UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

SECOND AMENDED AND SUPPLEMENTAL
COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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

NATURE OF THE ACTION

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

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

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

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

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

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

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

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

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

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

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

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

PARTIES

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

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

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

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

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

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

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

JURISDICTION AND VENUE

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

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

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

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

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

PLAINTIFFS' STANDING

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

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

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

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

Ongoing Injuries from Compelled Participation in Medicare Part A

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

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

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

Ongoing Injuries from Health Insurance Legislation

19. AAPS and ANH-USA members include without limitation the owners of businesses with more than 50 fulltime employees, who are subject to a new PPACA requirement to purchase health insurance for employees or else pay a penalty, and the imposition of this requirement reduces the present value of such businesses. AAPS and ANH-USA members include without limitation owners of such businesses that currently use high-deductible catastrophic medical insurance coupled with health-savings accounts for employees. This approach does not comply with PPACA's health-insurance controls. The addition of these major new costs in 2014 and subsequent years has reduced the value of these businesses *today*. Removing those new costs would restore the lost value.

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

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

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

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

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

Ongoing Injuries from PECOS- and NPI-Related Requirements

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

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

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

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

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

Physicians' Third-Party Standing to Assert Patients' Rights

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

Procedural Injuries

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

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

Zone of Interests

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

Associational Standing

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

RIPENESS

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

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

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

SOVEREIGN IMMUNITY

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

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

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

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

IRREPARABLE HARM AND INADEQUATE ALTERNATE REMEDIES

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

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

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

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

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

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

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

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

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

CONSTITUTIONAL, STATUTORY & REGULATORY BACKGROUND

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

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

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

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

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

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

Medicare and the Social Security Act

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

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

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

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

Online Registration of "Health Care Providers"

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

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

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

Patient Protection and Affordable Care Act

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

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

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

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

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

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

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

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

69. If a tax, the penalties associated with PPACA's insurance mandates are either an un-apportioned capitation or direct tax or a non-uniform excise tax, all of which violate Article I, sections 2 and 9, of the Constitution.

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

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

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

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

Administrative Procedure Act

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

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

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

IFC Requirement to Enroll or Opt Out via PECOS

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

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

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

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

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

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

State Laws on Health Insurance

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

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

FACTUAL BACKGROUND

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

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

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

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

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

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

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

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

COUNT I
POMS'S TYING OF MEDICARE AND SOCIAL SECURITY

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

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

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

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

COUNT II
UNLAWFUL EMPLOYER INSURANCE MANDATE

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

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

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

COUNT III
UNLAWFUL INDIVIDUAL MANDATE

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

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

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

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

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

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

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

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

104. Nothing in PPACA authorizes HHS to require non-Medicare providers to obtain an NPI, outside a specific action by that provider that independently requires an NPI (*e.g.,* HIPAA transactions).

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

COUNT V
ACCOUNTING FOR MEDICARE

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

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

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

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

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

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

COUNT VI
ACCOUNTING FOR SOCIAL SECURITY

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

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

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

115. Defendant Astrue knows that PPACA's budget scoring would redirect in excess of $50 billion from Social Security, but has not taken any appropriate action to protect Social Security from PPACA on behalf of those who rely on him and Social Security for their retirement planning.

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

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

PRAYER FOR RELIEF

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Medicare's solvency; and

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

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

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

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

Dated: September 8, 2010

Respectfully submitted,

/s/ Lawrence J. Joseph

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