IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS

DIALYSIS PATIENT CITIZENS; U.S. RENAL CARE, INC.; DAVITA INC.; and FRESENIUS MEDICAL CARE HOLDINGS, INC.; *Plaintiffs*, v. SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ANDY SLAVITT, Acting Administrator, Centers for Medicare and Medicaid Services, and CENTERS FOR MEDICARE AND MEDICAID SERVICES; *Defendants.*	Civil Action No. _____

COMPLAINT

Plaintiffs Dialysis Patient Citizens ("DPC"); U.S. Renal Care, Inc. ("USRC"), DaVita Inc. ("DaVita"), and Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care North America ("FMCNA") ("Provider Plaintiffs") (collectively, "Plaintiffs") hereby allege:

INTRODUCTION

1. In a transparent effort to ensure its regulation takes effect before a new administration takes office, the Department of Health and Human Services ("HHS") on December 14, 2016, announced a sea-changing rule without any notice or comment—making it effective on an expedited basis on January 13, 2017—upending twenty years of HHS guidance governing the way in which End Stage Renal Disease ("ESRD") patients obtain health insurance coverage necessary to obtain life-sustaining care. *See Interim Final Rule with Comment Period, Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third-Party Payment*, 81 Fed. Reg. 90,211 (Dec. 14, 2016) (the "Rule" or "Interim Final Rule").

2. If permitted to take effect, the Rule will cause immediate and irreparable harm to patients who are among the most vulnerable in society: ESRD patients who require routine dialysis treatments or transplants to survive.

3. For twenty years, HHS has consistently affirmed guidance permitting ESRD patients to obtain financial assistance from charitable organizations to secure public or private health-insurance coverage enabling access to life-sustaining care. The Rule reverses that paradigm with no warning, requiring dialysis providers, within thirty days of the Rule's announcement, to make disclosures to and seek permission from insurance companies for these sick patients to continue to receive charitable premium assistance.

4. The Department's about-face will dramatically disrupt those patients' ability to obtain private insurance, interfering with and potentially compromising outright their access to

life-sustaining medical treatment while remarkably imposing greater healthcare costs on many patients and their families.

5. At the same time—with no offsetting benefits to patients—the Rule will impose significant and unrecoverable costs on dialysis providers, and threaten the economic viability of many dialysis facilities, leading to facility closures that will damage providers and patients alike.

6. As the Rule's history and extraordinary timing make clear, HHS' true motive is to shift hundreds of millions of dollars in health-care costs from private insurers to taxpayers, making it more attractive for those insurers to offer qualified health plans (or "QHPs") under the Affordable Care Act ("ACA") (colloquially known as "Obamacare"). That objective, however, could not possibly have satisfied the demanding "good cause" showing required by the APA to implement a final rule without notice-and-comment. For that reason, HHS purported to rationalize its Rule and emergency, pre-Inauguration Day implementation as necessary to prevent harm to ESRD patients. Those claims collapse upon inspection. In fact, overwhelming evidence, logic, and common sense compel the conclusion that the Rule will create the very disruptions in coverage to care that it is purportedly designed to prevent.

7. Because HHS's rush to enact its Rule without the benefit of notice-and-comment, and to put it into effect a midnight rule before a new administration takes over, violates the APA in multiple respects, and because it would impose serious, discriminatory, and irreparable harm on thousands of ESRD patients, whose interests are represented by Plaintiff DPC here and, as well as dialysis providers, the Court should grant this motion for an emergency temporary restraining order and preliminary injunction against the Rule's enforcement.

JURISDICTION AND VENUE

8. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1361, and 2201-2202, the Social Security Act and the Medicare Act, 42 U.S.C. § 405(g), and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706.

9. Venue is proper in this Court under 28 U.S.C. § 1391(e) and 42 U.S.C. § 405(g), because Plaintiff USRC is headquartered in this District and because the Rule affects a substantial number of individuals and businesses in this District.

PARTIES

10. Plaintiff DPC is a non-profit educational and social welfare organization operating under section 501(c)(4) of the Internal Revenue Code. Its purpose is to improve the quality of life of patients with kidney (renal) disease, including those with ESRD, through advocacy and education. DPC's membership is restricted to kidney disease patients and their family members. DPC has more than 28,000 total members. Twenty-three percent of DPC members with ESRD have received funding from the American Kidney Fund to help pay their premiums, including premiums for both Medicare and private coverage. Many of DPC's members who are currently receiving third-party assistance for private insurance would risk losing that assistance or having their coverage cancelled if the Rule is made effective. As part of DPC's mission to assist patients with kidney disease, DPC has an interest in ensuring that those patients have the resources to make the insurance choices that are in their best interests, including continued access to charitable assistance for insurance premiums and other out-of-pocket costs.

11. Plaintiff USRC was founded in 2000 with the goal of growing the Company into the highest-quality dialysis provider available to patients with chronic and acute renal disease. USRC is headquartered in Plano, Texas. It owns, co-owns, and manages hundreds of dialysis

facilities across the United States, each of which is enrolled in the Medicare program. The Company's dialysis facilities provide both in-center and in-home dialysis services for ESRD. The Company also manages several acute-setting dialysis programs in conjunction with local hospitals. USRC serves more than 23,000 patients across 31 states and the Territory of Guam, making it the third-largest dialysis-provider chain in the United States by number of patients. The Company has a significant rural presence, with 43 dialysis facilities more than 10 miles from the nearest alternative and 20 facilities more than 20 miles from the nearest alternative.

12. Plaintiff DaVita is a leading provider of kidney care in the United States, delivering dialysis services to patients with chronic kidney failure and ESRD. As of November 30, 2016, DaVita operated or provided administrative services at 2,418 outpatient dialysis centers spread across 46 states and the District of Columbia, serving approximately 199,000 patients. Within the Eastern District of Texas, DaVita owns and operates 26 in-center dialysis facilities in the cities of Allen, Atlanta, Bonham, Cleveland, Denison, Denton, Frisco, Gilmer, Henderson, Kilgore, Lewisville, Livingston, Longview, Lufkin, Marshall, McKinney, Plano, Sherman, Texarkana, and Wylie. Within the Sherman division alone, DaVita owns and operates 14 in-center dialysis facilities in Allen, Bonham, Denison, Denton, Frisco, Lewisville, McKinney, Plano, Sherman, and Wylie. DaVita also provides acute inpatient dialysis services in hospitals and related laboratory services throughout the United States.

13. Plaintiff Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America ("FMCNA") is a premier health care company focused on delivering the highest quality care to people with renal and other chronic conditions. Since its formation, FMCNA has grown into the largest vertically integrated dialysis provider in North America and its employees are dedicated to the mission of delivering superior care that improves the quality of life for people

with kidney disease, including end-stage renal disease ("ESRD"), better known as kidney failure. FMCNA owns, operates or provides administrative services to more than 2300 dialysis clinics in North America. Within the Eastern District of Texas, FMCNA owns, operates, or provides administrative services for 21 in-center dialysis facilities in the cities of Allen, Athens, Carthage, Center, Crockett, Frisco, Gilmer, Jacksonville, Lewisville, Liberty, McKinney, Mineola, Palestine, Paris, Plano, Sulphur Springs and Tyler. Within the Sherman division alone, FMCNA owns, operates, or provides administrative services for 7 in-center dialysis facilities in Allen, McKinney, Paris, Plano, and Sulphur Springs. FMCNA provides dialysis treatment and services to approximately 183,326 patients with ESRD across the country. Of those, approximately 1,649 ESRD patients receive dialysis treatment at FMCNA facilities in the Eastern District of Texas.

14. Defendant United States Department of Health and Human Services ("HHS") is an agency of the United States Government, located at 200 Independence Avenue, S.W., Washington, D.C. 20546. It is the federal agency responsible for, among other things, regulating the Medicare and Medicaid programs. *See* 42 U.S.C. § 1395rr. It is also responsible for regulating the Affordable Care Act's health care exchanges, and the insurance plans offered on those exchanges. 42 U.S.C. § 18041(a)(1)(B).

15. Defendant Sylvia Mathews Burwell is the Secretary of HHS, and is named as a defendant in this action in her official capacity as Secretary.

16. Defendant Centers for Medicare and Medicaid ("CMS") is an agency of the United States Government within HHS, located at 7500 Security Boulevard, Baltimore, MD 21244. It is the agency within HHS responsible for promulgating rules and regulations governing Medicare and Medicaid. *See* 42 CFR § 413.1 (2014).

17. Defendant Andy Slavitt is the Acting Administrator of CMS, and is named as a defendant in this action in his official capacity as Acting Administrator.

FACTUAL ALLEGATIONS

Statutory and Regulatory Provisions Governing Emergency Rulemaking

18. The APA requires an agency seeking to promulgate a substantive rule to do so through notice-and-comment procedures. 5 U.S.C. § 553. The Medicare Act—which was invoked here by HHS—imposes the same requirements. 42 U.S.C. § 1395hh(b)(1). Under those procedures, an agency must "publish[]" a "notice of proposed rulemaking"—also called a NPRM—"in the Federal Register," and the notice must include "the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). An agency must also "give interested persons an opportunity to" submit "written data, views, or arguments." *Id.* § 553(c).

19. After "consideration of the relevant matter presented," the agency publishes a final rule. *Id.* The APA typically requires that a final rule may not be effective until 30 days pass from publication. *Id.* § 553(d). For certain rules, however, a separate statute—the Congressional Review Act—imposes a 60-day delay before a rule may take effect. *See id.* § 801(a)(3).

20. These requirements serve vital purposes, helping to ensure accountability and well-informed and well-reasoned decision-making. *See, e.g., Brown Exp., Inc. v. United States*, 607 F.2d 695, 701 (5th Cir. 1979). Congress intended "the notice and comment provisions" "'to assure fairness and mature consideration of rules of general application.'" *Id.* Notice-and-comment is "especially" important "in the context of health risks" because guaranteeing a role for stakeholder participation "assure[s]" the "dialogue" "necessary" for "reasonable rules." *Nat'l Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 621 (D.C. Cir.

1980). Taken together these provisions ensure that the public's right to know is protected and that the general public, as well as persons potentially impacted by regulations, have an opportunity to be heard before regulations are imposed on them.

21. Congress has provided exceptions to the notice-and-comment requirement, but given the requirement's importance to the rule of law, the exceptions are exceedingly narrow. An agency may dispense with the requirements for "good cause," which exists only when notice-and-comment would be "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B); 42 U.S.C. § 1395hh(b)(2)(C). This "exception" is "read narrowly," however, "to avoid providing agencies with an 'escape clause' from the requirements Congress prescribed." *United States v. Garner*, 767 F.2d 104, 120 (5th Cir. 1985); *Texas v. United States*, 809 F.3d 134, 171 (5th Cir. 2015). Otherwise, the good-cause exception would "carve the heart out of the statute." *Action on Smoking & Health v. CAB*, 713 F.2d 795, 800-801 (D.C. Cir. 1983).

Health Insurance Options Available To End-Stage Renal Disease Patients

22. ESRD is the last stage of chronic kidney disease. At this stage, the kidneys can no longer filter and clean blood. The most common causes of ESRD are diabetes and high blood pressure, although it may also be caused by a variety of other conditions, such as lupus and nephrotic syndrome. A person suffering from ESRD will die within a short period of time if that person does not receive kidney dialysis or a kidney transplant. Dialysis is a process of artificially cleaning the blood and removing excess fluid from it, essentially simulating working kidneys. This is accomplished using specialized equipment in a specialized facility, such as Plaintiff Providers' dialysis facilities, or at home under the periodic care of a renal professional.

23. ESRD patients are some of the most vulnerable people in the country. Many are of extremely limited means, and many are minorities. ESRD is about 3.7 times more prevalent in

African Americans than Caucasians, 1.5 times more prevalent in both Hispanics and Asian Americans than Caucasians, and 1.4 times more prevalent in Native Americans than Caucasians. Furthermore, adjusted for race, kidney disease is two to three times more prevalent in low income individuals than higher income individuals.

24. ESRD patients have a variety of insurance options available to them—from private insurance offered by an employer or purchased individually, to whole or partial public coverage through Medicare, Medicaid and similar programs. The exact options available to a given patient depend on a number of factors, including, but not limited to, state of residence, age, and financial status. ESRD patients have relied on the availability of these options and have made decisions they find in the best interest of their families and themselves.

Medicare

25. Given the vulnerability and limited means of ESRD patients, Congress has long recognized the importance of effective health insurance for this population and has sought to ensure it has meaningful choice of insurance options.

26. Since 1972, certain individuals under the age of 65 suffering from ESRD have been eligible for Medicare. *See* 42 U.S.C. § 426-1(a). To be eligible for Medicare, an ESRD patient is required to (1) possess a certain number of work credits based on the patient's age, earned by working and paying Social Security taxes; and (2) maintain U.S. citizenship. *Id*.

27. Congress has never required these ESRD patients to enroll in Medicare. To the contrary, unlike enrollees *over* age 65, ESRD patients under that age are free to defer enrollment without facing late-enrollment penalties, with certain exceptions. This is a recognition by Congress that for some ESRD patients Medicare may not be the correct option and that ESRD patients who choose a different health insurance option should not be punished with penalties.

28. Medicare coverage for ESRD patients is typically initiated on the first day of the fourth month of a patient's dialysis treatments. During the initial waiting period, patients need alternate coverage to remain insured.

29. ESRD patients electing Medicare coverage have limited access to additional assistance. Due to Medicare's requirement that patients pay 20% coinsurance of treatment costs (among other out-of-pocket costs), Medicare-enrolled ESRD patients are exposed to substantial out-of-pocket expenses. While Medicare patients may enroll in Medi-Gap plans that provide coverage of out-of-pocket expenses, Medi-Gap plans are not available to ESRD patients under age 65 in 23 States.

30. Nor are ESRD patients under 65 typically eligible for Medicare Advantage plans, which combine the coverage of the different parts of Medicare under a single plan, unless they had already enrolled in a Medicare Advantage plan pre-diagnosis.

31. Medicare also does not cover family members, a matter of particular concern to ESRD patients under 65 as they are more likely to have minor children and Medicare-ineligible dependents than older patients.

Medicaid

32. Medicaid is another government-subsidized insurance plan. Eligibility for Medicaid is primarily based on income, not health status or age.

33. Each state's Medicaid program is administered by the individual state, and the states may individually determine the services Medicaid will cover and the applicable Medicaid-provider reimbursement rates. Coverage under Medicaid is typically more circumscribed than Medicare or private insurance.

34. Individuals that are eligible for or enrolled in Medicaid are permitted to enroll in a QHP or individual market plan while retaining Medicaid as secondary coverage. Many eligible individuals thus use Medicaid as secondary insurance, rather than primary insurance, to pick up the costs not covered by Medicare or a private plan.

35. Some types of state Medicaid programs may only cover a single individual, and not his or her family members.

36. In addition, many health-care providers are increasingly refusing to accept new Medicaid patients. Only 67% of primary care providers treat Medicaid patients, and only 44% of those providers accept new Medicaid patients.

Marketplace Insurance Under the Affordable Care Act

37. Although individuals with ESRD are not prohibited from enrolling in private insurance, historically many had difficulty obtaining affordable coverage in the private market because insurers denied coverage on the basis of ESRD as a pre-existing condition.

38. In 2010, Congress passed the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, collectively the Affordable Care Act ("ACA"). In the ACA, Congress deliberately addressed that problem for all Americans suffering from pre-existing medical conditions, including those suffering from ESRD.

39. Because one of the central goals of the ACA was to provide access to private health insurance to individuals with pre-existing health conditions, such as ESRD, the ACA also severely restricts insurers' ability to deny coverage to applicants based on pre-existing conditions and to discriminate on the basis of health status or on certain other prohibited bases. *See, e.g.*, 42 U.S.C. § 300gg-1(a); *id.* § 300gg-4(a); *id.* § 18116(a).

40. The ACA established health insurance "Exchanges" or "Marketplaces" to make available to individuals qualifying health insurance plans, called "QHPs." The ACA authorizes HHS to regulate the Exchanges and QHPs offered on them. *See* 42 U.S.C. § 18041(a)(1)(B). QHPs must afford specified health benefits, and the ACA makes premium and cost-sharing credits available to help individuals and families that meet qualifying income levels to afford the premiums, subject to certain limitations. *See* 45 C.F.R. § 155.340.

41. As a result of the ACA, ESRD patients received broader access to insurance options on the individual healthcare Exchanges and thus increased ability to choose private health care coverage instead of Medicare or Medicaid.

42. This choice was far more than a mere matter of convenience. To the contrary, many patients receive significantly better care through a QHP than through Medicare or Medicaid. QHPs typically offer better integration of medical, prescription, and dental coverage than the government programs.

43. They also cover family members, while Medicare and some state Medicaid plans do not. Additionally, compared with Medicare and Medicaid in most States, QHPs offer far better access to and choice of providers, especially specialists.

44. Moreover, critically, ESRD patients with commercial coverage have better health outcomes, including higher transplant rates, fewer infections, and lower hospitalization rates, than patients with government coverage.

Regulatory Framework for Dialysis Providers

45. As owners of dialysis facilities that are enrolled in the Medicare and Medicaid programs, Provider Plaintiffs and their clinics are subject to rules and regulations promulgated by HHS.

46. Within HHS, CMS has been charged with Medicare-related rulemaking. This includes requirements, known as Conditions for Coverage or CfCs, with which dialysis providers must comply to receive Medicare funds.

47. In 2008, using a notice-and-comment rulemaking process, CMS significantly revised the Conditions for Coverage governing dialysis providers' treatment of ESRD patients. *See Conditions for Coverage for End-Stage Renal Disease Facilities*, 73 Fed. Reg. 20,370, 20,371 (April 15, 2008).

48. These revisions were intended to implement a more patient-centric, outcome-oriented approach to dialysis treatment. *See* 73 Fed. Reg. at 20,371.

49. Among other things, the CfCs establish a series of patient rights and responsibilities. *See* 42 C.F.R. § 494.70. Among other things, the CfCs require providers to ensure that patients are fully informed of treatment options and charges for services not covered under Medicare, and they guarantee patients the right to fully participate in all aspects of care and to receive all information in a way that they can understand. *See id*. The CfCs also require each provider to establish an interdisciplinary team to "develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs." 42 C.F.R. § 494.90.

50. CMS conducts regulation and enforcement activities to ensure that Medicare dialysis facilities comply with the Conditions for Coverage. It also administers a survey and certification program. This program is a joint effort of the federal and state governments. At the federal level, CMS sets the Conditions for Coverage. State survey agencies audit dialysis facilities' compliance with the Conditions for Coverage and investigate complaints made against dialysis providers.

51. With limited exceptions, failure to comply with CfCs results in termination from the Medicare program. 42 C.F.R. § 488.604; 42 U.S.C. § 1395rr(g)(1).

Third-Party Premium Assistance

52. Dialysis treatment is expensive. Each treatment typically lasts about four hours, must be done three times per week, and involves a complex process of removing blood from the body and filtering it through a manufactured membrane called a dialyzer, or artificial kidney, and then returning the filtered blood to the body.

53. The costs would be out of reach for most Americans, requiring some form of insurance to pay the bills. But ESRD patients are particularly vulnerable, as they are sick and they disproportionally have extremely limited means. ESRD also disproportionately affects minorities.

54. In response to this problem, charitable organizations—most notably AKF, through its Health Insurance Premium Program ("HIPP")—have provided premium assistance to eligible ESRD patients since 1997 and direct financial assistance for treatment related needs since 1971.

55. Patients on either a government or a private plan may receive assistance, and grants are offered based on financial need.

56. The majority (more than 60%) of those benefitting from charitable premium assistance use the funds to pay Medicare insurance premiums.

57. Before the enactment of the ACA, premium assistance was vitally important to patients who had pre-existing insurance coverage but lost their jobs due to their illness and needed help continuing to pay premiums to maintain coverage once they became ill.

58. Since the advent of the ACA and the QHPs available on the ACA's health insurance exchanges, premium assistance has allowed more ESRD patients to obtain beneficial private coverage.

59. Thus, charitable assistance has long been and continues to be a critical component of the ESRD treatment framework.

60. Charities helping ESRD patients raise the funds from a variety of sources, including dialysis providers. Dialysis providers have long been committed to providing financial support to AKF's premium assistance program. Provider Plaintiffs all donate to AKF.

61. In 1997, AKF and six unnamed providers obtained from the HHS Office of Inspector General ("OIG") an advisory opinion establishing that, if certain conditions are met, the providers could make contributions to AKF without triggering certain statutory penalties. *See* Advisory Opinion No. 97-1, Office of Inspector General, Dep't of Health and Human Services at 5 (1997). The OIG's Advisory Opinion provides guidance for both charities and providers.

62. Additional guidance followed in 2005 and 2014 that, although made within the pharmaceutical context, suggests that programs that meet the requirements of the OIG's Advisory Opinion are also insulated from liability under the Federal anti-kickback prohibitions, 42 U.S.C. 1320a-7b(b). *See Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31,120 (May 30, 2014); *Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623 (Nov. 22, 2005).

63. In the 2014 Bulletin, the OIG provided notice to all charitable patient assistance programs that had obtained favorable advisory opinions, including AKF, that it was reviewing all previously issued advisory opinions on charitable patient assistance programs. Following the 2014 Bulletin, the OIG modified ten advisory opinions related to charitable patient assistance programs and terminated three others, but did not make any changes to Advisory Opinion 97-1 applicable to AKF.

64. To meet the criteria identified in the Advisory Opinion, a charity like AKF must be a "bona fide," independent, publicly funded, 501(c)(3) organization that awards assistance based on the consistent application of its own independent, financial need-based criteria. *See* Advisory Opinion No. 97-1 at 6.

65. Providers, such as Provider Plaintiffs, must not (among other things) track the money that a given charity pays on behalf of its patients for the purpose of calculating future contributions, earmark contributions for the use of a particular beneficiary or groups of beneficiaries, or consult other providers in determining the amount of its contributions.

66. The Opinion expressly prohibits providers from "disclos[ing] directly or indirectly to individual patients they refer [to AKF] that such members have contributed to AKF to fund the grants." *See id.*at 4.

67. OIG's guidance has provided the framework for the provision of charitable premium assistance to ESRD patients for two decades, and has facilitated support to ESRD patients that has undoubtedly saved many lives.

68. This guidance provided the framework for charitable premium assistance at the time Congress enacted the ACA in 2010.

Recent HHS Actions to Restrict Third-Party Assistance

69. After the enactment of the ACA, insurers increasingly expressed concern with the fact that third-party assistance was enabling seriously ill—and thus expensive-to-insure—patients to acquire private coverage through QHPs. Ex. D ¶ 80.

70. Concerned that insurers facing increased cost might abandon the ACA Exchanges, HHS expressed "significant concerns" in a November 4, 2013 Frequently Asked Question ("FAQ response") about "hospitals, other healthcare providers, and other commercial entities" supporting

QHP premium and cost-sharing obligations, "because it could skew the risk pool and create an unlevel field in the Marketplaces." CMS, *Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces* (Nov. 4, 2013). HHS mentioned no concerns about patient health.

71. As insurers began refusing to accept payment from federal, state, and government-protected programs and grantees, however, HHS revised its position.

72. On February 7, 2014, it issued additional FAQ responses stating that the earlier FAQ response did not apply to premium and cost-sharing payments on behalf of QHP enrollees made by Indian tribes and organizations, or state and federal government programs or grantees, such as the Ryan White HIV/AIDS Program. CMS, *Third Party Payments of Premiums for Qualified Health Plans in the Marketplaces* (Feb. 7, 2014). The additional FAQ responses also stated that the earlier FAQ response did not apply to payments from private, not-for-profit foundations "if they are made on behalf of QHP enrollees who satisfy defined criteria that are based on financial status and do not consider enrollees' health status." *Id*.

73. When insurers continued to refuse payment, HHS published a rule *requiring* insurers offering individual market QHPs to accept premium and cost-sharing payments made on behalf of enrollees by the Ryan White HIV/AIDS Program; Indian tribes, tribal organizations, or urban Indian organizations; and state and federal government programs. *See* 45 C.F.R. § 156.1250. This requirement does not apply to not-for-profit charitable organizations. 79 Fed. Reg. 15,240 (Mar. 19, 2014). The rule was originally promulgated as an interim final rule, relying for good cause on the harm to patients *from insurers' failure to accept* third-party premium assistance. 79 Fed. Reg. at 15,243.

74. The content of the interim final rule was then included in a proposed rule relating to operation of the exchanges. *See Notice of Benefit and Payment Parameters for 2017*, 80 Fed. Reg.

75,488 (Dec. 2, 2015). The notice stated that a number of comments requested that the final regulations require insurers to accept third-party payments from charitable organizations, including those whose eligibility criteria include diagnosis of a particular condition or disease. *Id.* at 75,559.

75. HHS responded that, while it was "considering" whether to "expand the list of entities from whom issuers are required to accept payment," it needed "to carefully review data provided by entities currently making third party premium payments and *data related to the overall risk pool* to better understand the impact of these payments." *Id.* (emphasis added).

76. When HHS published the final rule, *Notice of Benefit and Payment Parameters for 2017*, 81 Fed. Reg. 12,204 (Mar. 8, 2016), it "defer[red] the question of acceptance of third-party payments made by non-profit organizations to future rulemaking." *Id.* at 12,320.

77. Since the issuance of this regulation, certain insurers have continued to reject premium assistance from charities that support ESRD patients, and recent communications from insurers to Provider Plaintiffs strongly suggest that this trend is increasing rapidly.

The Request for Information

78. On August 16, 2016, HHS issued a request for information ("RFI") regarding concerns that providers and others were "offering premium and cost-sharing assistance in order to steer people eligible for or receiving Medicare and/or Medicaid benefits to individual market plans for a provider's financial gain." *Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and Medicaid Benefits to Individual Market Plans*, 81 Fed. Reg. 57,554, 57,556 (Aug. 23, 2016).

79. HHS expressed concern that this practice, if it exists, "not only could raise overall health system costs, but could potentially be harmful to patient care and service coordination

because of changes to provider networks and drug formularies, result in higher out-of-pocket costs for enrollees, and have a negative impact on the individual market single risk pool (or the combined risk pool in states that have chosen to merge their risk pools)." *Id.* at 57,554. Notably, two of these articulated concerns related to patients, while the other two related to systemic concerns—overall costs and risk pools—under the ACA.

80. HHS stated that the RFI was for "information and planning purposes" only. *Id.* at 57,555. It did not propose new rules.

81. The RFI made very clear the true source of HHS's concern: insurers' objections that "steering" patients into private insurance under the ACA (and away from Medicare/Medicaid) was having a negative effect on "the individual market risk pool." *Id.* at 57,557.

82. Statements on social media by Defendant Slavitt confirmed that this was Defendants' central concern. *E.g.*, Andrew Slavitt (@ASlavitt), Twitter (Aug. 18, 2016, 3:12 PM), ("Let me be clear. We have tools to make sure the Marketplace is strong for the long-term and, like today's announcement, will use them."), *available at* https://twitter.com/aslavitt/status/766397270791188480.

83. Although the RFI was not expressly limited to the dialysis industry, CMS issued a letter soliciting responses from dialysis facilities specifically. *See* Sample Letter from Shantanu Agarwal, MD to Medicare-Enrolled Dialysis Facilities, *available at* https://www.cms.gov/about-cms/components/cpi/downloads/rfi-medicare-dialysis.pdf.

84. In addition, Defendant Slavitt posted on social media that CMS "welcome[s] public statements from some kidney & dialysis orgs who do not improperly steer Medicare/caid patients into exchange plans." Andrew Slavitt (@ASlavitt), Twitter (Aug. 20, 2016, 7:07 AM) https://twitter.com/aslavitt/status/767000220546641921.

85. HHS received 829 responses to the RFI. Dozens of ESRD patients wrote personal letters explaining the value of charitable premium assistance and urging HHS to continue to permit the use of charitable premium assistance. Sixteen different patient advocacy organizations and charities, including AKF, explained the critical importance of their programs to patients and the rigorous controls in place to prevent steering and comply with the OIG guidance. Eighteen providers explained the benefits of such payments to patients, while also recognizing that any improper steering should be eliminated. On the other side, fifteen insurance companies responded, urging HHS to end premium assistance. The social workers who responded came out on both sides, some supporting premium assistance and others urging greater transparency to patients.[1]

The Interim Final Rule

86. On November 8, 2016, Donald Trump was elected President, with his Administration to take office on January 20, 2017.

87. Thirty-six days later, on December 14, without notice and comment, and in contradiction to its previously issued guidance, HHS issued the Rule with an effective date of January 13, a week ahead of the start of the new administration.

88. At the same time, HHS sought comment on the requirements of the Interim Final Rule, as well as other potential regulatory changes. *E.g.*, 81 Fed. Reg. at 90,226

89. The Rule amends the CfCs governing dialysis providers' treatment of ESRD patients, to impose on providers disclosure requirements aimed at helping insurance companies drive ESRD patients off QHPs. The requirements are poorly thought-through and ill-defined and

[1] All comments are available at https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=CMS-2016-0145&refD=CMS-2016-0145-0002.

will have immediate negative effects on ESRD patients. HHS has afforded providers just thirty days to come into full compliance.

90. The Rule applies to any provider that "make[s] payments of premiums for individual market health plans (in any amount), whether directly, through a parent organization …, or through another entity." 81 Fed. Reg. at 90,227.

91. The Rule's breadth is staggering. It applies not only to providers who directly support patients' premium payments; not only providers who contribute to organizations "that make[] a financial contribution to another organization[] that is able to use the funds to make payments of premiums for individual market plans"; but, indeed, to any provider "that makes contributions through a third party that in turn contributes to an entity that is able to use the contribution to make third party premium payments." *Id*. at 90,219 n.16.

92. The Rule requires that these providers make certain disclosures to both patients and insurers.

93. With respect to patients, the Rule requires providers (1) to inform patients "of all available health coverage options," including how those options "will affect the patient's access to and costs for" medical services; (2) to inform patients of the availability of third-party premium assistance, including the risks of such assistance; and (3) to inform patients of the provider's contributions to individuals and organizations that "subsidize the individual's enrollment in individual market health plans for individuals on dialysis, including the reimbursements for services rendered that the facility receives as a result of subsidizing such enrollment." 81 Fed. Reg. at 90,228.

94. With respect to insurers, the Rule imposes on such providers disclosure requirements expressly aimed at helping insurance companies drive ESRD patients off QHPs.

Specifically, the Rule requires providers (1) to disclose to insurers "each policy for which a third party payment" is made by an organization supported by provider contributions; (2) to "obtain assurance from the issuer that the issuer will accept such payments for the duration of the plan"; and (3) to "not make payments of premiums" and take "reasonable steps" to ensure that such payments are not made by third parties, if such assurances are not provided. 81 Fed. Reg. at 90,228.

95. In purpose and effect, the Rule's insurer-disclosure obligations will drive ESRD patients to public insurance options or off insurance entirely by enabling insurers to drop coverage of patients receiving premium assistance. Indeed, HHS concedes there is a "significant risk" that insurers will refuse to accept premiums from ESRD patients paid in part through charitable premium assistance when an insurer is informed of that fact, 81 Fed. Reg. at 90,217, yet the Rule compels dialysis providers to make that very information available to insurers.

96. As HHS's discussion of the supposed "benefits" of public coverage makes clear, *id.* at 90,216-90,217, the whole point of this new regulatory regime is to deny disadvantaged patients access to private coverage even when it would benefit them, thereby leaving them with only the support available through government programs, if such support is even available.

97. These disclosure requirements are vague and unworkable. For example, the Rule does not expressly say whether a provider may rely on its current knowledge of patients' use of premium assistance, whether it must actively solicit that information from patients, whether it must attempt to collect this information from organizations to which it donates, or whether it must take other steps to obtain this information. It does not provide guidance on how providers should treat an insurer's failure to respond. And it does not describe what would constitute "reasonable

steps," nor does it explain how a provider is to identify beneficiaries without violating the OIG prohibition on disclosing to patients that the provider "ha[s] contributed to AKF."

98. The disclosure requirements are also arbitrary and capricious. HHS failed to consider relevant factors, such as the advantages of private insurance over public benefits for many individuals, and it failed to conduct an appropriate cost-benefit analysis. HHS also failed to adequately consider reasonable alternatives, including requiring insurers to accept charitable premium assistance. HHS failed to provide a reasoned explanation for its departure from past guidance and precedent regarding charitable premium assistance. Further, HHS did not consider that the Rule is contrary to the congressionally mandated anti-discrimination provisions of the ACA.

99. Instead of providing an opportunity for public stakeholder comment on this significant regulatory change, as HHS was required to do under the APA and the Medicare Act, the agency invoked the emergency good-cause exception by claiming a health-related emergency, and it further cut short the 60-day period required under the Congressional Review Act from publication to effective date, making the Rule effective on January 13, 2017, just 30 days after publication. Worse yet, this short 30-day period straddled the recent holiday season, a time when the public's attention is diverted, and the public is less likely to notice or engage in matters involving the administrative process. Both procedural maneuvers were necessary—and quite obviously intended—to put a new rule into effect before the incoming administration would as a matter of course suspend it as a pending midnight regulation.

100. In justifying its departure from required procedures, HHS relied extensively on assertions made by insurers in response to the RFI, much of it biased and incorrect, suggesting that

patients were being harmed by the use of charitable premium assistance and that charitable premium assistance distorts the Marketplaces.

101. Numerous responses to the RFI provided information that rebutted this information and established that restricting ESRD patients' access to charitable premium assistance would result in substantial harm.

102. Defendants have been presented with Plaintiffs' objections and challenges to the Rule and its underlying issues in a number of ways. Many Plaintiffs made submissions in response to the RFI, contesting the agency's tentative determination that charitable premium support was problematic.

103. Efforts to seek clarification regarding ambiguities in the Rule, or to raise with Defendants the harm that the Rule will cause, have been unsuccessful.

The Effect of the Interim Final Rule on Plaintiffs

104. Although the Rule ostensibly seeks to protect ESRD patients, in many cases it will result in substantial harm to patient health and financial stability. The Rule will provide a green light to insurance carriers to target and deny coverage to ESRD patients, thus causing the very disruptions in coverage that the Rule claims harm consumers. The harm to patients is undeniable. Although the Rule ostensibly seeks to protect ESRD patients, it in fact exposes patients to serious and immediate health risks by forcing a transition to public coverage or off insurance entirely, as demonstrated above.

105. For example, for patients who are compelled to switch to Medicaid, there is a severe shortage of Medicaid providers—especially in rural areas and among specialists—which can jeopardize care for ESRD patients. Only 67% of primary care providers treat Medicaid patients, and only 44% of those providers accept new Medicaid patients. Thus, under the Rule,

patients may not be able to find specialists in the Medicaid network close by, or if they can, there can be unreasonable waits to get an appointment. For dialysis patients, this lost time can have a significant impact on health.

106. There are equally serious access-to-care risks for patients forced onto Medicare. Some ESRD patients do not qualify for Medicare, due to duration-of-work requirements or citizenship requirements, and under the Rule those individuals would lose access to any insurance option in perpetuity. Even a week without dialysis for ESRD patients risks a serious medical setback, possibly death.

107. In addition, Medicare coverage does not extend to family members. If individuals suffering from ESRD lose their access to private family plans, other family members will be forced onto individual plans that the household may be unable to afford—which is also irreparable harm.

108. Patients, whose interests are represented by Plaintiff DPC, will be irreparably harmed by the loss of *choice* of coverage. Patient choice is a cornerstone of the ACA, 42 U.S.C. § 18032, and Congress has long recognized the right of ESRD patients to remain on private insurance for certain periods of time, 42 U.S.C. § 426-1(a). The Rule countermands those congressional judgments by steering patients to public coverage, even when a patient would prefer private coverage.

109. Notably, these harms will fall disproportionately on some of the country's most vulnerable people, contrary to the ACA's intent to protect minorities, individuals with disabilities, and individuals with preexisting health conditions.

110. The Rule will also harm the Provider Plaintiffs in multiple ways.

111. *First*, the Rule likely will lead to dialysis-facility closures. The cost of treating patients covered by public insurance is often more than the reimbursement received from the government for that treatment. Dialysis providers are able to remain in business largely because the reimbursements they receive from private insurers are sufficient to make provision of care to all patients, including those covered by public insurance, financially viable. Because of the Rule, however, many ESRD patients receiving private insurance will switch to public insurance. This will cause at least some of Plaintiff Providers' facilities to become financially unsustainable, leading to facility closures, employee lay-offs, and harm to the patients who will need to travel significant distances to receive treatment.

112. *Second*, the Rule risks catastrophic economic injury resulting from termination from Medicare. Given the complexity, uncertainty, and inconsistency of the Rule as well as the unrealistic timeline for implementation, although Provider Plaintiffs will work hard to comply, there is a significant risk they will be unable to do so. Under the Medicare Act and HHS rules, the default sanction for non-compliance with a CfC is termination from Medicare. 42 U.S.C. § 13955rr(g), 42 C.F.R. § 488.604. Termination from Medicare would be financially ruinous for providers.

113. *Third*, the Rule will cause Provider Plaintiffs to incur significant and substantial compliance costs—which cannot be recovered later from the government. The Rule will compel significant changes to Provider Plaintiffs' operations, and imposes substantial costs, particularly given the compressed thirty-day compliance schedule.

114. *Fourth*, the Rule risks serious reputational injury to Provider Plaintiffs and interference with their business relationships. For one thing, because the Rule applies only to providers who donate to organizations that provide third-party assistance, the Rule may drive

patients to other providers not covered by the Rule, so they can keep their QHP coverage. The Rule also compels providers to disclose private details about how patients are paying for their insurance; thus, patients will lose QHP coverage, and they may blame their provider for this result, damaging Providers' reputations and undermining goodwill. And Provider Plaintiffs will suffer further reputational harm if facilities are terminated for noncompliance with the CfCs imposed by the Rule.

COUNT ONE

(Administrative Procedure Act, 5 U.S.C. §§ 553,706, Medicare Act, 42 U.S.C. § 1395hh(b))

115. Paragraphs 1 through 114 are incorporated by reference as if set forth fully herein.

116. The Interim Final Rule was promulgated without notice and comment and does not qualify for any of the limited exceptions to the notice-and-comment requirement in either 5 U.S.C. § 553(b) or 42 U.S.C. § 1395hh(b). It therefore violates both the APA and the Medicare Act.

117. The APA, 5 U.S.C. § 553, requires that administrative agencies promulgate legislative rules after following a notice-and-comment process. The Medicare Act, 42 U.S.C. § 1395hh(b)(1), contains an explicit notice-and-comment requirement applicable to regulations implementing the Medicare Act's substantive provisions.

118. HHS deliberately did not comply with the notice-and-comment requirement in promulgating the Rule, claiming it had "good cause" to waive the requirement. 81 Fed. Reg. at 90,220; *see* 5 U.S.C. § 553(b)(3)(B) (agency may waive requirement "for good cause" only when compliance would be "impracticable, unnecessary, or contrary to the public interest"); *id.* § 1395hh(b)(2)(C).

119. HHS asserts that good cause exists because notice-and-comment would be "contrary to the public interest," as delay would "harm" patients. 81 Fed. Reg. at 90,221. HHS

identifies "three kinds of harms" that purportedly would arise from the brief delay that would have been required to comply with the notice-and-comment requirement: (1) kidney transplant risks; (2) additional costs of QHP coverage; and (3) mid-year coverage disruptions. *Id.*

120. The three harms from delay identified by HHS do not withstand scrutiny, under fact or law. In fact, the Rule will *create* an emergency by exposing patients to coverage gaps and interrupting the continuity of care—the very concerns that purportedly prompted the Rule. Had HHS abided by its notice-and-comment obligation, these are precisely the issues Plaintiffs and others would have brought to HHS's attention during a rulemaking proceeding.

121. For example, HHS speculates that QHPs supported by premium assistance could interfere with a patient's ability to receive a transplant because ESRD patients may have difficulty demonstrating continued access to care due to loss of premium support after the transplant. But HHS identifies no empirical support for that claim, and it ignores that ESRD patients are permitted to enroll in Medicare and remain on Medicare for 36 months' post-transplant. There is thus no genuine risk that a patient would be unable to show continued access to care. In addition, HHS ignored overwhelming evidence that public options, not private insurance, hamper ESRD patients' access to transplants.

122. In addition, HHS's assertion that QHPs may not be financially beneficial for certain patients does not remotely satisfy the exacting standards for showing good cause and is also entirely unsupported. Substantial evidence, before HHS and otherwise, demonstrates that many patients with QHPs would experience a significant increase in financial costs if they were forced into public coverage. Indeed, HHS admits that for some patients, QHPs are financially beneficial, yet HHS made *no* effort to quantify or otherwise demonstrate whether ESRD patients in the aggregate would financially benefit from being forced into Medicare coverage by the Rule.

123. Finally, HHS's claim that immediate implementation of the Rule is necessary to prevent mid-year coverage disruptions is contradicted by HHS's own findings, and it ignores that the very purpose of the Rule is to force transitions to public insurance options. It was entirely irrational for HHS to enact a Rule to prevent coverage disruptions when the agency knew the Rule would cause those very disruptions.

124. Moreover, RFI responses already before HHS, including individual ESRD patient letters, either contradict the agency's justifications or demonstrate that the Rule will impose harms that the agency failed to address.

125. Even if the Court overlooks the patent defects identified above in HHS's reasoning, the good-cause rationales offered by HHS fail as a matter of law for other reasons. For example, each of HHS's theories of patient harm rests upon anecdotes and sheer speculation, which is insufficient to establish a "crisis" sufficient to bypass notice-and-comment. *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706-707 (D.C. Cir. 2014); *Horsehead Resource Dev. Co., Inc. v. Browner*, 16 F.3d 1246, 1269 (D.C. Cir. 1994) (per curiam).

126. In addition, the "problem" identified by the Rule—even accepted at face value—does not amount to an emergency sufficient to invoke the "public interest" prong of the good-cause exception. *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 94 (D.C. Cir. 2012) ("public interest" prong of the exception is "rare[ly]" satisfied); *Nat'l Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 621 (D.C. Cir. 1980) ("bare need to have regulation" is not good cause).

COUNT TWO

(For violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A))

127. Paragraphs 1 through 114 are incorporated by reference as if set forth fully herein.

128. Although HHS's failure to permit public comment prevents judicial review based on a complete administrative record, the Rule remains subject to review under the APA's "arbitrary [and] capricious" standard. 5 U.S.C. § 706(2)(A); *see, e.g.*, *American Acad. of Pediatrics v. Heckler*, 561 F. Supp. 395, 399 (D.D.C. 1983) (applying arbitrary-and-capricious review to interim HHS rule issued without notice-and-comment).

129. The Rule fails that standard in many respects, including, but not limited to, the following:

130. The Rule failed to consider important aspects of the problem. *See Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2016) ("[R]easonable regulation ordinarily requires paying attention to the advantages *and* disadvantages of agency decisions."). This includes, among other things, HHS's total failure to consider the numerous RFI responses that detailed the benefits of QHPs to ESRD patients, as compared to Medicare and Medicaid, including the lower out-of-pocket costs for many ESRD patients, the greater availability of coverage for treatment and specialists, and the extension of coverage to family members.

131. In addition, HHS ignored the fact that patients are generally happy with their individual market plans, and place great value on the ability to choose. Patient choice is a cornerstone of the ACA, and is an important factor that should have been evaluated. *See* 42 U.S.C. § 18032.

132. HHS also acted arbitrarily and capriciously by adopting a Rule that is premised upon and facilitates the ability of insurers to engage in unlawful steering of patients off of QHPs.

133. The purpose of the Rule is to drive ESRD patients to public coverage by singling out ESRD patients as a single category, for which providers must make disclosures to insurers,

enabling insurers to drop coverage. That was not reasoned decision-making because the insurer-steering enabled by the Rule will itself violate the law in multiple ways.

134. For example, the Rule invites unlawful discrimination. Insurers who drop coverage of ESRD patients in the wake of the Rule will do so in violation of these non-discrimination requirements—an issue that was put before the agency in RFI responses, but to which HHS did not respond.

135. Specifically, Section 1557 of the ACA provides that "an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 . . . or Section 504 of the Rehabilitation Act of 1973 … be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." *See* 42 U.S.C. § 18116; *see also* 45 C.F.R. § 92.101.

136. Insurers offering QHPs must comply with this provision. HHS regulations define "health program or activity" to include "health-related insurance coverage." 45 C.F.R. § 92.4. "Federal financial assistance" is defined broadly to include "any grant, loan, credit, subsidy, contract (other than a procurement contract but including a contract of insurance), or any other arrangement by which the Federal government provides or otherwise makes available assistance." *Id.* This includes "all tax credits under Title I of the ACA, as well as payments, subsidies, or other funds extended by the Department to *any entity providing health-related insurance coverage* for payment to or on behalf of an individual obtaining health-related insurance coverage from that entity or extended by the Department directly to such individual for payment to any entity providing health-related insurance coverage." *Id.* (emphasis added), *see also* Dep't of Health and Human Servs., *Nondiscrimination in Health Programs and Activities*, 81 Fed. Reg. 31,376, 31,445 (May 18, 2016). This coverage applies broadly, and is not just limited to the specific program for

which the activity receives federal financial assistance. *See* 81 Fed. Reg. at 31,385-86 (rejecting comments that urged that approach).

137. By refusing to accept charitable assistance from ESRD patients for QHP premiums, insurers violate that non-discrimination mandate on at least two prohibited bases—disability and race. ESRD is a disability protected under the statute. Disability is defined in the ACA by reference to the Rehabilitation Act, which incorporates the definition of "disability" in the Americans with Disabilities Act. *See* 45 C.F.R. § 92.4. ESRD is a "disability" under that statute. *See Heiko v. Colombo Sav. Bank, F.S.B.*, 434 F.3d 249, 258 (4th Cir. 2006); *Fiscus v. Wal-Mart Stores, Inc.*, 385 F.3d 378, 382 (3d Cir. 2004).

138. By refusing to accept third-party premium assistance, insurers intentionally discriminate against ESRD patients. The entire point of refusing to accept third-party charitable assistance is to keep costly patients, and especially costly patients with ESRD, from purchasing health insurance from private insurers. This is exactly the sort of discrimination on the basis of disability that Section 1557 is meant to prohibit—singling out persons with a disability, and specifically low-income persons with that disability—from participation in the insurer's health program. *See Delano-Pyle v. Victoria Cnty., TX*, 302 F.3d 567, 570-571 (5th Cir. 2002).

139. In addition, even if refusal to accept third-party charitable assistance was a neutral policy without discriminatory intent, the Rule will create a disparate impact on ESRD patients. *E.g.*, 81 Fed. Reg. 31,376, 31,440 (May 18, 2016) (stating that HHS "interprets Section 1557 as authorizing a private right of action for claims of disparate impact discrimination on the basis of *any* of the criteria enumerated in the legislation") (emphasis added). By channeling requests for assurance to insurers, who are likely to refuse to provide such assurance, the effect of the rule will

be to limit coverage to the disabled and the significant minority populations that suffer from ESRD.

140. The Rule facilitates the violation of other provisions of the ACA as well. For example, multiple parts of the ACA prohibit insurers from setting rules for eligibility based on discriminatory factors. *See* 42 U.S.C. §§ 300gg-4(a), 18031(c)(1)(A), 18022(b)(4)(D). The Rule violates these prohibitions by facilitating insurers' ability to deem patients receiving third-party charitable assistance ineligible for coverage.

141. HHS also violated principles of reasoned decision-making in issuing the Rule because it failed to acknowledge, much less justify, its departure from prior guidance and precedent. *See FCC v. Fox Television Stations*, 556 U.S. 502, 515 (2009). HHS violated those principles here by abruptly departing from a settled approach to charitable support that has governed for almost two decades, without acknowledging that change in its position, much less justifying why it was required to be done on an emergency basis on the eve of a change of administrations.

142. The 1997 OIG Advisory Opinion allows AKF to operate HIPP while permitting providers to join the thousands of donors supporting AKF and other charities. The opinion set forth specific guidelines expressly aimed at ensuring that donors would be walled from HIPP's operations and preventing undue influence or patient steering in selecting a provider. *See* Advisory Opinion No. 97-1. The guidance has successfully governed charitable giving in this context for almost two decades.

143. The Rule abruptly breaks from that longstanding precedent by permitting and encouraging insurers to *reject* charitable assistance that fully complies with OIG guidance. Indeed, in the wake of the Rule, insurers are doing just that.

144. The Rule also conflicts with OIG guidance in other ways. For example, it forces providers to make disclosures to insurers and patients that conflict with the OIG-imposed safeguards.

145. This direct conflict should have at least been addressed by HHS, with an acknowledgement and explanation as to why the agency was changing course.

146. Yet, HHS fails to display any "awareness" that it was "changing [its] position" from its longstanding guidance, requiring vacatur of the Rule. *Fox Television Stations*, 556 U.S. at 515.

147. The Rule is also arbitrary and capricious because it contains vague and unworkable requirements. For example, the Rule fails to define critical terms, such as what constitutes "reasonable steps" for providers to take in preventing third-party charities from providing premium assistance to the providers' patients; does not say whether a provider may rely on its current knowledge of patients' use of premium assistance, or whether it must actively solicit that information from patients; and it does not provide guidance on how providers should treat an insurer's failure to respond. It also does not explain how providers can meet the Rules' requirements without taking actions in conflict with the OIG safeguards.

148. HHS also failed to meaningfully consider reasonable alternatives, including requiring insurers to accept charitable premium assistance.

149. For these and other reasons, the disclosure requirements set forth in the Rule are arbitrary, capricious, and not in accordance with law, in violation of 5 U.S.C. § 706(2)(A).

PRAYER FOR RELIEF

150. WHEREFORE, Plaintiffs pray that the Court grant the following relief:

a. Declare that the Interim Final Rule violates the Administrative Procedure Act and the Medicare Act because it was unlawfully promulgated without notice and comment;

b. Declare that the Interim Final Rule violates the Administrative Procedure Act because the disclosure requirements set forth therein are arbitrary, capricious, and contrary to law;

c. Declare that the Interim Final Rule violates the Administrative Procedure Act because the disclosure requirements set forth therein are contrary to the anti-discrimination provisions of the Affordable Care Act;

d. Enjoin Defendants from administering or enforcing the Interim Final Rule;

e. Award Plaintiffs their costs and reasonable attorney's fees in connection with this action, pursuant to 28 U.S.C. § 2412 and other applicable authority; and

f. Grant such other relief as the Court deems necessary, just, and proper.

Dated: January 6, 2017

Respectfully submitted,

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I hereby certify that the foregoing Complaint has been served by certified mail on the following, this 6th day of January, 2017:

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