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

CAMI JO TICE-HAROUFF, on behalf of herself and her patients,

Plaintiff,

v.

CAROLE JOHNSON, et al.,

Defendants.

No. 6:22-cv-00201-JDK

Oral Argument Scheduled
July 12, 2022

PLAINTIFF'S REPLY BRIEF IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

HRSA's basic defense to Dr. Tice-Harouff's injunction motion is a newly drafted declaration from a subordinate agency official, but this declaration is incorrect, irrelevant, and inadmissible under the APA.

I. HRSA's declaration is a *post hoc* litigation tactic and cannot negate the government's obligation to comply with the APA.

A. The 2021 Guidelines deleted the requirement to cover fertility awareness instruction.

In December 2021, without following the notice and comment process required by the APA, HRSA modified a binding nationwide health insurance coverage requirement by, among other things, deleting the following sentence:

> Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

Compl. Ex. A at 3. Women had an explicit legal right to this instruction—until 2021.

In response, HRSA admits that it deleted this sentence. Defs.' Br. in Opp'n to Mot. for TRO and Prelim. Inj. ("Gov. Br.") at 5, ECF. No. 20. ("[t]he 2021 Guidelines do not include the final sentence discussing FABM counseling."). HRSA also admits that when the guidelines added this sentence, coverage was mandatory, even though

the guidelines are called "guidelines" and use words like "should" or "recommend." *Id.* at 4. What is more, HRSA further admits that fertility-awareness instruction coverage was only ever required by *adding* this sentence in 2016. *Id.* at 3–4; Gov. Br. Ex. A, Decl. of Lee A. Wilson ¶ 3, ECF. No. 20-1. (FABM instruction coverage was required "beginning in 2016").

But the 2021 Guidelines did not replace this sentence with any other reference to fertility awareness instruction. Compl. Ex. A, ECF No. 1-1. Nor did HRSA say that fertility awareness instruction must still be covered. *Id.*

B. HRSA's declaration and opposing counsel's interpretations are not properly before this Court.

HRSA's declarant, however, offers an alternative interpretation. In his view, "FABM instruction is included in the 2021 Guidelines, as part of contraceptive counseling and education." Gov. Br. Ex. A ¶ 6. But "counseling" was already required in the previous guidelines, Compl. Ex. A at 3. That leaves "education," but only "contraceptive . . . education." "[P]atient education and counseling" were required in the *pre-2016* guidelines. *See Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 697 (2014) (quoting 77 Fed. Reg. 8725 (2012)). Yet, as noted above, HRSA's declarant admits that fertility awareness instruction was *not* covered by the pre-2016 guidelines—it was only covered by adding the explicit fertility awareness sentence. Declarant makes no mention, much less does he offer an explanation, of how the public or insurers are to interpret HRSA's deletion of the fertility awareness instruction sentence, especially given his assertion that such instruction was only covered because that sentence was inserted in the first place.

Counsel for the government offers yet another gloss on the text. They argue that because fertility awareness instruction is not "contraception listed by the FDA," it would be "misplaced" to include the fertility awareness sentence in the paragraph listing those methods. Gov. Br. at 5–6. This claim ignores two basic questions. (1) If

the sentence was merely "misplaced," why was it deleted, rather than simply moved to another paragraph? And (2) why was the sentence not "misplaced" in the preceding guidelines, when it *already* appeared in the paragraph listing FDA-approved contraceptives? The text of the previous guidelines is clear that the sentence was not "misplaced," because it begins with the word "[a]dditionally," offsetting the fertility awareness instruction from FDA-approved methods. More to the point, the previous Guidelines explicitly said that fertility awareness instruction must be covered. Counsel for HRSA does not explain how deleting that sentence maintains the coverage requirement. The plain reading of the 2021 Guidelines is that fertility awareness instruction was deleted, and "contraceptive counseling and education" includes contraceptives on the FDA listing but not fertility awareness instruction.

HRSA counsel also may be suggesting requirements to cover the "full range" of contraceptives or contraceptive methods encompasses every possible form of contraception, counseling, and education. Gov. Br. at 5–6. But that position makes it superfluous to list any methods in the 2016 and 2021 Guidelines, and to "[a]dditionally" list fertility awareness instruction in 2016. Compl. Ex. A at 3.

Because HRSA never offered these interpretations in its 2021 Guidelines, both the declaration and opposing counsel's views are inadmissible. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891 (2020). No "*post hoc* rationalizations" are permitted to defend agency actions, and when offered, they "are not properly before" the Court. *Id.* at 1909. The 2021 Guidelines can be defended only on the record as it existed in December 2021. HRSA is "limited to the agency's original reasons, and [its] explanation 'must be viewed critically' to ensure that the [decision] is not upheld on the basis of impermissible 'post hoc rationalization.' " *Id.* at 1908 (citation omitted).

HRSA offered no "original reasons" for deleting fertility awareness instruction coverage from the 2021 Guidelines. It never told the public it intended to do so. It never allowed the public to comment to HRSA—only to comment to an outside entity,

and not on this specific issue since HRSA omitted mention of this change in its notice. It never responded to the comments, even though several groups explicitly objected to this deletion. Compl. ¶ 116 n.11. And HRSA gave no rationale or explanation in the 2021 Guidelines, much the rationales offered here. If the text of the Guidelines is as clear as HRSA now asserts, it seems remarkable that the government felt the need to submit a declaration about it.

C. HRSA's actions harmed Dr. Tice-Harouff and her patients.

Since the government now contends fertility awareness instruction is within the 2021 Guidelines, it is unclear why it opposes this injunction, which would restore the coverage explicitly. But the government's verbal gymnastics interpreting these Guidelines should not distract from the harms HRSA caused. HRSA has deprived tens of millions of women, including many of Dr. Tice-Harouff's patients, of an explicit right to no-cost-sharing coverage of fertility awareness instruction, and the loss of this guarantee this will create uncertainty as well as financial and health injuries.

The government implausibly suggests that insurance plan attorneys will read the 2021 Guidelines as if they include fertility awareness instruction, even though the sentence including it was deleted, it was only required after that sentence was added in 2016, and the 2021 Guidelines provide no explanation to support this view. Nor is it clear how any judge hearing a patient's denial of claims case would look at the 2021 guidelines and adopt the government's interpretation. The ACA seeks to prevent patients from needing to fight an uphill battle against insurance companies to get the treatment they need with no cost-sharing.

HRSA's declaration cannot fix the problem it created by failing to consider and respond to comments about its serious changes to the Guidelines. First, a declaration by a subordinate HRSA official has no import. The statute gives authority to issue the Guidelines to HRSA, not to Mr. Wilson, who is only a director of one division in

HRSA. Gov. Br. Ex. A. ¶ 1. HRSA presented no evidence that HRSA Administrator Johnson delegated her authority to issue the Guidelines to Mr. Wilson—he merely says his duties include "advising" HRSA "regarding" the Guidelines. *Id.*

Nor is it clear that the declaration would have any effect if Ms. Johnson issued it. Only HHS's General Counsel, not HRSA, can issue legal opinions at HHS. 86 Fed. Reg. 6,349 (Jan. 21, 2021). And the statute here authorizes HRSA to issue only "guidelines," not interpretations. 42 U.S.C. § 300gg-13(a)(4). If this pronouncement is, essentially, a new or amended Guideline, it cannot go into effect for at least a year under § 300gg-13(b)(2). But if it is not a new Guideline, no insurer needs to follow it under paragraph (a). The only instrument for the Court to apply here is the 2021 Guidelines themselves, not the declaration, and the Guidelines deleted fertility awareness instruction coverage. As the government concedes, HRSA does not even enforce these Guidelines—that happens mainly through the Internal Revenue Code and ERISA, Gov. Br. at 13—so HRSA's mere interpretation is not dispositive.[1]

II. Dr. Tice-Harouff has standing for herself and her patients.

The 2021 Guidelines injure Dr. Tice-Harouff and her patients by removing their legal right to coverage and consequently their guarantee of reimbursement. HRSA's main argument against standing is its implausible interpretation of the Guidelines, but that argument cannot defeat standing because adopting it would impermissibly assume the merits of the case against Dr. Tice-Harouff. "For standing purposes, we accept as valid the merits of [plaintiffs'] legal claims." *FEC v. Cruz*, 142 S. Ct. 1638, 1647 (2022). The Court must assume Dr. Tice-Harouff's interpretation that the 2021 Guidelines remove coverage in assessing her standing and injury.

The record also establishes Dr. Tice-Harouff's independent financial injury. Even if a legal right were not at stake, a plaintiff would need only show she "will

[1] HRSA did not ask for judicial deference to this declaration, and deference would not be available under the limits of *Kisor v. Wilkie*, 139 S. Ct. 2400 (2019).

likely suffer financial harm" from a rule. *Tex. Med. Ass'n v. HHS*, 2022 WL 542879 at *5 (E.D. Tex. Feb. 23, 2022). Dr. Tice-Harouff has done so. On its face, eliminating an insurance coverage requirement—especially one that precludes cost-sharing—makes it "likely" that Dr. Tice-Harouff, who obtains tens of thousands of dollars in reimbursements for these services each year, will likely lose financial compensation.

The government contends that Dr. Tice-Harouff lacks proof that she will lose reimbursements or coverage, Gov. Br. at 7–8, but Dr. Tice-Harouff's verified complaint is affidavit evidence, *see, e.g.*, Compl. ¶¶ 46–64. Plus, beyond her own practice, Dr. Tice-Harouff submitted HHS's own evidence, which attests that because HRSA includes items in the contraceptive coverage Guidelines, women use the coverage more and receive more of that care. Compl. ¶¶ 70–71 & n.5. This means their providers receive more reimbursements. HRSA and HHS trumpeted this study in issuing the 2021 Guidelines and cannot credibly disavow its own evidence now.[2] This evidence, and Dr. Tice-Harouff's attestation that her instruction costs hundreds of dollars, Compl. ¶ 52–55, rebuts the government's contention that insurance companies will not drop coverage or impose cost-sharing. In any event, any uncertainty supports standing, because HRSA created this doubt by removing what had been a clear legal right to guaranteed coverage.

The government also contends Dr. Tice-Harouff cannot rely on her procedural injury from being denied the right to notice and comment under the APA. But a "threat of reduced sales" resulting from a rule suffices for standing, *Tex. Ass'n of Mfs. v. U.S. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 377 (5th Cir. 2021). This is Dr. Tice-Harouff's claim, that she "will face reduced demand for and compensation for her instruction in fertility awareness-based methods of family planning under the 2021 Guidelines." Compl. ¶ 75. Even where a rule merely causes "pressure" for a

[2] *See* https://www.hhs.gov/about/news/2022/01/11/hrsa-updates-affordable-care-act-preventive-health-care-guidelines-improve-care-women-children.html

different reimbursement outcome, "[t]his claimed procedural injury is sufficient to confer Article III standing." *Tex. Med. Ass'n*, 2022 WL 542879, at *4.

Finally, the government contends Dr. Tice-Harouff cannot assert third party standing on behalf of her patients. Gov. Br. at 9–10. The government says the rule does not punish Dr. Tice-Harouff, but even though it is not a criminal law, she is an object of the regulatory action because a requirement to provide insurance coverage is by definition a requirement to reimburse a service provider. Third party standing is also appropriate where an action "prevents a third-party from entering into a relationship with the litigant (typically a contractual relationship), to which relationship the third party has a legal entitlement." *Pa. Psychiatric Soc'y v. Green Spring Health Servs., Inc.*, 280 F.3d 278, 288 (3d Cir. 2002) (quoting *U.S. Dep't of Labor v. Triplett*, 494 U.S. 715, 720 (1990)). Dr. Tice-Harouff also has the "existing" patient relationships the court looked for in *Kowalski v. Tesmer*, 543 U.S. 125, 131 (2004), and her continuing receipt of those patients by referrals renders her future patients not hypothetical at all. *See* Compl. ¶¶ 47–59. Nor is HRSA correct that Dr. Tice-Harouff's current patients will not receive instruction next year: the complaint describes both their "first five months" of expenses, and also alleges this rule will preclude "follow-up sessions." Compl. at ¶ 53, 76.

An individual "need not face insurmountable hurdles to warrant third-party standing." *Pa. Psychiatric Soc'y*, 280 F.3d at 290. Only "some hindrance" need exist. *Powers v. Ohio*, 499 U.S. 400, 411 (1991). Patients' interest in keeping their family planning choices private is a well-recognized chill on direct suits. S*ee Singleton v. Wulff*, 428 U.S. 106, 117 (1976); *Carey v. Population Servs., Int'l*, 431 U.S. 678, 684 n.4 (1977); *Aid for Women v. Foulston*, 441 F.3d 1101, 1114 (10th Cir. 2006) (privacy concerns supported physicians' third-party standing to assert patients' rights). Litigation costs can also overshadow the costs to an individual patient, and the fact

that HRSA's rule will injure women who are not patients yet, but who will begin care after January, also hinders them from preventing that injury now.

A. HRSA violated the APA's notice and comment requirements.

On the merits, HRSA lacks any real argument that its guidelines are *not* final agency action subject to the APA's requirements.

HRSA does argue that the 2021 Guidelines are not substantive or binding. Gov. Br. at 13. But the Guidelines say plans and issuers "must" follow them, as does § 300gg-13(a). This is binding language. HRSA suggests that because the ACA incorporates the Guidelines into the Internal Revenue Code and ERISA, the Guidelines themselves are not binding. This conclusion does not follow. The Code and ERISA as enforcement instruments, and the Guidelines as substantive requirements, are all binding. These Guidelines are *what* the ACA incorporates into those codes. If HRSA lists an item in these Guidelines, it must be covered, and if not, the obligation does not apply. HRSA's declarant thus admits that when the guidelines added this sentence, coverage was mandatory. Gov. Br. at 4. HHS has always contended that § 300gg-13(a)(4) lets HRSA decide what "must be covered. . . ." *Little Sisters of the Poor v. Pennsylvania*, 140 S. Ct. 2367, 2380 (2020). And policies are rules where they impose "rights and obligations" and leave no discretion to be treated as optional. *Texas v. United States*, 809 F.3d 134, 171 (5th Cir. 2015).

HRSA also states that because other guidelines under § 300gg-13(a), such as for immunizations, exist separately and are created by external entities, the Guidelines here do not need notice and comment. Gov. Br. at 13. No case exempts those other guidelines from the APA. Regardless, these Guidelines under § 300gg-13(a)(4) are a new creation of the ACA. They did not predate the statute and come only from HRSA. They were never mere "recommendations."

The government's argument that it actually followed the APA's notice and comment requirements is deeply flawed. Gov. Br. at 13–15. HRSA invited comments but to an external entity not the government, and HRSA did not specify its intent to delete the fertility awareness sentence. Nothing indicates HRSA considered or read any comments. HRSA gave no response to them, discussed none of their objections, and gave no rationale for the deletion (much less the interpretation offered here). Telling the public to send their comments elsewhere, about other topics, and then ignoring their objections and offering no response, violates the APA.

The government thus fails to show its errors were "harmless." Gov. Br. at 15–17. HRSA's claim that the Catholic Medical Association's comments were sufficiently similar to Dr. Tice Harouff's objections lends no aid, because nothing in the 2021 Guidelines responded to those objections or offered any rationale for the alternate approach, and if anything their comments on behalf of her and other members support her sworn intent to file comments if given a future opportunity. Just as in *Texas Medical Association*, the presumption against harmless error applies. "Courts should 'rare[ly]' find harmless error for failure to provide notice and comment." *Tex. Med. Ass'n*, 2022 WL 542879, at *13 (quoting *United States v. Johnson*, 632 F.3d 912, 932 (5th Cir. 2011)). "[A]gencies cannot bypass notice and comment by claiming after the fact that they would not have changed anything." *Id.*

III. The 2021 Guidelines were arbitrary and capricious.

By mostly repeating its implausible interpretation of the Guidelines, HRSA essentially leaves undefended its choice not to consider or respond to significant comments (or any comments at all), discuss reliance interests, or offer a rationale in its 2021 Guidelines. Gov. Br. at 17–18. HRSA outsourced the Guidelines to a non-governmental entity and rubber-stamped its recommendations.

IV. Dr. Tice-Harouff and her patients face irreparable harm, and their need for relief is urgent.

The government says Dr. Tice-Harouff gave "no reason" why the injunction must issue now rather than in December. Gov. Br. at 19. But she cited state insurance regulations that required policy filings to begin earlier this year. Pl.'s Mot. at 14, ECF No. 4; Compl. ¶ 66 & n.4. HHS itself required many health plans to begin filing their changes in April.[3] And the ACA gives insurers a full year to know how the Guidelines will affect them—Guidelines this injunction will change. 42 U.S.C. § 300gg-13(b). In *Texas Medical Association*, HHS contended insurers "need months of lead time" to adjust to plan changes. 2022 WL 542879, at *11. This is universally true.

V. The balance of equities and the public interest favor relief.

HRSA's claim that fertility awareness instruction remains covered, while incorrect and non-binding, is nevertheless a concession that if this Court *actually* preserves that coverage with an injunction, no harm will result.

HRSA conclusively states it cannot issue the Guidelines if it must use notice and comment, but it did not attempt any showing, in either its brief or the 2021 Guidelines. HRSA's claim belies the fact that it went through a kind of comment period in 2021, albeit a poor imitation of one. Instead HRSA could have used that time to truly consider and respond to comments and offer rationales in compliance with the APA. HHS much more specifically alleged its need to avoid public comment in *Texas Medical Association*. 2022 WL 542879, at *11. Yet this Court rejected HHS's argument despite a statutory one-year deadline, which does not exist here. *Id.*

Finally, HRSA does not dispute that the proper remedy under the APA is to delay the effective date of the Guidelines as a whole, not just for Dr. Tice-Harouff.

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[3] CMS, "DRAFT Bulletin: Proposed Timing of QHP Data Submission and Certification for the 2023 Plan Year for Issuers in the Federally-facilitated Exchanges" (Nov. 23, 2021), https://www.cms.gov/files/document/Proposed-PY2023-QHP-Data-Submission-Certification-Timeline-Bulletin.pdf.

Respectfully submitted on this 29th day of June, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on June 29, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States District Court Eastern District of Texas by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Matthew S. Bowman
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