IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

PATIENT SERVICES, INC.,

Plaintiff,

v.

UNITED STATES OF AMERICA

and

DEPARTMENT OF HEALTH AND HUMAN SERVICES, 200 Independence Ave., S.W., Washington D.C. 20201

and

OFFICE OF INSPECTOR GENERAL, 300 Independence Ave., S.W., Washington D.C. 20201

and

Daniel R. Levinson, *In His Official Capacity as Inspector General of the United States Department of Health and Human Services*, 330 Independence Ave., S.W., Washington D.C. 20201

and

Eric D. Hargan, *in His Official Capacity as Acting United States Secretary of the Department of Health and Human Services*, 200 Independence Ave., S.W., Washington D.C. 20201

Defendants.

Civil Action No. 3:18-cv-16

Document Electronically Filed

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

Plaintiff Patient Services, Inc. ("PSI") brings this Complaint against the Department of Health and Human Services ("HHS"), the Acting Secretary of HHS ("Secretary"), the Office of the Inspector General ("OIG") and the Inspector General (collectively, "Defendants") seeking a declaratory judgment and related injunctive relief.

INTRODUCTION

1. Twenty-eight years ago, Dr. Dana Kuhn founded PSI, a non-profit charity, to help indigent patients with severe, chronic or life-threatening diseases afford their health insurance and medication. In the years since, PSI has helped hundreds of thousands of Americans avoid financial devastation while receiving treatment, and tens of thousands of patients rely on PSI today to do the same. Unfortunately, Defendants have put a stranglehold on PSI, depriving PSI of its First Amendment right to ascertain needs and communicate program capabilities with donors, potential donors and their affiliates, thus frustrating PSI's ability to provide needy patients with life-saving assistance.

2. For more than 15 years, PSI has operated under an OIG opinion and ensured that its various funds provided support to government beneficiaries without regard to the patient's choice of product or choice of provider, respecting the treatment decisions made by independent practitioners. Today, however, HHS' most-recent guidance stifles PSI's fundamental right to free speech by placing restrictions on PSI's ability to communicate with its donors and potential donors about PSI's programs and effectiveness, severely impairing PSI's ability to operate. PSI seeks an order that will allow PSI to exercise its constitutionally protected right to free speech so that it can continue to assist the nation's most vulnerable patient populations.

NATURE OF THE CASE

3. Plaintiff, Patient Services, Inc. brings this action to declare unlawful and to enjoin enforcement of restrictions that the Office of the Inspector General for the Department of Health and Human Services ("OIG") imposed in March 2017 through a Modified Advisory Opinion ("2017 Modified Advisory Opinion") that violate PSI's constitutionally protected right to communicate with pharmaceutical manufacturer donors and other donors, prospective donors, and their purported "affiliates," (including other health and medicine stakeholders such as disease treatment centers, hospitals and other healthcare facilities, disease specific charities, medical societies, pharmacies, individuals, and governmental entities such as the Commonwealth of Virginia) that possess critical information about chronic diseases and available treatment options that is essential to PSI's charitable mission.

4. PSI is a non-profit charitable foundation that operates Patient Assistance Programs ("PAPs"), which provide financial and other assistance to indigent patients who have chronic and often life threatening diseases that require expensive treatment and management. The federal government has explained that PAPs "have long provided important safety net assistance to patients of limited means who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs." 70 Fed. Reg. 70623, 70623-24 (Nov. 14, 2005); *see also* 79 Fed. Reg. 31120, 31121 (May 30, 2014) (same). Since 2002, OIG has provided public guidance directing how PAPs should be structured and operate in accordance with its view of the Anti-Kickback statute.

5. Specifically, since 2002, and like all other PAPs, PSI has operated pursuant to an Advisory Opinion from OIG that provides specific guidance as to how PSI should operate and structure its programs to avoid a risk of an enforcement action subjecting it to criminal and civil

penalties. The 2017 Modified Advisory Opinion, however, imposes new and oppressive restrictions that cripple PSI's ability to carry out its charitable efforts. In particular, the 2017 Modified Advisory Opinion imposes new restrictions that prevent PSI from communicating with donors, potential donors or their purported "affiliates" about new or modified programs to treat chronic diseases affecting indigent populations. This government-imposed censorship shuts off essential avenues for PSI to obtain information necessary to create or modify a PAP and thereby places an untenable burden on PSI's operations.

6. The 2017 Modified Advisory Opinion ushers in a brave new world of government censorship and puts PSI in the impossible position of having to plan and set up new and modified disease funds without the benefit of the expertise of donors, prospective donors, or their purported "affiliates" who operate on the front lines in fighting these chronic diseases. OIG's restraint on speech threatens access to life sustaining and other critically important treatments and other essential medical assistance.

7. The 2017 Modified Advisory Opinion denies PSI the ability to communicate with these experts about (i) the available treatments for a disease, including new treatments either on the market or in the developmental pipeline, (ii) the costs of the new or evolving treatments, (iii) the manner in which treatments are administered, including where they are administered and whether there are significant diagnostic, transportation, or other costs associated with obtaining treatment, and (iv) the burdens faced by patients receiving treatment, including associated conditions, complications, or side effects and the costs associated with managing those issues. This information is essential to PSI's ability to maintain and develop the scope of its charitable efforts.

8. The 2017 Modified Advisory Opinion, however, shuts off PSI's ability to communicate with entities with unique perspectives and knowledge necessary to design new diseases funds or to modify existing disease funds.

9. Under the 2017 Modified Advisory Opinion, PSI must refrain from engaging in even casual conversations with donors, prospective donors and their affiliates about diseases and their treatment. PSI cannot operate its business without an OIG Advisory Opinion because many donors and prospective donors simply will not participate in a PAP without prior assurance that it is subject to an Advisory Opinion issued by OIG. And OIG recently rescinded an advisory opinion on behalf of another PAP after OIG concluded that the PAP allowed donors "to directly or indirectly influence the identification or delineation of [PAPs'] disease categories." On January 4, 2018, that PAP announced that, as a consequence of having its advisory opinion rescinded, it will not be providing financial assistance to patients in 2018.

10. PSI is committed to compliance with OIG's pre-existing published Advisory Opinion governing how it should operate, which did not infringe PSI's First Amendment rights. As a direct result of the unconstitutional restrictions in the 2017 Modified Advisory Opinion, however, PSI is now facing a fundamental threat to its mission to help save the lives of indigent patients. Accordingly, PSI has no other recourse than to request relief from this Court.

11. The 2017 Modified Advisory Opinion impermissibly prohibits protected communications between a charitable organization and its donors in violation of the First Amendment of the United States Constitution. Although the government has an interest in preventing violations of the Anti-Kickback statute, the restrictions on lawful, truthful and non-misleading speech at issue here sweep significantly more broadly than is necessary to further that interest. Under the First Amendment, restrictions on speech, at a minimum, must be properly and

narrowly tailored to serve a legitimate and important interest. The restrictions in the 2017 Modified Advisory Opinion prohibit lawful, truthful and non-misleading speech concerning medical treatments for chronic and life-threatening diseases. This speech is at the core of PSI's charitable mission of ensuring that patients receive such critical treatments when they cannot afford them without PSI's assistance. If these impermissible restrictions on the free-flow of truthful, lawful and non-misleading information are allowed to remain in place, PSI's future survival, and with it the critical, and in many cases, life-saving assistance to tens of thousands of needy patients every year, will be placed in jeopardy.

12. The ongoing threat of prosecution and civil penalties for engaging in constitutionally protected communications with donors and prospective donors has resulted and will continue to result in an intolerable chill on PSI's First Amendment right to communications to and from donors and potential donors. These restrictions have caused tangible harm to PSI's efforts to assist indigent patients suffering from chronic and debilitating diseases, and have contributed to material reductions in PSI's ability to develop new or modified funds and to obtain charitable donations necessary to assist these needy patients. Accordingly, PSI is forced to seek declaratory and injunctive relief to protect its ability to engage in communications at the core of the First Amendment from the risk of unwarranted prosecution and administrative sanction.

THE PARTIES

13. PSI is a Virginia 501(c)(3) organization with its principal place of business in Virginia. As discussed, PSI provides Patient Assistance Programs ("PAPs"), which provide financial assistance—including insurance premium and copayment assistance—to indigent individuals suffering from severe chronic or life threating illnesses that are treated, *inter alia*, with prescription medications or through other means that these indigent patients might not otherwise be able to afford.

14. Defendant HHS is an executive department of the United States. HHS oversees the activities of the Office of Inspector General. HHS's headquarters are located in Washington, D.C. at 200 Independence Ave., S.W., Washington D.C. 20201.

15. OIG is a subdivision of HHS that investigates Medicare and Medicaid claims and seeks to improve the efficiency of HHS's programs. Pursuant to 42 U.S.C. § 1320a-7d(b) ("the Act") and 42 C.F.R. 1008 *et seq.* ("the Regulation"), OIG issues advisory opinions regarding the scope of OIG's enforcement authority as it applies to the requesting parties' existing or proposed business activities. OIG's headquarters are located in Washington, D.C. at 300 Independence Ave., S.W., Washington D.C. 20201.

16. Defendant Daniel R. Levinson is the Inspector General at HHS.[1] As Inspector General, Mr. Levinson oversees the Advisory Opinions rendered by his office pursuant to the Act and the Regulation. Defendant Levinson maintains his office at 330 Independence Ave., S.W., Washington D.C. 20201. He is being sued in his official capacity.

17. Defendant Eric D. Hargan is the Acting Secretary of HHS. The Acting Secretary of HHS is the Inspector General's immediate superior and is ultimately responsible for the administration of the Act and the Regulation. Defendant Wright maintains his office at 200 Independence Ave., S.W., Washington D.C. 20201. He is being sued in his official capacity.

[1] Title 5, Section 702 of the United States Code provides that "the United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: Provided, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance." 5 U.S.C. § 702.

JURISDICTION AND VENUE

18. PSI brings this action pursuant to the First Amendment of the United States Constitution, the Administrative Procedure Act, 5 U.S.C. §§ 701-706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

19. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1361.

20. This Court has authority to grant the relief requested by PSI pursuant to the First Amendment, the Administrative Procedure Act, 5 U.S.C. §§ 701-706, and the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

21. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e) because Plaintiff PSI resides in this judicial district.

GENERAL ALLEGATIONS

I. The Constitution Protects Speech Concerning Public Health Issues and Speech Between Charitable Organizations and Their Donors and Prospective Donors.

22. The First Amendment of the United States Constitution provides that "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend. I.

23. Under the First Amendment, content-based restrictions on speech are presumptively invalid and subject to strict scrutiny. *Sorrell v. IMS Health Inc*., 564 U.S. 552, 571 (2011) (citing *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992)). "Government regulation of speech is content based if a law applies to particular speech because of the topic discussed or the idea or message expressed." *Reed v. Town of Gilbert*, 135 S. Ct. 2218, 2227 (2015). For a content-based restriction on core free speech to survive scrutiny, the government has the burden of showing that the restriction of speech is "narrowly tailored to serve compelling state interests." *Id.* at 2226.

24. In *Sorrell v. IMS Health Inc.*, the Supreme Court explained that speech regarding prescription drug prescribing practices, medicine and public health warranted constitutional

protection under the First Amendment even where such speech may be intertwined with commercial activities. 564 U.S. at 566.

25. The *Sorrell* Court underscored that the concern for maintaining the free flow of information "has great relevance in the fields of medicine and public health, *where information can save lives*." *Id*. (emphasis added). As a result, in the context of prescription medication and prescribing practices, "the creation and dissemination of information are speech within the meaning of the First Amendment." *Id*. at 570.

26. Further, at a minimum, content-based restrictions on even commercial speech are invalid unless they satisfy intermediate scrutiny. *Id*. at 572 (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980)). To satisfy intermediate scrutiny, (i) the government "must assert a substantial interest to be achieved by" the restriction; (ii) "the restriction must directly advance the state interest involved"; (iii) "the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose," and (iv) the restriction must not be "more extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 564, 566; *see also Sorrell*, 564 U.S. at 572 (holding that a State must show at least that a speech restriction "directly advances a substantial governmental interest and that the measure is drawn to achieve that interest").

27. The First Amendment also grants constitutional protection to truthful and non-misleading communications between a charity and its donors. *Village of Schaumburg v. Citizens for a Better Env't*, 444 U.S. 620, 632 (1980). For example, the government may not impose a "direct restriction on the amount of money a charity can spend on fundraising activity" because that is a "direct restriction on protected First Amendment activity." *Secretary of State of Md.* v. *Joseph H. Munson Co.*, 467 U.S. 947, 967 & n.16 (1984).

28. Further, "[s]olicitation of charitable contributions is protected speech." *Riley v. Nat. Fed'n of the Blind*, 487 U.S. 781, 796 (1988)). Indeed, "charitable appeals for funds . . . involve a variety of speech interests—communication of information, the dissemination and propagation of views and ideas, and the advocacy of causes—that are within the protection of the First Amendment." *Schaumberg*, 444 U.S. at 632.

29. Indeed, "solicitation is characteristically intertwined with informative and perhaps persuasive speech seeking support for particular causes or for particular views on economic, political, or social issues, and . . . without solicitation the flow of such information and advocacy would likely cease." *Id*.

30. This case lies at the intersection of both of these avenues of constitutionally protected speech. The restrictions imposed by the 2017 Modified Advisory Opinion on lawful, truthful and non-misleading communications cripple PSI's ability to establish new disease funds or to modify existing disease funds. For example, if PSI learns of a new drug or a new treatment for a disease, before setting up a new fund or modifying an existing fund, PSI must know: (i) the number of affected individuals; (ii) the demographics of the patient population; (iii) the cost of the new treatment or drug; (iv) the expected utilization of the drug; (v) coverage and other restrictions that payors are likely to impose, including government payors; (vi) the likely duration of any likely therapy; (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home); (viii) any ancillary patient needs such as transportation services; (ix) assistance for other supportive therapies that may be necessary; (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug; (xi) the costs associated with addressing side effects of the drugs or treatments;

and (xii) whether any current donors or prospective donors have an interest in supporting this prospective new disease fund through donations.

31. Donors, prospective donors, and their "affiliates" are the best, and oftentimes *the only*, source of this essential disease-related and treatment-related information. Many of them are pharmaceutical manufacturers, patient advocacy groups that may be funded by pharmaceutical manufactures, and research facilities that operate day-to-day at the cutting edge of treatment development. If PSI is cut off from these sources of critical information, it would be required, at great burden and expense, to recreate this expertise within PSI itself by becoming an expert on the development of new molecules and by monitoring new drug applications or supplementary drug applications submitted to the FDA. As a practical matter, it would not be possible for PSI to recreate this expertise if it is cut off from these critical sources of information.

32. Absent critical information from donors, prospective donors or their purported affiliates, PSI would have to set up countless funds for all manner of chronic diseases in the hope that a new drug will be approved to treat that disease, and that donors or prospective donors will fund the PAP without any interaction with PSI, at enormous cost to PSI, depriving PSI of funds it could and should use to assist patients. Both of these "options" would cripple PSI's charitable mission and would divert PSI's scare resources from providing relief to patients to funding the independent creation of in-house clinical expertise far beyond the capabilities of PSI or other PAPs.

33. The practical result of the 2017 Modified Advisory Opinion's restrictions on the free flow of information is to hobble PSI's efforts to establish new or modified disease funds that could provide life-saving assistance to patients who, without PSI's assistance, would have to forego effective treatment because they lack the resources to pay for it themselves.

34. The chill imposed on PSI's communications with donors, prospective donors, and their purported affiliates affects both PSI's efforts to solicit charitable donations as well as the free-flow of communication about medical research and public health. *See Schaumberg*, 444 U.S. at 632 (explaining that "solicitation is characteristically intertwined with informative and perhaps persuasive speech seeking support for particular causes or for particular views on economic, political, or social issues, and . . . without solicitation the flow of such information and advocacy would cease"). Indeed, as with the prescription practice information at issue in *Sorrell*, the information that PSI would like to communicate to and receive from donors, prospective donors, and purported affiliates that is restricted by the 2017 Modified Advisory Opinion is "information [that] can save lives." 564 U.S. at 566.

II. The Statutory and Regulatory Regime Governing OIG Advisory Opinions.

35. The Act establishes a process whereby private parties can request an advisory opinion from HHS regarding the agency's enforcement policy as it applies to the requesting party's current activities or activities it would like to undertake. 42 U.S.C. § 1320a-7d(b)(2); 42 C.F.R. 1008.

36. The Secretary of HHS has issued regulations setting specific procedures to guide a requesting party's submission and the OIG's process for rendering an advisory opinion. *See* 42 C.F.R. § 1008, *et seq.*

37. An advisory opinion provides the requesting party HHS' views of whether the proposed or actual conduct described in the submission is a violation of the Medicare Act or whether HHS views such conduct as permissible.

38. The OIG issues advisory opinions based solely on the facts that the requesting party represents as either its current practices or as a proposed course of conduct that it "in good faith specifically plans to undertake." 42 C.F.R. §§ 1008.1, 1008.11.

39. The Secretary can issue an advisory opinion regarding whether any activity or proposed activity constitutes grounds for the imposition of sanctions under 42 U.S.C. §§ 1320a-7, 1320a-7a, 1320a-7b. 42 U.S.C. § 1320a-7d(b)(2); *see also* 42 C.F.R. § 1008.5.[2]

40. Advisory opinions are binding on both the Secretary and on the party that requested the opinion. *See* 42 U.S.C. § 1320a-7d(b)(4). Once rendered, the Secretary cannot penalize or prosecute the actions approved of in the advisory opinion as violations of the Medicare statute. *See* 42 U.S.C. § 1320a-7d. In turn, the party requesting an advisory opinion can only operate safely without the risk of enforcement if it acts consistent with the OIG advisory opinion. *See* 42 C.F.R. § 1008.1; Exhibit A, OIG Advisory Opinion No. 02-1, at 8.

41. In contrast, conduct that violates the restrictions described in an advisory opinion subjects a private party to the risk of administrative investigation or criminal prosecution. *See* 42 C.F.R. § 1008.18(c); Exhibit A, at 1, 8.

42. OIG can rescind, terminate or modify any advisory opinion it renders. *See* 42 C.F.R. § 1008.45(a).

43. Once OIG issues its final modified advisory opinion to the requesting party, the requesting party may terminate its course of action or proposed course of action, or it may modify its conduct to conform to that prescribed in the modified advisory opinion. 42 C.F.R. §§ 1008.45(a) & (b)(3).

[2] Section 1320a-7 excludes certain individuals from participating in any Federal health care program. *Id.* Section 1320a-7a (1128A(a)(5) of the Social Security Act) provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or Medicaid program beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or Medicaid. *Id.* Finally, Section 1320a-7b, also known as the Anti-Kickback Statute, makes it a criminal offense to knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. *Id.*

44. Once OIG renders an advisory opinion, the statute and regulations do not provide the requesting party with an administrative mechanism through which it can appeal OIG's advisory opinion. *See* 42 U.S.C. § 1320a-7d; 42 C.F.R. § 1008.45. Rather, the advisory opinion is final agency action for which the statute and regulations provide no procedures or redress that a requesting party must exhaust before seeking judicial review under the APA. *Compare*, 42 C.F.R. § 1008 *et seq.* (procedures for seeking, receiving, and modifying an advisory opinion from *OIG*), *with* 21 C.F.R. § 10.45(c) (detailing the administrative remedies a party must exhaust before obtaining judicial review of an advisory opinion rendered by the *Commissioner of the FDA*).

45. Having and maintaining an OIG advisory opinion is essential to PSI and other PAPs. Because PSI and other PAPs assist indigent patients who are federally funded healthcare beneficiaries, they operate in a highly regulated area. As a result, PSI and other PAPs rely heavily on advisory opinions to convince donors to make donations without fear of criminal enforcement for making those donations. Many of PSI's donors and prospective donors, in particular pharmaceutical manufacturers, will not donate to any PAP that does not operate pursuant to an advisory opinion from OIG. As a result, operating without an advisory opinion is practically impossible because it would cut PAPs such as PSI off from many critical sources of information and donor funding.

46. As relevant here, OIG has recognized that the Medicare Act and the Anti-Kickback Act are "extremely broad" and has taken action in the past with the understanding that "[s]ince the statute on its face is so broad, concern has arisen among a number of health care providers that many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution." 56 Fed. Reg. 35952 (July 29, 1991).

47. Such is the case here. Absent an OIG advisory opinion, PSI and other PAPs could not operate because the threat of criminal or administrative penalty would be pervasive for any manner of innocent or beneficial communications between PSI and its donors, prospective donors, or their purported affiliates. And, as discussed, PAPs would be unable to obtain necessary funding because many donors and prospective donors simply will not donate to a PAP without an advisory opinion.

48. PSI required an advisory opinion precisely so it could have clarity that its operations fell well within the bounds of the law and still benefit patients, and so prospective donors would be willing to provide donations. Unilateral withdrawal of its current advisory opinion would be devastating to PSI's ability to carry out its charitable activities without fear of prosecution.

49. On November 28, 2017, OIG rescinded an advisory opinion (No. 06-04) on behalf of another PAP after concluding that the PAP "allowed donors to directly or indirectly influence the identification or delineation of [the PAP's] disease categories." OIG noted that the PAP "stated that if OIG were to rescind or terminate [its existing advisory opinion], [it] likely would cease operations and no longer provide copayment assistance to patients." OIG nevertheless rescinded the PAP's advisory opinion and rejected its proposal to "modify 06-04 to add provisions related to its new compliance program." On January 4, 2018, that PAP announced that it will not be providing financial assistance to patients in 2018.

III. PSI and Its Charitable Mission

50. PSI is a non-profit charitable foundation that provides a wide variety of services and information to indigent patients with chronic and/or often life-threatening diseases and who require expensive treatment to manage those diseases.

51. PSI was founded by Dana Kuhn, a former minister and advocate for patient care, who serves as PSI's President. Dr. Kuhn holds a Ph.D. in clinical counseling from Emory University and the Christian Bible Seminary.

52. Prior to founding PSI, Dr. Kuhn worked as a clinical counselor at the Hemophilia Treatment Center in Richmond, Virginia from 1988 to 1995. During that time, he counseled families and individuals who had been devastated, both financially and emotionally, by the cost and burden of managing the treatment of expensive chronic illnesses. Dr. Kuhn also served during this time on the Governor's subcommittee studying HIV/AIDS to help seek policy solutions that were challenging the Commonwealth of Virginia.

53. Dr. Kuhn observed families facing, and often suffering, financial ruin. These families were forced to take drastic steps such as selling their homes to afford the co-payments necessary to provide their chronically or gravely sick children with necessary medical treatment.

54. Dr. Kuhn also has personal experience with the challenges and costs of living with multiple chronic illnesses that are expensive to treat. Dr. Kuhn is a hemophiliac who contracted the HIV virus from a factor treatment derived from tainted blood in the 1980s.

55. Dr. Kuhn founded PSI in 1989 to provide critical assistance to the chronically ill who do not have the financial resources to manage their illnesses without suffering severe financial consequences.

56. Since 1989, PSI has provided financial assistance to hundreds of thousands of indigent patients. In 2016 alone, PSI donated a total of $100.2 million in financial assistance to almost 21,000 patients. Ninety-four percent of PSI's total functional expenses in that year were devoted to patient financial assistance. PSI consistently has received a four-star "exceptional"

rating from Charity Navigator, the nation's largest charity evaluator, honoring PSI as one of the most efficient, financially sound, and transparent non-profit charities in the nation.

57. Patients learn about PSI and its charitable work through a number of different sources, including their physicians, health care providers, patient advocacy groups that may be funded, in part, by drug manufacturers, and governmental entities such as the Commonwealth of Virginia.

58. PSI provides many different types of financial support to pay or defray the costs associated with the treatment of a list of specific diseases. The types of financial support currently available, depending on the disease, include assistance with health insurance premiums, travel expenses, copayment obligations, ancillary services, and infusion nursing services. The financial support for each patient is drawn from pools of funds that PSI establishes and maintains for each medical condition for which PSI provides assistance.

59. PSI currently provides financial assistance for patients suffering from a vast array of life-threatening medical conditions. Those medical conditions include (i) several bleeding disorders such as hemophilia; (ii) cancers such as gastrointestinal stromal tumors; (iii) digestive and urinary conditions; (iv) endocrine conditions such as Mucopolysaccharidosis; (v) immunodeficiency conditions; (vi) leukemia and lymphoma; (vii) nervous system conditions such as Parkinson's disease; and (viii) respiratory conditions such as cystic fibrosis.

60. To qualify for assistance, patients must provide their (i) medical diagnosis and the type of assistance requested; (ii) demographic and contact information; (iii) income information; and (iv) health insurance information. Some of PSI's patient assistance programs also require the patients' physicians to provide additional information about the diagnosis and treatment.[3]

[3] *See* https://www.patientservicesinc.org/Patients/Apply.

61. As required by OIG's pre-existing guidance, to qualify for assistance, PSI evaluates the patient's available financial resources—which it considers in light of the cost of living in an applicant's area—and other variables defining the threshold of indigence. PSI then compares the patient's available financial resources to the expected cost of that patient's medical treatment. *See* 79 Fed. Reg. at 31122.

62. Based on established criteria for evaluating financial need, some of which are prescribed by the 2017 Modified Advisory Opinion, some patients receive funding to cover the full cost of their insurance premiums, while others receive funds to cover only copayments and potentially some other costs.

63. Requests for assistance are evaluated and determined on a first-come/first-served basis, subject to the funding available in a given disease fund. *See* Exhibit A; 79 Fed. Reg. at 31122.

64. Patients are eligible to receive PSI's financial assistance regardless of their choice of provider, and regardless of the specific treatment that a patient and provider may choose. *See* Exhibit A; 79 Fed. Reg. at 31122.

65. PSI advises its prospective patients that provider and treatment decisions "should be made by the individual after consultation with a physician in consideration of their best interests," and that "PSI employees will not encourage or direct patients to select a specific provider or treatment in order to receive PSI assistance."[4]

66. The financial assistance that PSI offers to patients depends on their particular treatment needs, but does not encompass all types of financial assistance for all diseases covered

[4] *See* https://www.patientservicesinc.org/Patients/FAQS.

by its funds.[5] For some of the diseases for which it provides assistance to patients, PSI assists with paying copayments or a portion of insurance premiums. For others, PSI may also provide financial assistance for infusion (*i.e.*, intravenous administration of drugs) and nursing services associated with a patient's treatment. PSI also provides assistance for other costs associated with the treatment and management of chronic illnesses. As one example, PSI provides funds for hemophiliac patients to obtain kneepads or helmets, which can help protect them from severe bruising and internal bleeding. For some of the diseases, PSI provides assistance with the cost of transportation to and from treatment. Transportation costs can be a critical barrier to treatment for low-income or disabled patients, especially those living in rural communities or in places far from available treatment facilities.

67. For families and individuals served by PSI, the assistance they receive can be, and often is, the difference between life and death. One of PSI's patients described her experience as follows: "My mom was diagnosed with Chronic Myeloid Leukemia several years ago. Her doctor was the one that referred us to you. . . . The medication that is keeping her white blood cells in check, costs over $3,000 for a 30-day supply. She has to take this medication every day for the rest of her life. Her insurance picks up a little over $1,000. PSI picks up the rest. We do not have the means to pay for this wonder drug so you see how this would not have a happy ending if it wasn't for you guys. If I could hug an organization, it would be done in an instant."

68. Beyond financial assistance, PSI also provides information to patients on how to search for and evaluate potential insurance options in the United States. PSI also provides information directing patients to specific support organizations that can provide additional

[5] *See* http://www.patientservicesinc.org/Patients/Supported-Illnesses.

resources and knowledge about the latest treatment options, research and advocacy for the patients' conditions or diseases.

69. Although PSI was one of the first organizations to provide assistance of this kind, a number of other charitable organizations now also provide financial assistance through disease funds to indigent individuals facing high health care costs.

70. To provide these life-saving services, PSI must establish disease funds through the receipt of charitable donations. PSI's donors, prospective donors, and their affiliates include pharmaceutical manufacturers, disease treatment centers, hospitals and other healthcare facilities, disease specific charities, pharmacies, individual donors, and governmental entities such as the Commonwealth of Virginia.[6]

71. Donors, potential donors, and their purported affiliates often are directly involved in treating patients suffering from chronic diseases and thus have critical information regarding emerging treatment options for these diseases. These donors, potential donors, and their purported affiliates are at the front line of medical developments in treating these chronic and acute conditions.

72. As permitted by the OIG guidance, and consistent with the conditions described therein, donors often earmark their contributions for specific disease funds. For example, a donor may donate money specifically to PSI's breast cancer screening fund or to PSI's Parkinson's disease fund. *See* Exhibit A; 79 Fed. Reg. at 31121.

73. PSI is independent from its donors and prospective donors and is devoted to ensuring the highest standards of patient privacy and free choice in selecting treatment methods.

[6] *See* PSI, 2016 Annual Report at 4-5, available at https://www.patientservicesinc.org/Portals/0/PSI%20Annual%20Report_2016_.pdf.

74. PSI's Board of Directors has eight board members, one of whom is PSI's President. PSI's Executive Team has four members and is made up of PSI's President, Vice President, General Counsel and General Manager.

IV. OIG's Restriction of Lawful, Truthful, and Non-Misleading Communications Between PSI And Its Donors, Prospective Donors or their Purported Affiliates.

75. On April 4, 2002, OIG responded to PSI's request for an advisory opinion regarding whether grants provided by a non-profit charitable organization to financially needy Medicare beneficiaries to subsidize their costs of medical care would be in violation of 1128A(a)(5) or 1128A(b)(7) of the Social Security Act. *See* Exhibit A.

76. The 2002 Advisory Opinion concluded that PSI's proposed activities of providing copay, deductible, and Medigap assistance to Medicare beneficiaries "would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act as well as the anti-kickback statute," nor would OIG "impose administrative sanctions under the anti-kickback statute in connection with the Proposed Arrangement." Exhibit A, at 5.

77. OIG explained that because PSI's "particular design and administration of the Proposed Arrangement interposes an independent charitable organization between donors and patients in a manner that effectively insulates beneficiary decision-making from information attributing the funding of their benefit by any donor, it appears unlikely that donor contributions would influence any Medicare or Medicaid beneficiary's selection of a particular provider, practitioner, or supplier." Exhibit A, at 5. That advisory opinion did not purport to restrict the exercise of PSI's rights under the First Amendment.

78. In addition to the 2002 Advisory Opinion, over the span of more than a decade, OIG has issued two advisory bulletins and no fewer than 18 advisory opinions to various other

charities. Those bulletins and advisory opinions approve of manufacturer donations to 501(c)(3) patient assistance funds such as PSI. *See* 70 Fed. Reg. at 70626; 79 Fed. Reg. at 31121.[7]

79. In the 2005 advisory bulletin, OIG recognized that PAPs "have long provided important safety net assistance to patients of limited means who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs." 70 Fed. Reg. at 70623-24. "Given the importance of ensuring continued access to drugs for beneficiaries of limited means and the expedited time frame for implementation of the Part D benefit, [OIG issued the 2005] Special Advisory Bulletin to identify potentially abusive PAP structures, as well as methods of providing assistance that mitigate or vitiate the potential for fraud and abuse." *Id.* at 70624.

80. On May 21, 2014, OIG issued another Supplemental Special Advisory Bulletin. *See* 79 Fed. Reg. 31120. In the 2014 Supplemental Special Advisory Bulletin, OIG again acknowledged the work the PAPs do in helping needy patients facing extreme financial hardship from the high cost of medical care. "PAPs have long provided important safety net assistance to such patients, many of whom have chronic illnesses and high drug costs." 79 Fed. Reg. at 31120. OIG explained that "[l]ongstanding OIG guidance . . . makes clear that pharmaceutical manufacturers can effectively contribute to the safety net by making cash donations to independent, bona fide charitable assistance programs." *Id.* at 31121.

81. Following the 2014 Supplemental Special Advisory Bulletin issued to all PAPs, OIG specifically required PSI to make a series of certifications to retain an advisory opinion. OIG and PSI discussed over a period of several months the modifications OIG was requiring. During

[7] *See also* Adv. Op. Nos. 02-1, 04-15, 06-04, 06-09, 06-10, 06-13, 07-06, 07-11, 07-18, 08-17, 10-7, 10-12, 11-05, 13-19, 14-11, 15-06, 15-16, 15-17.

those discussions, PSI raised concerns about the detrimental effect that the modifications would have on PSI's operations. In particular, PSI explained that preventing communications between PSI and donors, prospective donors and their purported affiliates was not only impractical, but that it would violate the First Amendment.

82. OIG responded that if PSI did not participate in the modification process and accept these modifications, OIG would rescind the 2002 Advisory Opinion, and that PSI would no longer enjoy any of its benefits.

83. The final modifications that OIG imposed on PSI are set forth in the formal Notice of Modification to Advisory Opinion No. 02-1 that OIG issued to PSI on March 3, 2017.

84. The Notice of Modification includes nearly two dozen certifications that PSI was required to accept to retain the 2002 Advisory Opinion that PSI needs to operate as a charitable fund. *See* Exhibit B, Notice of Modification to Advisory Opinion No. 02-01 (March 3, 2017) ("2017 Modified Advisory Opinion"). PSI challenges three of those certifications.

85. It is first important to note the certifications that PSI does not challenge. By way of example, PSI does not challenge the certification, which requires PSI to refrain from defining any of its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages or particular diseases, types of drug treatment, or "any other way of narrowing the definition of widely recognized disease states." *See* Exhibit B, at 2. This ensures that one set of treatment options is not favored over others and prevents, along with the independent judgment of the patient's prescriber, any steering of patients to a donor's product over another manufacturer's product.

86. Nor does PSI challenge the certification, which specifies that PSI will not limit its financial assistance to only high-cost or specialty drugs and will make assistance available for all

products including generics or bioequivalents. Exhibit B, at 3. This, too, prevents steering of patients to particular products.

87. Nor does PSI challenge the certifications which (i) prohibit PSI from maintaining a disease fund for "only one drug or therapeutic device, or only the drugs or therapeutic devices made or marketed by one manufacturer or its affiliates," Exhibit B, at 3; or (ii) require PSI to refrain from providing "donors with any individual patient information or any data related to the identity, amount, or nature of drugs, devices, or services subsidized by the [patient assistance program]." Exhibit B, at 6.

88. Several of the restrictions in the 2017 Modified Advisory Opinion, however, prohibit broad categories of communication between PSI and its donors, prospective donors, or their purported affiliates that violate the First Amendment.

89. *First*, OIG's 2017 Modified Advisory Opinion required a certification that "[PSI] does not, and will not, solicit suggestions from donors regarding the identification or delineation of disease funds." Exhibit B, at 5.

90. *Second*, OIG's 2017 Modified Advisory Opinion required a certification that "[n]o donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor (including without limitation, any wholesaler, distributor, or pharmacy benefits manager)) directly or indirectly influences or will influence the identification or delineation of any of [PSI's] disease funds." Exhibit B, at 5.

91. *Finally*, OIG required PSI to certify that "[PSI] will not establish or modify funds for specific diseases at the request or suggestion of donors or prospective donors (or affiliates of donors or prospective donors) that manufacture drugs or devices for the treatment of such diseases

or that otherwise have a financial interest in the establishment of modification of such funds." Exhibit B at 5-6.

92. On March 3, 2017, Defendants issued the 2017 Modified Advisory Opinion at issue in this case. The 2017 Modified Advisory Opinion explicitly and directly prohibits significant categories of communications among PSI and donors, prospective donors, or their purported affiliates that are at the heart of PSI's ability to engage in its charitable mission.

93. Defendants' issuance of the 2017 Modified Advisory Opinion on March 3, 2017 is final agency action that causes direct and cognizable harm to PSI.

94. When PSI deliberates whether to expand its charitable offerings to include a new disease fund or whether to expand the types of assistance offered from an existing fund, PSI thoroughly must investigate the diseases, the patient population, and treatments in advance of establishing a fund and soliciting donations for the fund. PSI's charitable mission requires it to educate itself about recent medical developments, including new drugs and therapies to treat diseases for which PSI has existing disease funds and diseases for which PSI might establish new disease funds.

95. Prior to establishing a new disease fund, PSI must learn all it can about the disease, the population that suffers from it, the available treatments, and any new treatments in the developmental pipeline.

96. PSI must educate itself about the prevalence of the disease as well the demographics of the patient population suffering from it. For example, some diseases and conditions primarily affect the elderly, such as Parkinson's disease, whereas others affect patients from birth, such as cystic fibrosis. Treatments for each affected demographic patient group have unique costs and burdens and thus require properly tailored patient assistance.

97. PSI must then determine (i) what treatments are currently available for that condition; (ii) how much the treatments cost; and (iii) how treatments for specific diseases are administered.

98. For each treatment currently available or in development for a given disease, PSI must ascertain: (i) the number of affected individuals; (ii) the demographics of the patient population; (iii) the cost of the new treatment or drug; (iv) the expected utilization of the drug; (v) coverage and other restrictions that payors are likely to impose, including government payors; (vi) the likely duration of likely therapy; (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home); (viii) any ancillary patient needs such as transportation services; (ix) assistance for other supportive therapies that may be necessary; (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug; (xi) the costs associated with addressing side effects of the drugs or treatments; and (xii) whether any current donors or prospective donors have an interest in supporting this prospective new disease fund through donations. All of these data are critical to providing effective, properly tailored, efficient, and beneficial assistance to needy individuals suffering from debilitating diseases.

99. The information necessary to assess treatment options for specific diseases does not remain static. Rather, medical research is constantly identifying new treatments for chronic diseases. New drugs and treatments can revolutionize care for a particular disease, making treatment less complicated and time consuming, lowering the cost of treatment, or minimizing or eliminating previously unavoidable symptoms or side effects. When considering whether to create a new disease fund, PSI must know whether there are new drugs or treatments that will soon be available for that disease. Further, if patients are not to be denied access after the product is

launched, PSI must have the required information to make a fund decision before the product is launched, when the manufacturer is the only means to answer most, if not all, of the relevant questions.

100. Before setting up a disease fund, PSI also must understand the following at a granular level: (i) the trials and challenges facing patients suffering from the disease; (ii) the treatment options available to physicians seeking the best course of treatment for these patients; (iii) the hospitals or care facilities that will be administering and treating the patients; (iv) the payors, including government payors, who will cover a portion of the cost for the treatments; and (v) the needs of the family caretakers most directly responsible for the care of patients.

101. To gather this broad-array of information necessary to ensure effective charitable operations, PSI must engage in conversations with donors, prospective donors, and their purported affiliates that are often on the front lines of developing new drugs and treatments.

102. One telling example of these types of conversations occurs when PSI attends medical industry conferences to stay abreast of developments in the field and to identify potential new donors. At these conferences, representatives from pharmaceutical companies, hospital organizations and other healthcare groups often will approach PSI to discuss diseases and treatments. OIG demands, as a price of the advisory opinion that is essential to continued existence, that PSI not engage in these communications that lie at the heart of the First Amendment.

103. In the absence of a free flow of information between PSI and its donors, prospective donors, and purported affiliates, PSI simply may not know about the development of new drugs and thus will not be able to establish or modify disease funds to ease the financial burden and help provide access to cutting-edge care for needy patients.

104. In the past, OIG permitted PSI to communicate with donors, prospective donors and their purported affiliates about new treatments that were in development or that government regulators had recently approved, as none of the certifications at issue here were required as part of Advisory Opinion No. 02-1, which applied for approximately 15 years.

105. Since the 2017 Modified Advisory Opinion took effect, however, OIG has required that PSI not be permitted to participate in conversations with donors, prospective donors or their purported affiliates, notwithstanding that such communications allow PSI to gather the critical information necessary to determine whether PSI should establish a new fund for a disease.

106. OIG's 2017 Modified Advisory Opinion explicitly and directly restricts lawful, truthful and non-misleading speech concerning an area of public interest.

107. The 2017 Modified Advisory Opinion directly prohibits communications between PSI to and from any donor, or prospective donor, with regard to constitutionally protected speech, including communications with donors, prospective donors, or their purported affiliates that are individuals, pharmaceutical manufacturers, patient advocacy organizations, hospitals, or governmental organizations such as the Commonwealth of Virginia.

108. The 2017 Modified Advisory Opinion prevents and chills PSI's lawful, truthful and non-misleading speech to and from *all donors or prospective donors*, even in circumstances where such entity may be, or is in fact, the only source of information about a newly available treatment.

109. Compounding the burden imposed by these restrictions on lawful, truthful and non-misleading communications, the 2017 Modified Advisory Opinion further prohibits such communications between PSI and any "affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager))." Exhibit B at 5. The 2017 Modified Advisory

Opinion does not define what is meant by an affiliate of a donor or how close the relationship between a donor and an entity must be for the entity to be considered an "affiliate" by OIG.

110. For example, patient advocacy groups often receive grants from pharmaceutical manufacturers. If a particular pharmaceutical manufacturer were a donor to one of PSI's disease funds, but also provided a grant to a patient advocacy group, even if that patient advocacy group is neither a donor nor prospective donor to PSI, then OIG might consider the advocacy group to be an affiliate of a donor or prospective donor and thus subject to the restriction on communication with PSI set forth in the 2017 Modified Advisory Opinion. Indeed, when PSI asked OIG for clarification on this question, OIG simply referred PSI to the text of the 2017 Modified Advisory Opinion, which left PSI threatened with a rescission of its advisory opinion if it guessed wrong as to the meaning of the inherently vague term "affiliate."

111. The 2017 Modified Advisory Opinion also prohibits lawful, truthful and non-misleading communications to and from PSI regardless of the types of financial assistance that the potential new disease fund might provide.

112. The 2017 Modified Advisory Opinion prohibits a broad array of lawful, truthful and non-misleading communications to and from PSI that have no connection to, and would not in any way result in, a violation of the Medicare statute.

113. The 2017 Modified Advisory Opinion restricts significantly more speech than necessary to serve any legitimate governmental goals.

114. The 2017 Modified Advisory Opinion's restrictions on speech between PSI and its donors, prospective donors, and their purported affiliates are particularly unnecessary given the numerous other restrictions in the 2017 Modified Advisory Opinion that PSI does not challenge and that serve to advance the government's interest in preventing violations of the Medicare Act.

115. By restricting PSI's communications with donors, prospective donors, and their purported affiliates, PSI is forced to operate in the dark about: (i) available treatment options for chronic diseases; (ii) the financial needs of patients seeking such treatments; (iii) how many such patients there might be; and (iv) whether there will be any new drugs coming to market that will treat that disease. Although donors, prospective donors and their purported affiliates may not be the sole source of *all* the relevant information necessary to create or modify a charitable disease fund, they remain a critical source of information to PAPs such as PSI about new drugs and the costs and burdens associated with them.

116. Under the 2017 Modified Advisory Opinion, PSI has no practical options for setting up new disease funds or modifying existing disease funds. The restrictions on communications imposed by the 2017 Modified Advisory Opinion would require PSI to devote untold resources to investigate all new drug applications and to hire a staff of expensive clinical experts to recreate the information that PSI could obtain from donors, prospective donors and their affiliates if OIG did not impose this restriction on lawful, truthful and non-misleading speech. Even if PSI were forced to that route, PSI would be unable to obtain complete and accurate information regarding the pricing structure of the drug, the pre-approval requested indications, planned distribution methods, expected use by site or source, use by type of payor, expected dosage, anticipated frequency of use, projected contraindications and side effects, and many other pieces of information critical to establishing a new disease fund that can be provided only by drug manufacturers that are also important sources of donations for these funds.

117. Another impractical option would be for PSI to establish hundreds of new disease funds for every type of chronic and expensive disease and then hope that prospective donors will find out about the fund and decide to donate to it.

118. The most likely result from these restrictions is that PSI will cease efforts to establish new disease funds and that donors and prospective donors will not themselves have sufficient information about these funds to make donations. Indeed, since adoption of the 2017 Modified Advisory Opinion, PSI has experienced material reductions in donor support and estimates a 17% reduction in donations for its patient funds in 2018.

119. As a result, PSI's ongoing efforts to establish new disease funds have been crippled. PSI has been cut off from its best source of information regarding diseases and their treatment. PSI is no longer able to gauge prospective donor interest for a potential new disease fund and is now in a position of having to decide whether to establish new disease funds that might not receive enough donations to help any patients.

120. PSI would engage in lawful, truthful and non-misleading communications with donors, prospective donors, and their affiliates on the topics described above if it were not subject to the free-speech restrictions in the 2017 Modified Advisory Opinion.

121. As a direct result of the 2017 Modified Advisory Opinion, PSI is unable to discuss any diseases, disease treatments, or new disease funds with any donor, prospective donor, or other entities that might be deemed by OIG to be purported "affiliates" of donors or prospective donors. PSI is concerned that that any such communications regarding any new disease fund or modification of an existing fund would be perceived by OIG as a violation 2017 Modified Advisory Opinion and thus would subject PSI to an administrative penalty or even a criminal investigation.

122. The threat of administrative penalty or criminal investigation for acting beyond the bounds of an OIG Advisory Opinion is well supported. OIG required PSI to accept these restrictions based upon its expressed position that OIG "believe[s] that Independent Charity PAPs

raise serious risks of fraud, waste, and abuse if they are not sufficiently independent from donors." 79 Fed. Reg. 31123. As noted above, on November 28, 2017, OIG rescinded an advisory opinion of another PAP because, *inter alia*, the PAP "allowed donors to directly or indirectly influence the identification or delineation of [PAP's] disease categories."

123. Further, Defendants cannot deny PSI a government benefit on a basis that infringes PSI's constitutionally protected rights under the First Amendment. *See Rutan v. Republican Party of Illinois*, 497 U.S. 62, 72 (1990); *Alliance for Open Soc'y Int'l, Inc. v. U.S. Agency for Int'l Dev.*, 651 F.3d 218, 243 (2d Cir. 2011) ("In the First Amendment context, . . . 'the government may not deny a benefit to a person on a basis that infringes his constitutionally protected . . . freedom of speech even if he has no entitlement to that benefit'") (quoting *Rumsfeld v. Forum for Academic & Institutional Rights, Inc.*, 547 U.S. 47, 59 (2006)). Specifically, Defendants cannot condition the grant of an advisory opinion on PSI agreeing to restrict its constitutionally protected speech or associations because doing so would penalize and inhibit PSI's exercise of those rights. Defendants cannot, indirectly, interfere with PSI's constitutional rights by denying PSI the benefits of an advisory opinion based on grounds that violate PSI's First Amendment rights.

124. As a result, PSI reasonably fears that engaging in these constitutionally protected communications will result in an administrative penalty or criminal investigation.

COUNT I

The 2017 Modified Advisory Opinion's Restrictions Should Be Construed Not To Encompass PSI's Proposed Lawful, Truthful and Non-Misleading Communications With Donors, Potential Donors, and Their Affiliates.

125. The allegations in the paragraphs above are incorporated here by reference.

126. The Administrative Procedure Act allows a person suffering a wrong or adversely affected by an agency action to receive judicial review of the agency's action. 5 U.S.C § 702. The reviewing court must set aside an agency's action that is "arbitrary, capricious, an abuse of

discretion, or otherwise not in accordance with law," and "contrary to constitutional right." 5 U.S.C. § 706(2)(A) & (B).

127. The First Amendment protects PSI's lawful, truthful and non-misleading communications with donors, potential donors and their affiliates.

128. The First Amendment protects communications between a charity and its donors regarding charitable contributions and communications concerning public health and medical research.

129. The 2017 Modified Advisory Opinion restricts lawful, truthful and non-misleading communications between PSI and its donors, prospective donors and their affiliates regarding (i) the number of affected individuals; (ii) the demographics of the patient population; (iii) the cost of the new treatment or drug; (iv) the expected utilization of the drug; (v) coverage and other restrictions that payors are likely to impose, including government payors; (vi) the likely duration of likely therapy; (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home); (viii) any ancillary patient needs such as transportation services; (ix) assistance for other supportive therapies that may be necessary; (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug; (xi) the costs associated with addressing side effects of the drugs or treatments; and (xii) whether any current donors or prospective donors have an interest in supporting this prospective new disease fund through donations. Exhibit B, at 5.

130. The 2017 Modified Advisory Opinion's restrictions are content-based restrictions that violate the Free Speech Clause of the First Amendment. Such restrictions would not be narrowly tailored to serve a compelling interest, nor would they directly advance a substantial governmental interest.

131. The 2017 Modified Advisory Opinion's restriction of PSI's right to communicate with donors, prospective donors and their purported affiliates is final agency action that results in current harm to PSI.

132. PSI has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile.

133. PSI is entitled to challenge the restrictions in Defendants' 2017 Modified Advisory Opinion under the First Amendment, 5 U.S.C. §§ 701-706 and 42 U.S.C. § 1320a–7d.

134. Defendants' 2017 Modified Advisory Opinion, if permitted to restrict constitutionally protected speech, would be arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law and in excess of Defendants' statutory jurisdiction, authority and limitation.

135. PSI has no adequate remedy at law.

136. PSI is entitled to a declaratory judgment and injunctive relief confirming that the 2017 Modified Advisory Opinion does not restrict communications between PSI and donors and prospective donors and their purported affiliates regarding: (i) the number of affected individuals; (ii) the demographics of the patient population; (iii) the cost of the new treatment or drug; (iv) the expected utilization of the drug; (v) coverage and other restrictions that payors are likely to impose, including government payors; (vi) the likely duration of likely therapy; (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home); (viii) any ancillary patient needs such as transportation services; (ix) assistance for other supportive therapies that may be necessary; (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug; (xi) the costs associated with addressing side effects of the drugs or treatments; and (xii) whether any current donors or

prospective donors have an interest in supporting this prospective new disease fund through donations. Exhibit B, at 5.

COUNT II

The 2017 Modified Advisory Opinion's Restrictions On Communications Are Unconstitutional to the Extent That They Prohibit PSI's Proposed Lawful, Truthful and Non-Misleading Speech to Donors, Potential Donors and Their Affilliates

137. The allegations in the paragraphs above are incorporated here by reference.

138. The Administrative Procedure Act allows a person suffering a wrong or adversely affected by an agency action to receive judicial review of the agency's action. 5 U.S.C § 702. The reviewing court must set aside an agency's action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and "contrary to constitutional right." 5 U.S.C. § 706(2)(A) & (B).

139. The First Amendment protects PSI's truthful and non-misleading communications with donors, potential donors and their affiliates.

140. The First Amendment protects communications between PSI and its donors, prospective donors and their purported affiliates about charitable contributions and communications related to public health and medical research.

141. The 2017 Modified Advisory Opinion violates the First Amendment because it prohibits communications between PSI and donors, prospective donors and their purported affiliates regarding (i) the number of affected individuals; (ii) the demographics of the patient population; (iii) the cost of the new treatment or drug; (iv) the expected utilization of the drug; (v) coverage and other restrictions that payors are likely to impose, including government payors; (vi) the likely duration of likely therapy; (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home); (viii) any ancillary patient

needs such as transportation services; (ix) assistance for other supportive therapies that may be necessary; (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug; (xi) the costs associated with addressing side effects of the drugs or treatments; and (xii) whether any current donors or prospective donors have an interest in supporting this prospective new disease fund through donations. Exhibit B, at 5.

142. Upon information and belief, Defendants have interpreted the 2017 Modified Advisory Opinion to restrict lawful, truthful, non-misleading speech regarding lawful activities. These restrictions are not narrowly tailored to advance the government's interest in prohibiting violations of the Medicare Act as they restrict significantly more speech between PSI and its donors or prospective donors than is necessary to achieve any legitimate governmental end.

143. Out of fear of prosecution or crippling administrative sanction, since the 2017 Modified Advisory Opinion took effect, PSI has ceased its lawful, truthful and non-misleading communications with donors, prospective donors and their affiliates regarding: (i) the number of affected individuals; (ii) the demographics of the patient population; (iii) the cost of the new treatment or drug; (iv) the expected utilization of the drug; (v) coverage and other restrictions that payors are likely to impose, including government payors; (vi) the likely duration of likely therapy; (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home); (viii) any ancillary patient needs such as transportation services; (ix) assistance for other supportive therapies that may be necessary; (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug; (xi) the costs associated with addressing side effects of the drugs or treatments; and (xii) whether any current donors or prospective donors have an interest in supporting this prospective new disease fund through donations. Exhibit B, at 5.

144. The 2017 Modified Advisory Opinion prohibits such speech and violates the Free Speech Clause of the First Amendment.

145. The 2017 Modified Advisory Opinion's restriction of PSI's right to engage in lawful, truthful and non-misleading communications with donors, prospective donors and their affiliates is final agency action that results in current harm to PSI.

146. PSI has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile.

147. PSI is entitled to challenge the Defendants' issuance of the 2017 Modified Advisory Opinion under the First Amendment, 5 U.S.C. §§ 701-706 and 42 U.S.C. § 1320a–7d.

148. Defendants' actions, implemented through the 2017 Modified Advisory Opinion, are arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with the law and in excess of Defendants' statutory jurisdiction, authority and limitation.

149. PSI has no adequate remedy at law.

150. Accordingly, PSI seeks a declaratory judgment that the 2017 Modified Advisory Opinion as applied to communications between PSI and its donors, prospective donors and their affiliates is unconstitutional and an injunction prohibiting Defendants from enforcing that restriction on truthful non-misleading speech concerning lawful activities.

PRAYER FOR RELIEF

PSI respectfully requests that this Court:

a. Enter a declaratory judgment that the Modified Advisory Opinion does not restrict PSI's lawful, truthful and non-misleading communications with donors, prospective donors, and their affiliates regarding: (i) the number of affected individuals; (ii) the demographics of the patient population; (iii) the cost of the new treatment or drug; (iv) the expected utilization of the drug; (v) coverage and other restrictions that payors are likely to impose, including government

payors; (vi) the likely duration of likely therapy; (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home); (viii) any ancillary patient needs such as transportation services; (ix) assistance for other supportive therapies that may be necessary; (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug; (xi) the costs associated with addressing side effects of the drugs or treatments; and (xii) whether any current donors or prospective donors have an interest in supporting this prospective new disease fund through donations. Exhibit B, at 5.

b. Enter a declaratory judgment that the Modified Advisory Opinion violates the First Amendment of the United States Constitution to the extent that it restricts PSI's lawful, truthful and non-misleading communications with donors, prospective donors, and their affiliates regarding: (i) the number of affected individuals; (ii) the demographics of the patient population; (iii) the cost of the new treatment or drug; (iv) the expected utilization of the drug; (v) coverage and other restrictions that payors are likely to impose, including government payors; (vi) the likely duration of likely therapy; (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home); (viii) any ancillary patient needs such as transportation services; (ix) assistance for other supportive therapies that may be necessary; (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug; (xi) the costs associated with addressing side effects of the drugs or treatments; and (xii) whether any current donors or prospective donors have an interest in supporting this prospective new disease fund through donations. Exhibit B, at 5.

c. Enjoin Defendants from enforcing the restrictions in the Modified Advisory Opinion to the extent that they prohibit lawful, truthful and non-misleading communications between PSI and its donors, prospective donors, and their affiliates regarding: (i) the number of

affected individuals; (ii) the demographics of the patient population; (iii) the cost of the new treatment or drug; (iv) the expected utilization of the drug; (v) coverage and other restrictions that payors are likely to impose, including government payors; (vi) the likely duration of likely therapy; (vii) how and where the drug or treatment will be administered (such as by a doctor in a hospital or by the patient in their own home); (viii) any ancillary patient needs such as transportation services; (ix) assistance for other supportive therapies that may be necessary; (x) the frequency and likelihood of complications or adverse events that can occur as a result of the treatment or drug; (xi) the costs associated with addressing side effects of the drugs or treatments; and (xii) whether any current donors or prospective donors have an interest in supporting this prospective new disease fund through donations. Exhibit B, at 5.

d. Enter any other relief that is just and proper.

Dated: January 8, 2018

Respectfully Submitted,

By: */s/ Robert D. Keeling*

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JS 44 (Rev. 06/17)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Patient Services, Inc.,

(b) County of Residence of First Listed Plaintiff Chesterfield County, VA
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Robert Keeling, Sidley Austin LLP
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DEFENDANTS

United States of America; Department of Health and Human Services Office of Inspector General; Inspector General, Daniel R. Levinson; Acting Secretary of DHHS, Eric D. Hargan

County of Residence of First Listed Defendant District of Columbia
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☒ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
5 U.S.C. §§ 701; 28 U.S.C. §§ 2201

Brief description of cause:
Declaratory Judgment action to enjoin violation agency action violating federal constitutional rights

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
01/08/2018

SIGNATURE OF ATTORNEY OF RECORD
/s/ Robert Keeling

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Office of Inspector General
Washington, D.C. 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor*.]

Issued: April 4, 2002

Posted: April 11, 2002

[name and address redacted]

Re: OIG Advisory Opinion No. 02-1

Dear [name redacted]:

We are writing in response to your request for an advisory opinion, in which you ask whether grants provided by a non-profit, charitable organization to financially needy Medicare beneficiaries in order to subsidize their costs of medical care (including cost-sharing amounts under Part B of the Medicare program and premium expenses for Medicare Supplementary Health Insurance ("Medigap") coverage) (the "Proposed Arrangement") would be grounds for the imposition of sanctions under section 1128A(a)(5) of the Social Security Act (the "Act") or under the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, and, while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute (if the requisite intent to induce or reward referrals of Federal health care program business were present), the Office of Inspector General ("OIG") would not impose administrative sanctions on [S Organization] in connection with the Proposed Arrangement under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act).

This opinion may not be relied on by any persons other than [S Organization], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[S Organization] (the "Requestor") is a non-profit, tax-exempt, charitable corporation that is not subject to control, directly or indirectly, by any donor. The Requestor provides financial assistance to help defray the medical expenses of financially needy patients suffering from specific chronic illnesses or rare disorders.[1] The financial assistance includes paying all or part of a patient's health insurance premiums and copayments for privately insured and otherwise uninsured patients. The Requestor desires to provide similar financial assistance to financially needy Medicare beneficiaries, using the same eligibility criteria and grant procedures. That process is described below.

Requests for financial assistance are reviewed on a first-come, first-served basis, to the extent funding is available for the applicant's medical condition. The Requestor first examines an applicant's available financial resources in relation to certain established national standards of indigence and then compares those resources to the applicant's expected costs of treatment. The Requestor uses a pre-set sliding scale to determine a patient's eligibility for assistance, which can range from full subsidization of the patient's private health insurance premiums and copayments to significant cost-sharing with the patient. In most cases, the Requestor does not make cash grants directly to patients;[2] rather, checks are made out to the patients' insurance companies, physicians, providers,

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[1]The Requestor currently supports treatment for the following conditions: [redacted].

[2]In a small number of cases where third-party payments are refused, checks are made payable to the patient as reimbursement only upon proof of payment.

and suppliers of items and services (including drugs).[3] The Requestor provides financial assistance for a specific period of time (up to two years), after which the patient may reapply.

Potential applicants learn about the Requestor's financial assistance programs from a variety of sources, including physicians, health care providers, patient advocacy groups, and drug manufacturers' patient assistance programs. However, approximately half of those who receive assistance annually from the Requestor are referred by donors who make contributions to the Requestor**.** The Requestor has certified that its staff does not take the identity of the referring person or organization or the amount of any donor's contribution into consideration when assessing patient applications or making grant determinations. The Requestor has further certified that its staff does not refer applicants to or recommend providers, practitioners, or suppliers of items or services.

A substantial portion of the Requestor's funding is provided by manufacturers of drugs used to treat the specific chronic illnesses or diseases that are covered by the Requestor's programs and by suppliers of services to patients that the Requestor is assisting, such as home care infusion companies and specialty pharmacies. Donors may change or discontinue their contributions at any time. Virtually all contributions are earmarked for the support of patients with a particular disease or condition. Donors that refer patients to the Requestor are informed quarterly or monthly, depending upon the specific disease category, of the aggregate number of all applicants for assistance in the disease category specified by the donor and the aggregate number of patients qualifying for assistance in that disease category. No individual patient information is conveyed to donors. Patients are not informed of the identity of specific donors of funds for specific disease categories.

In many cases, donors enter into Participation Agreements with the Requestor. Participation Agreements cover approximately half of the Requestor's total average annual donations. These agreements generally obligate the donor to make contributions to the Requestor under fixed conditions. Contributions made pursuant to these agreements are earmarked to assist patients with particular illnesses or diseases designated by the donor. Currently, the Participation Agreements obligate the Requestor to assess the eligibility of patients referred to it by the donor and to submit periodic reports to the donor listing the number of patient referrals made by donor; the number by donor of patient applications mailed, received, and accepted; and the number by donor of

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[3]While the Requestor pays a patient's providers and insurers directly, the Requestor notifies patients that they are free at all times to switch to another provider. Of course, depending on the comparative costs of the new provider, the amount of financial assistance might change.

patients accepted and denied. Upon implementation of the Proposed Arrangement, this reporting requirement will be changed so that, as the Requestor has certified, patient information will be reported to donors on an aggregate basis only within specific disease categories.

II. LEGAL ANALYSIS

A. Law

Section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or Medicaid program beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by the Medicare or Medicaid. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) as including "the waiver of coinsurance and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value."

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and State health care programs. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

B. Analysis

The Proposed Arrangement by which the Requestor would subsidize, in whole or in part, certain Medicare beneficiaries' Part B copayments and deductible amounts and Medigap premiums, implicates section 1128A(a)(5)of the Act, as well as the anti-kickback statute. Nevertheless, for the reasons set forth below, we conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act. We further conclude that, in the particular circumstances presented here, we would not seek to impose administrative sanctions under the anti-kickback statute in connection with the Proposed Arrangement.

1. Donor Contributions to the Requestor

Because the Requestor's particular design and administration of the Proposed Arrangement interposes an independent charitable organization between donors and patients in a manner that effectively insulates beneficiary decision-making from information attributing the funding of their benefit by any donor, it appears unlikely that donor contributions would influence any Medicare or Medicaid beneficiary's selection of a particular provider, practitioner, or supplier. Thus, donor contributions to the Requestor would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act.

The Requestor is an independent, non-profit, tax-exempt charitable organization that is not subject to control, directly or indirectly, by any donor. A variety of sources refer patients to the Requestor for financial assistance, many of which sources are not affiliated with any donor that contributes to the Requestor.

Eligibility for the Requestor's financial assistance is available to any financially qualified patient suffering from the specific chronic illnesses or diseases targeted by the Requestor's program, regardless of the particular physicians, providers, suppliers of items or services, or drugs that the patient may use. The Requestor makes all financial eligibility determinations using its own criteria and does not take into account the identity of any physician, provider, supplier of items or services, or drug that the patient may use or the amount of any contributions made by a donor whose services or products are used or may be used by the patient.

Moreover, before applying for financial assistance, all patients have selected their health care providers (and, where appropriate, the providers have prescribed drugs for the patient) freely based on their best medical interests after consultation with their physicians and other providers and remain free while receiving the Requestor's financial

assistance to change their health care providers. The Requestor does not refer patients to any donor or other provider.

In sum, the Requestor's interposition as an independent charitable organization between donors and patients and the design and administration of the Proposed Arrangement provide sufficient insulation so that the Requestor's subsidy of Medicare Part B copayments and deductibles and Medigap premiums should not be attributed to any of its donors. Donors are not assured that the amount of financial assistance their patients, clients, or customers receive will bear any relationship to the amount of their donations. Indeed, donors are not guaranteed that any of their patients, clients, or customers will receive any financial assistance whatsoever from the Requestor. In these circumstances, we do not believe that the contributions made by donors to the Requestor can reasonably be construed as payments to eligible beneficiaries of the Medicare program.

2. The Requestor's Subsidy of Medicare Part B Copayments and Deductibles and Medigap Premiums

In the circumstances presented by the Proposed Arrangement, we believe that the Requestor's subsidy, in whole or in part, of Medicare Part B copayments and deductible amounts and Medigap premiums for certain financially qualified Medicare beneficiaries is not likely to influence any beneficiary's selection of a particular provider, practitioner, or supplier.

First, the Requestor assists all financially qualified patients on a first-come, first-served basis, to the extent funding is available for the patient's medical condition. In virtually all cases, the patient is already being treated for his or her condition and has thus already selected providers. Even if asked, the Requestor makes no referrals or recommendations regarding specific providers, practitioners, or suppliers.

Second, the Requestor's determination of a patient's financial qualification for assistance is based solely on the patient's aggregate financial need, without considering the identity of any of the patient's health care providers or the identity of any donor that may have contributed for the support of the specific medical condition. The Requestor notifies all grant recipients that they are free at any time to switch providers, practitioners, or suppliers without affecting their continued eligibility for financial assistance. While we consider problematic the Requestor's reporting of certain patient data to donors, we consider that the Requestor has appropriately minimized the risks of fraud and abuse by ensuring that such reports contain aggregate patient data, rather than data relating to specific patients; this method precludes donors from tracking the specific patients utilizing their products or the amounts paid by the Requestor to such patients.

Finally, the Requestor's subsidy of Medicare Part B copayments and deductible amounts and Medigap premiums for the patient populations it serves will expand, rather than limit, beneficiaries' freedom of choice. As a practical matter, most patients will have already selected a provider, practitioner, or supplier of items or services, and drugs will have been prescribed for the patient, prior to the patient's application for the Requestor's financial assistance or prior to the Requestor's initial payment of Medicare Part B copayments and deductibles or Medigap premiums. Most importantly, once in possession of Medicare Part B or Medigap coverage, a beneficiary will be able to select any provider, practitioner, or supplier of items or services (and have any drug prescribed), regardless of whether that provider, practitioner, or supplier (or drug manufacturer) has made contributions to the Requestor's support programs.

In light of all of the foregoing considerations and for similar reasons, we would furthermore not subject the Requestor to sanctions under the anti-kickback statute in connection with the Proposed Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, and, while the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute (if the requisite intent to induce or reward referrals of Federal health care program business were present), the OIG would not impose administrative sanctions on [S Organization] in connection with the Proposed Arrangement under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act).

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [S Organization], which is the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor of this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [S Organization] with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [S Organization] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General

EXHIBIT B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: March 3, 2017

Posted: March 10, 2017

[Name and address redacted]

Re: Notice of Modification of OIG Advisory Opinion No. 02-1

Dear [Name redacted]:

On May 21, 2014, the Office of Inspector General ("OIG") issued a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs (the "Supplemental Bulletin").[1] The Supplemental Bulletin provides additional guidance on patient assistance programs ("PAPs") operated by independent charities to address certain risks about these programs that have come to our attention in recent years. We sent the Supplemental Bulletin, together with targeted letters, to all independent charities that have received favorable advisory opinions from us to request certain clarifications and modifications to those opinions.

On April 4, 2002, the OIG issued to [name redacted] (the "Charity") OIG Advisory Opinion No. 02-1, which is a favorable opinion regarding the Charity's operation of a PAP to provide grants to defray medical expenses (including cost-sharing obligations for drug treatments and health insurance premiums) for patients who meet certain financial need criteria and suffer from specific chronic illnesses or rare disorders. In that opinion, we did not address certain features that we have since determined are problematic. In accordance with our authority at 42 C.F.R. § 1008.45, we sent the Charity a letter on May 21, 2014, that highlighted our areas of concern, explained that certain aspects of the PAP

[1] The Supplemental Bulletin is available at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf and was subsequently published in the Federal Register at 79 Fed. Reg. 31120 (May 30, 2014).

would have to be modified for the Charity to retain its favorable advisory opinion, and proposed certifications to address these points.

The Charity has responded to our request and has addressed the concerns we described in the Supplemental Bulletin through the following three certifications:

(1) Except as specifically provided in this paragraph, the Charity will not define its disease funds by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states. The Charity has requested the following three exceptions to this general principle:

> (a) The Charity intends to develop and maintain disease funds that would be limited to patients with certain metastatic cancers. In those disease funds, the Charity will cover, at a minimum, all drugs that are approved by the U.S. Food and Drug Administration ("FDA") for the type of cancer (not limited to drugs expressly approved for the metastatic stage of the cancer).
>
> (b) The Charity will have a fund that provides, at a minimum, copayment support for all prescription drugs used to manage (but not treat) any cancer. For example, the fund will cover anti-nausea medications, opioid and non-opioid pain medications, antidepressants prescribed for depression secondary to a patient's cancer diagnosis, medications that treat opioid-induced constipation, and any other drug that manages an issue related to cancer.
>
> (c) The Charity also will have a fund for patients with [disease state redacted], a condition affecting certain patients with neurological disorders. While limited to patients with [disease state redacted], this fund will cover, at a minimum, copayment support for all prescription drugs that are used to treat either [disease state redacted] or the neurological disorders that underlie a patient's [disease state redacted], such as [three specific neurological disorders redacted]. Patients who qualify for the fund may receive cost-sharing assistance or premium assistance. Patients who receive cost-sharing assistance may apply it toward drugs addressing [disease state redacted] or the underlying neurological condition, and they will be informed of this fact. The Charity may impose an across-the-board cap on this particular fund that would limit the total assistance provided to individual patients.

We find that these three proposed exceptions, as set out by the Charity, do not materially raise the risk of this arrangement. The funds for patients with certain metastatic cancers will cover all drugs approved by the FDA for the type of cancer in question, which should ensure the support of a broad range of drugs by each such fund. The cancer

management fund and the fund for patients with [disease state redacted] will each be broadly defined in a manner that covers a wide spectrum of products. Neither fund will limit assistance to a subset of available products. The two funds will be subject to all of the safeguards applicable to any other disease fund described in OIG Advisory Opinion 02-1, as further modified herein. The cancer management fund and the fund for patients with [disease state redacted] therefore will be unlikely to support exclusively or primarily the products of their donors and will be unlikely to otherwise be operated to induce the purchase of those products.

(2) The Charity will not maintain any disease fund that provides copayment assistance for only one drug or therapeutic device, or only the drugs or therapeutic devices made or marketed by one manufacturer or its affiliates. If the Charity sponsors a fund for a disease for which the FDA has approved only one drug or therapeutic device (including one drug and a therapeutic device used to administer that drug), the Charity will provide support for other medical needs of patients with the disease, in addition to copayment support for the FDA-approved treatment of the disease. (This includes one fund for patients with a disease for which there is only one FDA-approved stand-alone treatment, although there is an additional drug approved by the FDA for use in combination with the single stand-alone treatment.) At a minimum, the Charity will provide copayment support for all prescription drugs used by a patient in connection with managing the disease, including, but not limited to, prescription drugs to treat symptoms of the disease, such as pain medications, and prescription drugs to treat side effects of treatments, such as anti-nausea medications.

(3) The Charity will not limit its assistance to high-cost or specialty drugs. Instead, the Charity will make assistance available for all products, including generic or bioequivalent drugs, covered by the applicable payor, including Medicare, when prescribed for the treatment of the disease state(s) covered by the fund.[2]

[2] We note that some charities implement systems that require a minimum claim amount, in part to avoid the administrative burdens of reimbursing numerous claims for small amounts of money. Such a system would be consistent with this certification as long as it does not have the effect of denying reimbursement for lower copayments while paying higher copayments in full. For example, a charity may require a recipient of assistance to accumulate receipts for claims up to a certain threshold (e.g., $50) and then submit them together for reimbursement. A charity may also require a recipient to pay a certain amount of the cost-sharing on all claims (e.g., the first $20 on any claim). However, any system that would result in patients paying more for an inexpensive drug than they would for a high-cost drug would be inconsistent with the Charity's certification that it would not limit its assistance to high-cost drugs.

In addition, we asked the Charity to certify, and it did certify, that it determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. The Charity employs a process for screening all applicants for compliance with a fund's designated financial eligibility criteria prior to enrolling applicants in a fund or within a reasonable time thereafter. Such screening process is applied uniformly across funds, and involves: verifying each applicant's financial resources through information provided by a third party service, collecting documentation of financial need from the applicant, or some combination thereof.

In addition to the certifications above, the Charity proposed the following additional modifications to Advisory Opinion 02-1.

(1) Some of the Charity's disease funds provide forms of assistance in addition to cost-sharing assistance for drugs. Such additional assistance may include cost-sharing assistance with infusion services, office visits, health care counseling, diagnostic testing, nursing services, and therapy services; support for medical devices and equipment; and reasonable transportation (if applicable) associated with the administration of certain medication therapies, such as chemotherapy treatment, utilized to treat the underlying disease covered by the fund. When these additional forms of assistance are covered, they are and will be covered in the same disease fund as the drug therapies to treat the underlying disease that is the subject of the fund. The Charity certified that the same safeguards applicable to drug cost-sharing assistance described in OIG Advisory Opinion 02-1, as modified herein, apply to the Charity's administration of these forms of assistance. Extending one or more of these additional forms of assistance to patients qualified for a given disease fund, in this context, should not raise the risk to Federal health care programs.

(2) The Charity proposes to establish disease funds that would provide financial assistance only to qualified Federal health care program beneficiaries. Such funds would operate in accordance with all of the safeguards and parameters set forth in OIG Advisory Opinion 02-1, as modified herein. Consistent with our existing guidance, we will not impose sanctions in connection with the Charity's establishment of disease funds that provide assistance only to qualified Federal health care program beneficiaries, provided that the operation of these disease funds is otherwise consistent with the certifications set forth in Advisory Opinion 02-1 and herein.

(3) In addition to (or in lieu of) cost-sharing assistance for drug therapies and therapeutic devices (if applicable) used to treat or manage, as applicable, the underlying disease state, some of the Charity's disease state funds would provide premium assistance to all qualifying enrollees. We do not believe adding premium support to a disease fund that meets the criteria set forth in OIG Advisory Opinion 02-1, as modified herein, or maintaining a fund that provides only premium support, increases the risk.

(4) The Charity proposes to provide cost-sharing assistance for qualified applicants for therapeutic devices that treat underlying diseases, in addition to drug therapy. Any such devices would be covered in the same disease state fund as the drugs that treat the disease. With this request for modification, the Charity would be expanding the items covered within a disease fund. All of the same safeguards would apply, and thus we do not believe adding therapeutic devices to a disease fund increases the risk.

More recent favorable advisory opinions issued to independent charity PAPs incorporated safeguards that did not appear in OIG Advisory Opinion 02-1. We therefore asked the Charity to make certain additional certifications, to ensure compliance with our long-standing guidance regarding independence from donors:

(1) The Charity certified that donors may earmark their contributions to a specific disease fund, but the donations are and will be otherwise unrestricted. The Charity's discretion to use the donations otherwise is and will be absolute, independent, and autonomous.

(2) The Charity certified that it is and will be governed by an independent board of directors (the "Board"). No donor, or affiliate of a donor, exerts or will exert any direct or indirect influence over the Charity or its PAP. No donor, or immediate family member, director, officer, employee, or person otherwise affiliated with a donor is or will be eligible to serve on the Board. No former director, officer, or employee of a donor who maintains an ongoing relationship with the donor (via consulting or otherwise), or immediate family members of such former director, officer, or employee of a donor is or will be eligible to serve on the Board. Finally, no Board member or employee of the Charity receives or will receive, directly or indirectly, any form of compensation from any donor.

(3) The Charity certified that it, in its sole discretion, determines, and will determine, the diseases it supports through its funds. Such funds are, and will be, defined by the Board based on its independent assessment of whether a new fund will best serve patient needs. The Charity defines and will define its disease funds in accordance with widely recognized clinical standards. The Charity's disease funds are, and will be, defined in a manner that covers within each a broad spectrum of products. The Charity does not, and will not, solicit suggestions from donors regarding the identification or delineation of disease funds. No donor or affiliate of any donor (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) directly or indirectly influences or will influence the identification or delineation of any of the Charity's disease funds. The Charity certified, more specifically, that it will not establish or modify funds for specific diseases at the request or suggestion of donors or prospective donors (or affiliates of donors or prospective donors) that manufacture drugs or devices for the treatment of

such diseases or that otherwise have a financial interest in the establishment or modification of such funds.

(4) The Charity certified that it assesses and will assess patient applications and makes grant determinations without regard to: (i) the interests of any donor or any donor affiliates; (ii) the applicant's choice of product, provider, practitioner, supplier, or insurance company; (iii) the identity of the referring person or organization, including whether the referring entity is a donor; or (iv) the amount of contributions made by any donor whose services or products are used or may be used by the patient. The Charity certified that it does not, through its staff or otherwise, refer applicants or potential applicants to or recommend any items or services, or any providers, practitioners, or suppliers of items or services. For example, if the Charity provides information regarding a donor's PAP, the Charity also will provide, in the same place or at the same time, and with the same prominence, information about all manufacturer-sponsored PAPs for drugs that treat or manage the same condition; if the Charity provides a link on its website to a PAP offered by a donor to a fund, the Charity also will provide links to all manufacturer PAPs that support drugs covered by the fund. These certifications help ensure that the Charity's PAP will not steer patients to the products of its donors.

(5) The Charity proposes to provide donors with quarterly or monthly projected estimates of when a particular fund is likely to be exhausted, based on current donations and assistance provided to fund enrollees. However, the Charity will not provide donors with any individual patient information or any data related to the identity, amount, or nature of drugs, devices, or services subsidized by the PAP. The Charity's reports to donors will not contain any information that would enable a donor to correlate the amount or frequency of its donations with the number or medical condition of patients who use its products or services or the volume of those products or services. The Charity does not and will not inform applicants of the identities of donors or when a particular manufacturer donates to the Charity. Finally, patients do not and will not receive any information about donors, and donors do not receive any information regarding other donors, except that the Charity's annual report and list of donations may be publicly available to the extent required by the Internal Revenue Service, or as otherwise required by law.

The Charity certified that, except as expressly provided above, all other material facts to which the Charity certified in its submissions in connection with OIG Advisory Opinion No. 02-1 remain accurate.[3] Accordingly, the Charity's PAP, as modified herein:

[3] The Charity has not sought an opinion on, and we express no opinion regarding, any of the Charity's operations (past or future) that may have fallen outside of the facts presented to us; any operations that deviate from the express certifications provided in connection with an advisory opinion are not protected by the advisory opinion. However,

(i) would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Social Security Act (the "Act"); and (ii) although the PAP could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on the Charity under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the PAP, as modified herein.

Pursuant to 42 C.F.R. § 1008.45(a), this letter serves as final notice of the OIG's modification of OIG Advisory Opinion No. 02-1. The modification of OIG Advisory Opinion No. 02-1 means that the advisory opinion continues in full force and effect in modified form. See 42 C.F.R. § 1008.45(b)(3).

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General

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the OIG will not proceed against the Charity with respect to any action taken in good faith reliance on OIG Advisory Opinion No. 02-1 up until the date of this modification, as long as the material facts were fully, completely, and accurately presented, and the arrangement in practice comported with that information at all times.