

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

DIALYSIS PATIENT CITIZENS )  
1001 Connecticut Avenue, N.W. )  
Suite #1230 )  
Washington, D.C. 20036 )

*Plaintiff,* )

v. )

ALEX AZAR, Secretary, United States )  
Department of Health and Human Services )  
Hubert H. Humphrey Building )  
200 Independence Avenue, S.W. )  
Washington, D.C. 20201 )

UNITED STATES DEPARTMENT OF )  
HEALTH AND HUMAN SERVICES )  
Hubert H. Humphrey Building )  
200 Independence Avenue, S.W. )  
Washington, D.C. 20201 )

SEEMA VERMA, Administrator, Centers for )  
Medicare and Medicaid Services )  
7500 Security Boulevard )  
Baltimore, MD 21244 )

and )

CENTERS FOR MEDICARE AND )  
MEDICAID SERVICES )  
7500 Security Boulevard )  
Baltimore, MD 21244 )

*Defendants.* )

**COMPLAINT**

1. Plaintiff Dialysis Patient Citizens (“DPC” or “Plaintiff”) hereby brings this action to protect the lives of hundreds of thousands of End Stage Renal Disease (“ESRD”) patients who are being severely and irreparably injured by a Final Rule in direct contravention of the intent of Congress and in a manner that is legally impermissible as set forth herein.

2. Despite Congressional intent to mandate that ESRD patients receive necessary protections for their health needs under the Medicare managed care program called Medicare Advantage (“MA”), on May 22, 2020, the Centers for Medicare and Medicaid Services (“CMS”) issued a rule that permits MA insurance plans to drop outpatient dialysis facilities from their networks, creating substantial burdens for thousands of ESRD patients.

3. The Final Rule largely codifies longstanding regulatory “network adequacy” requirements designed to ensure that every Medicare Advantage plan maintains a network that provides reasonable, prompt, and adequate patient access to key types of healthcare services. Those requirements include “time-and-distance” standards that measure the time and distance it takes patients to access certain specified types of healthcare facilities. Since the 2011 contract year, CMS has published in guidance the time-and-distance requirements and the list of facilities to which they apply. Throughout that time, outpatient dialysis has always been included on the list, year in and year out. The Final Rule, however, drops outpatient dialysis from the list, allowing MA plans to avoid complying with the time-and-distance standards for dialysis facilities.

4. The Final Rule causes immediate and irreparable harm to patients who are among the most vulnerable in society: ESRD patients who require regular routine dialysis treatments to survive. Because ESRD patients must receive dialysis at least three times a week to stay alive, and most cannot exclusively dialyze at home, having access to dialysis facilities within a reasonable distance from home is crucial.

5. In issuing the Final Rule that is challenged here, CMS impermissibly ignored comments and evidence presented to it and moved forward with treating ESRD patients differently from other similarly situated individuals in a manner that is both arbitrary and capricious and directly contrary to Congressional intent. Indeed, the Final Rule retains and codifies the time-and-

distance requirements for all of the forty other providers and facilities that were subject to those requirements prior to the issuance of the Rule; only outpatient dialysis has been removed.

6. The Final Rule discriminates against ESRD patients, forecloses additional options that Congress intended to make available in order for ESRD patients to obtain the care they need, and seeks to alter the patterns by which ESRD patients most effectively dialyze—contrary to the evidence provided by patient groups during rulemaking.

7. There are two categories of ESRD patients who will suffer harm as a result of the Final Rule: (1) ESRD patients who are already enrolled in an MA plan and receive dialysis treatment at a clinic that their insurer will likely drop from the network once the time and distance requirements no longer apply, thereby risking the patients' access to dialysis treatment if they stay in the MA program; and (2) ESRD patients who for the first time have the opportunity to enroll in an MA plan as Congress intended but who will be unable to do so because there will no longer be MA plans that adequately cover their outpatient dialysis treatment needs. The Final Rule forces ESRD patients to either remain insured under their original fee-for-service Medicare benefit (sometimes referred to as "Original Medicare"), make costly changes in their insurance coverage if already enrolled in an MA plan with inadequate access to outpatient dialysis, and/or shift to a new modality of care that is contrary to what doctors and patients have decided together is the best course of care in order to continue with their life-saving dialysis treatment.

#### **PARTIES**

8. 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 approximately 28,000 total members. Approximately 48% of DPC's members require

in-center dialysis. By removing outpatient dialysis facilities from the categories of health care providers subject to MA time-and-distance standards—thus removing a protection designed to ensure that ESRD patients receive care close to home—these DPC members will be directly impacted by the Final Rule and face immediate discrimination because of it.

9. Defendant U.S. 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.

10. Defendant Alex Azar is the Secretary of HHS and is named as a defendant in this action in his official capacity as Secretary.

11. Defendant 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).

12. Defendant Seema Verma is the Administrator of CMS and is named as a defendant in this action in her official capacity as Administrator.

#### **JURISDICTION AND VENUE**

13. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1361, 2201-2202, and the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 701-706.

14. Venue is proper in this Court under 28 U.S.C. § 1391(e), because DPC is headquartered in this District, many of its members are residents of the District of Columbia, Defendants also reside in this District, and a substantial part of the events or omissions giving rise to the claims occurred in this District.

## **FACTUAL ALLEGATIONS AND REGULATORY SCHEME**

### **A. End Stage Renal Disease**

15. ESRD is the final stage of chronic kidney disease, when 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 he or she does not receive ongoing kidney dialysis or a kidney transplant. According to the United States Renal Data System, there were more than 800,000 ESRD patients in the U.S. in 2017.<sup>1</sup> The total prevalence of ESRD in the United States has been rising by about 20,000 to 25,000 cases per year since 2007 and is projected to increase by another 29% to 68% from 2015 to 2030.<sup>2</sup>

16. 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 hospital unit or outpatient facility, such as outpatient dialysis facilities, or at home under the periodic care of a renal professional.

17. Each dialysis treatment typically lasts about four hours, must be done at least 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, before returning the filtered blood to the body.

18. There are two forms of dialysis: hemodialysis and peritoneal dialysis. In hemodialysis, a patient's blood is pumped out of the body into an artificial kidney machine before being returned to the body. Hemodialysis requires the assistance of a care partner, especially if

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<sup>1</sup> U.S. Renal Data System. 2019 Annual Data Report Reference Tables.

<sup>2</sup> Keith P. McCullough, et. al., *Projecting ESRD Incidence and Prevalence in the United States through 2030*, 30 J. Am. Soc. Nephrology 127 (2019), <https://doi.org/10.1681/ASN.2018050531>.

the patient has secondary symptoms such as tremors. Hemodialysis can be done at home or in a clinic. However, because of the requirement for a care partner, the majority of home dialysis patients rely on peritoneal dialysis. Moreover, the vast majority of hemodialysis patients receive dialysis in outpatient dialysis facilities, rather than at home. According to the U.S. Renal Data System, about 90% of ESRD patients receive hemodialysis, while the other 10% receive peritoneal dialysis.

19. In peritoneal dialysis, a plastic tube or catheter is surgically placed in the patient's abdomen so that sterile cleansing fluid can be washed in and out of the abdomen in cycles. This procedure uses the abdomen as a natural filter to complete the exchange. Peritoneal dialysis is not appropriate for everyone, particularly the obese or those with prior abdominal surgeries. Moreover, there is a risk of abdominal infection without appropriate precautions, and peritoneum muscles may wear out and require a change in treatment type. Finally, patients must receive training and be able to perform each step of the treatment unless a trained helper is used.

20. Most ESRD patients in the United States—over 90%—receive dialysis at an outpatient clinic.<sup>3</sup> While the Administration has called for more patients to choose home dialysis for their care, home dialysis is still not a viable medical option for many and, even for home patients, an outpatient center is a necessary part of treatment. For example, some patients might require in-center catheterization, or they may have other health factors that prevent them from being able to perform dialysis on themselves. Moreover, home hemodialysis and some peritoneal dialysis patients require the aid of a care partner to help perform dialysis, and not everyone has that support at home. Peritoneal dialysis additionally can only be administered in locations meeting

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<sup>3</sup> See Christopher T. Chan et al., *Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference Outcomes Report*, 73 *Am. J. Kidney Diseases* 363, 363 (2019).

certain space and cleanliness requirements, which not every home environment meets. Furthermore, even patients who dialyze at home must go to outpatient dialysis facilities for training, for regular clinical visits every month, and, in the case of hemodialysis patients, when their care partners are away. Over two-thirds of patients on home dialysis have used in-center dialysis at some point; over half began on in-center dialysis before transitioning to home dialysis. Therefore, all ESRD patients are required to travel to outpatient dialysis facilities.

21. Many patients lack the social or economic resources needed to support home dialysis. For this reason, in part, home dialysis patients are disproportionately white and affluent, while in-center dialysis patients are disproportionately black or Hispanic and more likely to live in poorer areas.<sup>4</sup> These lower-income ESRD patients are more likely to face barriers to home dialysis, such as lack of caregiver support, lack of stable housing, and lack of a home environment that is able to store necessary supplies and equipment.

22. 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. The disease exacerbates patients' vulnerability because dialysis is very expensive, and the length and frequency of treatment commonly impedes continued employment.

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<sup>4</sup> Jenny L. Shen, et al., *Socioeconomic Factors and Racial and Ethnic Differences in the Initiation of Home Dialysis*, 2 *Kidney Medicine* 105 (March-April 2020).

23. For those ESRD patients who do not have cars and must rely on family members and friends or public transportation to take them to outpatient dialysis facilities, travel times to outpatient dialysis facilities are especially important. Studies (including some submitted to the agency in the rulemaking here) demonstrate that patients who must travel longer distances to their dialysis clinics suffer from higher death rates and worse overall health. For example, a study in the American Journal of Kidney Diseases found that “[l]onger travel time is associated significantly with greater mortality risk and decreased” “health-related quality of life.” Based on those findings, the authors concluded that “[e]xploring opportunities to decrease travel time should be incorporated into the dialysis clinical routine.”<sup>5</sup>

24. Even a single missed appointment can be catastrophic for an ESRD patient. Dialysis patients who miss treatments—for example, because their dialysis clinic is far away—have worse health outcomes, more hospital trips, and higher death rates than those who do not. Another study in the American Journal of Kidney Diseases found that “missed treatments were positively associated with all-cause mortality, cardiovascular mortality, sudden death/cardiac arrest, hospitalization, ... higher kidney disease burden, and worse general and mental health.”<sup>6</sup> For that reason, researchers have concluded that “[a]ddressing systemic and patient barriers that impede access to hemodialysis care may ... reduce patient morbidity.”<sup>7</sup>

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<sup>5</sup> See Louise M. Moist, et al., *Travel time to dialysis as a predictor of health-related quality of life, adherence, and mortality: The Dialysis Outcomes and Practice Patterns Study (DOPPS)*, 51(4) Am. J. Kidney Diseases 641 (Apr. 2008).

<sup>6</sup> See Issa Al Salmi, et al., *Missed Hemodialysis Treatments: International Variation, Predictors, and Outcomes in the Dialysis Outcomes and Practice Patterns Study (DOPPS)*, 72(5) Am. J. Kidney Diseases 634 (Nov. 2018).

<sup>7</sup> Kevin E. Chan, et al., *Adherence barriers to chronic dialysis in the US*, 25 J. Am. Soc’y Nephrology 2642 (2014).



**B. Medicare Advantage and the Cures Act**

25. Because dialysis is expensive, most ESRD patients could not afford this life-saving treatment without access to insurance. Recognizing that fact, Congress has taken repeated steps to ensure ESRD patient access to and choice in health insurance.

26. For example, in 1972, Congress amended Medicare to extend insurance to the permanently disabled, regardless of age—and for the first time explicitly included a specific disease, namely ESRD. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, tit. II, § 299I, 86 Stat. 1463 (codified as amended at 42 U.S.C. § 426-1(a)). In doing so, Congress sought to create “a national program of kidney disease treatment assistance” to ensure Americans would not “die ... from kidney disease who could have been saved if they had been able to afford [dialysis].” S. Rep. No. 92-1230, at 1243-1244 (1972) (statement of Sen. Hartke). Today, ESRD is one of only two diseases that generally makes a person eligible for all benefits available under Medicare regardless of age. *See* 42 U.S.C. § 426-1(a).

27. Decades after Congress created a statutory entitlement giving ESRD patients the option to enroll in Medicare, Congress created “Medicare Advantage”—also referred to as Medicare Part C. But Congress did not initially make MA available to patients already suffering from ESRD.

28. MA is an “all-in-one” alternative to Original Medicare, in which plans are offered by private insurance companies approved by CMS. The plans must offer coverage equivalent to Original Medicare, although they typically offer greater coverage. For example, MA plans cover hospital and medical benefits and often also include prescription drug coverage, as well as some services not covered by Medicare, such as vision, hearing, and dental. Many MA plans offer integrated managed care models that have been shown to be valuable tools for patients that suffer

from multiple chronic conditions. MA plans also tend to have lower out-of-pocket costs. Unlike Original Medicare, MA plans must establish an out-of-pocket maximum for in-network services; currently that limit is \$6,700 per year. *See* 42 C.F.R. § 422.100(f)(4). While some Original Medicare beneficiaries can obtain supplemental private insurance policies (Medigap) to cover these out-of-pocket costs (when available in a State), these plans tend to be very expensive, and may be able to charge higher premiums based on age or health status. Given the wider coverage and lower costs, MA plans are considered beneficial to many.

29. Although ESRD patients were generally prohibited for years from enrolling in MA plans, *see* 42 U.S.C. § 1395w-21(a)(3)(B) (prior version, Dec. 12, 2016), some ESRD patients were able to enroll under limited circumstances—*e.g.*, when an individual develops ESRD while already enrolled in an MA plan or when a special needs plan opted to enroll individuals with ESRD. 42 U.S.C. § 1395w-21(a)(3)(B) (2015); 42 C.F.R. § 422.50(a)(2) (2019); *see also* 70 Fed. Reg. 4588, 4717-4718 (January 28, 2005) (adding special needs plan exception). This means certain ESRD patients were able to enroll in or maintain MA plans, but most were not.

30. Recognizing the benefits to ESRD patients of participating in MA, in 2016, Congress enacted the 21st Century Cures Act (“Cures Act”), which expressly repealed the prohibition on ESRD patient enrollment in MA plans. *See* § 17006, Pub. L. 114-255, 130 Stat. 1033, 1334-1336 (Dec. 13, 2016). In doing so, Congress observed the now-repealed prohibition was “unfair” to ESRD patients. *See* House Ways and Means Committee Report (No. 114-751) at 3.

31. When passing the Cures Act, Congress recognized that “MA offers better coordinated and integrated care, flexibility, and financial protections for beneficiaries, but ESRD

patients are the only group of beneficiaries specifically denied enrollment in MA plans.” H. Rpt. 114-751, at 2-4 (2016).

**C. Network Adequacy and Time-and-Distance Requirements**

32. Under the applicable regulatory regime, MA plans can choose which providers may join their networks, subject to certain restrictions and minimum requirements imposed by CMS. For example, MA plans must attest each year that they have enough providers that are geographically dispersed to ensure beneficiary access to care remains available “with reasonable promptness and in a manner which assures continuity in the provision of benefits.” SSA § 1852(d)(1)(A), 42 U.S.C. 1395w-22 § (d)(1)(A).

33. In order to provide more concrete specifications for MA plans to meet these access requirements and to obtain CMS approval for each plan, CMS implemented “network adequacy requirements.” *See* 42 C.F.R. § 422.112(a)(1)(i).

34. A primary component of these network adequacy requirements are “time and distance” standards, which indicate the maximum number of minutes or miles away an in-network specialty provider or facility may be located from plan enrollees.

35. To meet these time-and-distance standards, MA plans must submit provider network information to CMS for approval, showing that at least 90% of the enrollees in their service area have access to a sufficient number of providers and facilities of certain specialty types within the published time-and-distance standards. Medicare Advantage and Section 1876 Cost Plan Network Adequacy Guidance (<https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance-pdf.pdf>) (last updated Feb. 20, 2018).

36. Prior to the 2011 contract year, CMS evaluated network adequacy based on a “rough benchmark” that providers should be located roughly within 30 minutes or 30 miles of plan

enrollees. 74 Fed. Reg. 54634-01, 54644-54645 (Oct. 22, 2009). But in advance of the 2011 contract year, CMS decided “this standard is not sufficiently nuanced to stand on its own, and does not fully address [CMS’s] needs.” 75 Fed. Reg. 19678, 19692 (Apr. 15, 2010). Thus, CMS created a system to review and approve MA plans based on published time-and-distance standards, varying by geography and region. *Id.* at 19691. In doing so, CMS sought to “make the standard of community patterns of care more transparent and consistent across the country.” *Id.*

37. CMS has recognized, for example, that prior to the 2011 plan cycle, network adequacy was assessed through a “largely manual process” that “lacked concise and standardized definitions of an ‘appropriate’ and ‘adequate’ network.” CMS, *Contract Year 2012 Medicare Advantage Health Delivery Guidance* at 1.<sup>8</sup> And CMS has explained that time-and-distance protections ensure that networks “do not unduly burden beneficiaries in terms of travel time and distance to network providers/facilities,” reflecting the reality that time-and-distance protections are important benefit for MA enrollees. CMS, *Medicare Advantage and Section 1876 Cost Plan Network Agency Guidance* at 10 (Feb. 2018) (emphasis added).<sup>9</sup>

38. The purpose of quantitative protections was to remedy the network adequacy problems that had arisen before CMS began to use a more rigorous approach. As the Government Accountability Office (“GAO”) has explained, the changes beginning in 2011 were “designed to be more objective and defensible.” GAO, *Medicare Advantage: Actions Needed to Enhance CMS Oversight of Provider Network Adequacy*, at 9 (Aug. 2015). GAO explained that “[h]ealth care researchers have noted that network adequacy criteria measured by provider type and geographic

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<sup>8</sup> <https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/downloads/HSDGuidanceCY2012122110.pdf>.

<sup>9</sup> <https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance-pdf>.

designation serve to protect beneficiary access while preserving [Medicare Advantage Organization (“MAO”)] flexibility in provider network design. Furthermore, some researchers have pointed out that quantitative standards derived from sound research provide clarity and certainty, and level the playing field among insurers.” *Id.* at 11 n. 30 (collecting studies). The approach CMS used before the 2011 contract year involved “ambiguous” criteria that “did not allow for more objective and consistent application.” *Id.* at 11-12.

39. Since the 2011 contract year, and even before, outpatient dialysis facilities were among the specialties subject to time-and-distance standards. CMS has since stated that the specialties it identifies as needing to meet time-and-distance standards are those “critical to providing services,” based in part on “the clinical needs of Medicare beneficiaries.” 85 Fed. Reg. 33796, 33853. Not all service or facility types are subject to time-and-distance standards. For example, durable medical equipment (“DME”), home health, and transplant services were historically subject only to a “minimum number” requirement and, as of 2018, have been subject to no quantitative standards at all. However, each of these specialties is incomparable to outpatient dialysis. Organ transplants are significant events that usually occur only once; home health services occur at home where the provider travels to the patient; and DME suppliers deliver equipment such as wheelchairs or walkers to a patient’s home.

40. Travel times are not a barrier to optimal patient health for these exceptions, because the treatment itself is isolated by nature. Dialysis patients, by contrast, must return to treatment three times per week across extended periods of time—making time-and-distance requirements an essential consideration. Moreover, CMS has not excluded other provider and facility types from time-and-distance standards that furnish care comparable to that of outpatient dialysis facilities.

For example, specialties that treat heart disease and cancer, which—like ESRD—require frequent outpatient or ambulatory care, remain subject to time-and-distance standards.

41. As such, lengthy travel times for outpatient dialysis can be severely detrimental to ESRD patient health and create substantial burdens for patients who must travel to dialysis three times a week for the rest of that patient’s life, unless he or she receives a kidney transplant.

**D. President Trump’s Executive Order Regarding Home Dialysis**

42. On July 10, 2019, the Trump Administration issued the Executive Order on Advancing American Kidney Health with a stated purpose of promoting home dialysis for the treatment of kidney disease.

43. The Executive Order stated that “current treatment options are expensive and do not produce an acceptable quality of life.”

44. The Executive Order instructs the HHS Secretary to create payment incentives to increase the use of home dialysis, asserting that “[g]reater rates of home dialysis and transplantation will improve quality of life and care for patients who require dialysis” but provides no instruction to loosen or eliminate time-and-distance standards under network adequacy requirements for facilities performing dialysis outside of the home.

45. Also on July 10, 2019, HHS published its vision for advancing kidney health, including a goal to have 80% of new ESRD patients in 2025 either receiving dialysis at home or receiving a transplant. “Advancing American Kidney Health,” HHS, available at <https://aspe.hhs.gov/system/files/pdf/262046/AdvancingAmericanKidneyHealth.pdf>.

46. Underlying the “Advancing American Kidney Health” initiative driving home dialysis is the desire to save money notwithstanding the burden it imposes on and danger it presents to some dialysis patients. The HHS report noted that “[t]oday’s status quo in kidney care also

carries a tremendous financial cost,” with “more than one in five dollars spent [on ESRD patients] by the traditional Medicare program.” *Id.* at 3.

47. The HHS initiative proposed providing financial incentives to dialysis facilities to promote home dialysis but did not reference any intention to alter time-and-distance standards under MA network adequacy requirements that benefit ESRD patients.

**E. Contract Year 2021 Medicare Advantage and Part D Final Rule**

48. On February 18, 2020, CMS issued a proposed rule, which, among other things, would amend the agency’s regulations in response to the Cures Act’s expansion of MA to permit new enrollment by ESRD patients (“Proposed Rule”). 85 Fed. Reg. 9002, 9073.

49. CMS also sought to codify its network adequacy requirements by regulation, including in a new provision found at 42 C.F.R. § 422.116, which listed provider types subject to time-and-distance requirements. *See* 85 Fed. Reg. 9002, 9092. Outpatient dialysis facilities *were* initially included in that list in the Proposed Rule—depending on the density of county, the Proposed Rule would impose a maximum travel time ranging from 20 minutes to 100 minutes, and a maximum travel distance ranging from 10 miles to 90 miles for outpatient dialysis facilities. *Id.* at 9096. Indeed, the proposed rule stated that it was merely codifying “the list of provider and facility specialty types that have been subject to CMS network adequacy standards in the past.” *See id.* at 9093. The only question posed in the Proposed Rule was whether outpatient dialysis facilities should be broadly defined to also include in-patient hospital dialysis. *Id.* at 9093. Only later in the Proposed Rule did CMS add one sentence soliciting comment on removing outpatient dialysis from the list of facility types that must meet time-and-distance standards. *Id.* at 9099.

50. On March 10, 2020, in response to the Proposed Rule, DPC submitted a comment to CMS “vigorously” opposing loosening network adequacy standards by removing outpatient dialysis facilities from the list of specialties required to meet time-and-distance standards. DPC

explained that placing an emphasis on home dialysis at the expense of in-center dialysis fails to satisfy network adequacy requirements and has a discriminatory impact on enrollees. DPC emphasized that home-dialysis patients are disproportionately white and affluent, while in-center dialysis patients are disproportionately black or Hispanic and are more likely to live in an economically disadvantaged zip code, be unemployed, and be uninsured or on Medicaid. Removing outpatient dialysis facilities from MA time-and-distance standards would serve only to unnecessarily further burden those enrollees who are already impacted by social determinants of health. DPC told CMS it is “completely unrealistic” to expect home treatment alone to suffice when it is simply not a viable option for many patients, and that removing time-and-distance standards for outpatient dialysis facilities lacks a nexus to patient access-to-care needs.

51. On April 3, 2020, the Medicare Payment Advisory Commission (“MedPAC”), an independent, non-partisan, legislative branch agency that provides Congress with analysis and policy advice on the Medicare program, submitted a comment to CMS in connection with the Proposed Rule, responding, in part, to MA network adequacy. MedPAC “strongly oppose[d] the proposals to eliminate or alter time and distance standards for dialysis facilities,” and its comment supported and furthered points made by DPC’s own comment.

52. MedPAC acknowledged that network adequacy is “critical for ensuring access to MA plan options at a level that is equal to the level of access for other Medicare beneficiaries.” Indeed, MedPAC questioned whether CMS had even identified a specific concern or goal it was trying to achieve by removing time-and-distance standards for outpatient dialysis, because although ESRD patient enrollment in MA should increase in 2021 due to the elimination of the prior restrictions on such enrollment, time-and-distance standards are based on beneficiary and facility locations and are unaffected by the actual number of MA enrollees. In addition, even if



CMS is concerned about an MA plan's limited ability to negotiate payment rates in a concentrated dialysis facility market, MedPAC explained that "relaxing network adequacy requirements should not be the remedy."

53. MedPAC explained that the "vast majority of all ESRD beneficiaries receive treatment in a dialysis facility," not at home. MedPAC explained that many patients are not clinically suited for home dialysis or cannot conduct home dialysis for other reasons, and that home dialysis patients often need to visit a facility before starting or while on home dialysis, such that home dialysis could not replace in-center dialysis for all patients. For these reasons, MedPAC rejected CMS's suggestion that home dialysis is a substitute for in-center dialysis for all ESRD patients. MedPAC Comments at 17.

54. In support, MedPAC cited studies showing that "increased travel time to a facility increases missed treatments and is associated with worse outcomes for patients. Specifically, a longer travel time to the dialysis facility creates a substantial burden for many patients and has been linked to decreased adherence by patients to the dialysis prescription (i.e., more missed treatments) and increasing mortality." MedPAC Comments at 16.<sup>10</sup>

55. MedPAC also explained that, contrary to CMS's suggestion in the Proposed Rule, allowing MA plans simply to attest to having an adequate network of dialysis facilities would be insufficient because, without time-and-distance standards, plans would be able to discourage ESRD patients from enrolling in the first place. A plan that contracts with no outpatient dialysis facilities likely would attract no or very few ESRD enrollees, such that it could truthfully attest that its network was adequate to meet the needs of its current enrollees while simultaneously failing to provide an adequate network of dialysis care. MedPAC Comments at 17.

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<sup>10</sup> See Salmi, *supra* n. 6, at 634–643; Moist, *supra* n.5, at 641–650.

56. On May 22, 2020, CMS published its Final Rule on the Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program (“Final Rule”).

57. In the Final Rule, CMS adopted the opposite of the rule that it had proposed. While CMS had proposed to *include* outpatient dialysis facilities in its list of provider types subject to time-and-distance standards, the Final Rule *removed* outpatient dialysis facilities from that list. Instead, CMS will require MA plans only to attest that they have an adequate network for outpatient dialysis facilities, a process adopted for the evaluation of network adequacy for any provider specialty or facility types, “even where [CMS does] not evaluate access ourselves.” 85 Fed. Reg. 33796, 33853. The Final Rule provides that this new time-and-distance regulation excluding outpatient dialysis facilities takes effect on August 3, 2020 (meaning that it will affect the Fall annual election period—during which new ESRD MA enrollees may enroll in MA plans beginning on January 1, 2021) and becomes applicable on January 1, 2021 (which is the start of the Medicare Advantage open enrollment period for those currently enrolled in MA plans).

58. In support of the removal of outpatient dialysis facilities, CMS cited to research suggesting cost-savings would be realized by home dialysis. Outpatient dialysis facilities were the *only* provider type removed from the list of specialties required to meet time-and-distance standards.

59. CMS asserted in conclusory terms that MA plan attestation and other requirements would be sufficient to protect ESRD patients. But if that were true, there would be no need for time-and-distance standards at all for any type of provider. These objective, quantitative measures of network adequacy were developed precisely because of the need to improve CMS’s ability to assess network adequacy. The existence of such standards for other provider- and facility-types, *see* § 422.116(a)(1) (listing 27 provider-types), § 422.116(a)(2) (listing 13 facility-types),

demonstrates that CMS continues to understand that they have substantial value in protecting patients above and beyond the attestation requirement—evidencing that the intent of the Rule is to single out ESRD patients for discriminatory treatment. Given the crucial importance of time and distance to ESRD patients, it was deeply irrational to subject the patients most in need of that protection to a vague, difficult-to-enforce attestation requirement.

60. CMS also noted that commenters “pointed out that this change would be consistent with how CMS monitors and ensures beneficiary access to durable medical equipment, home health care, and transplant services.” 85 Fed. Reg. at 33859. CMS did not explain, however, how outpatient dialysis is similar to durable medical equipment and transplant services, which only need to be provided occasionally, not multiple times per week, or home health care, which necessarily is not provided at an outpatient facility. *Id.*

61. CMS then turned to some of the many concerns raised by commenters who strongly opposed weakening time-and-distance protections for ESRD patients. CMS pointed to comments explaining, for example, that removal of outpatient dialysis “would result in the discrimination of ESRD patients by MA plans,” “would conflict with the intent of the 21st Century Cures Act, which allows ESRD patients to enroll in MA plans in 2021,” would disregard “barriers to home dialysis,” and would not “leave the treatment choice in the hands of the patient.” 85 Fed. Reg. at 33858-33859.

62. CMS disregarded these concerns. CMS asserted that “we do not agree ... that the removal of outpatient dialysis facilities will result in network designs that discriminate against or discourage ESRD beneficiaries from enrolling in MA plans.” 85 Fed. Reg. at 33858-33859. CMS further claimed that it did not “believe that removal of outpatient dialysis as a facility type would cause access to care concerns.” *Id.* These conclusory assertions—to the extent they were

supported at all—relied generally on CMS’s claim that the overriding network adequacy standard would continue to apply; that MA plans would have to attest to satisfying that standard; and that MA plans would have to continue to abide by antidiscrimination protections. CMS, however, failed to acknowledge that the reason it had developed quantitative time-and-distance standards in the first place was to ensure a consistent, reliable means of enforcing network adequacy for certain “critical” types of medical providers or facilities, an acknowledgment that the general standard, standing alone, was insufficient.

63. CMS also offered no explanation, much less a reasoned one, for why, if the general adequacy standard and attestation were sufficient, time-and-distance standards were necessary for the 40 other facility and providers to which CMS *did* and continues to apply time-and-distance protections. CMS further failed to respond to, or even acknowledge, MedPAC’s comments, including its explanation that attestation would provide little protection for ESRD enrollees who never enroll in an MA plan in the first place because the network is designed without sufficient access to outpatient dialysis.

64. Finally, although CMS’s decision to exclude outpatient dialysis facilities from time-and-distance protection was premised on the theory that home dialysis could substitute for outpatient dialysis facilities, CMS did not even attempt to address the multiple evidence-based comments in the record making clear home dialysis was not a universal substitute.

65. The Final Rule is contrary to the comments put forth by multiple stakeholders that had explained that removing time-and-distance requirements for outpatient dialysis would discriminate against ESRD patients and discourage them from enrolling in MA plans, in contravention of the Cures Act. CMS did not directly respond to MedPAC’s comments.

**F. The Effect of the Final Rule on DPC and Its Members**

66. DPC's membership is composed of at least 28,000 kidney disease patients and their family members, all who are committed to promoting access to high-quality dialysis care for individuals with ESRD.

67. With a president, vice president, and board consisting of exclusively current or former dialysis patients, DPC is committed to the safe and effective treatment of chronic kidney disease. DPC board members have appeared on CMS technical expert panels and advisory committees of other healthcare organizations, and DPC conducts annual research to ascertain patients' experiences with their care and views on health policy issues.

68. Both Section 1852(b)(1) of the Social Security Act ("SSA"), found at 42 U.S.C. § 1395w-22 (b)(1), and Section 1557 of the Patient Protection and Affordable Care Act ("ACA"), found at 42 U.S.C.A. § 18116, prohibit discrimination, including that which discourages enrollment by certain MA eligible individuals and deters protected individuals from participating in a health program. The Final Rule does exactly that.

69. The Final Rule impermissibly and irrationally discriminates against ESRD patients—the patients for whom provider time-and-distance standards are perhaps the most necessary. Dialysis requires three sessions a week, with each session lasting about four hours. ESRD patients will die within a short period of time if they do not receive full and consistent dialysis treatment. Some patients are able to perform dialysis at home, but many are not. Approximately 48% of DPC's members require in-center dialysis. Some have health conditions that simply prohibit home dialysis. Additionally, home dialysis often requires a caregiver to administer dialysis, as well as adequate home settings, which not all ESRD patients have. Even home dialysis patients must visit outpatient dialysis facilities to receive training and return every month. The Final Rule seeks to force ESRD patients to perform dialysis at home, permitting MA

plans to make access to outpatient dialysis facilities out of reach for some patients requiring in-center dialysis, to their great detriment. The Final Rule creates hardships for those ESRD patients who cannot perform dialysis at home and thus discourages these patients from enrolling in an MA plan that cannot meet their needs.

70. Given ESRD patients' great reliance on outpatient dialysis facilities, it is no surprise that the vast majority of ESRD patients have indicated that keeping their current outpatient dialysis facility is one of the most important factors in choosing a health insurance plan. A 2019 DPC member survey showed that 53% of DPC members surveyed said keeping their current outpatient dialysis facility was "Most Important" in choosing an insurance plan, while another 29% said it was "Very Important." These results indicate that ESRD patients, including DPC members specifically, are not likely to enroll in an MA plan that does not include their current outpatient dialysis facilities. The Final Rule encourages MA plans to remove outpatient dialysis facilities from their plans—the single most important factor for many ESRD patients in choosing a plan—thus discouraging many ESRD patients from enrolling in MA.

71. Many ESRD patients are already enrolled in an MA plan, including 16% of DPC's members. The Final Rule will lead to disruptions in reliable access to care and may force some enrollees to leave their MA plans or MA altogether. In addition, because of the increased inconvenience of outpatient dialysis facilities under weakened network adequacy standards, some ESRD patients enrolled in MA plans could be forced to shift to home dialysis, even though in-center dialysis is more medically appropriate or preferable. While CMS contends that newly designated out-of-network dialysis facilities may be made available at in-network cost sharing when network providers are unavailable to an ESRD patient, these patients will have to undergo substantial and time-consuming procedural hurdles to demonstrate the lack of access and obtain

the approvals necessary to visit their regular outpatient facility at in-network cost-sharing rates. As stated previously, ESRD patients cannot afford any delay in their care, as a single missed dialysis appointment could be a matter of life and death. These roadblocks create substantial hardships for these patients and will discourage ESRD patients from enrolling in MA plans at all.

72. Furthermore, ESRD patients are some of the most vulnerable people in the country. Many are of extremely limited means, and many are minorities. Adjusted for race, kidney disease is two to three times more prevalent in low-income individuals than higher-income individuals. ESRD patients are disproportionately harmed by the Final Rule's addition of complicated procedural requirements ESRD patients must endure to maintain the level of care required for their survival.

#### COUNT ONE

**(For discrimination in violation of the Social Security Act § 1852(b)(1) and Patient Protection and Affordable Care Act § 1557, and thus not in accordance with the law, in violation of Administrative Procedure Act, 5 U.S.C. § 706(2)(A))**

73. Paragraphs 1 through 72 are incorporated by reference as if set forth fully herein.

74. Agency actions found to be “not in accordance with law” or “arbitrary, capricious, [or] an abuse of discretion” shall be held unlawful and set aside. 5 U.S.C. § 706(2)(A).

75. The Medicare Act provide robust protections for enrollees. Congress designed the Medicare Act to ensure that enrollees would have prompt access to medical benefits on equal footing with Original Medicare and that MA plans may not discriminate against enrollees or potential enrollees. The Medicare Act thus guarantees enrollees access to benefits at least equal to those provided under “the original[M]edicare fee-for-service program option.” 42 U.S.C. § 1395w-22(a). In addition, the statute requires that those benefits must be “available and accessible ... within the plan service area with reasonable promptness.” *Id.* § 1395w-22(d)(1)(A).

76. In addition, Congress included significant antidiscrimination protections. MA plans are prohibited from limiting coverage based on certain “health-related factors.” *Id.* § 1395w–22(b)(1). In fact, the “Secretary shall not approve a plan of an organization if the Secretary determines that the design of the plan and its benefits are likely to substantially discourage enrollment by certain MA eligible individuals with the organization.” *Id.*

77. In its role of reviewing and approving MA benefits, CMS must ensure that “MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services.” 42 C.F.R. § 422.100(f).

78. Furthermore, Section 1557 of the Patient Protection and Affordable Care Act (“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.

79. In interpreting the anti-discrimination provision (§ 1557) of the ACA, HHS stated “We believe the regulatory text, as it is currently written, conveys the intent to prohibit discriminatory deterrence from participation in a health program or activity.” 81 Fed. Reg. 31376, 31405 (May 18, 2016).

80. While home dialysis may be an option for some, it is not for many ESRD patients. Some of the sickest ESRD patients and those with certain health factors must receive dialysis in outpatient dialysis facilities. *See, e.g.*, AKF Comments to Proposed Rule, at 3; DaVita Comments to Proposed Rule, at 4. Others may not have adequate home settings for peritoneal dialysis or the



aid of an in-home caregiver for hemodialysis, making home dialysis difficult or impossible for many. AKF Comments at 3.

81. Additionally, home dialysis patients need to visit a facility at least once a month even when predominantly dialyzing at home. *See* AKF Comments at 3; *see also* KCC Comments at 6. Thus, while HHS may wish to encourage home dialysis, it cannot do so at the expense of those patients who require in-center dialysis.

82. Removing time-and-distance standards for outpatient dialysis facilities means that MA plans are no longer required to ensure outpatient dialysis facilities are located near their ESRD beneficiaries. As a result, ESRD patients will be left with three equally unattractive options: (1) travel inordinate distances to outpatient dialysis facilities three days a week; (2) endure the burden and time-consuming effort of seeking approval, which may be denied, to visit their regular outpatient facility at in-network cost-sharing rates; or (3) not enroll in MA and be denied the benefits of enrollment that Congress intended to confer to them.

83. By removing outpatient dialysis facilities from time-and-distance standards, the Final Rule permits plans to remove in-network access to life-saving outpatient dialysis facilities, making the plans less attractive to ESRD patients and discouraging them from enrolling in MA plans, particularly because the vast majority of DPC members surveyed indicated that keeping their current outpatient dialysis facilities is one of the most important factors in choosing an insurance plan. In doing so, the Final Rule discriminates against the very patients Congress intended to protect when it made MA plans—which offer greater coverage and lower out-of-pocket costs than original Medicare—newly available to ESRD patients.

84. The lack of time-and-distance standards for outpatient dialysis facilities significantly and uniquely impacts ESRD patients. The Final Rule dissuades ESRD patients from

enrolling in MA, contrary to Congress's intent in Section 17006 of the 21<sup>st</sup> Century Cures Act, allowing ESRD patients to choose MA plans and preventing them from enjoying the same level of benefits and access to care that all other enrollees would be ensured to receive.

85. By removing protections for ESRD patients, thereby deterring ESRD patients from enrolling in MA, HHS unlawfully discriminates against ESRD patients.

86. For these and other reasons, the removal of outpatient dialysis facilities from time-and-distance requirements in the Final Rule is not in accordance with law in violation of 5 U.S.C. § 706(2)(A).

## COUNT TWO

### **(The Final Rule is arbitrary and capricious, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A))**

87. Paragraphs 1 through 72 are incorporated by reference as if set forth fully herein.

88. Agency actions found to be “arbitrary, capricious, [or] an abuse of discretion” shall be held unlawful and set aside. 5 U.S.C. § 706(2)(A). The Final Rule fails that standard in many respects, including, but not limited to, the ways set forth herein.

89. First, the Rule failed to consider important aspects of the problem. *Dep't of Homeland Sec. Regents of the Univ. of California Wolf v. Vidal*, No. 18-587, 2020 WL 3271746, at \*14 (U.S. June 18, 2020); *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, CMS's total failure to consider how the Final Rule will negatively affect ESRD patients, particularly those who cannot dialyze at home. The Final Rule removes requirements that ensure ESRD patients have access to outpatient dialysis facilities near where they live, thus leading to the eventual removal of certain outpatient dialysis

facilities from many MA plan networks. For ESRD patients already enrolled in an MA plan, including DPC members, that means their current dialysis facilities may no longer be in network. And for others, also including DPC members, it means ESRD patients who otherwise want to join an MA plan may be dissuaded from doing so if their regular outpatient dialysis facility is no longer available in network and requires greater beneficiary cost-sharing. While the Final Rule claims in-network cost sharing may be available to offset this loss, this places the onus on patients to obtain approval and endure procedural delays. A single missed dialysis appointment can be catastrophic for an ESRD patient. Placing onerous procedural hurdles in their path can have serious health repercussions. Moreover, DPC survey results indicate that keeping their current outpatient dialysis facility is one of the most important factors for DPC members in choosing an insurance plan, meaning that any actual, perceived, or potential disruption of access to their current outpatient dialysis facility will discourage many from enrolling in MA.

90. Second, the explanation provided for the elimination of outpatient dialysis from time-and-distance standards in the Final Rule runs counter to the evidence before the agency. *See Dep't of Homeland Sec. Regents*, at \*15; *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43; *see also Mayor & City Council of Baltimore v. Azar*, No. CV RDB-19-1103, 2020 WL 758145, at \*9 (D. Md. Feb. 14, 2020). CMS failed to adequately consider concerns raised in comments submitted to CMS by ESRD patients—the very people whose interests the Final Rule claims to be protecting. *See Nat. Res. Def. Council v. U.S. Dep't of Energy*, 362 F. Supp. 3d 126, 148 (S.D.N.Y. 2019) (finding agency assertions are contrary to the record before it where “the entities whose interests DOE claimed to be protecting stated that a stay was not in their interests”). CMS also failed to adequately consider concerns raised by MedPAC.

91. Under the APA, “‘an agency’s failure to consider and address during rulemaking ‘an important aspect of the problem’ renders its decision arbitrary and capricious.” *United Parcel Serv., Inc. v. Postal Regulatory Comm’n*, 2020 WL 1856495 (D.C. Cir. Apr. 14, 2020). That duty of reasoned decision-making ordinarily requires an agency to “provide a reasoned response to ... ‘relevant and significant public comment[ ].’” *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 211 (D.C. Cir. 2011). That obligation is heightened when the comments come from an independent expert agency established by Congress—with regard to such comments, the reviewing agency must provide a “good faith, reasoned analysis in response.” *Silva v. Lynn*, 482 F.2d 1282, 1285 (1st Cir. 1973). Here, CMS disregarded this obligation in failing to address the comments of MedPAC at all with respect to network adequacy for dialysis. *See Dep’t of Homeland Sec. Regents*, at \*14-15.

92. Third, CMS failed to identify and explain any problem with existing standards that the significant regulatory change was designed to address. The APA presupposes that the agency has identified a “problem” in need of a remedy, *State Farm*, 463 U.S. at 43; it follows that a regulation cannot be “a solution in search of a problem,” *New York v. U.S. Dep’t of Health & Human Servs.*, 414 F. Supp. 3d 475, 546 (S.D.N.Y. 2019). Here, CMS identified no evidence in the record justifying its precipitous abandonment of time-and-distance protections for ESRD patients. MedPAC made this point directly to CMS, but CMS still failed to identify a problem.

93. CMS did claim that it acted to give MA plans the option to “contract[] with dialysis providers that offer dialysis treatment through home-based modalities.” CMS’s stated objective was thus to ensure that “all dialysis treatments ... be treated equally.” The error in that reasoning is CMS’s unexplained assumption that home-based and outpatient dialysis treatment are substitutes in their ability to meet the needs of ESRD patients. Home-based and outpatient dialysis

are not substitutes, and CMS's decision to peg network adequacy to home dialysis is fundamentally irrational and will be profoundly detrimental to patients. CMS's unadorned assumption that home dialysis would ensure an adequate network for many ESRD patients was not only unexplained, it ran counter to the record before the agency.

94. The agency could have taken other steps to promote the development of home dialysis, if that was the agency's objective. In particular, CMS could have applied time-and-distance standards to facilities offering home dialysis only. CMS's failure to explain why it rejected that and other obvious alternatives to weakening patient protections was independently arbitrary and capricious. *See Shieldalloy Metallurgical Corp. v. NRC*, 624 F.3d 489, 493 (D.C. Cir. 2010) ("agencies must evaluate ... 'significant and viable' alternatives").

95. Rather than grappling with these concerns, CMS asserted in conclusory terms that MA plan attestation and other requirements would be sufficient to protect ESRD patients. But if that were true, there would be no need for time-and-distance standards at all. These objective, quantitative measures of network adequacy were developed precisely because of the need to improve CMS's ability to assess network adequacy. It was irrational to relegate dialysis patients—the patients most in need of the protection of time-and-distance standards—to the "protection" of a vague, difficult-to-enforce attestation requirement.

96. In advocating that CMS weaken time-and-distance protections for ESRD patients, some commenters pointed to similar regulatory treatment for durable medical equipment, home health services, and transplant services. But that tortured analogy demonstrates the illogic behind CMS's decision. Outpatient dialysis bears little resemblance to those services. As one commenter explained, "[h]ome health agencies deliver care in the beneficiary's place of residence, regardless of where the home health agency is quartered. Similarly, durable medical equipment is typically

delivered to the beneficiary's home by a local vendor or available through a nearby pharmacy, regardless of where the durable medical equipment provider is located. Transplant is delivered in hospital transplant centers specifically approved to provide transplant." NKCA Comments at 5. In other words, there is little reason to think that the time and distance between patients and providers of durable medical equipment, home health care, or transplant would affect patient outcomes. The same is not true for ESRD patients, who need access to dialysis clinics in order to survive, as the record demonstrated.

97. Fourth, CMS violated principles of reasoned decision-making in issuing the Final 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). CMS violated those principles here by abruptly departing from its longstanding practice of including outpatient dialysis facilities in its list of specialties that must meet time-and-distance standards that determine an MA plan's network adequacy. In reversing this longstanding practice without acknowledging the hardship it will place on ESRD patients, HHS fails to display any "awareness" that it was "changing [its] position" from its longstanding guidance, requiring vacatur of the Final Rule. *Fox Television Stations*, 556 U.S. at 515.

98. Finally, CMS unreasonably deviated from the approach it takes to network adequacy in all other contexts, and CMS's failure to address or even acknowledge this internal inconsistency renders the rule arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A).

99. Agency action is arbitrary and capricious when the agency's "reasoning" is "internally inconsistent." *ANR Storage Co. v. Fed. Energy Regulatory Comm'n*, 904 F.3d 1020, 1024 (D.C. Cir. 2018); *accord Sierra Club v. EPA*, 884 F.3d 1185, 1195-1196 (D.C. Cir. 2018). Indeed, "an unacknowledged and unexplained inconsistency is the hallmark of arbitrary and

capricious decision-making.” *Bauer v. DeVos*, 325 F. Supp. 3d 74, 109 (D.D.C. 2018); *see also Encino Motorcars*, 136 S. Ct. at 2126.

100. CMS’s decision to exclude outpatient dialysis facilities from time-and-distance protection suffers from precisely this sort of internal incoherence. As reflected in the preamble to the Rule and embodied in regulation, the agency’s governing approach for assessing network adequacy is tied to existing patterns of health care treatment. In particular, CMS’s regulations define adequacy based on the “prevailing patterns of community health care delivery,” including the existing “number and distribution of health care providers contracting with other health plans (both commercial and Medicare) operating in the service area of the plan.” 42 C.F.R. § 422.112(a)(10). This standard, in CMS’s own words, is meant to “ensure[] that MA enrollees have similar reasonable access to providers and facilities as beneficiaries in FFS Medicare.” 85 Fed. Reg. at 33859. CMS’s approach to time-and-distance protections reflects this emphasis on how patients currently obtain treatment. Time-and-distance standards, CMS explained, are “based on a review of Medicare FFS utilization patterns, utilization of provider/facility specialty types in Medicare FFS, specialties in other managed care programs, and the clinical needs of Medicare beneficiaries.” *Id.* at 33858 (emphasis added).

101. In excluding outpatient dialysis facilities from time-and-distance protections, however, CMS grounded its decision in a completely different—and inconsistent—view of network adequacy. Far from seeking to support existing patterns of treatment, CMS explained that it aimed to “change” how patients receive treatment, from dialyzing at outpatient facilities to home dialysis. 85 Fed. Reg. at 33860. Whether network adequacy could be interpreted as a vehicle to transform how patients obtain care, that is not how the agency has defined adequacy in its own regulations—and it is not how it explained network adequacy in issuing the Rule itself.

102. Nor did CMS offer any reasoned explanation for why outpatient dialysis would be the single type of facility not measured according to existing treatment patterns. Specialties that treat heart disease and cancer, which like ESRD require frequent outpatient and ambulatory care, are included on the list that is subject to time-and-distance standards. CMS has failed to explain why it would exclude outpatient dialysis from the list but not these other types of comparable care. *See Transactive Corp.*, 91 F.3d 232, 237 (D.C. Cir. 1996) (finding that “agency action is arbitrary when the agency offered insufficient reasons for treating similar situations differently”).

103. For these and other reasons, the removal of outpatient dialysis facilities from time-and-distance standards in the Final Rule is arbitrary and capricious, in violation of 5 U.S.C. § 706(2)(A).

### **COUNT THREE**

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

104. Paragraphs 1 through 72 are incorporated by reference as if set forth fully herein.

105. The Final Rule was promulgated without adequate 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 Medicare Act and the APA.

106. 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. Under this provision, “before issuing in final form any regulation under subsection (a), the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.” Here, CMS proposed to make no change to its existing requirement that applied the network adequacy standards to



outpatient dialysis facilities, but ultimately adopted the opposite of that proposal, exempting outpatient dialysis facilities from that requirement. Removing outpatient dialysis facilities from time-and-distance standards was not incorporated in the Proposed Rule; there was no draft language regarding the change or any details surrounding potential removal of time-and-distance standards. By ultimately adopting a rule that it had never proposed, the agency has violated Section 1395hh(b)(1) of the Medicare Act.

107. The Final Rule, which incorporated the removal of time-and-distance standards for outpatient dialysis facilities, was not a “logical outgrowth” of the proposed rule. *See Envtl. Integrity Project v. E.P.A.*, 425 F.3d 992, 996 (D.C. Cir. 2005); *see also Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1108 (D.C. Cir. 2014) (finding that final rule governing treatment of MA days in the Medicare disproportionate share hospital calculation was not a logical outgrowth of proposed rule where agency had “adopted an interpretation precisely opposite to the one it had proposed codifying”).

108. The agency therefore did not provide adequate notice and, as such, violated the notice-and-comment procedures under the APA and Medicare Act.

#### **PRAYER FOR RELIEF**

109. WHEREFORE, Plaintiff prays that the Court grant the following relief:
- a. Declare that the Final Rule, to the extent that it excludes outpatient dialysis facilities from time-and-distance requirements, violates the Administrative Procedure Act because it is contrary to the anti-discrimination provisions of the Affordable Care Act and Social Security Act;
  - b. Declare that the Final Rule, to the extent that it excludes outpatient dialysis facilities from time-and-distance requirements, is arbitrary and capricious under the Administrative Procedure Act;

- c. Vacate the Rule, insofar as it excludes outpatient dialysis facilities from time-and-distance protections for ESRD patients;
- d. Enjoin Defendants from administering or enforcing the Final Rule, to the extent that it excludes outpatient dialysis facilities from time-and-distance requirements;
- e. Award Plaintiff its 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: June 22, 2020

Respectfully submitted,

By: /s/ Lynn E. Calkins

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