IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

DIALYSIS PATIENT CITIZENS, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 4:17-cv-16-ALM
	)	
SYLVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	

PLAINTIFFS' REPLY IN SUPPORT OF THEIR EMERGENCY MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

In their moving papers, Plaintiffs established that the Rule will seriously interfere with patient choice and, in some instances, result in denial of any insurance coverage to ESRD patients. Plaintiffs demonstrated that the Rule will inflict immediate, systemic, and serious harm on those patients, as well as dialysis providers. In response, HHS offers not even one concrete example of harm under the current regulatory program—not one. Instead, it relies upon speculation that collapses under inspection. Indeed, HHS defends the Rule as needed to protect patients, but it rejected (in a footnote) the obvious solution of compelling insurers to accept charitable assistance for ESRD patients (as it presently does, for example, for AIDS patients). HHS ignores that the Rule will leave without any insurance coverage the many ESRD patients who are not eligible for Medicaid or Medicare and that, for those who do qualify, the Rule will force disruptive transitions in coverage, at great cost to patients' health, finances, or both. Contrary to HHS's flimsy claim of "good-cause," it is the Rule's break with two-decades of guidance regarding charitable assistance that will irreparably harm patients and providers unless it is enjoined for the brief period required to allow the notice-and-comment contemplated by law. Plaintiffs respectfully ask that the Court enjoin enforcement of the Rule before it goes into effect on **January 13, 2017,** so that HHS can follow those procedures before so radically changing the status quo and thereby preempting the incoming administration.

I. PLAINTIFFS WILL BE IRREPARABLY INJURED ABSENT PRELIMINARY RELIEF

HHS's response on irreparable harm is entirely unpersuasive. ***First***, HHS improperly dismisses (Opp. 31) as "speculative" the grave health- and financial-injuries the Rule will create for patients. Sworn affidavits establish that more than 6,000 DPC members receive "AKF-funded health coverage," some of whom "have obtained private coverage through AKF assistance." Ex. B ¶ 29. As a result of the Rule, those patients face a significant risk that—*not*

by their own choice but as a result of the insurer-assurance requirements—they will be forced to abandon their preferred existing coverage. Indeed, some insurers have *already* taken the position they will use the deny access to commercial insurance under the Rule, Ex. C ¶ 90; Ex. D. ¶¶ 107-108, a result HHS expected, 81 Fed. Reg. at 90,217. HHS's refrain that the Rule simply enables patients to make informed choices is backwards: the Rule will exclude patients from private coverage even when a patient has chosen and benefits from that coverage. Ex. D ¶ 108.

The coverage disruptions resulting from the Rule will threaten patients' health and impose serious financial injuries for patients with existing QHPs. *E.g.*, Ex. B ¶¶ 30, 34. Some ESRD patients, for example, are *not* eligible for public insurance. Ex. C ¶ 49 ("over 1,000 DaVita patients are … ineligible"), ¶ 50 (in Texas, "78 DaVita patients receiving charitable premium assistance on QHPs are ineligible"); Ex. F ¶ 17 ("310 USRC patients are ineligible"). HHS ignores that point, both in the preamble and in its opposition here. Those patients alone will suffer irreparable injuries that dwarf the speculative concerns HHS recites. Moreover, the forced coverage transitions caused by the Rule will create serious coverage gaps for *dependents*, which is also irreparable harm. Ex. B ¶ 34. HHS dismisses these consequences as "rank speculation" (Opp. 31), but unlike HHS's unfounded speculation, Plaintiffs' supporting affidavits contain concrete examples of individuals likely harmed by the Rule, Ex B. ¶¶ 31, 36. Patient injury, standing alone, warrants injunctive relief.[1]

Second, providers will also suffer irreparable injury. It is established in this Circuit that unrecoverable compliance costs are irreparable. *See Texas v. EPA*, 829 F.3d 405, 434 (5th Cir. 2016); TRO 28-29. HHS fails to cite *Texas v. EPA*, much less distinguish it. HHS itself found

[1] HHS also ignores the serious risk that the Rule will imperil AFK's HIPP program, threatening the ability of tens thousands of low-income patients to pay premiums and other health-care costs, Ex. D ¶¶ 115, 125-126, and that the Rule will inevitably curtail patient choice by equipping insurers with a means to drop QHP coverage, TRO 27.

that compliance will cost nearly $30 million *annually*, 81 Fed. Reg. at 90,225, and its suggestion (Opp. 30) that all of those costs will be incurred "before" the Rule takes effect is thus irrational. HHS also does not rebut sworn testimony that the Rule risks facility closures by disrupting the insurance mix necessary to make some facilities sustainable. These closures are much more than issues of "dollars and cents" (Opp. 32), as they will have irreparably deleterious effects on patients and employees. Ex. C ¶¶ 73-77, Ex. E. ¶¶ 69, 82-84, Ex. F. ¶¶ 52-53, 60-62.[2]

II. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

A. HHS Bypassed Notice-And-Comment Requirements Without Good Cause

HHS's brief adds nothing to its prior inadequate good-cause justifications. Indeed, the good-cause claim fails at the threshold for several reasons. *First*, HHS's delay in issuing the Rule is fatal to its claim of an "emergency." HHS asserts it needed to take "immediate regulatory action" (Opp. 5, 6, 18), but HHS did not act immediately. HHS has been aware of charitable assistance issues for two decades, and it has known of any supposed "problem created by the ACA" since 2014. And if HHS did first learn of these issues during the RFI process (an implausible assertion), the RFI period closed on September 22, 2016 but HHS waited nearly three months—and six weeks after ACA open enrollment began on November 1—before issuing the Rule. That delay is inconsistent with any claim that HHS was addressing a *bona fide* emergency. *E.g.*, *United States v. Johnson*, 632 F.3d 912, 929 (5th Cir. 2011); Opp. 14.

Second, that some unidentified segment of ESRD patients might benefit from public coverage does not itself establish good cause. TRO 20. Otherwise, almost all HHS rules could

[2] HHS also fails to address that the Rule will immediately place providers in a perilous dilemma. *E.g.*, Ex. C ¶¶ 94-101. Failure to comply will risk Medicare termination, 42 U.S.C. § 13955rr(g); 42 C.F.R. § 488.604, yet compliance will put providers in conflict with OIG guidance, exposing them to potentially significant liability under other federal laws, Ex. C ¶¶ 94-101; Ex. E ¶¶ 70-74; Ex. F ¶¶ 45-46. That is an intolerable dilemma that can be remedied only by preliminary relief. And HHS entirely ignores the Rule's irreparable harm to patient goodwill. TRO 29.

bypass notice and comment. That is obviously not the law. *See American Acad. Of Pediatrics v. Heckler*, 561 F. Supp. 395, 401 (D.D.C. 1983).

Third, HHS admits it could have addressed its purported patient concerns by "mandating that insurers accept payment of premiums from third parties." Opp. 22. But, it asserts, that would have "distort[ed]" the ACA Exchanges. *Id.* HHS does not attempt to explain why, as a temporary measure, HHS could not have required insurers to accept such payments while it conducted a rulemaking or why any temporary effects on ACA Exchanges amount to an emergency. Nor does HHS explain why reasonable patient-disclosure requirements (without the disruptive insurer-assurance requirements) could not have fully addressed any concerns.

Apart from those threshold defects, each of HHS's patient-harm claims fails.

Alleged transplant risk. HHS leads with this rubric but—fatal to its position—fails to cite even a *single* example of a patient denied a transplant because of charitable assistance.[3] Given that HHS is defending a Rule that would disrupt the status quo, that failure is telling. Speculation that some patients will not "have … foresight" to arrange for "alternative coverage," Opp. 17, ignores that providers already offer such assistance, *e.g.*, Ex. C ¶¶ 30-39.

Alleged financial harm. HHS fails to address the holding of *Mack Trucks, Inc. v. EPA*, 682 F.3d 87 (D.C. Cir. 2012)—namely, that supposed private financial benefits of a rule cannot supply good cause. Moreover, HHS concedes (Opp. 19) that it does not know whether affected patients, on the whole, will be better off financially under the Rule.

Alleged coverage disruptions. Despite attempting to rehabilitate its coverage-disruption theory, HHS continues to ignore that the Rule—by requiring providers to seek insurer permission for patients to receive charitable assistance—will *cause* the very disruptions to coverage the Rule

[3] HHS points to (at 15) a family "given inaccurate information by a dialysis facility" but the child received a transplant and the family signed up for Medicare. HHS Ex. 11.

is purportedly aimed to remedy. *E.g.*, Ex. B ¶¶ 14-15, 37-48. In fact, by requiring providers to obtain assurance from insurers for *all* ESRD patients receiving premium assistance for QHPs, the Rule necessarily will result in quantitatively more disruptions than would occur without the Rule.

Finally, HHS's APA violation was not "[h]armless." Opp. 26. Because the RFI was for "information purposes" "only," was not specific to ESRD, and disclosed none of the specific provisions that make the Rule so damaging, it was "[t]oo open-ended to allow for meaningful comment" on key aspects of the Rule actually adopted. *Prometheus Radio Project v. FCC*, 652 F.3d 431, 450 (3d Cir. 2011); *see N. Carolina Growers' Ass'n, Inc. v. UFW*, 702 F.3d 755, 770 (4th Cir. 2012). Had the Rule been issued as an NPRM, stakeholders could have commented on the harm claims made by HHS and explained why particular aspects of the Rule are unworkable or will injure patients and providers.[4] HHS's decision to bypass notice-and-comment prevented that dialogue from occurring. TRO 21 n.14.[5]

* * *

For those reasons, Plaintiffs respectfully request that the Court enjoin enforcement of the Rule **before January 13, 2017.** [6]

[4] For example, had HHS suggested it was considering requiring providers to disclose the fact of AKF donations to patients, commenters would have explained the conflict with OIG's guidance. Or, had HHS suggested it might require providers to seek insurer permission for charitable assistance, commenters would have described deleterious consequences for patients.

[5] The notice in *United Steelworkers v. Schulkill Metals Corp.*, 828 F.2d 314 (5th Cir. 1987), is not analogous because the RFI here, unlike that notice, was not focused on any specific regulatory provision (or even dialysis providers), was not part of a broader proposed rulemaking, did not include hearings, and did not indicate that a final rule would result.

[6] If the Court denies this request, Plaintiffs ask that the Court enter an injunction pending appeal to preserve Plaintiffs' ability to seek emergency appellate review. Fed. R. App. P. 8(a).

Dated: January 12, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on January 12, 2017, I filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record who are deemed to have consented to electronic service.

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