

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. §
§
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 §

CIVIL ACTION NO. 4:17-CV-16
Judge Mazzant

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 the implementation of a new regulation promulgated by the Department of Health and Human Services (“HHS”) set to go into effect on January 13, 2017. The Court, having considered the pleadings and oral argument, finds the motion should be granted.¹

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

¹ Due to the expedited nature of these proceedings, this Order will stay the effective date of the new regulation until a final adjudication of Plaintiffs’ claims, with a more detailed written decision explaining the Court’s reasoning to follow. The Court is issuing a temporary restraining order to maintain the status quo—it is not granting a preliminary injunction at this time.

effectively clean the blood. Treatments last four hours. This limits ESRD patients' means to work full time, and 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 they 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 expense and vulnerability of ESRD patients, 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—whether private or public—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 and Human Services, at 5 (1997). These guidelines seek to prohibit dialysis providers from (a) disclosing to ESRD patients that it makes charitable contributions or (b) suggesting to AKF that any contribution should be directed to a particular group of beneficiaries. The Rule would require insurers to make disclosures that violate these OIG guidelines.

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 patients eligible for public insurance options 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 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 notify insurers which premiums will be paid for by charitable organizations. The Rule would also require dialysis providers to disclose to patients that they are contributing to charities such as AKF. The Rule is 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 held a telephonic hearing on the motion.

LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 65, any court issuing a temporary restraining order (“TRO”) must: “(A) state the reasons why it was issued; (B) state its terms specifically; and (C) describe in reasonable detail—and not by referring to the complaint or other document—the act or acts restrained or required.” Fed. R. Civ. P. 65(d). Although by its terms Rule 65(b) only sets a fourteen-day time limit for restraining orders issued without notice, restraining orders issued with brief, informal notice are also subject the same time constraints. *See Granny Goose Foods, Inc. v. Bhd. of Teamsters & Auto Truck Drivers Local No. 70 of Alameda Cty.*, 415 U.S. 423, 432 n.7 (1974); *see also* Fed. R. Civ. P. 65(b)(2).

A party seeking injunctive relief must establish that they are likely to succeed on the merits, likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in their favor, and that an injunction is in the public interest. *See Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *Tex. Midstream Gas Servs., LLC v. City of Grand Prairie*, 608 F.3d 200, 206 (5th Cir. 2010). Injunctive relief is an extraordinary remedy that requires the applicant to unequivocally show the need for its issuance. *See Valley v. Rapides Par. Sch. Bd.*, 118 F.3d 1047, 1050 (5th Cir. 1997). The movant has the burden of introducing sufficient evidence to justify granting a preliminary injunction or temporary restraining order. *PCI Transp. Inc. v. Fort Worth & W. R.R. Co.*, 418 F.3d 535, 546 (5th Cir. 2005). The party seeking relief must satisfy a cumulative burden of proving each of the four elements enumerated before a temporary restraining order or preliminary injunction can be granted. *Miss. Power & Light Co. v. United Gas Pipe Line Co.*, 760 F.2d 618, 621 (5th Cir. 1985).

ANALYSIS

For the Court to grant a TRO, Plaintiffs must demonstrate (1) a substantial likelihood of success on the merits; (2) a substantial threat that the movant will suffer irreparable injury if the injunction is denied; (3) that the threatened injury outweighs any damage that the injunction might cause a defendant; and (4) that the injunction will not disserve the public interest. *See Affiliated Prof'l Home Health Care Agency v. Shalala*, 164 F.3d 282, 285 (5th Cir. 1999) (citations omitted).

Plaintiffs have shown a reasonable probability of success by showing the Defendants likely violated the procedures of the Administrative Procedures Act (“APA”). 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). 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 probably 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 and the agency had good cause to forgo notice. (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). This exception is read 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). Further, the Rule departs 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). While the Court reserves its judgment as to whether good cause exists, Plaintiffs have met their burden in showing at least a reasonable probability of success necessary for issuing a TRO.

Plaintiffs also satisfy their burden in regard to the second element—a substantial threat that the movant will suffer irreparable injury if the injunction is denied. As to ESRD patients, the Rule will cause them to shift to public insurance options, and many patients would be better served by private insurance options. Not all ESRD patients qualify for Medicare and Medicare does not cover families. Therefore, some ESRD patients and their family members would lose insurance coverage altogether if forced to change to public insurance. Finally, profits would decline for dialysis providers because private insurers often reimburse facilities at a higher rate than public insurance. Further, compliance costs—which cannot be recovered later from the Government if the Rule is invalidated on the merits—are irreparable and estimated by HHS at more than \$29 million annually. *See Texas v. EPA*, 829 F.3d 405 (5th Cir. 2016); 81 Fed. Reg. at 90,225.

The balance of equities favors granting a TRO 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.

Finally, the Court is not convinced a TRO would disserve the public interest. While HHS contends the status quo is causing irreparable harm, preserving the status quo would ensure ESRD patients have the choice to select private or public insurance based on their health care needs and financial means.

CONCLUSION

Plaintiffs have satisfied each of the four requisites for a TRO. 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 v. United States*, 809 F.3d 134, 188 (5th Cir. 2015) (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.

This Order shall remain in full force and effect for a period of fourteen (14) days pursuant to Fed. R. Civ. P. 65.

It is further **ORDERED** that the parties appear for a hearing on the motion for preliminary injunction on Wednesday, January 18, 2017, at 2:00 p.m. at the Paul Brown United States Courthouse, 101 E. Pecan Street, Sherman, Texas 75090.

SIGNED this 12th day of January, 2017.


AMOS L. MAZZANT
UNITED STATES DISTRICT JUDGE