UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

DIALYSIS PATIENT CITIZENS, et al.,)
Plaintiffs,)
v.)
ALEX M. AZAR II, Secretary of Health and Human Services, et al.,)
Defendants.)

Civil Action No. 20-cv-1664 (TSC)

MEMORANDUM OPINION

Plaintiffs Dialysis Patient Citizens ("DPC"), DaVita Inc. ("DaVita"), Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, and U.S. Renal Care, Inc. have sued Alex M. Azar II (Secretary of Health and Human Services), the U.S. Department of Health and Human Services, the Centers for Medicare and Medicaid Services ("CMS"), and Seema Verma (CMS Administrator). Plaintiffs' claims arise out of a Final Rule published on June 2, 2020, codifying network adequacy standards for Medicare Advantage Organizations ("MAOs").¹ The Final Rule removes outpatient dialysis centers from the list of facilities to which quantitative "time-and-distance" standards apply for purposes of assessing the adequacy of MAO networks. Plaintiffs claim the Final Rule discriminates in violation of the Social Security Act, 42 U.S.C. § 1395w-22, and Section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. § 18116; that the Final Rule violates the Administrative Procedure Act because it is arbitrary and

¹ As discussed below, Medicare Advantage, also known as Medicare Part C, allows Medicare beneficiaries to obtain covered healthcare services through "managed care" arrangements offered by approved private health insurers, collectively referred to as MAOs.

capricious, and was propagated without adequate notice and comment, also in violation of the Medicare Act, 42 U.S.C. § 1395hh(b).

Plaintiffs have moved for summary judgment and Defendants have moved to dismiss or, in the alternative, for summary judgment. Defendants have also filed a Motion to Strike certain factual allegations set forth by Plaintiffs in their Opposition to Defendants' motion for summary judgment, as well as the declarations of Phyllis Lenss, a DPC member, and Zachary Dolzani, a Senior Director at Davita, which were attached thereto. A Consent Motion for Leave to File Excess Pages and an Unopposed Motion for Leave to File an Amicus Curiae Brief are also currently pending. For the reasons set forth below, the court will GRANT Defendants' Motion to Dismiss (ECF No. 24) without prejudice and will therefore DENY Plaintiffs' Motion for Summary Judgment. (ECF No. 21.) The court will also DENY Defendants' Motion for Summary Judgment (ECF No. 24), Defendants' Motion to Strike (ECF No. 36), Defendants' Consent Motion for Leave to File Excess Pages (ECF No. 35), Better Medicare Alliance's Motion for Leave to File an Amicus Curiae Brief (ECF No. 38), and Plaintiffs' Unopposed Motion for Leave to File Response to Brief of Amicus Curiae Better Medicare Alliance (ECF No. 40) as moot.

I. BACKGROUND

A. Factual Background

Medicare is a federal health insurance program for the elderly and persons with disabilities and is administered by CMS. *See* 42 U.S.C. § 1395 *et seq*. Medicare has four parts: Part A, hospital insurance; Part B, supplemental medical insurance for outpatient services; Part C, managed care plans administered by private insurers; and Part D, prescription drug coverage.

42 U.S.C. §§ 1395w-101–54. The allegations in this lawsuit relate to the coverage of Medicare beneficiaries with End Stage Renal Disease ("ESRD") under Medicare Part C.

1. End Stage Renal Disease

ESRD is the final stage of chronic kidney disease. Patients suffering from ESRD must receive ongoing kidney dialysis or a kidney transplant to survive. *See* Admin. R. at 1132, 2121.

Dialysis is the process of artificially cleaning the blood, simulating the function of working kidneys. CMS, MEDICARE COVERAGE OF KIDNEY DIALYSIS & KIDNEY TRANSPLANT SERVICES 15 (Dec. 1, 2019), https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf. Each dialysis treatment lasts approximately four hours, and a patient with ESRD must receive dialysis at least three times per week. Admin. R. at 0416, 0931, 0933. Approximately 90% of ESRD patients in the United States receive dialysis at an outpatient clinic. 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). Although home dialysis is an option, it is not feasible for patients without caregiver support, stable housing, a home environment with the capacity to safely store necessary supplies and equipment, or who have serious comorbidities. Admin. R. at 0408, 1767, 1885, 2953, 3169–70. Even patients who dialyze at home still need access to outpatient dialysis facilities for training, regular monthly clinical visits, and for dialysis when a care partner is away. Admin. R. at 0934, 1236–37, 1885, 2953.

2. <u>Medicare Coverage of ESRD Patients</u>

The Medicare statutory and regulatory landscape is complex, and the court will provide only a relatively brief synopsis. Under Medicare Parts A and B, payment on a fee-for-service basis is provided for services to qualified individuals. *See* 42 U.S.C. §§ 1395g, 1395k, 1395l;

see also id. § 1395w-21(a)(1)(A). In 1972, Congress expanded Medicare eligibility to include individuals with ESRD regardless of their age. Social Security Amendments of 1972, Pub. L. No. 92-603, tit. II, § 299I, 86 Stat. 1463–64 (codified as amended at 42 U.S.C. § 426-1(a)).

The Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4001, 111 Stat. 251, 275–327 (1997), added a new Part C (now known as Medicare Advantage, or MA) to the Medicare statute. *See* 42 U.S.C. §§ 1395w-21–28. MA allowed Medicare beneficiaries to obtain covered Medicare services through "managed care" plans offered by private health insurers and approved by CMS. *See id.* § 1395w-21. MA plans must offer coverage at least equivalent to traditional Medicare, and often provide broader benefits, including dental and vision coverage. *Id.* §§ 1395w-22(a)(1)(A), (a)(3); CMS, UNDERSTANDING MA PLANS 5 (Sept. 2019), https://www.medicare.gov/Pubs/pdf/12026-Understanding-Medicare-Advantage-Plans.pdf. Many MA plans also have lower out-of-pocket costs. *See* UNDERSTANDING MA PLANS at 5.

Before passage of the 21st Century Cures Act ("the Cures Act"), Pub. L. No. 114–255, § 17006, 130 Stat. 1033, 1334–36 (2016), Medicare beneficiaries who were entitled to Medicare due to their ESRD status were specifically excluded from Part C plans. 42 U.S.C. § 1395w-21(a)(3)(B) (2015); 42 C.F.R. § 422.50(a)(2) (2019). As a result, most ESRD beneficiaries obtained dialysis coverage under Medicare Part B. On December 13, 2016, Congress passed the Cures Act, § 17006, 130 Stat. at 1334–36, amending the Medicare statute to remove the original prohibition on individuals with ESRD enrolling in MA plans beginning on or after January 1, 2021. *See id.*

3. Medicare Advantage

CMS oversees the MA program and contracts with MAOs to provide health care to Medicare beneficiaries pursuant to approved MA health plans. 42 U.S.C. § 1395w-27. Under

the MA statute, private insurers must make "benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits." *Id.* § 1395w-22(d)(1)(A). An MAO's obligations are prescribed by statute, regulation, sub-regulatory guidance, and by the terms of the contract between the MAO and CMS. *See generally id.* §§ 1395w-22, 1395w-27(d); 42 C.F.R. §§ 422.100–422.136.

CMS has promulgated regulations, known collectively as "network adequacy" requirements, which require insurers to "[m]aintain and monitor a network of appropriate providers that is . . . sufficient to provide adequate access to covered services to meet the needs of the population served." 42 C.F.R. § 422.112(a)(1). Under these regulations, MA insurers provide access to a network of providers "consistent with the prevailing community pattern of health care delivery in the areas where the network is being offered," based in part on the "number and geographical distribution of . . . providers" and "time and distance standards." *Id.* § 422.112(a)(10). Initially, CMS used a "rough benchmark" that required providers be located within approximately 30 minutes or 30 miles of enrollees. *See* 74 Fed. Reg. 54,634, 54,644–45 (Oct. 22, 2009). In 2009, however, CMS determined that it needed to "explicitly define" "more specific criteria" for assessing network adequacy. *Id.* at 54,644–45.

To that end, in 2010 CMS created a system to review proposed MA plan networks based on, among other things, specifically defined time-and-distance standards that vary by geographic location. *See* 75 Fed. Reg. 19,678, 19,691–92 (Apr. 15, 2010). Since this rule went into effect in 2011, CMS has published guidance regarding its time-and-distance standards; outpatient dialysis has been among the specialties covered by those standards. *See, e.g.*, Daniella Stanley et al., HSD TECHNICAL TRAINING FOR 2010 MEDICARE ADVANTAGE APPLICATIONS 30, https://www.

cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/downloads/Technical_HSD_ Training_Slides.pdf (last visited January 1, 2021); *see also* Admin. R. 0317 (noting "the lack of change to the list [CMS has] used over the past several years").

4. The Final Rule

In February 2020, CMS issued a new proposed rule setting network adequacy standards.² The proposed rule codified the same list of 41 facility and provider types—including outpatient dialysis—that had been subject to the sub-regulatory "time-and-distance" network adequacy requirements. Admin. R. at 0001, 0092, 0214. The proposed rule did not exempt MA plans from the "time-and-distance" requirements for outpatient dialysis, *see* Admin. R. at 0003, 0214, but CMS stated that it was "considering several options about how to improve our proposal as it relates to measuring and setting minimum standards for access to dialysis services," Admin. R. at 0097–98, and "solicit[ed] comment on" those options, which included "remov[ing] outpatient dialysis from the list of facility types for which MA plans need to meet time and distance standards." *Id.*

On June 2, 2020, CMS published its Final Rule. Admin. R. 0260. In the Final Rule, CMS adopted a regulation which, unlike its proposed regulation, omitted outpatient dialysis facilities from those facilities and providers covered by the codified time-and-distance requirements.³ Outpatient dialysis was the only facility type removed from the list; CMS

codified time-and-distance requirements for the other 40 proposed specialty and facility types. *See* Admin. R. 0368–71. Instead of requiring that MA plans continue meeting time-and-distance requirements for dialysis facilities, the Final Rule allows MA insurers to attest that their network provides adequate access to dialysis. *See* Admin. R. 0317, 0324; *see also* Admin. R. 0368–71; 42 C.F.R. § 422.116(a)(1)(i).

The Final Rule took effect on August 3, 2020 and became the governing standard for MA plans at the beginning of the new plan year, on January 1, 2021. Admin. R. 0260; *see also* 42 C.F.R. § 422.62(a). The regulation thus impacted the October through December 2020 openenrollment period during which ESRD patients, who are newly eligible for enrollment in MA as a result of the Cures Act, chose whether to enroll in MA plans beginning on January 1, 2021. *See* 42 C.F.R. § 422.62(a)(2)(iii).

II. LEGAL STANDARD

A. Motion to Dismiss

Federal courts are of limited jurisdiction and "may not exercise jurisdiction absent a statutory basis." *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 552 (2005). "Limits on subject-matter jurisdiction 'keep the federal courts within the bounds the Constitution and Congress have prescribed,' and those limits 'must be policed by the courts on their own initiative." *Watts v. SEC*, 482 F.3d 501, 505 (D.C. Cir. 2007) (quoting *Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 583 (1999)). Plaintiffs bear the burden of establishing

Dialysis (including hospital-based outpatient dialysis)" as a "provider and facility-specialty type[] to which the network adequacy evaluation" applies), *with* 42 C.F.R. § 422.116(b) (newly adopted regulation listing 27 provider-types at subsection (b)(1) and 13 facility-types—but removing outpatient dialysis—at subsection (b)(2)), *and* Admin. R. at 0368–71 (text of regulation 42 C.F.R. § 422.116(b)(2) in Final Rule omitting dialysis providers).

jurisdiction by a preponderance of the evidence. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992); *Shekoyan v. Sibley Int'l Corp.*, 217 F. Supp. 2d 59, 63 (D.D.C. 2002). The court must decide whether it has subject matter jurisdiction before addressing the merits of the complaint. *See Steel Co. v. Citizens for Better Env't*, 523 U.S. 83, 94–95 (1998). Where multiple grounds for dismissal under Rule 12(b)(1) are at issue "a court may inquire into either and, finding it lacking, dismiss the matter without reaching the other." *Moms Against Mercury v. FDA*, 483 F.3d 824, 826 (D.C. Cir. 2007).

In evaluating a motion to dismiss for lack of jurisdiction under Federal Rule of Civil Procedure 12(b)(1), a court must "assume the truth of all material factual allegations in the complaint and 'construe the complaint liberally, granting plaintiff[s] the benefit of all inferences that can be derived from the facts alleged." *Am. Nat'l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (quoting *Thomas v. Principi*, 394 F.3d 970, 972 (D.C. Cir. 2005)); *see also Warth v. Seldin*, 422 U.S. 490, 501 (1975) (discussing this standard as applied to ruling on a motion to dismiss for want of standing). But the court "need not accept factual inferences drawn by plaintiffs if those inferences are not supported by facts alleged in the complaint, nor must the Court accept [plaintiffs'] legal conclusions." *Disner v. United States*, 888 F. Supp. 2d 83, 87 (D.D.C. 2012) (quoting *Speelman v. United States*, 461 F. Supp. 2d 71, 73 (D.D.C. 2006)).

A motion to dismiss under 12(b)(1) "is not limited to the allegations of the complaint." *Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64 (1987). And "a court may consider such materials outside the pleadings as it deems appropriate to resolve the question [of] whether it has jurisdiction to hear the case." *Scolaro v. D.C. Bd. of Elections & Ethics*, 104 F. Supp. 2d 18, 22 (D.D.C. 2000) (citing, *inter alia, Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992)); *see also Warth*, 422 U.S. at 501 ("[I]t is within the trial court's power to allow or to require the plaintiff to supply, by amendment to the complaint or by affidavits, further particularized allegations of fact deemed supportive of plaintiff's standing.").

III. DISCUSSION

A. Defendants' Motion to Dismiss

Defendants argue that Plaintiffs' claims are not ripe for adjudication, that Plaintiffs lack standing, that this court does not have subject matter jurisdiction over Plaintiffs' claims, and that Plaintiffs have failed to state any claim for which relief may be granted. The court need only reach the first argument.⁴

1. <u>Ripeness</u>

Federal courts are vested with the power of judicial review extending only to "Cases" and "Controversies." U.S. Const. art. III, § 2. Courts have, in interpreting this limitation on judicial power, "developed a series of principles termed 'justiciability doctrines,' among which are standing ripeness, mootness, and the political question doctrine." *Nat'l Treasury Emps. Union v. United States*, 101 F.3d 1423, 1427 (D.C. Cir. 1996) (citing *Allen v. Wright*, 468 U.S. 737, 750 (1984)). In cases concerning agency action, the ripeness doctrine requires that a litigant's claims be "constitutionally and prudentially ripe," so as to protect (1) "the agency's interest in crystallizing its policy before that policy is subjected to judicial review," (2) "the court's interests in avoiding unnecessary adjudication and in deciding issues in a concrete setting," and (3) "the petitioner's interest in prompt consideration of allegedly unlawful agency action." *Nevada v. U.S.*

⁴ Although the court today rules only on the issue of ripeness, the parties are cautioned that, should Plaintiffs' claims come back before this court, the other threshold questions addressed in Defendants' Motion to Dismiss, including justiciability and subject matter jurisdiction, will be reviewed closely by the court, and should be briefed accordingly.

Dep't of Energy, 457 F.3d 78, 83–84 (D.C. Cir. 2006) (quoting *Eagle-Picher Indus., Inc. v. EPA*, 759 F.2d 905, 915 (D.C. Cir. 1985)). The court lacks subject-matter jurisdiction if a plaintiff's claims are not ripe. *Exxon Mobil Corp. v. FERC*, 501 F.3d 204, 208 (D.C. Cir. 2007) ("[R]ipeness goes to our subject matter jurisdiction.").

The prudential elements of ripeness require that "courts consider 'both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Am. Tort Reform Ass'n v. Occupational Safety & Health Admin.*, 738 F.3d 387, 396 (D.C. Cir. 2013) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). In actions against agencies, that inquiry focuses on three factors: "(1) whether delayed review would cause hardship to the plaintiffs; (2) whether judicial intervention would inappropriately interfere with further administrative action; and (3) whether the courts would benefit from further factual development of the issues presented." *Nevada v. U.S. Dep't of Energy*, 457 F.3d at 84 (quoting *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 733 (1998)).

Defendants argue that the issues raised by Plaintiffs do not satisfy any of these three factors: first, because Plaintiffs do not specifically allege that delayed review would cause significant hardship; second, because judicial review would improperly interfere with appropriate additional administrative action by CMS to ensure compliance with the Final Rule, including adequate provision of outpatient dialysis services; and third, because the court would benefit from further factual development regarding the Rule's practical impacts and whether it achieves its stated goal of innovation for dialysis services. (*See* ECF No. 24 at 28–30 (citing, *inter alia, Ohio Forestry Ass'n*, 523 U.S. at 733).)

Plaintiffs failed to respond to any of Defendants' ripeness arguments in their opposition to Defendants' Motion to Dismiss. (*See* ECF No. 30.) Plaintiffs' first argument regarding

ripeness was made, almost in passing, in a footnote in their Opposition to Defendants' Motion to Strike,⁵ in which Plaintiffs suggest that their arguments as to standing should have been understood—presumably by both the court and the Defendants—to be likewise applicable to ripeness. (ECF No. 39, Pls. Opp. to Defs. MTS at 6 n.1.) Not only did Plaintiffs still fail to substantively address Defendants' ripeness argument in that brief, even if they had, the response would have come too late. See Hopkins v. Women's Div., General Bd. of Global Ministries, 238 F. Supp. 2d 174, 178 (D.D.C. 2002) ("It is well understood in this Circuit that when a plaintiff files an opposition to a motion to dismiss addressing only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded."); cf. United States v. Sum of \$70,990,605, 4 F. Supp. 3d 189, 197 n.5 (D.D.C. 2014) (refusing to adjudicate argument "raised for the first time in a second, unrequested supplemental brief"); Cmty. Hous. Tr. v. Dep't of Consumer & Regulatory Affairs, 257 F. Supp. 2d 208, 216 n.12 (D.D.C. 2003) (where court granted permission for supplemental briefing on specific issue, refusing to "consider defendants' other, unrelated arguments, raised for the first time in their supplemental motion").

The court is unpersuaded by Plaintiffs' contention that they need not have made separate standing and ripeness arguments. (*See* Pls. Opp. to Defs. MTS at 6 n.1.) First, on a motion to dismiss under Federal Rule of Civil Procedure 12(b)(1), the plaintiff bears the burden of establishing jurisdiction by a preponderance of the evidence, *see Lujan*, 504 U.S. at 561; *Shekoyan*, 217 F. Supp. 2d at 63, and this burden is particularly weighty in the agency review

⁵ In fact, Plaintiffs failed to make even a single reference to ripeness in any of their filings prior to the Opposition to Defendants' Motion to Strike—their final pleading. (*See* Pls. Opp. to Defs. MTS; *see also* ECF No. 6; ECF No. 21; ECF No. 30.)

context, where "Congress is free to choose the court in which judicial review of agency decisions may occur." *Am. Petroleum Inst. v. SEC*, 714 F.3d 1329, 1332 (D.C. Cir. 2013) (internal quotation marks omitted) (quoting *Watts*, 482 F.3d at 505).

Second, Defendants attest that, had Plaintiffs timely introduced evidence of postcomplaint occurrences in support of ripeness rather than conceding the issue, Defendants would likewise have introduced further arguments and evidence to rebut that evidence. Therefore, they contend, allowing Plaintiffs to rely on such a belated and cursory argument without any opportunity for full briefing would be prejudicial. (ECF No. 42 at 6-8.) The court agrees. The well-recognized rule in this Circuit that "a court may treat those arguments that the plaintiff failed to address [in their opposition brief] as conceded," Hopkins, 238 F.Supp.2d at 178, is premised in part on the principle that belatedly raising new arguments and theories "would be manifestly unfair to" the opposing party who would be unable to respond. Herbert, 974 F.2d at 196; see also Taitz v. Obama, 754 F. Supp. 2d 57, 61-62 (D.D.C. 2010) ("[A] reply brief containing new theories deprives the respondent of an opportunity to brief those new issues." (citation omitted)). As the D.C. Circuit has noted, moreover, to allow such a belated argument would be unfair to the court itself, as "it would risk the possibility 'of an improvident or illadvised opinion," given the dependence of Article III courts "on the adversarial process for sharpening the issues for decision." Herbert, 974 F.2d at 196 (quoting McBride v. Merrell Dow & Pharmaceuticals, Inc., 800 F.2d 1208, 1211 (D.C. Cir. 1986)). Here, Plaintiffs' first mention of ripeness came not even in a reply to Defendants' motion to dismiss, but in opposition to another motion entirely, after the briefing on Defendants' motion to dismiss and the parties' cross-motions for summary judgment had concluded.

Given these considerations, the court will treat Defendants' ripeness argument as conceded. *See Wilkins v. Jackson*, 750 F. Supp. 2d 160, 162 (D.D.C. 2010) (when a party fails to respond to an argument raised in a motion, "it is proper to treat that argument as conceded"); *Three Lower Ctys. Cmty. Health Servs. Inc. v. U.S. Dep't of Health & Human Servs.*, 517 F. Supp. 2d 431, 434 (D.D.C. 2007) ("Plaintiff fails to respond to this argument [from Defendant's Motion to Dismiss], and therefore the Court will treat this argument as conceded"), *aff'd*, 317 F. App'x 1 (D.C. Cir. 2009); *Day v. D.C. Dep't of Consumer & Regulatory Affairs*, 191 F.Supp.2d 154, 159 (D.D.C. 2002) ("If a party fails to counter an argument that the opposing party makes in a motion, the court may treat that argument as conceded."). Accordingly, Defendants' motion to dismiss on this ground will be granted without prejudice.

IV. CONCLUSION

For the foregoing reasons, the court will GRANT Defendants' Motion to Dismiss (ECF No. 24) without prejudice and will therefore DENY Plaintiffs' Motion for Summary Judgment. (ECF No. 21.) The court will also DENY Defendants' Motion for Summary Judgment (ECF No. 24), Defendants' Motion to Strike (ECF No. 36), Defendants' Consent Motion (ECF No. 35), Better Medicare Alliance's Motion for Leave to File an Amicus Curiae Brief (ECF No. 38), and Plaintiffs' Unopposed Motion for Leave to File Response to Brief of Amicus Curiae Better Medicare Alliance (ECF No. 40) as moot. A corresponding order is forthcoming.

Date: January 18, 2021

Tanya S. Chutkan

TANYA S. CHUTKAN United States District Judge