

United States District Court
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DIALYSIS PATIENT CITIZENS;	§	
U.S. RENAL CARE, INC.;	§	
DAVITA INC.; and	§	
FRESENIUS MEDICAL CARE	§	
HOLDINGS, INC.	§	
	§	
v.	§	Civil Action No. 4:17-CV-16
	§	Judge Mazzant
	§	
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	§	

MEMORANDUM OPINION AND ORDER

Pending before the Court is Plaintiffs’ Emergency Motion for Temporary Restraining Order and Preliminary Injunction (Dkt. #3). On January 6, 2017, Plaintiffs filed this emergency motion to stop implementation of a new regulation promulgated by the Department of Health and Human Services (“HHS”) that was set to go into effect on January 13, 2017. On January 12, 2017, the Court entered a temporary restraining order. The Court, having considered the pleadings and oral argument, finds the motion should be granted.

BACKGROUND

End-stage renal disease (“ESRD”) is the last stage of chronic kidney disease. ESRD patients require either a kidney transplant or regular dialysis treatments to survive. Dialysis treatment is expensive and must be performed in specialized facilities three times per week to

effectively clean the blood. Treatments last four hours. This limits ESRD patients' means to work full time, and the majority of patients cannot afford treatment without insurance.

Congress has long recognized the importance of dialysis treatment for ESRD patients and has afforded patients the opportunity to elect coverage that best serves their needs. In 1972, Congress amended the Social Security Act to allow ESRD patients to selectively enroll in Medicare regardless of their age so long as they met certain employment and citizenship requirements. *See* 42 U.S.C. § 426-1(a). For decades, ESRD patients have had the choice of selecting private insurance options over Medicare if those options better served their treatment needs. Private insurance is particularly attractive to ESRD patients with families because Medicare does not provide coverage for spouses and dependents.

Given the vulnerability of ESRD patients and the expense of treatment, charitable organizations provide premium assistance to eligible ESRD patients. These charities, such as the American Kidney Fund ("AKF"), often provide assistance to patients based on financial need, regardless of which insurer the ESRD patient has selected. Dialysis providers have long donated to these charities, which HHS has approved of and regulated. For example, in 1997, the Office of Inspector General ("OIG") of HHS published an advisory opinion affirming the legality of such donations and setting certain guidelines. *See* Advisory Opinion No. 97-1, Office of Inspector General, Dep't of Health & Human Servs., at 5 (1997). These guidelines seek to prohibit dialysis providers from (a) disclosing to ESRD patients that the provider makes charitable contributions or (b) suggesting to charities such as the AKF that any contribution should be directed to a particular group of beneficiaries. The new regulation Plaintiffs are challenging would require insurers to make the very disclosures that OIG guidelines prohibit.

On August 16, 2016, HHS issued a request for information (“RFI”) regarding concerns that health care providers, who receive higher reimbursement from private insurers, were offering premium assistance to steer Medicare-eligible patients to private insurers. *See Request for Information: Inappropriate Steering of Individuals Eligible for or Receiving Medicare and/or Medicaid Benefits to Individual Market Plans*, 81 Fed. Reg. 57,554 (Aug. 23, 2016). The RFI sought information about all third-party premium and cost-sharing assistance, not just dialysis patients. HHS stated the RFI was for “information and planning purposes” only and did not propose a new rule. *Id.* at 57,555. Of the 829 responses HHS received, many ESRD patients; patient advocacy organizations; charities, including AKF; and dialysis providers supported premium assistance and explained the current system’s controls to prevent steering and to comply with the OIG’s guidance. Fifteen insurance companies responded, criticizing charitable premium assistance. Social workers’ responses varied.

On December 14, 2016, HHS announced a new regulation: 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) (to be codified at 42 C.F.R. pt. 494) (the “Rule”). The Rule would require dialysis providers to disclose to patients that they are contributing to charities such as AKF. The Rule would also require dialysis providers to notify insurers which premiums will be paid for by charitable organizations. The dialysis providers would then have to “obtain assurance” from insurers that they will accept charitable premium assistance payments, and if such assurances are not provided, the dialysis providers would need to take “reasonable steps” to ensure such payments are not made. In effect, the Rule would allow insurers to refuse to insure ESRD patients who receive charitable premium assistance. The Rule was set to go into effect on January 13, 2017.

On January 6, 2017, Plaintiffs filed an Emergency Motion for Temporary Restraining Order and Preliminary Injunction (Dkt. #3). On January 11, 2017, Defendants filed their Response in Opposition (Dkt. #29). On January 12, 2017, the Court issued a temporary restraining order (Dkt. #33). On January 18, 2017, the Court held oral argument on the request for a preliminary injunction.

LEGAL STANDARD

The Fifth Circuit set out the requirements for a preliminary injunction in *Canal Authority of the State of Florida v. Callaway*, 489 F.2d 567, 572 (5th Cir. 1974). To prevail on a preliminary injunction, the movant must show: (1) a substantial likelihood that the movant will ultimately prevail on the merits; (2) a substantial threat that the movant will suffer irreparable injury if the injunction is not granted; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) granting the injunction is not adverse to the public interest. *Id.*; *see also Nichols v. Alcatel USA, Inc.*, 532 F.3d 364, 372 (5th Cir. 2008).

To qualify for a preliminary injunction, the movant must clearly carry the burden of persuasion with respect to all four requirements. *Karaha Bodas Co. v. Perusahaan Pertambangan Minyak Dan Gas Bumi Negara*, 335 F.3d 357, 363 (5th Cir. 2003). If the movant fails to establish any one of the four requirements for injunctive relief, relief will not be granted. *See Women's Med. Ctr. of Nw. Hous. v. Bell*, 248 F.3d 411, 419 n.15 (5th Cir. 2001). A movant who obtains a preliminary injunction must post a bond as security any wrongful damages the non-movant suffers as a result of the injunction. Fed. R. Civ. P. 65(c).

The decision to grant or deny preliminary injunctive relief is left to the sound discretion of the district court. *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985) (citing *Canal*, 489 F.2d at 572). A preliminary injunction “is an extraordinary and

drastic remedy, not to be granted routinely, but only when the movant, by a clear showing, carries the burden of persuasion.” *White v. Carlucci*, 862 F.2d 1209, 1211 (5th Cir. 1989) (quoting *Holland Am. Ins. Co. v. Succession of Roy*, 777 F.2d 992, 997 (5th Cir. 1985)). Even when a movant satisfies each of the four *Canal* factors, the decision whether to grant or deny a preliminary injunction remains discretionary with the district court. *Miss. Power & Light Co.*, 760 F.2d at 621. The decision to grant a preliminary injunction is treated as the exception rather than the rule. *Id.*

ANALYSIS

Plaintiffs argue that Defendants violated the Administrative Procedures Act (“APA”) and the Medicare Act because the Rule was unlawfully promulgated without notice and comment, and the Rule’s disclosure requirements are arbitrary, capricious, and contrary to law.

Defendants assert that Plaintiffs are not entitled to a preliminary injunction because: (1) HHS articulated a reasonable explanation for the Rule; (2) HHS’s good cause determination was not arbitrary and capricious; (3) Defendants’ procedural errors were harmless and did not violate the APA; and (4) an injunction would harm ESRD patients.

The first consideration is whether Plaintiffs have shown a substantial likelihood of success on the merits for their claims. Plaintiffs claim that they have shown a substantial likelihood that they will prevail on the merits because Defendants have violated the APA by (1) circumventing the notice and comment process and (2) issuing final agency action that is contrary to law. To satisfy the element of substantial likelihood of success, a plaintiff need not prove their case with absolute certainty. *See Lakedreams v. Taylor*, 932 F.2d 1103, 1109 n.11 (5th Cir. 1991). “A reasonable probability of success, not an overwhelming likelihood, is all that need be shown for preliminary injunctive relief.” *Casarez v. Val Verde Cty.*, 957 F. Supp. 847, 858 (W.D. Tex. 1997).

Plaintiffs have shown a reasonable probability of success by showing Defendants likely violated the procedures of the APA. The APA requires courts to “hold unlawful and set aside agency action” that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706. The APA requires an agency seeking to promulgate a substantive rule to do so through notice and comment procedures. 5 U.S.C. § 553. Plaintiffs contend that HHS’s failure to comply with § 553 constitutes a reasonable probability of success on the merits of their claim. HHS admits a “technical departure from the requirements of § 553(b)” but argues the August 2016 RFI was sufficient notice and the agency had “good cause” to forgo notice and comment (Dkt. #29 at p. 23).

An agency may dispense with the requirements for “good cause” when notice and comment would be “impracticable, unnecessary, or contrary to public interest.” 5 U.S.C. § 553(b)(3)(B); 42 U.S.C. § 1395hh(b)(2)(C). The parties disagree on what standard the Court should apply to HHS’s good cause determination. Plaintiffs cite *United States v. Johnson* and argue the Court should only uphold HHS’s good cause determination if the Court finds HHS’s “reasons for bypassing the APA’s notice-and-comment and thirty day provisions persuasive.” 632 F.3d 912, 928 (5th Cir. 2011). Defendants argue the Court should apply an arbitrary and capricious standard of review to the good cause finding because the APA requires courts to “hold unlawful and set aside agency action” that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706. Plaintiffs counter that nothing in *Johnson* suggests the Fifth Circuit should apply a deferential standard of review for the legal question of whether good cause was satisfied. The Court agrees and will follow the Fifth Circuit precedent in *Johnson* but notes that the Rule is also arbitrary and capricious, as discussed below.

Defendants contend that notice and comment would be “contrary to public interest.” The D.C. Circuit has determined “[t]he public interest prong of the good cause exception is met only in the rare circumstance when ordinary procedures—generally presumed to serve the public interest—would in fact harm that interest.” *Mack Trucks, Inc. v. E.P.A.*, 682 F.3d 87, 95 (D.C. Cir. 2012). The Court adopts the reasoning of the D.C. Circuit and finds that notice and comment should only be dispensed where “announcement of a proposed rule would enable the sort of . . . manipulation the rule sought to prevent.” *Id.* (citing *Util. Solid Waste Activities Grp. v. E.P.A.*, 236 F.3d 749, 755 (D.C. Cir. 2001)).

The Fifth Circuit reads the good cause exception narrowly “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); *see Texas v. United States*, 809 F.3d 134, 171 (5th Cir. 2015) (“the full panoply of notice-and-comment requirements must be adhered to scrupulously. The ‘APA’s notice and comment exemptions must be narrowly construed.’”). “The proper test is whether the notice would fairly apprise interested persons of the subjects and issues the agency was considering. The notice need not specifically identify ‘every precise proposal which [the agency] may ultimately adopt as a rule.’” *Am. Transfer & Storage Co. v. I.C.C.*, 719 F.2d 1283, 1303 (5th Cir. 1983) (citations omitted).

Other courts similarly read the good cause exception narrowly. For example, the Third Circuit refused to find good cause where the attorney general asserted a sex offender registration regulation needed immediate enactment to protect the public from sexual assaults. *See United States v. Reynolds*, 710 F.3d 498, 510 (3d Cir. 2013). The court concluded, “If the mere assertion that [some real or perceived harm] will continue while an agency gives notice and receives comments were enough to establish good cause, then notice and comment would always have to

give way.” *Id.* at 512. One court analyzing an HHS regulation reasoned that good cause should be “narrowly construed and only reluctantly countenanced . . . particularly . . . where the issues affect the general public and involve complex and controversial questions of ethics and public policy.” *Am. Acad. of Pediatrics v. Heckler*, 561 F. Supp. 395, 401 (D.D.C. 1983) (citations omitted).

Defendants contend that notice and comment would have been contrary to public interest because they were facing a crisis situation in which swift, emergency rulemaking was necessary to prevent further harm to dialysis patients. Specifically, Defendants claim that delaying the Rule would leave patients exposed to three kinds of unacceptable risks: (1) having their ability to be determined eligible for a kidney transplant negatively affected; (2) being exposed to additional costs for health care coverage; and (3) being exposed to a significant risk of mid-year disruption in coverage. But Defendants have not provided a single example of a patient denied a kidney transplant because of charitable assistance. Speculation that some patients will not have foresight to arrange for alternative coverage does not provide good cause to bypass notice and comment. Plaintiffs have shown that DaVita and other providers assist patients in enrolling in Medicare leading up to and after the patient receives a transplant (Dkt. #3, Exhibit C). The second alleged unacceptable risk is purely economic, which does not supply good cause. *See Mack Trucks Inc.*, 682 F.3d at 95. Finally, the Rule effectively provides insurers the means to stop paying for dialysis treatment once the insurer discovers the patient received charitable premium assistance. Thus, the Rule would cause the very mid-year disruptions that it seeks to prevent.

In support of their position, Defendants identified two cases in which courts found good cause for health care regulation without notice and comment. In *North American Coal*, the Secretary of Labor published a proposed rule permitting eligible miners to file claims for medical

benefits under the Black Lung Act. *N. Am. Coal Corp. v. Dir., Off. of Workers' Comp. Prog.*, 854 F.2d 386, 387 (10th Cir. 1988). After publishing the final rule, the Secretary of Labor promulgated an amended rule—without notice and comment—that extended the deadline of the prior rule. The Tenth Circuit determined “the loss or delay of medical benefits to many eligible coal miners was a real harm” that satisfied the APA’s good cause exception. In *National Federation of Federal Employees v. Devine*, the Office of Personnel Management (“OPM”) published a new rule—without notice and comment—in response to a district court order that postponed federal employees’ period of open enrollment in health benefit plans. 671 F.2d 607, 610–12 (D.C. Cir. 1982). The District of Columbia Circuit found the OPM had good cause to forgo notice and comment because “the agency’s action was required by events and circumstances beyond its control.” *Id.* at 611.

The circumstances here are distinguishable from the cases offered by Defendants. Unlike *North American Coal*, the Rule is not an amended rule that followed an original, APA-compliant proposed rule, which might have permitted the Court to determine HHS “substantial[ly] compli[ed] with the requirements of the APA.” 854 F.2d at 388. Unlike the OPM in *National Federation of Federal Employees*, HHS’s action was not a “necessary” response to a court order, and HHS had “substantial prior notice” of the enrollment deadline. 671 F.2d at 611.

The parties have identified several cases in which a court found good cause for bypassing the notice and comment procedures required by the APA. For example, in *Hawaii Helicopter Operators Ass’n v. F.A.A.*, the Ninth Circuit found good cause to invoke the exception where a “recent escalation of fatal air tour accidents” permitted the FAA to enact helicopter regulations requiring helicopter pilots to fly at a minimum 1,500 feet over Hawaii’s unique, complicated topography. 51 F.3d 212, 214–15 (9th Cir. 1995). In *Jifry v. F.A.A.*, the District of Columbia

Circuit found good cause to bypass notice and comment and to revoke certain FAA airman certificates following the September 11, 2001, attacks as a matter of national security. 370 F.3d 1174 (D.C. Cir. 2004). The court recognized the “emergency situation[]” and concluded, “[g]iven the respondents’ legitimate concern over the threat of further terrorist acts involving aircraft in the aftermath of September 11, 2001, the agencies had ‘good cause’ for not offering advance public participation.” *Id.* at 1179–80 (citations omitted). There are no such emergencies presented to the Court.

The Court is not persuaded that HHS had good cause to bypass notice and comment. When pressed at oral argument for why HHS could not go through the procedures required by the APA, Defendants were unable to identify any emergency that justified publishing a rule without notice and comment. Defendants claimed HHS decided it was facing a crisis situation after reviewing the information gathered through the RFI. Defendants further claimed immediate action was necessary because delay would put lives at risk. But such arguments “could as easily be used to justify immediate implementation of any sort of health or safety regulation.” *Am. Acad. of Pediatrics*, 561 F. Supp. at 401.

The Court is also not persuaded that the procedural violations were harmless. Defendants contend that the lack of notice and comment did not prejudice Plaintiffs. The Fifth Circuit has determined that an agency’s failure to comply with notice and comment is harmless only when it is “clear that the petitioner was not prejudiced by APA deficiencies.” *United States v. Johnson*, 632 F.3d 912, 930 (5th Cir. 2011) (citing *United States Steel Corp. v. E.P.A.*, 595 F.2d 207, 215 (5th Cir. 1979)). The Fifth Circuit finds harmless error “rare[ly]” because the “vast majority of agency rulemaking, which produces nuanced and detailed regulations[,] greatly benefit[s] from expert and regulated entity participation.” *Id.* at 932. The only relevant case that Defendants cite

finding harmless error, *City of Arlington v. F.C.C.*, is distinguishable because unlike the situation before the Court, the FCC put the petitioners on notice that they were considering a rule change. 688 F.3d 229, 244 (5th Cir. 2012); *see also United Steelworks of Am., AFL-CIO-CLC v. Schuylkill Metals Corp.*, 828 F.2d 314, 317–18 (5th Cir. 1987) (finding no error where a modified rule was a “logical outgrowth” of the original proposed rule that was introduced with proper notice and comment procedures). Defendants claim that the RFI was sufficient to give Plaintiffs adequate notice and make any “technical departures from § 553(b)” harmless. This claim is without merit. The RFI (1) did not give Plaintiffs notice that HHS was considering promulgating a rule; (2) was not specific to ESRD; (3) disclosed no information regarding the provisions that made the Rule so damaging; and (4) was “[t]oo open-ended to allow for meaningful comment” on key aspects of the Rule actually adopted. *Prometheus Radio Project v. F.C.C.*, 652 F.3d 431, 450 (3d Cir. 2011). It is not “clear that the petitioner was not prejudiced by APA deficiencies.” *Johnson*, 632 F.3d at 930. In fact, when combined with the shortcomings and deficiencies of the Rule itself, the Court finds Plaintiffs were clearly prejudiced by HHS’s decision to violate the procedures of the APA.

The Court determines that HHS did not have good cause to bypass notice and comment; thus, the Rule should be vacated. Independent of this determination, Plaintiffs are likely to succeed on the merits because the Rule is arbitrary and capricious. “[R]easonable regulation ordinarily requires paying attention to the advantages *and* disadvantages of agency decisions.” *Michigan v. E.P.A.*, 135 S. Ct. 2699, 2707 (2016). HHS failed to consider the benefits of private qualified health plans and ignored the disadvantages of the Rule. The Supreme Court has determined an agency rule would be arbitrary and capricious if the agency “entirely failed to consider an important aspect of the problem.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). HHS failed to consider that the Rule would leave thousands of

Medicare-ineligible ESRD patients without health insurance, which is clearly an important aspect of the problem. Finally, the Rule departed from HHS's prior guidance without acknowledging that it was doing so. *See FCC v. Fox Television Stations*, 556 U.S. 502, 516 (2009) (concluding HHS's failure to display "awareness" it was "changing its position" from its longstanding guidance required vacatur of the rule). HHS has long accepted the practice of charitable premium assistance, and the Rule neither addresses that HHS is changing its position nor provides a reasoned explanation for why the Rule violates OIG guidance. *See Advisory Opinion No. 97-1*, Office of Inspector General, Dep't of Health & Human Servs., at 5 (1997).

Plaintiffs must demonstrate irreparable injury for the Court to provide injunctive relief. Dialysis providers contend that they will suffer irreparable injury because the Rule would cause financial unsustainability for its facilities. DaVita, Inc. has shown that up to six of its Texas facilities would likely close if ESRD patients were forced off of private insurance plans, which reimburse at a much higher rate than Medicare. *See Texas v. E.P.A.*, 829 F.3d 405, 434 (5th Cir. 2016) (finding permanent closure of facilities to be an irreparable harm). Additionally, compliance costs cannot be recovered later from the government if the Rule is invalidated on the merits. These costs are irreparable under Fifth Circuit law. *Id.* Here, HHS estimates such costs at more than \$29 million annually. 81 Fed. Reg. at 90,225. ESRD patients would also suffer irreparable injury were the Rule to go into effect. The Fifth Circuit finds irreparable injury where a proposed rule would deny patients needed medical care or "the legal right to the qualified provider of their choice." *Planned Parenthood of Gulf Coast, Inc. v. Gee*, 837 F.3d 477, 501 (5th Cir. 2016). Not all ESRD patients qualify for Medicare, and Medicare does not cover family members. Further, many health care providers do not accept Medicare. Therefore, some ESRD patients and their families could

lose access to their health care providers or even lose insurance coverage altogether. The Court finds Plaintiffs have satisfied their burden in showing irreparable injury.

The balance of equities weighs in favor of granting a preliminary injunction because HHS will suffer no comparable harm if the Rule's implementation is delayed while the Court addresses the merits of Plaintiffs' challenges to the Rule.

Granting injunctive relief would serve the public interest. HHS contends the status quo disserves the public interest, but the Court is not convinced. Preserving the status quo ensures ESRD patients have the choice to select private or public insurance options based on their health care needs and financial means.

CONCLUSION

Plaintiffs have satisfied each of the four requirements for a preliminary injunction. The Court has authority to enjoin the Rule's implementation on a nationwide basis, and finds that it is appropriate to do so in this case. *See Texas*, 809 F.3d at 188 (upholding a nationwide injunction because "partial implementation of [a federal rule] would 'detract from the integrated scheme of regulation' created by Congress").

It is therefore **ORDERED** that Plaintiffs' Emergency Motion for Temporary Restraining Order (Dkt. #3) is hereby **GRANTED**.

It is further **ORDERED** that HHS's 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) is hereby enjoined. Defendants and their agents are enjoined from implementing and enforcing the following regulations as amended by 81 Fed. Reg. 90,211: 42 C.F.R. § 494.70 and 42 C.F.R. § 494.180, pending further order of this Court.

The Court has considered the issue of security pursuant to Rule 65(c) of the Federal Rules of Civil Procedure and finds that Defendants will not suffer any financial loss that warrants the need for Plaintiffs to post security. The Fifth Circuit has held that a district court has the discretion to “require no security at all.” *Kaepa, Inc. v. Achilles Corp.*, 76 F.3d 624, 628 (5th Cir. 1996). After considering the facts and circumstances of this case, the Court concludes that security is unnecessary and exercises its discretion not to require posting security in this situation.