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 Hearing Requested

MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION, AND BRIEF IN SUPPORT

Plaintiff Cami Jo Tice-Harouff hereby moves for a temporary restraining order, a preliminary injunction, and a delay of effective date, and requests an oral hearing.

CONCISE STATEMENT OF REASONS AND AUTHORITIES

Does the Administrative Procedure Act require a federal agency to use notice-and-comment rulemaking when it issues a final, binding, nationwide change to health insurance coverage requirements that deprives women of care, or can it do so without offering any rationale or responding to critical comments?

In December 2021, Defendants acting through the Health Resources and Services Administration (collectively, HRSA) issued a final change to requirements authorized under the Affordable Care Act at 42 U.S.C. § 300gg-13(a)(4). Verified Compl. Ex. A ("2021 Guidelines"), ECF No. 1–1. That change removed an item from the contraceptive coverage requirement of the women's preventive services mandate. HRSA deleted language that had required plans to cover "instruction in fertility awareness-based methods" of family planning. *Id.* at 2–3. HRSA did not previously tell the public about that change, did not accept comments, did not respond to comments the public tried to submit, and did not offer any rationale. *See id.*

HRSA violated the Administrative Procedure Act (APA) in two ways. First, final agency actions that bind the public must provide public notice and meaningfully consider and respond to comments. 5 U.S.C. §§ 553, 706(2)(D). Second, agencies cannot act arbitrarily but must provide rationales for changes. 5 U.S.C. § 706(2)(A).

The Fifth Circuit requires agencies to comply with the APA "scrupulously," and exemptions "must be narrowly construed." *Texas v. United States*, 809 F.3d 134, 171 (5th Cir. 2015) (cleaned up). No exemptions apply here. The 2021 Guidelines are final and reviewable, as they consummated the agency's decision-making process, determined obligations of external insurance plans and the rights of beneficiaries, and the decision had legal consequences. *See id.* at 171, 177 (change to substantive standard requires notice and comment)*; Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). Courts also should only "rarely" find harmless error for failure to provide notice and comment. *Texas Med. Ass'n v.HHS*, No. 6:21-CV-425-JDK, 2022 WL 542879, at *13 (E.D. Tex. Feb. 23, 2022).

HRSA did not follow the notice-and-comment process. HRSA gave notice that other changes were recommended by a private entity, but it did not tell the public this specific change would happen, nor did it say why. 86 Fed. Reg. 59,741 (Oct. 28, 2021). Then HRSA did not accept comments, it told the public to send comments (about those other changes) to the private entity only. Some commenters raised concerns about this possible change, Compl. ¶116, but HRSA gave no response to their objections, nor any rationale at all. *See* Compl. Ex. A at 2–11.

HRSA also acted arbitrarily and capriciously under the APA. "An agency must consider and respond to significant comments." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). They must acknowledge changes are being made, offer good reasons, and address reliance interests. *See, e.g.*, *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020). HRSA did none of these things.

This illegal change injures Dr. Tice-Harouff and her patients. Insurance plans covered by this mandate provide tens of thousands of dollars in reimbursements for Dr. Tice-Harouff's fertility awareness instruction each year. Compl. ¶¶55–56. Her patients will lose the right to that coverage, causing them financial harm and negative health consequences when they cannot afford her care. Compl. ¶¶67–87. They urgently need relief from this Court, and the APA provides for that relief. The 2021 Guidelines go into effect at the end of December, but that lead time exists because insurance companies need many months to get regulatory approval for their next plan year, and they have already started this process. Compl. ¶¶6, 66. Under 5 U.S.C. § 705, this Court can delay the effective date of this change while this case is pending and enjoin Defendants from implementing the change. The government readily agrees to delays under § 705 in other cases. With this relief, women will not lose coverage while this case is pending.

FACTUAL BACKGROUND

The facts are set forth in the verified complaint, which is evidence supporting this motion. *King v. Dogan*, 31 F.3d 344, 346 (5th Cir. 1994).

Dr. Cami Jo Tice-Harouff is a family nurse practitioner in Gregg County, Texas, who is licensed to practice in Texas and licensed to provide telehealth in several states. Compl. ¶¶15, 45. She provides instruction in fertility awareness-based methods of family planning to patients in person and through telehealth across the country. Compl. ¶¶44–48, 62. An essential part of Dr. Tice-Harouff's ability to care for her patients, and their ability to receive her care, is her ability to bill her patients' private health insurance plans for her instruction. Compl. ¶¶54, 62.

A provision of the Affordable Care Act (42 U.S.C. § 300gg-13(a)4)) requires private health insurance plans to cover, with no co-pays or deductibles, women's preventive services as set forth in guidelines supported by the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and

Human Services (HHS). Compl. ¶¶17, 21. Since 2016, those guidelines have explicitly included "instruction in fertility awareness-based methods" of family planning (hereinafter "fertility awareness instruction"). Compl. ¶¶23–24.

But in December 2021, HRSA announced on its website that it is deleting that coverage language, to take effect after December 30, 2022. Compl. Ex. A at 9. On the 2021 Guidelines, Compl. Ex. A at 3–4, there is a side-by-side comparison of the current guidelines in effect until the end of 2022, and the 2021 Guidelines with its changes to go into effect at the end of the year. A sentence specifically requiring coverage of "instruction in fertility awareness-based methods" of family planning was deleted, and no reference to such methods remains in the new version. *Id.*

In making this change, HRSA did not use the notice-and-comment process set forth in the APA. HRSA gave notice in October 2021 that a private entity recommended *other* changes to the guidelines, but HRSA did not say fertility awareness instruction would be deleted or offer a reason for doing so. 86 Fed. Reg. 59,741 (Oct. 28, 2021). HRSA informed the public they could comment to that private entity about those other changes, but not that the public could comment to the government itself, nor that they could comment about fertility awareness instruction. *Id.* Some members of the public sent comments to the private entity objecting to the possible removal of fertility awareness instruction, asking for it not to be removed, and asking for an explanation. Compl. ¶116. But in issuing the final changes in the 2021 Guidelines, HRSA deleted the fertility awareness instruction language, offered no rationale for doing so, and did not respond to any comments. Compl. Ex. A at 3–4; *see also* Update to the Women's Preventive Services Guidelines, 87 Fed. Reg. 1,763 (Jan. 12, 2022) (publishing the changed guidelines).

Under state insurance regulations, companies are now pursuing approval of their January 2023 policies, to which the 2021 Guidelines apply. Compl. ¶¶6, 66.

STANDARD FOR GRANTING THE MOTION

Under the Administrative Procedure Act, "to prevent irreparable injury," this Court may "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705; *see Wages & White Lion Invs., LLC v.FDA*, 16 F.4th 1130, 1143 (5th Cir. 2021).

A plaintiff seeking a temporary restraining order, a preliminary injunction, or a delay under § 705 must show: (1) a substantial likelihood of success on the merits; (2) a substantial threat that the plaintiff will suffer irreparable harm without an injunction; (3) that the threatened injury outweighs any damage that the injunction might cause the defendants; and (4) that the injunction will not disserve the public interest. *Nichols v. Alcatel USA, Inc.*, 532 F.3d 364, 372 (5th Cir. 2008).

ARGUMENT

This Court should grant prompt injunctive relief to delay the effective date of the 2021 Guidelines' deletion of language covering fertility awareness instruction to protect Dr. Tice-Harouff's medical practice interests in offering care to her patients and to protect the health interests of her patients from the injury they face because of this illegal agency action.

I. Dr. Tice-Harouff and her patients have standing to sue.

Dr. Tice-Harouff and her patients have standing to sue, and their claims are ripe for review. Dr. Tice-Harouff may bring claims not just for herself but also on behalf of her patients. *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2118–20 (2020). They all face injuries in fact that are "concrete and particularized," "actual or imminent, not conjectural or hypothetical," fairly traceable to the challenged action, and likely to be redressed by the relief requested. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). Plaintiffs have standing if "they will likely suffer financial harm" from the new rule and if they "merely show a reasonable claim of minimal impact" on

their practices, which is why healthcare "providers" can sue over an insurance reimbursement rule when they "furnish services to patients [and] negotiate with insurers." *Texas Med. Ass'n*, 2022 WL 542879, at *4–5 (quotations omitted).

Dr. Tice-Harouff and her current and future patients face both tangible and procedural injuries that are ripe. Dr. Tice-Harouff generates tens of thousands of dollars every year from private insurance company reimbursements for her fertility awareness instruction. Compl. ¶¶55–56. Dr. Tice-Harouff generously directs the funds from her care to a nonprofit health clinic to benefit the poor in her community. Compl. ¶¶43, 57. Dr. Tice-Harouff's patients possess a right under the pre-2021 Guidelines to insurance coverage of fertility awareness instruction, which is enforceable, for example, under ERISA. *See* 29 U.S.C. § 1132(a). Compl. ¶¶23–24, 96, 99–100. Without that coverage guarantee, and its protection from co-pays and deductibles, Dr. Tice-Harouff's patients will suffer direct financial harm, which will result in many being unable to afford continuing to receive the care, and their health will suffer as a result. Compl. ¶¶67–87. HRSA itself admits that its inclusion of family planning methods in this very section of the guidelines on contraceptive coverage saves costs and improves health for tens of millions of women nationwide. Compl. ¶¶70–71. Thus, by deleting language on fertility awareness instruction in the 2021 Guidelines, HRSA harmed Dr. Tice-Harouff's practice, and injured her patients medically, financially, and legally. Dr. Tice-Harouff and her patients have suffered a procedural injury, too: being deprived of the right to participate in a meaningful notice-and-comment process. *See Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019).

All these injuries are directly traced to the 2021 Guidelines, the illegality of which this Court must assume for standing purposes. *See FEC v. Cruz*, No. 21-12, 142 S. Ct. 1638, 2022 WL 1528348, at *5 (U.S. May 16, 2022). The relief requested—delaying the change's effective date and enjoining its implementation—would directly

remedy these injuries by maintaining the pre-2021 coverage requirements and maintaining the status quo.

Finally, to bring an APA claim, a plaintiff must fall within the "zone of interests" of the statute at issue. *Texas v. United States*, 809 F.3d 134, 162 (5th Cir. 2015). That test "is not meant to be especially demanding . . . and is applied in keeping with Congress's 'evident intent' when enacting the APA 'to make agency action presumptively reviewable." *Id.* (cleaned up). Dr. Tice-Harouff and her patients are within the zone of interests to be protected by law. The ACA coverage mandate exists to ensure that women receive certain items covered in their insurance plans with no cost sharing. Dr. Tice-Harouff's patients, for whom she can assert these claims, thus fall within the underlying statute's interests. Patients cannot receive such care except from a licensed provider reimbursed by that plan. Dr. Tice-Harouff is such a provider, and she is integral to the delivery of the services protected by the ACA provision here. The APA's procedural requirements for allowing meaningful public participation in rulemaking exists to protect Dr. Tice-Harouff and her patients' rights against the government improperly changing standards like this one. *Cf. id.* at 163 (states may bring procedural APA challenge to immigration policy changes).

II. Dr. Tice-Harouff and her patients are likely to succeed on the merits.

A. The 2021 Guidelines are subject to review under the APA.

The 2021 Guidelines are final agency action subject to APA review. Agency action is final if it is: (1) the "consummation' of the agency's decisionmaking process"; and (2) "one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (cleaned up).

The 2021 Guidelines are the consummation of HRSA's decision-making process. The ACA says health plans "shall" cover women's preventive services items without cost sharing if they are listed in guidelines "supported" by HRSA. 42 U.S.C. § 300gg-13(a)(4). In the 2021 Guidelines HRSA said it was taking "formal action by

the Administrator" to implement that statutory provision. Compl. Ex. A at 8–9. The 2021 Guidelines have an effective date starting after December 30, 2022, because the statute requires that delay. § 300gg-13(b). The 2021 Guidelines are themselves the final agency decision issued by HRSA that triggers the effective date.

The 2021 Guidelines determine rights and obligations, and legal consequences flow from them. Although the statute calls them "guidelines," they operate as binding rules. When HRSA includes items in these guidelines, insurance providers "shall" provide coverage and "shall not" impose cost sharing for those items. 42 U.S.C. § 300gg-13(a). When HRSA includes an item, the mandate triggers, and when it omits an item, the mandate disappears. The guidelines themselves say health insurers "must provide coverage without cost sharing for the screenings and services in the guidelines," and that the guidelines "make sure" women receive these services. Compl. Ex. A at 2. This is the very definition of an "obligation" on the insurance company. And that obligation gives patients the concomitant right to receive the coverage. In particular, the 2021 Guidelines' deletion of language requiring fertility awareness instruction to be covered takes away an obligation that currently exists for health insurers to cover that instruction, and it takes away a right that patients in those plans currently have to receive that coverage.

B. The 2021 Guidelines violated notice-and-comment procedures.

1. The 2021 Guidelines are subject to notice and comment.

The 2021 Guidelines are not only subject to judicial review, they are subject to the APA's notice-and-comment requirements. An agency action is a substantive rule that must undergo notice and comment based on whether it (1) "imposes any rights and obligations," or (2) "genuinely leaves the agency and its decision-makers free to exercise discretion." *Texas v. United States*, 809 F.3d at 171.

The 2021 Guidelines are substantive rules. They impose obligations and yield rights. On their face and by statute, they oblige insurance companies and plans to

cover the items HRSA includes in the guidelines, and if, as here, HRSA withdraws an item from that list, the obligation does not apply. HRSA has discretion in creating the guidelines, but once issued, the guidelines leave no HRSA official with discretion to tell insurance plans that they need not cover an item listed, or vice versa. The guidelines are simply a list: items in the list must be covered, and items omitted fall outside the mandate. An action "applied by the agency in a way that indicates it is binding" is subject to notice and comment. *Id.* at 173. The 2021 Guidelines insist that "health insurers must provide coverage" of items in the list. Compl. Ex. A at 2.

No other exception to the APA's notice-and-comment requirements applies. For example, the 2021 Guidelines are not one "of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). The guidelines are externally facing, and they bind private entities. They are not concerned with internal government procedures.

2. The 2021 Guidelines did not follow the APA's notice-and-comment procedures.

The 2021 Guidelines did not follow the APA's notice-and-comment procedures, for three reasons: they failed to notify the public of the change in fertility awareness instruction coverage, they failed to let the public comment to the government on that topic, and they failed to respond to comments submitted.

a) HRSA did not fairly inform the public.

The APA requires an agency to publish a general notice of proposed rulemaking in the Federal Register, including "a statement of the time, place, and nature of public rule making proceedings" and "either the terms or substance of the proposed rule or a description of the subjects and issues involved," or else find good cause on the record to omit these procedures. 5 U.S.C. § 553(b).

In October 2021 HRSA published a notice in the Federal Register, but it did not satisfy the APA, for two reasons. *See* 86 Fed. Reg. 59,741. First, it did not purport to be a notice of proposed rulemaking. It is styled as a notice that a private contractor

hired by HRSA, the Women's Preventive Services Initiative, proposed to change what it *recommends* HRSA put into the guidelines. Second, and more substantively, the October 2021 notice nowhere mentions a proposal to remove fertility awareness instruction from the guidelines. *Id.* Instead, it specifies that the recommendations will: (a) rephrase "contraceptive methods" as "contraceptives"; (b) add condoms and delete the phrase "female controlled-contraceptives"; (c) add removal or discontinuation of contraceptives; and (d) amend language about HIV screening. 86 Fed. Reg. at 59,742. Nowhere does the notice say it is removing from the guidelines the sentence—which HRSA did eventually remove—that explicitly includes fertility awareness instruction. And nowhere does the notice offer a rationale for such a change to give the public adequate notice of it. Such "notice" is inadequate because it does not "fairly apprise interested persons of the nature of the rulemaking." *United Steelworkers of Am., AFL-CIO-CLC v. Marshall*, 647 F.2d 1189, 1221 (D.C. Cir. 1980) (cleaned up). When a notice states a "proceeding was limited to changing" one part of a standard and "substantive sections focus entirely" on that part, the notice is inadequate to reasonably inform the public the agency proposes to change another part. *MCI Telecomms. Corp. v. FCC*, 57 F.3d 1136, 1141 (D.C. Cir. 1995).

b) HRSA gave no real opportunity to comment.

HRSA did not allow public comment to the government, nor did it specifically allow comment on deleting coverage of fertility awareness instruction.

Because the October 2021 notice focused on other changes and failed to mention a proposal to delete language covering fertility awareness instruction, HRSA deprived the public of the opportunity to comment on deleting this language. Some private parties worried that HRSA or its contractor might wish to omit this language, and they submitted comments to HRSA's private contractor (more on that later). Compl. ¶116. But the fact that some parties raised that concern does not render the October 2021 notice adequate. Courts have "repeatedly" rejected the idea that

"because at least a few parties to the rulemaking did in fact comment upon the question" the notice must have been adequate. *MCI*, 57 F.3d at 1142. The October 2021 notice only invited comment on other topics, saying nothing about a possible removal of language covering fertility awareness instruction. "[T]he comments received do not cure the inadequacy of the notice given." *Id.*

More important still, the October 2021 notice gave no opportunity to comment to the government. The October 2021 notice directed all comments to the private agency WPSI and its website, not to HRSA, HHS, or www.regulations.gov. 86 Fed. Reg. at 59,741. HRSA admitted it would not review the comments; rather, "comments received on or before this date will be reviewed and considered *by the WPSI Multidisciplinary Steering Committee*." *Id.* (emphasis added). HRSA later clarified that WPSI's actions were not "part of the formal action by the Administrator under Section 2713." Compl. Ex. A at 7–8. There is no reason to believe HRSA ever reviewed the comments directed to WPSI, because as discussed below, the 2021 Guidelines gave no response to and did not mention any comments. Unlike comments on other proposed HHS rules, to date the comments WPSI received are not even publicly viewable. The October 2021 notice is framed, not as an invitation to comment *to HRSA* about *what HRSA plans to do*, but rather as an opportunity to comment *to WPSI* about *what WPSI plans to recommend* HRSA do. But "a federal agency may not abdicate its statutory duties by delegating them to a private entity." *Texas v. Rettig*, 987 F.3d 518, 531 (5th Cir. 2021) (cleaned up). An agency must "independently perform its reviewing, analytical and judgmental functions." *Sierra Club v. Lynn*, 502 F.2d 43, 59 (5th Cir. 1974). Only HRSA can fulfill its duties under the APA to issue the guidelines using proper procedures. 42 U.S.C. § 300g-13(a)(4).

c) HRSA did not respond to any comments.

The 2021 Guidelines also violated the APA because HRSA responded to no comments. Several groups, suspicious that this administration might be hostile to

fertility awareness instruction, submitted comments to WPSI objecting to the possible deletion of this language. Compl. ¶116. Their comments raised multiple issues, including the evidence-based nature of the methods; that many women rely on them and providers are reimbursed for them; and the possible costs and harms to women. *Id.* The 2021 Guidelines included no response to these comments or issues.

This violated the APA, which requires agencies to respond to significant issues raised in comments. Even "wan responses" to significant comments and issues violate the APA, *Delaware Dep't of Nat. Res. & Env't Control v. EPA*, 785 F.3d 1, 15 (D.C. Cir. 2015), but here HRSA offered no response or discussion. "[M]erely hearing is not good enough," the agency "must respond to serious objections." *Id.* at 16. HRSA did not even bother to "hear" the objections submitted.

3. The 2021 Guidelines were arbitrary and capricious.

HRSA's deletion of language covering fertility awareness instruction in the 2021 Guidelines should be enjoined under the APA for a related but distinct reason: the decision was "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A). This standard includes the agency's duty to reasonably explain its action. *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). It includes showing awareness that it is changing its position. *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221–22 (2016). It includes a duty to address important aspects of the issue. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). And it includes the duty to explain the impact on reliance interests and to consider alternatives. *Regents*, 140 S. Ct. at 1910–13.

The government did none of these things. Compl. Ex. A at 2–11; *see also* 87 Fed. Reg. 1,763. HRSA offered no discussion or even an acknowledgment that it was deleting the sentence covering fertility awareness instruction. It offered no rationale or explanation. It responded to no comments at all, much less comments objecting to deleting this language. It did not discuss the significant issues raised in those

comments, or significant issues inherent to deleting coverage of such a service, such as the reliance interests of women like Dr. Tice-Harouff's patients who currently receive no-cost-sharing coverage for this care.

III. Dr. Tice-Harouff and her patients face irreparable harm.

Dr. Tice-Harouff and her patients are "likely to suffer irreparable harm in the absence of preliminary relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). "[H]arm is irreparable where there is no adequate remedy at law, such as monetary damages." *Janvey v. Alguire*, 647 F.3d 585, 600 (5th Cir. 2011).

Dr. Tice-Harouff's patients will suffer health injuries when they need to forego this care due to cost when their coverage is lost or co-pays and deductibles are imposed. Compl. ¶¶67–87. They will also lose their legal right to require their health plans, insurers, and employers to cover the care due to it no longer being included in the guidelines, and therefore no longer enforceable. Compl. ¶¶23–24, 85–86, 96, 99–100. Dr. Tice-Harouff will likely lose future patients who will not seek her care due to lack of coverage. Compl. ¶76. And, as discussed above, losing this coverage will impose financial costs to Dr. Tice-Harouff and her patients. Compl. ¶¶67–87. There is no cause of action to recover damages from the government for violating the APA in making this change to the 2021 Guidelines. *Cf. Texas v. United States*, 328 F. Supp. 3d 662, 737 (S.D. Tex. 2018). Their harms from loss of coverage are thus irreparable.

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

This threatened injury to Dr. Tice-Harouff, her patients, and others like them outweigh whatever damage the proposed injunction may cause the government, and the balance of the equities and the public interest strongly favor an injunction.

First, relief would not harm the government. An injunction blocking the deletion of this sentence covering fertility awareness instruction would simply leave in place coverage that has existed in these guidelines since 2017. Compl. ¶¶2, 24, 99. HRSA offered no rationale for removing this coverage, and therefore can cite no

reason why it would harm the government or the public to retain it while this case is pending. Injunctive relief would "'simply suspend *administrative* alteration of the *status quo*.'" *Wages & White Lion Invs., LLC v FDA*, 16 F.4th 1130, 1144 (5th Cir. 2021) (quoting *Nken v. Holder*, 556 U.S. 418, 430 n.1 (2009)). HHS regularly consents to using 5 U.S.C. § 705, including by court order, to delay the effective date of challenged rules, for time-periods well over a year. *See, e.g.*, HHS Services Grants Regulation, 87 Fed. Reg. 31,432 (May 24, 2022) (delays totaling over 15 months so far); Delay of SUNSET Rule, 87 Fed. Reg. 12,399 (Mar. 4, 2022) (delay totaling 18 months so far). Relief would also not deprive any member of the public of insurance coverage of any preventive service.

In contrast, the harm to Dr. Tice-Harouff and her patients is imminent and serious, as discussed above. And time is of the essence. Insurance plans are already creating new policies and submitting them for regulatory approval. Compl. ¶6, 66; *see also* Cal. Ins. Code § 1758.991 (West 2002); Fla. Stat. Ann. § 627.410 (West 2020); N.Y. Ins. Law § 3201 (McKinney 2015); Tex. Ins. Code Ann. § 1701.051 (West 2005). Federal marketplace plans, also subject to these guidelines, begin open enrollment on November 1, a full two months before the next plan year starts.[1] The statute governing the 2021 Guidelines explicitly acknowledges that changes affecting health plan coverage need at least a year of lead time. 42 U.S.C. § 300gg-13(b)(2). The same is true for an injunction by this Court to provide effective relief.

For these reasons, an order of this Court retaining fertility awareness coverage language in the guidelines (by enjoining deletion of that language) is needed now, so regulators and insurers can prepare and approve January 2023 policies and conduct

[1] HHS, U.S. Centers for Medicare & Medicaid Servs., *When can you get health insurance?* https://www.healthcare.gov/quick-guide/dates-and-deadlines/ (last visited May 26, 2022).

open enrollment periods to include this coverage, thereby preventing any injury to Dr. Tice-Harouff and her patients.

An order pertaining to the 2021 Guidelines' deletion of fertility awareness coverage is fully appropriate. When an agency rule of broad applicability is unlawful, "the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual." *Texas Med. Ass'n*, 2022 WL 542879, at *15 (quotations omitted). Dr. Tice-Harouff cares for patients in Texas, and by telehealth cares for patients in California, Connecticut, Delaware, Florida, Kentucky, and Nevada, a list that she seeks to grow to address the provider shortage. Compl. ¶¶44–48, 62. Dr. Tice-Harouff's patients may receive care in places other than the states where they live or where their plan was issued. Compl. ¶¶59–62. Uniform mandatory coverage without cost sharing allows patients to receive uninterrupted care despite insurance changes, such as new plans from new jobs. Compl. ¶¶63–64. And, as noted above, HHS regularly consents to delaying the effective date of entire regulations under 5 U.S.C. § 705.

Finally, Plaintiff asks the Court to exercise its discretion to not require any security or bond under Fed. R. Civ. P. 65(c). This case serves the public interest by vindicating the statutory rights of patients and healthcare professionals. *See City of Atlanta v. Metro. Atlanta Rapid Transit Auth.*, 636 F.2d 1084, 1094 (5th Cir. 1981).

CONCLUSION

For these reasons, the Court should issue a temporary restraining order and preliminary injunction as set forth in the attached proposed order, delaying under 5 U.S.C. § 705 the effective date of the deletion of the language in the 2021 Guidelines requiring coverage of "instruction in fertility awareness-based methods" of family planning by two years to encompass the pendency of this case, and enjoining Defendants from deleting the language without notice-and-comment rulemaking.

Respectfully submitted on this 27th day of May, 2022.

/s/ Matthew S. Bowman

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CERTIFICATE OF SERVICE

I certify that this document was electronically filed on May 27, 2022, sent by email to James Gillingham, Assistant United States Attorney at the U.S. Attorney's Office for the Eastern District of Texas at James.Gillingham@usdoj.gov, and sent via certified mail, return receipt requested on May 27, 2022, to:

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CERTIFICATE OF CONFERENCE

On May 25, 2022, because counsel for Defendants had not yet appeared in the case, I contacted the Federal Programs Branch of the Civil Division of the U.S. Department of Justice, which regularly provides defense in response to Administrative Procedure Act claims filed against HHS and its components. I first spoke by telephone with DOJ Trial Attorney Cassandra M. Snyder. Ms. Snyder referred me to Michelle Bennett, Assistant Branch Director. I telephoned Ms. Bennett but had to leave a voicemail, and I also emailed her. On May 26, Ms. Bennett emailed me to refer me to James Gillingham at the U.S. Attorney's Office in Tyler. I spoke with Mr. Gillingham by phone on May 26 and conducted the conference and meeting under Local Rule CV-7(h). After consulting with his client on May 27, Mr. Gillingham informed me that the government opposes this motion. As a result, discussions conclusively led to an impasse and Defendants oppose this motion, leaving an open issue for the Court to resolve.

/s/ Matthew S. Bowman
MATTHEW S. BOWMAN