physician's name and NPI match; and that the referring physician (or non-physician professional) is of a specialty eligible to refer. See Change Request 6421, CMS Manual System, Pub. 100-20, Transmittal 643, Attachment at 1-2 (Feb. 26, 2010). To validate this information, claims are compared against the names, NPIs, and specialties contained in PECOS. See id. at 2.

4. The Affordable Care Act

The ACA ratified the improved enforcement efforts set in motion by the change requests. As explained above, prior to the ACA, physicians and suppliers were required to submit an enrollment application to obtain Medicare billing privileges and were required to report their NPI on their enrollment application. The ACA ratified this practice, amending the Medicare Act to require all physicians and suppliers "that qualify for [an NPI] to include their [NPI] on all applications to enroll in [Medicare]" by January 1, 2011. ACA § 6402(a). Similarly, the ACA ratified the practice of requiring physicians and suppliers to provide their NPI on all claims. ACA § 6402(a) (requiring such entities "that qualify for [an NPI] to include their [NPI] . . . on all claims for payment submitted under [Medicare]" by January 1, 2011).

The ACA also amended the Medicare Act by establishing that the cost of home health services and certain durable medical equipment would be reimbursed under Part B only if the physician ordering such care or equipment is enrolled in Medicare. ACA § 6405(b)(2); ACA § 6405(b)(1); see id § 6405(c). Finally, the ACA authorized the Secretary to extend its provisions "requiring certifications and written orders to be made by enrolled physicians and health professionals" to "all other categories of items or services" covered under the Medicare Act, as of July 1, 2010. ACA § 6405(c) (emphasis added).

5. Interim Final Rules

The Secretary implemented these ACA provisions by issuing an interim final rule with comment period on May 5, 2010. 75 Fed. Reg. 24437. The interim final rule announced two new regulations relevant here. First, 42 C.F.R. § 424.506 provides that (1) the NPI, rather than any other identification number, must be reported by a physician on his or her enrollment applications, unless the physician has validly opted out, id. § 424.506(b)(1),(2),(3), and (2) that a

provider or supplier who submits a paper or an electronic 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). Second, 42 C.F.R. § 424.507 provides that (1) a billing supplier will not receive payment for "ordered or referred" Part B items or services unless the claim "contain[s] the legal name and [NPI] of the physician . . . who ordered or referred," 42 C.F.R. § 424.507(a)(1), and (2) the "physician or the eligible professional who ordered or referred must have an approved enrollment record or a valid opt-out record in the [PECOS]." 42 C.F.R. § 424.507(a)(2).[40]

HHS articulated several reasons for waiving a notice of proposed rulemaking and issuing the final rule on an interim basis. First, it determined that, because the effective date of ACA § 6405 (July 1, 2010) was less than 150 days after the ACA's enactment (March 23, 2010), the Medicare Act exempted regulations implementing those provisions from ordinary notice and comment requirements. 75 Fed. Reg. at 24446 (citing 42 U.S.C. § 1395hh(b)(2)(B)). Second, HHS concluded that, under the circumstances, notice and comment procedures were unnecessary and impracticable and that there was therefore good cause to waive them. 75 Fed. Reg. at 24446. It decided that delaying the rule was unnecessary because, under prior law, Medicare already required the use of unique provider numbers, so the regulations would not add new burdens to providers and suppliers. Id. It also concluded that notice and comment would be impracticable because the relevant ACA provisions set forth short statutory deadlines (July 1, 2010, and January 1, 2011), and it was therefore "imperative that the regulatory provisions be set forth as soon as possible to deliver the guidance necessary to enact" them. Id. HHS provided a 60-day comment period, which has closed. Id. Plaintiffs do not allege that they submitted a comment. See SAC ¶ 31.

[40] The requirements for payment of claims for home health services are similar but not identical. 42 C.F.R. § 424.507(b). The differences are not material here.

B. Argument

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

Plaintiffs lack standing to raise their Medicare physician enrollment and NPI claims for much the same reasons they lack standing to raise their Social Security claims. Because those reasons have been explained at length, see supra Part I.B.1, they are outlined more briefly here.

First, plaintiffs purport to sue on behalf of their members, but identify no particular member allegedly harmed by the interim final rule (or the change requests) that they challenge. See Summers, 129 S. Ct. at 1151. 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 allege that if they decline to enroll or to opt out of Medicare (and thus establish a PECOS record) or 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 will be properly reimbursed. SAC ¶ 25. But plaintiffs identify no member physician who has actually suffered this alleged injury. For that matter, they identify no physician who treats Medicare beneficiaries but has neither enrolled nor opted out of Medicare; no physician who does not already have a PECOS record; and no physician who does not already have an NPI. This flaw is fatal to their Medicare enrollment and NPI claims.

Second, even if plaintiffs could identify such a member, any competitive disadvantage befalling a physician who declined to participate in Medicare would be entirely of his own making. Such self-inflicted harm cannot constitute a cognizable injury. Nat'l Family Planning & Reprod. Health Ass'n, 468 F.3d at 831.

Third, no hypothetical plaintiff could trace any harm to the interim final rule (or the

change requests) or establish that the invalidation of those provisions would redress their injuries. See generally Newdow, 603 F.3d at 1012 n.6. Even before the new regulations, a referring physician was generally required either to enroll in Medicare, 42 U.S.C. §§ 1395w-4(g)(4), 1395cc(j)(1); 42 C.F.R. §§ 424.505, 424.510, or to opt out of the program, 42 U.S.C. § 1395a(b), either of which would generate a record in PECOS, see 75 Fed. Reg. at 24440. Similarly, many if not most physicians were already required to have an NPI under HIPAA and its implementing regulations. See 45 C.F.R. § 162.410. And, as explained below, the enrollment and NPI requirements that plaintiffs challenge are contained in the ACA itself, the pertinent provisions of which plaintiffs do not challenge. Thus, invalidation of the new regulations (or the change requests) would not provide relief to any hypothetical plaintiff.

2. Plaintiffs' Medicare Enrollment and NPI Claims Are Meritless.

a. The Requirement To Enroll or To Opt Out Is Valid.

Plaintiffs first assert that "nothing in Medicare or any other provision of law requires physicians to opt-out pursuant to 42 U.S.C. § 1395a(b)" to "treat Medicare beneficiaries for payment outside of Medicare." SAC ¶ 2(h); see also id. ¶ 103. Plaintiffs thus 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)." These contentions fly in the face of the text of the Medicare Act and D.C. Circuit precedent.

The Medicare Act entitles Part B beneficiaries to payment for certain "medical and other health services," 42 U.S.C. § 1395k(a)(2)(B), and provides that, when a physician furnishes a beneficiary with a covered service, he "shall complete and submit a claim for such service . . . on behalf of a beneficiary," id. § 1395w-4(g)(4), for payment in accordance with Medicare fee schedules. The Act also provides that the Secretary "shall establish by regulation a process for

the enrollment of providers of services and suppliers," including physicians. Id. § 1395cc(j)(1). In accordance with this statutory directive, the Secretary has adopted regulations establishing an enrollment process, which requires the submission of an enrollment application. 42 C.F.R. § 424.505, 424.510. The enrollment and claims submission requirements do not apply to private arrangements between a physician and beneficiary "for any [covered] item or service" if "no claim for payment is to be submitted," 42 U.S.C. § 1395a(b), provided that the physician has validly opted out of Medicare. See supra Part III.A; §§ 1395a(b)(2)(B); 1395a(b)(3)(B)(ii)-(iii) (providing two-year bar on submission of claims by doctor who opts out).

Plaintiffs contend that the Medicare Act does not mean what it plainly says. SAC ¶¶ 100-105. But any doubts about the meaning of 42 U.S.C. § 1395a(b) were laid to rest in United Seniors Ass'n, 182 F.3d at 965. The D.C. Circuit found the meaning of the statutory text clear with respect to "services that Medicare would reimburse but for the private contract," id. at 970: "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," id. at 968. Thus, plaintiffs' contention is meritless.

b. The PECOS Requirement Is Supported by Statute and Regulation.

Plaintiffs next argue that HHS "lacks the authority to make filing an enrollment or opt-out record in PECOS a prerequisite to refer items or services under Medicare." SAC ¶ 102. This misunderstands both the PECOS system and the Secretary's authority.

When a physician refers a Medicare beneficiary for a covered Part B item or service, his own physician services generally are covered services as well. See, e.g., 42 U.S.C. § 1395y(a)(1)(A). Even before the new regulations, then, a referring physician was generally required either to enroll in Medicare or to opt out, as described above. This requires the

submission of either an enrollment application, 42 C.F.R. §§ 424.505, 424.510, or an opt-out affidavit, id. §§ 405.405, 405.410, 405.420. And since 2003, submitting either an enrollment application or an opt-out affidavit has generated a record in PECOS, the database in which provider information is currently maintained. See 75 Fed. Reg. at 24440. Thus, the requirement to have an enrollment or opt-out record in PECOS follows inevitably from the longstanding statutory requirement either to enroll or to opt out when providing covered services.

The ACA confirms this requirement. The ACA provides that payment for home health services and certain durable medical equipment will not be made unless "order[ed]" or "certifi[ed]" by "a physician enrolled" in Medicaid. ACA § 6405(b)(1)-(2) (emphasis added). The ACA also authorizes the Secretary to require that "certifications and written orders . . . be made by enrolled physicians" for "all other categories of items or services." Id. § 6405(c) (emphases added). And, as explained, to enroll in Medicare a physician must submit an enrollment application, 42 C.F.R. §§ 424.505, 424.510, which generates a record in PECOS.

Thus, there is ample statutory authority to require physicians either to enroll in or to opt out of Medicare, and thus generate a PECOS record, in order to refer beneficiaries for covered Part B items or services.

c. The NPI Requirement Is Supported by Statute and Regulation.

Plaintiffs finally argue that "HHS lacks the authority to compel non-Medicare providers to obtain an NPI absent some independent event that lawfully requires obtaining an NPI." SAC ¶ 118(A)(x); see id. ¶ 104. That assertion, too, misreads the statutory scheme. There is no general requirement that physicians practicing entirely outside of Medicare obtain an NPI. But there is ample authority to require that a physician who refers a beneficiary for a Medicare-covered item or service must have an NPI.

Since 1992, the Medicare Act has required suppliers of Part B items or services to identify the referring physician by name and provider number. 42 U.S.C. § 1395*l*(q)(1). The Act also delegates general authority to the Secretary to prescribe regulations for the efficient administration of the Medicare program. 42 U.S.C. §§ 1302, 1395hh. And insurers, including Medicare, may use the NPI "for any . . . lawful purpose," 45 C.F.R. § 162.406(b), in addition to the standard electronic transactions for which Medicare (and other insurers) must use the NPI, id. § 162.412(a). Accordingly, since 2008, the Medicare program has required that the NPI be used on all claims, to identify both the billing provider or supplier and, where required, the referring physician. 75 Fed. Reg. at 24440. Thus, even before the ACA and its implementing regulations, the requirement that referring physicians use an NPI, rather than another provider number, fell squarely within the Secretary's authority.

In any event, the ACA ratified this practice. As explained, the ACA requires that payment for home health services and certain durable medical equipment be made only when ordered or certified by "a physician enrolled" in Medicare, ACA § 6405(b)(1)-(2) (emphasis added), and authorizes the Secretary to extend this requirement to "all other categories of items or services" covered under the Medicare Act, id. 6405(c) (emphasis added). The ACA also requires that all physicians "include their [NPI] on all applications to enroll." Id. § 6402(a). Thus, the ACA explicitly requires (or expressly authorizes the Secretary to require) that physicians referring for Part B items and services be enrolled in Medicare and have an NPI.

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

Plaintiffs' claim that HHS erred by failing to provide notice and an opportunity for comment before issuing the interim final rule and change requests. SAC ¶ 101. This claim is meritless. Before detailing this claim's legal flaws, there is an important equitable point to make.

The agency provided an opportunity for the public to comment on the interim final rule after it was issued, so that the public's views could be taken into account before issuing a final rule. Plaintiffs have not alleged that they submitted a comment. SAC ¶ 31. In light of this fact, it would be inequitable and promote inefficiency for plaintiffs to secure remand to comment on the substance of the rule if they have already squandered a chance to do so.

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

Notice and comment obligations attach to final agency actions, with exceptions. See Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin., 452 F.3d 798, 806 (D.C. Cir. 2006); 5 U.S.C. §§ 553, 704; 42 U.S.C. § 1395hh(b). One exception encompasses "rules of agency organization, procedure, or practice," 5 U.S.C. § 553(b)(3)(A); these are not subject to notice and comment requirements. To determine whether a rule is covered by this exception, courts ask whether it "encodes a substantive value judgment" about something other than "what mechanics and processes are most efficient." Public Citizen v. Dep't of State, 276 F.3d 634, 640 (D.C. Cir. 2002); JEM Broad. v. FCC, 22 F.3d 320, 328 (D.C. Cir. 1994). If the rule encodes such a value judgment, then the rule does not fall under this exception.

Neither the enrollment requirement nor the NPI requirement conveys a value judgment about which physicians can order, or refer patients for, Medicare-covered services. Rather, they reflect judgments about a process, namely, how to most efficiently identify those physicians who meet statutory and regulatory requirements for ordering, or referring patients for, Medicare-covered services. For example, the Medicare Act requires that a "physician" be licensed to practice by the state in which he performs the medical function. See 42 U.S.C. § 1395x(d), (r). To enforce this requirement, "it is necessary that their credentials be verified[,] [and] such

verification can occur only as part of the Medicare provider/supplier enrollment process." 75 Fed. Reg. 24443.[41] Moreover, Congress has mandated that HHS assign personal identification numbers to physicians to aid with the verification process. See 42 U.S.C. §§ 1395u(r), 1395*l*(q)(1). The NPI is just such a number, 45 C.F.R. § 162.406(a), and, accordingly, its use is aimed at improving the process of identifying those eligible to order and refer, and by extension, reducing fraud and abuse. 75 Fed. Reg. at 24438; id. at 24441-42. In short, the enrollment and NPI requirements amount to rules of agency procedure that are not subject to notice and comment requirements.

b. 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" in light of the need for prompt regulatory guidance, the lack of new burdens on physicians, and the interim nature of the rule. 75 Fed. Reg. at 24446.

An agency may dispense with pre-promulgation notice and comment when it "for good cause finds . . . that notice and public procedure thereon [i.e., comment] are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B); 42 U.S.C. § 1395hh(b)(2)(B). The good cause inquiry is "inevitably fact- or context-dependent." Mid-Tex Elec. Coop. v. FERC, 822 F.2d 1123, 1132 (D.C. Cir. 1987). And courts have found good cause in many different factual circumstances. Coalition for Parity v. Sebelius, 709 F. Supp. 2d 10, 19 (D.D.C. 2010). Among the facts or circumstances that support a finding of good cause are (i) statutory authorization to issue interim rules, (ii) the existence of tight statutory deadline, (iii) the need for prompt regulatory guidance, and (iv) the interim nature of the rule. Id. at 19-23; see

[41] This verification process is served not only when doctors enroll in Medicare, but also when they opt out by filing an affidavit that includes their identification information.

also Nat'l Women, Infants, and Children Grocers Ass'n v. Food and Nutrition Serv. ("Nat'l WIC Grocers Ass'n"), 416 F. Supp. 2d 92, 105-108 (D.D.C. 2006).

HHS's conclusion that there was a need for prompt regulatory guidance, 75 Fed. Reg. at 24446, finds support in both the text of the ACA and precedent. Section 6405 of the ACA, which was enacted March 23, 2010, requires physicians who refer patients to providers of home health services and certain durable medical equipment to enroll in Medicare, and it sets an effective date of July 1, 2010, for that provision. HHS thus had to act quickly to create regulatory guidance for enrolling in Medicare so that physicians and suppliers would have a roadmap for how they could remain eligible to receive valuable reimbursements from Medicare. See Nat'l WIC Grocers Ass'n, 416 F. Supp. 2d at 107. And while the ACA does not require enrollment forms to contain an NPI until January 1, 2011, see ACA § 6402, it would not have made sense to set up one enrollment system prior to July 1, 2010 which did not include NPIs, only to scrap it several months later for one which used NPIs. As a practical matter, then, HHS also had to provide regulatory guidance regarding the implementation of 6402's NPI requirement.

The lack of new regulatory burdens on physicians also supports the rule. An agency may forgo pre-issuance notice and comment if there is good cause to believe that notice and comment would be "unnecessary." 5 U.S.C. § 553(b)(B). Notice and comment were unnecessary here because the rule does not impose new burdens on physicians. Even before the new regulations, a referring physician was generally required either to enroll in Medicare or to opt out, as described above. See supra Part III.B.3.c. And the NPI-use requirement similarly predated the interim final rule. See supra Part III.B.3.d. As the regulatory landscape had not changed, there was no reason to provide notice and an opportunity for comment.

Finally, the interim nature of the rule also supports HHS's good cause finding. "[A] rule's temporally limited scope is among the key considerations in evaluating an agency's good cause claim." Mid-Tex Electric Coop., 822 F.2d at 1132; see also Coalition for Parity, 709 F. Supp. 2d at 22-23. This is so because notice and comment "gain in importance the more expansive the regulatory reach of agency rules," Mid-Tex Electric Coop., 822 F.2d at 1132 (brackets, citation, and quotation marks omitted), and an interim rule has a temporally limited regulatory reach. The rule here is an interim final rule which is to be replaced by a final rule. Indeed, HHS provided a 60-day comment period, collected comments that it received during that period, and is in the process of drafting a final rule.

c. The Medicare Act Eliminated Any Duty To Provide Notice and Comment with Respect to the Interim Final Rule Insofar as it Addresses Durable Medical Equipment and Home Health Services.

Because Congress directed HHS to issue a rule addressing referrals for home health services and certain durable medical equipment within 150 days of the ACA's enactment, the Medicare Act absolved HHS of the duty to provide notice and comment with respect to those portions of the rule, as plaintiffs concede. SAC ¶ 80 (citing 42 U.S.C. § 1395hh(b)); Asiana Airlines v. FAA, 134 F.3d 393, 398 (D.C. Cir. 1998); see 5 U.S.C. § 559. The Medicare Act provides that ordinary notice-and-comment procedures shall not apply when "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 . . . ." 42 U.S.C. § 1395hh(b)(2). In the ACA, Congress amended the Medicare Act to require that payment for home health services and durable medical equipment be made only when ordered or certified by a Medicare-enrolled physician, ACA § 6405(b)(1)-(2), and specifically provided that these "amendments . . . shall apply to written orders and certifications made on or after July 1, 2010," id. § 6405(d). ACA

was enacted on March 23, 2010. Thus, Congress allotted HHS only 100 days after the ACA's enactment within which to enact a rule. Congress's direction to act so quickly triggered the Medicare Act's notice-and-comment exemption.

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

Nothing obliged 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. For an action to be reviewable, it must "implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4); Indep. Dealers Ass'n v. EPA, 372 F.3d 420, 428 (D.C. Cir. 2004); see generally Monmouth Med. Ctr. v. Thompson, 257 F.3d 807, 814 (D.C. Cir. 2001). But if an agency document simply "restat[es]" existing legal obligations, it has "left the world just as it found it," and "thus cannot be fairly described as implementing, interpreting, or prescribing law or policy," Indep. Dealers Ass'n, 372 F.3d at 428. The enrollment and NPI obligations referenced in the change requests grow out of statutory provisions and regulations that pre-date the change requests. See above at III.A., III.A.1.-III.A.2. Thus, the change requests simply restate existing legal obligations and are not subject to review under the APA or Medicare Act.

CONCLUSION

For the above stated reasons, the Court should dismiss plaintiffs' complaint under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).

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Respectfully submitted,

TONY WEST
Assistant Attorney General

RONALD C. MACHEN JR
United States Attorney

SHEILA M. LIEBER
Deputy Director, Federal Programs Branch

/s/ Justin M. Sandberg
JUSTIN M. SANDBERG
(Ill. Bar No. 6278377)
ERIC B. BECKENHAUER
(Cal. Bar No. 237526)
U.S. Dept. of Justice, Civil Division,
Federal Programs Branch
Attorneys for Defendants