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

CAMI JO TICE-HAROUFF,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Case No. 6:22-cv-201-JDK
	§	
CAROLE JOHNSON, et al.,	§	
	§	
Defendants.	§	
	§	

MEMORANDUM OPINION AND ORDER

Plaintiff Dr. Cami Jo Tice-Harouff is a family nurse practitioner who instructs patients in fertility awareness-based methods of family planning. For the past five years, regulations issued by the Health Resources and Services Administration have required insurers to cover the full cost of this instruction. In December 2021, the agency deleted the sentence requiring coverage. Dr. Tice-Harouff argues that the change violates the Administrative Procedure Act because it was made without notice and comment and because it was arbitrary and capricious. Dr. Tice-Harouff now seeks a preliminary injunction to preserve the status quo pending the resolution of her claims. Docket No. 4.

As explained below, the Court concludes that this change was likely made in violation of the Administrative Procedure Act, Dr. Tice-Harouff is likely to be irreparably harmed by the change, and the balance of equities supports a preliminary injunction. Accordingly, the Court **GRANTS** Dr. Tice-Harouff's motion for a preliminary injunction.

I.

A.

Congress enacted the Patient Protection and Affordable Care Act ("ACA") in 2010, mandating that health insurance providers cover certain services as part of a qualified health plan. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2713, 124 Stat. 119, 131–32 (2010). At issue here is a requirement for "preventive health services," which provides that all group health and health insurance plans "shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for" preventive health services. 42 U.S.C. § 300gg-13(a). The ACA does not specify the preventive health services subject to the requirement, but rather delegates that determination to the Health Resources and Services Administration ("HRSA"). Section 300gg-13(a)(4) provides that, "with respect to women," insurers must cover the entire cost of "such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by the [HRSA]." 42 U.S.C. § 300gg-13(a)(4).

2011 Guidelines. The HRSA issued its first set of "comprehensive guidelines" in 2011. *See* Updated HRSA-Supported Women's Preventive Services Guidelines: Contraception and Screening for HIV Infection, 86 Fed. Reg. 59,741, 59,742 (Oct. 28, 2021). The 2011 Guidelines mandated coverage, without cost sharing, for several preventive services recommended by the Institute of Medicine (now known as the National Academy of Medicine) and included a section covering contraceptives to prevent unplanned pregnancies. *Id.* This section of the Guidelines is commonly referred to as the "contraceptive mandate." *See, e.g.*, *Little Sisters of the Poor Saints*

Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2374 (2020). The contraceptive mandate in the 2011 Guidelines provided a short recommendation for contraceptive methods and sterilization procedures approved by the U.S. Food and Drug Administration ("FDA"), as well as related education and counseling. *See id.* The 2011 Guidelines required coverage for: "All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." *Women's Preventive Services Guidelines Historical Files*, U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION, https://www.hrsa.gov/womens-guidelines-historical-files [hereinafter *HRSA Historical Files*].

The contraceptive mandate proved controversial and was the subject of many court challenges. *See, e.g.*, *Little Sisters of the Poor*, 140 S. Ct. at 2376–77 (discussing cases). Many women oppose the use of medical contraceptives for philosophical or religious reasons. Docket No. 1 ¶ 50. Additionally, many women are unable to use medical contraceptives due to health concerns. *Id.*

2016 Guidelines. In March 2016, the agency changed course by awarding a contract to the Women's Preventive Services Initiative ("WPSI"), an initiative by the American College of Obstetricians and Gynecologists, to draft and recommend new Guidelines for plan years 2018 through 2022. *See* 86 Fed. Reg. at 59,741–42. Like the 2011 Guidelines, the 2016 Guidelines mandate cost-free coverage of FDA-approved contraceptive methods, practices, and sterilization procedures, as well as related counseling and follow-up care. *See* Docket No. 1, Ex. A at 3–4.

The 2016 Guidelines also include a list of all covered FDA-approved methods—and add a new sentence at the end: "Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method." *Id.* Fertility awareness-based methods counseling ("FABM counseling"), also known as "natural family planning," helps women avoid or achieve pregnancy in many situations, including without using medical contraceptives. *See* Docket No. 1 ¶¶ 48–51, 58. HRSA approved these updates to the Guidelines on December 20, 2016. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792, 14,798 (Oct. 13, 2017). The 2016 Guidelines, which remain in effect today, provide as follows:

> WPSI recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (e.g., management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care.
>
> The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), 8) [sic] oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA.

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

Docket No. 1, Ex. A at 3–4.[1]

This lawsuit stems from the final sentence, which requires cost-free coverage for FABM counseling.

B.

In March 2021, HRSA awarded a second five-year cooperative agreement to WSPI to formulate new recommendations to the Guidelines. 86 Fed. Reg. at 59,742. On October 28, 2021, the agency posted a notice to the Federal Register ("the October Notice") announcing the renewed contract and seeking "comments on two updated draft recommendations for (1) providing contraception and (2) screening for human immunodeficiency virus (HIV) infection" under the Guidelines. *Id.* at 59,741. The October Notice explained that the recommended changes regarding contraception are intended to "clarify the terminology from contraceptive methods to contraceptives," remove "the term 'female-controlled contraceptives' to allow women to purchase male condoms for pregnancy prevention," and "further define[] the existing components of contraceptive follow-up care." *Id.* at 59,742. Although nothing in the Notice mentioned FABM counseling, the final sentence of the 2016 Guidelines requiring

[1] HRSA issued a web publication with a side-by-side comparison of the 2016 Guidelines with the 2021 Guidelines, which are set to take effect beginning in plan years starting with 2023. *See Women's Preventive Services Guidelines*, U.S. HEALTH RESOURCES AND SERVICES ADMINISTRATION, https://www.hrsa.gov/womens-guidelines/index.html. For simplicity, the Court will cite to the copy of this webpage that the parties have submitted into the record. *See* Docket No. 1, Ex. A.

cost-free coverage for FABM counseling was not included in the draft recommendation. *See id.*[2]

HRSA approved the changes to the Guidelines on December 30, 2021. Update to the Women's Preventive Services Guidelines, 87 Fed. Reg. 1,763, 1,763 (Jan. 12, 2022). The agency published a notice of the action in the Federal Register on January 12, 2022 ("the January Notice"). *Id.* The January Notice included a summary of the contraceptive mandate under the 2021 Guidelines and provided a hyperlink to view the full Guidelines on HRSA's website. *Id.* at 1,763–64. The summary explained that the contraceptive mandate requires "screening, education, counseling, and provision of" the "full range" of FDA-approved contraceptives. *Id.* at 1,764. The January Notice did not mention FABM counseling, and the final 2021 Guidelines lack a counterpart to the final sentence of the 2016 Guidelines. *See id.*; Docket No. 1, Ex. A. The 2021 Guidelines provide as follows:

> WPSI recommends that adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent unintended pregnancies and improve birth outcomes. Contraceptive care includes screening, education, counseling, and provision of contraceptives (including in the immediate postpartum period). Contraceptive care also includes follow-up care (e.g., management, evaluation and changes, including the removal, continuation, and discontinuation of contraceptives).
>
> WPSI recommends that the full range of U.S. Food and Drug Administration (FDA)-approved, -granted, or -cleared contraceptives, effective family planning practices, and sterilization procedures be available as part of contraceptive care.

[2] The October Notice invited members of the public to submit written comments to the WPSI Multidisciplinary Steering Committee by November 29, 2021. 86 Fed. Reg. at 59,741. WPSI's website advised commenters that it could not "provide responses to individual comments," Docket No. 1 ¶ 128, and submitted comments are currently unavailable to the public. *Id.* ¶ 121.

> The full range of contraceptives includes those currently listed in the FDA's Birth Control Guide: (1) sterilization surgery for women, (2) implantable rods, (3) copper intrauterine devices, (4) intrauterine devices with progestin (all durations and doses), (5) injectable contraceptives, (6) oral contraceptives (combined pill), 7) [sic] oral contraceptives (progestin only), (8) oral contraceptives (extended or continuous use), (9) the contraceptive patch, (10) vaginal contraceptive rings, (11) diaphragms, (12) contraceptive sponges, (13) cervical caps, (14) condoms, (15) spermicides, (16) emergency contraception (levonorgestrel), and (17) emergency contraception (ulipristal acetate), and any additional contraceptives approved, granted, or cleared by the FDA.

Docket No. 1, Ex. A at 3–4.

Under § 300gg-13(b)(2), HRSA must provide at least one year between the date it adopts a set of Guidelines and the start date of health plans subject to the new requirements. 42 U.S.C. § 300gg-13(b)(2). Thus, insurers must cover items in the 2021 Guidelines starting with plan year 2023. Docket No. 1, Ex. A at 9 n.*.

C.

Plaintiff Cami Jo Tice-Harouff, DNP, APRN, FNP-C, is a family nurse practitioner who instructs patients in fertility awareness-based methods of family planning and is compensated by insurance companies under the 2016 Guidelines. Docket No. 1 ¶¶ 15, 37–38. Generally, patients meet with Dr. Tice-Harouff six times during the first six months of counseling; each session lasts one to two hours; and Dr. Tice-Harouff is reimbursed by insurers at a rate of $300 to $450 per session. *Id.* ¶¶ 52–55. In the first six months of 2022, Dr. Tice-Harouff's FABM counseling has generated at least $20,000 in insurance reimbursement payments. *Id.* ¶ 56.

Dr. Tice-Harouff filed this suit on May 25, 2022, challenging the deletion of the final sentence of the 2016 Guidelines under the Administrative Procedure Act

("APA"). Docket No. 1. Defendants are the agencies responsible for adopting the 2021 Guidelines—the United States Department of Health and Human Services ("HHS") and its operating division the HRSA—along with their current heads, Secretary Xavier Becerra and Administrator Carole Johnson. *Id.* ¶ 16–19.

Dr. Tice-Harouff asserts two claims. First, she alleges that Defendants failed to provide notice and comment as required by the APA when adopting the 2021 Guidelines. *Id.* at 23–24. Second, she argues that Defendants' adoption of the 2021 Guidelines is arbitrary, capricious, and an abuse of discretion for failure to engage in reasoned decision making. *Id.* at 25–26.

It is uncontested that the 2021 Guidelines are a final agency action subject to judicial review under the APA. *See Texas v. United States*, 809 F.3d 134, 163 (5th Cir. 2015) (discussing the strong presumption of judicial review of final administrative action); *see also Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (explaining that agency action is final when it (1) represents the consummation of the decision-making process and (2) is the action from which legal consequences flow).

Before the Court is Dr. Tice-Harouff's motion for a temporary restraining order and preliminary injunction seeking to delay the effective date of the deletion of the final sentence of the 2016 Guidelines from December 30, 2022, until December 30, 2024. *See* Docket No. 4. Defendants filed an opposition. Docket No. 20. The Court held a hearing on the motion on July 12, 2022.

II.

Defendants contend that Dr. Tice-Harouff lacks standing to challenge the 2021 Guidelines because she "relies solely on her unsupported speculation of future injury." Docket No. 20 at 9.

The elements of Article III standing are: (1) "an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical;" (2) that the injury is "fairly traceable" to the defendant's conduct; and (3) that the injury is redressable by a favorable decision. *El Paso Cnty. v. Trump*, 982 F.3d 332, 337 (5th Cir. 2020) (quoting *Friends of the Earth, Inc. v. Laidlaw Env't. Servs. (TOC), Inc.*, 528 U.S. 167, 180–81 (2000)). "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

Here, Dr. Tice-Harouff pleads at least two injuries fairly traceable to the change made by the 2021 Guidelines.[3]

First, Dr. Tice-Harouff alleges a procedural injury from HRSA's failure to comply with the APA's notice-and-comment requirement. Docket No. 1 ¶¶ 85–92. A plaintiff may claim an injury in fact from the deprivation of "a procedural right to protect his concrete interests." *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (emphasis removed) (quoting *Lujan*, 504 U.S. at 573 n.7). "A violation of the APA's notice-and-comment requirements is one example of a deprivation of a

[3] Having found that Dr. Tice-Harouff pleads at least two injuries to herself, the Court need not consider the argument that she also has third-party standing to vindicate the rights of her patients. *See* Docket No. 4 at 5.

procedural right." *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019) (citing S*ierra Club v. EPA*, 699 F.3d 530, 533 (D.C. Cir. 2012)). And Dr. Tice-Harouff alleges a concrete interest in keeping and attracting new patients through coverage of FABM counseling without cost sharing. *See, e.g.*, *Sierra Club*, 699 F.3d at 533 (holding plaintiffs who lived in a zone exposed to emissions had a concrete interest creating a procedural right to notice and comment); *LifeNet, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 2022 WL 2959715, at *7 n.5 (E.D. Tex. July 26, 2022) (holding plaintiff could claim procedural injury based on concrete financial interest).

Second, Dr. Tice-Harouff alleges a financial injury from HRSA's removal of the final sentence expressly requiring coverage of FABM counseling. In her complaint, which Dr. Tice-Harouff verified, she alleges that fewer insurers will provide cost-free coverage of FABM counseling if such counseling is not specifically included in the Guidelines. Docket No. 1 ¶ 71. She also alleges that, based on government studies and her own experience as a healthcare provider, fewer patients will seek FABM counseling if insurers fail to provide cost-free coverage. *Id.* ¶¶ 70–77. Thus, the removal of FABM counseling from the 2021 Guidelines will inevitably result in fewer patients seeking Dr. Tice-Harouff's FABM counseling services, which in turn will reduce her income. *See id.* ¶¶ 52–56. Dr. Tice-Harouff states: "[I] will likely lose existing patients, have fewer new patients, have fewer patient follow-up sessions, have more patients self-pay at discounted rates below insurance reimbursements, and have more patients participate in charity care, under the 2021 Guidelines." *Id.* ¶ 76. "Such 'economic injury is a quintessential injury upon which to base standing.'"

Tex. Med. Ass'n v. United States Dep't of Health & Hum. Servs., 2022 WL 542879, at *5 (E.D. Tex. Feb. 23, 2022) (quoting *El Paso Cnty.*, 982 F.3d at 338).

Defendants argue that Dr. Tice-Harouff's financial injury "is too conjectural or hypothetical to confer standing." Docket No. 20 at 8 (citation omitted).[4] But Dr. Tice-Harouff has alleged the likelihood of each specific fact in the chain of events that will cause her to lose revenue. And the chain is neither long nor improbable. HHS's own studies demonstrate that insurers are more likely to impose cost sharing—or eliminate coverage altogether—for a contraceptive method that is not specifically identified in the HRSA Guidelines. *See* Docket No. 1 ¶ 71 (citing Assistant Secretary for Planning and Evaluation, *Access to Preventive Services without Cost-Sharing: Evidence from the Affordable Care Act*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES 1, 9–10 (Jan. 11, 2022), https://aspe.hhs.gov/sites/default/files/documents/786fa55a84e7e3833961933124d70dd2/preventive-services-ib-2022.pdf [hereinafter *Access to Preventive Services*]). These studies also show that imposing cost sharing or eliminating coverage results in fewer patients seeking those services. *See id.* And fewer patients means less income for FABM counselors like Dr. Tice-Harouff. *See Tex. Ass'n of Mfrs. v. Consumer Prod. Safety Comm'n*, 989 F.3d 368, 377–78 (5th Cir. 2021) (holding that "the threat of reduced sales to companies" was "sufficiently concrete" to confer standing); *see also Tozzi v. U.S. Dep't of Health & Hum. Servs.*,

[4] Defendants also contend that Dr. Tice-Harouff will not suffer her alleged injuries because the 2021 Guidelines do not actually eliminate the requirement to cover the cost of FABM counseling without cost sharing. *See* Docket No. 20 at 7. This is an argument more properly considered under the merits. *See, e.g.*, *FEC v. Cruz*, 142 S. Ct. 1638, 1647–48 (2022) (explaining that courts assume the validity of a plaintiff's legal claims when evaluating standing). In any event, as explained *infra*, part III.A., the argument fails for numerous reasons.

271 F.3d 301, 308–09 (D.C. Cir. 2001) (using evidence of local government action to determine that plaintiff was likely to lose sales).

Further, "[t]he Supreme Court routinely recognizes probable economic injury resulting from governmental actions that alter competitive conditions." *Tex. Ass'n of Mfrs.*, 989 F.3d at 377 (citing *Clinton v. City of New York*, 524 U.S. 417, 433 (1998)). Here, there is little doubt that eliminating the requirement to provide cost-free coverage for FABM counseling will affect the market for FABM instruction. It would, for example, almost certainly change how providers like Dr. Tice-Harouff are paid, which would have an immediate impact on ordinary business decisions regarding their practices. *See Sabre, Inc. v. Dep't of Transp.*, 429 F.3d 1113, 1117 (D.C. Cir. 2005) (finding an injury from the "Rule's immediate impact on [Plaintiff's] ability to make business decisions about the products it will offer in the market"). Such an impact "can itself create an Article III injury." *Clinton*, 524 U.S. at 433 n.22 (holding "that a denial of a benefit in the bargaining process" can create a cognizable injury).

Having pleaded at least two injuries that are actual and imminent, Dr. Tice-Harouff has satisfied the first element of Article III standing. And because Defendants do not challenge the other elements, the Court concludes that Dr. Tice-Harouff has adequately alleged standing.

III.

Dr. Tice-Harouff seeks a preliminary injunction delaying the deletion of the final sentence of the 2016 Guidelines to preserve the status quo until this suit has been resolved. Docket No. 4. The APA provides that "the reviewing court" may issue equitable relief "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. Courts grant relief under § 705 based on the traditional four equitable factors for injunctive relief: (1) plaintiff's likelihood of success on the merits; (2) plaintiff's threat of irreparable harm without a stay; (3) "whether other interested parties will be irreparably injured by a stay;" and (4) the public interests. *Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1135 (5th Cir. 2021) (citing *Nken v. Holder*, 556 U.S. 418, 426 (2009)). "The first two factors are the most critical." *Id.* (quoting *Valentine v. Collier*, 956 F.3d 797, 801 (5th Cir. 2020)). Once a plaintiff has made a showing under the first two factors, the third and fourth factors "merge when the Government is the opposing party." *Nken*, 556 U.S. at 435. As discussed below, each factor weighs in favor of issuing a preliminary injunction here.

A.

The first factor is Plaintiff's likelihood of success on the merits. This factor tilts strongly in favor of injunctive relief. On the merits, Dr. Tice-Harouff presents two independent claims for relief: (1) Defendants violated the APA by deleting the final sentence of the 2016 Guidelines regarding FABM counseling without notice and comment, and (2) Defendants' action is arbitrary and capricious under the APA because HRSA failed to offer any rationale for the decision. Docket No. 1 at 23–26.

As an initial matter, Defendants argue that deleting the FABM sentence did not remove the obligation to provide cost-free coverage for FABM counseling—and thus the notice-and-comment requirement did not apply, and the deletion was not arbitrary and capricious. Docket No. 20 at 5–6, 12–13. This argument is specious. When language is removed from a statute or rule, courts presume that the omission

changed the text's meaning. *See* ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 256 (2012) ("[A] change in the language of a prior statute presumably connotes a change in meaning."). In *Peavy v. WFAA-TV, Inc.*, for example, the Fifth Circuit held that Congress's deletion of language creating civil liability from the Federal Wiretap Act meant that Congress was eliminating such liability from the statute. 221 F.3d 158, 168–69 (5th Cir. 2000). "When Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect." *Id.* at 169 (quoting *Stone v. I.N.S.*, 514 U.S. 386, 397 (1995)). And when a lawmaker deletes substantive language, courts should presume that the lawmaker has "intentionally and purposely" done so. *See id.* (quoting *BFP v. Resolution Trust Corp.*, 511 U.S. 531, 537 (1994)).

Defendants contend that the 2021 Guidelines still require cost-free coverage for FABM counseling because the Guidelines require coverage for "contraceptive care," which includes "screening, *education, counseling*, and provision of contraceptives." Docket No. 20 at 5–6 (quoting Docket No. 1, Ex. A). But the 2011 Guidelines also required coverage for "patient education and counseling," and no one understood that to include FABM counseling. *See HRSA Historical Files*, *supra*; *see also* Docket No. 20-1, Declaration of Lee A. Wilson, ¶ 3. It was not until the 2016 Guidelines—with the final sentence expressly requiring cost-free coverage for "instruction in [FABM] methods"—that such coverage was required. *See* Docket No. 1, Ex. A; *see also* 82 Fed. Reg. at 47,798. Further, the 2016 Guidelines also required coverage for "contraceptive counseling," and yet the final sentence was

included to require coverage for FABM counseling. *See* SCALIA & GARNER, *supra*, at 174 (explaining courts should avoid "an interpretation that causes it to duplicate another provision"). Defendants' interpretation, moreover, renders superfluous two of the three paragraphs in the 2021 Guidelines. If the phrase "contraceptives and contraceptive care" in the first paragraph covers all forms of treatment and counseling to prevent unintended pregnancies, then there would be no need for the second and third paragraphs, which require coverage for "the full range" of FDA-approved "contraceptives, effective family planning practices, and sterilization procedures." Docket No. 1, Ex. A at 3–4; *see also, e.g.*, *Republic of Sudan v. Harrison*, 139 S. Ct. 1048, 1058 (2019) (explaining that courts should be "hesitant to adopt an interpretation" of a legal text that "renders superfluous another portion of the same" text (citation omitted)).[5]

[5] In a notice filed after the preliminary injunction hearing, Defendants informed the Court that HRSA has added a footnote to the 2021 Guidelines to clarify that "[e]ducation and counseling" includes "fertility-based awareness [sic] methods, including lactation amenorrhea." Docket No. 26 at 1; *see also id.*, Ex. A at 9 n.****. This does not change the meaning of the Guidelines for the purpose of the pending motion. If the footnote is an operative part of the Guidelines, the new requirement does not bind insurance companies for at least one year. *See* 42 U.S.C. § 300gg-13(b). Thus, health plans in plan year 2023 are not required to include cost-free coverage for FABM counseling. On the other hand, if Defendants added the footnote as an interpretive statement, the Court need not and does not consider it because (a) the 2021 Guidelines are not ambiguous after applying "all the 'traditional tools' of construction," and (b) "convenient litigation positions or *post hoc* rationalizations" are rarely entitled to deference. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2415, 2417–18 (2019); *see also, e.g.*, *Univ. of Tex. M.D. Anderson Cancer Ctr. v. United States Dep't of Health & Hum. Servs.*, 985 F.3d 472, 476 (5th Cir. 2021) (explaining courts review agency regulations *de novo* unless the agency demonstrates the regulation is genuinely ambiguous).

To further support their interpretation, Defendants also submitted the declaration of Lee A. Wilson, a Division Director for the Administration, Docket No. 20-1, Declaration of Lee A. Wilson, ¶ 6, and the "Frequently Asked Questions" page from the Center for Consumer Information and Insurance Oversight, Docket No. 26, Ex. B. Neither of these documents is entitled to deference for the same two reasons discussed above, and for the additional reason that they do not appear to be "authoritative" statements. *See Kisor*, 139 S. Ct. at 2416–17.

Accordingly, the Court concludes that the 2021 Guidelines eliminated the requirement to provide cost-free coverage of FABM counseling. The Court now turns to Dr. Tice-Harouff's procedural and substantive challenges to the 2021 Guidelines in light of this conclusion.

1.

Claim One alleges that Defendants violated the APA by adopting the 2021 Guidelines without notice and comment. Docket No. 1 at 23–24; Docket No. 4 at 8–12. As explained below, the Court concludes that Dr. Tice-Harouff is likely to prevail on the merits of this claim.

The APA requires agencies promulgating "substantive" or "legislative" rules to provide "notice of proposed rule making" through publication "in the Federal Register," "give interested persons an opportunity to participate . . . through submission of written data, views, or arguments," and then, after considering these public comments, "incorporate in the rules adopted a concise general statement of [the rules'] basis and purpose." 5 U.S.C. § 553(b)–(c). "[T]he full panoply of notice-and-comment requirements must be adhered to scrupulously" whenever an agency adopts a "substantive" rule. *Texas v. United States*, 809 F.3d at 171 (quoting *Prof'ls & Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995)). A substantive rule is "an agency statement of general . . . applicability and future effect" which "(1) imposes any rights and obligations" and (2) does not genuinely leave "the agency and its decision-makers free to exercise discretion." *Id.* at 171 & n.122 (cleaned up); *see also* 5 U.S.C. § 551(4) (defining "rule").

The purpose of the "notice-and-comment" requirement is to "assure fairness and mature consideration of rules having a substantial impact on those regulated" and for the agency to "disclose its thinking on matters that will affect regulated parties." *United States v. Johnson*, 632 F.3d 912, 931 (5th Cir. 2011) (cleaned up). Courts are to look beyond recitations of "[f]ormal labels" and instead consider whether the notice "air[ed] the relevant issues with sufficient detail for [interested parties] to understand the [agency's] position." *Little Sisters of the Poor*, 140 S. Ct. at 2384–85. Thus, "notice is sufficient if it affords interested parties a reasonable opportunity to participate in the rulemaking process, and if the parties have not been deprived of the opportunity to present relevant information by lack of notice that the issue was there." *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008) (cleaned up). An agency rule issued without notice and comment is "contrary to law" and must be "set aside" unless the agency can show a valid exception to the requirement or that the error was harmless. *See* 5 U.S.C. § 706(2)(A); *see also Tex. Med. Ass'n*, 2022 WL 542879, at *9.

Here, the 2021 Guidelines are substantive rules subject to the APA because they are an agency "statement of general or particular applicability and future effect designed to implement" the requirements of § 300gg-13(a). *See* 5 U.S.C. § 551(4); *Texas v. United States*, 809 F.3d at 171 & n.122. The Guidelines establish the rights of patients, specify the obligations of health insurance providers, and leave no discretion to other actors. *See Texas v. United States*, 809 F.3d at 171 (explaining the criteria for substantive rules); *cf. Little Sisters of the Poor*, 140 S. Ct. at 2380

(explaining that the government has long maintained that § 300gg-13(a)(4) authorizes HRSA to determine what preventive care "must be covered" and promulgate formal exemptions from the requirements); *Walmart Inc. v. U.S. Dep't of Just.*, 21 F.4th 300, 308–09 & n.5 (5th Cir. 2021) (holding negotiating positions are not "rules" subject to the APA because they do not apply beyond the litigation).

Yet, when HRSA provided notice of its intent to adopt the 2021 Guidelines, the agency failed to give adequate notice of the elimination of coverage for FABM counseling. The October 2021 Notice is the only publication that could have served as a notice of proposed rulemaking. *See* 86 Fed. Reg. at 59,742. That notice provided a brief statement that HRSA, based on recommendations by WPSI, intended to make three updates to the contraceptive mandate. *See id.* The specified changes were to (1) "clarify the terminology from contraceptive methods to contraceptives," (2) remove "the term 'female-controlled contraceptives,'" and (3) expand "the existing components of contraceptive follow-up care to include the management" of "the contraceptive." *Id.* The October Notice never discussed, mentioned, or alluded to instruction in fertility awareness-based methods. *See id.* Silence falls well short of "a description of the subjects and issues involved." *See* 5 U.S.C. § 553(b)(3). Dr. Tice-Harouff was harmed by this lack of notice because she was unable to exercise her right to comment on the benefits of the current Guidelines. *See* Docket No. 1 ¶¶ 89–91; *Air Transp. Ass'n of Am. v. FAA*, 169 F.3d 1, 8 (D.C. Cir. 1999) (finding prejudicial error when plaintiff "had no knowledge" of the agency's decision making until the final decision was made).

Defendants' arguments to the contrary fail. Defendants first argue that the notice-and-comment requirement does not apply because the Guidelines are merely "clinical recommendations," not a substantive rule. Docket No. 20 at 13 & n.9. But the Guidelines impose binding requirements on insurers and create rights for certain patients. Section 300gg-13(a) requires insurers to provide no-cost coverage for women for the "preventive care and screenings . . . as provided for in comprehensive guidelines supported by the [HRSA]." The Guidelines in turn identify the preventive care and screenings that insurers are required to cover. *See* Docket No. 1, Ex. A at 9 n.* ("Non-grandfathered plans and coverage . . . are *required* to provide coverage without cost sharing consistent with these guidelines." (emphasis added)). It does not matter that the Guidelines originated as "recommendations" from WPSI because HRSA has since adopted them as final agency action. *See* 87 Fed. Reg. at 1,763; *Texas v. United States*, 809 F.3d at 171; *see also Chao v. Rothermel*, 327 F.3d 223, 228 (3d Cir. 2003) ("It is not whether Congress uses the term 'guidelines' that determines whether the agency must proceed through notice-and-comment rulemaking. Rather . . . it is whether the resulting guidelines constitute procedural or legislative rules.").

Defendants next argue that, in any event, they complied with notice and comment by issuing the October 2021 Notice, which included the draft recommendations. Docket No. 20 at 15. But the October Notice nowhere mentioned the deletion of the FABM sentence. Instead, the Notice specified that the recommendations will "clarify the terminology from contraceptive methods to contraceptives," remove "the term 'female-controlled contraceptives' to allow women

to purchase male condoms for pregnancy prevention," and "further define[] the existing components of contraceptive follow-up care." 86 Fed. Reg. at 59,742. Although the FABM sentence was mysteriously missing from the draft recommendations, the Notice did not explain *why*. *See id.* And an "agency's *rationale* for the rule must be made clear and subjected to public comment." *Tex. Ass'n of Mfrs.*, 989 F.3d at 382 (emphasis added) (remanding because agency failed to provide notice regarding its changed justification for a rule). Indeed, as the D.C. Circuit has held, "the most critical factual material that is used to support the agency's position on review must have been made public in the proceeding and exposed to refutation." *Air Transp. Ass'n of Am.*, 169 F.3d at 7.

Finally, Defendants argue that any error was harmless. Docket No. 20 at 15–16. "An agency's failure to comply with the APA is harmless when the agency's mistake 'clearly had no bearing on the procedure used or the substance of decision reached.'" *City of Arlington v. FCC,* 668 F.3d 229, 243–44 (5th Cir. 2012) (quoting *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 215 (5th Cir. 1979)). But "[c]ourts should 'rare[ly]' find harmless error for failure to provide notice and comment." *Tex. Med. Ass'n*, 2022 WL 542879, at *13 (second alteration in original) (quoting *Johnson*, 632 F.3d at 932). And here, HRSA never explained the basis of its decision for eliminating coverage for FABM counseling. Had Dr. Tice-Harouff or other interested parties known why the agency intended to delete the coverage, they may have been able to craft a comment that more adequately answered Defendants' concerns. *See id.* (citing *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 96 (D.C. Cir. 2002))

(finding harmful error when the plaintiffs "could not have provided the extensive arguments and authorities raised here" due to a lack of notice); *see also Air Transp. Ass'n of Am.*, 169 F.3d at 8 (finding harmful error when interested parties "had no knowledge" of the information the agency relied upon).

Defendants note that the Catholic Medical Association submitted a comment similar to Dr. Tice-Harouff's objections in this lawsuit. Docket No. 20 at 15–16. But nothing in the record indicates that Defendants considered the comment—or any comment by anyone for that matter. And courts have found harmless error only where the agency showed that it "considered the arguments [complainant] has asserted and responded to those arguments." *Johnson*, 632 F.3d at 932; *see also City of Arlington*, 668 F.3d at 245 (finding harmless error where the agency showed there was not "a single argument the [plaintiffs] now present . . . that was not considered by the [agency] in the agency proceedings"); *Tex. Ass'n of Mfrs.*, 989 F.3d at 383 & n.121 (5th Cir. 2021) ("The fact that some commenters actually submitted comments . . . is of little significance." (quoting *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991)).

Accordingly, the Court finds that Dr. Tice-Harouff is likely to succeed on the merits of Claim One. This finding alone tilts the first factor in favor of a preliminary injunction.

2.

Dr. Tice-Harouff is also likely to succeed on the merits of Claim Two, which alleges that Defendants' adoption of the 2021 Guidelines was arbitrary, capricious, and an abuse of discretion. Docket No. 1 at 25–26; Docket No. 4 at 12–13.

The APA provides that a court must "hold unlawful and set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The APA thus "requires agencies to engage in 'reasoned decisionmaking.'" *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020) (quoting *Michigan v. EPA*, 576 U.S. 743, 750 (2015)). "Judicial review under that standard is deferential, and a court may not substitute its own policy judgment for that of the agency." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Courts must ensure only "that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Id.*

An agency's explanation is insufficient when it "entirely fail[s] to consider an important aspect of the problem" or when "'the agency's path'" cannot "'reasonably be discerned.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43–44 (1983) (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)). Although the agency is not required "to consider all policy alternatives in reaching [its] decision," when, as here, the agency changes course it must give a reason why. *Id.* at 51. At a minimum, "the agency must at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy.'" *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). Further, the agency "must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account." *Regents*, 140 S. Ct. at 1913

(cleaned up) (quoting *Encino Motorcars*, 579 U.S. at 221–22). And in light of these reliance interests, the agency must consider partial, rather than total, rescission of an existing policy. *See id.*; *see also State Farm*, 463 U.S. at 51 (requiring agencies to consider "alternative[s] within the ambit of the existing standard[s].").

Here, the only explanation identified by Defendants for the 2021 Guidelines is the January 2022 Notice in which HRSA provided a summary and hyperlink to view the full Guidelines on its website. *See* Docket No. 20 at 17 (citing 87 Fed. Reg. at 1,763–64). This Notice, however, did not even mention FABM counseling. It thus failed to acknowledge a change in coverage, a reason for the change, an acknowledgment of reliance interests in the 2016 Guidelines, or an explanation of why complete elimination of coverage for FABM counseling was preferable to a more incremental approach. *See id.* For this reason alone, the elimination of cost-free coverage for FABM counseling was arbitrary and capricious. *See Encino Motorcars*, 579 U.S. at 222 (holding that "an unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change." (cleaned up)).

Defendants argue that "the 2021 Guidelines are well supported" because HRSA "relied on WPSI's clinical recommendations." Docket No. 20 at 17. But, although "an agency's 'experience and expertise' presumably enable the agency to provide the required explanation, . . . they do not substitute for the explanation." *CS Wind Vietnam Co. v. United States*, 832 F.3d 1367, 1377 (Fed. Cir. 2016) (citation omitted); *accord Wages & White Lion*, 16 F.4th at 1137. Defendants also contend that

they need not consider reliance interests because the interests here are not as significant as the interests in *Regents*. *See* Docket No. 20 at 18 n.10. But this is just a reason Defendants might have discounted any reliance interests in eliminating cost-free coverage for FABM counseling. It does not excuse Defendants from engaging in the required cost–benefit analysis for purposes of the APA. *See Regents*, 140 S. Ct. at 1914 ("Making that difficult decision was the agency's job, but the agency failed to do it.").

Dr. Tice-Harouff is thus likely to prevail on the merits of Claim Two. This is a second, independent reason to find that the first factor tilts in favor of a preliminary injunction.

B.

The second factor is the likelihood of irreparable harm. To establish this factor, the party seeking injunctive relief must "demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (emphasis in original) (collecting cases). A mere "possibility of irreparable harm" is insufficient. *Id.* "Harm 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). As explained below, this factor also favors issuing an injunction.

Here, Dr. Tice-Harouff will suffer irreparable harm through the loss of patients and income if the 2021 Guidelines go into effect. *See* Docket No. 1 ¶¶ 70–78; *see also Access to Preventive Services*, *supra*, at 9–10. It is well established that this type of economic harm is irreparable where, as here, the harm is caused by a governmental policy affecting market conditions and the government has not waived sovereign

immunity to recover damages caused by the policy. *See, e.g.*, *Wages & White Lion*, 16 F.4th at 1142; *Ohio Oil Co. v. Conway*, 279 U.S. 813, 814 (1929).

Defendants argue that these injuries are "speculative," and they rely extensively on the points made in their opposition to Dr. Tice-Harouff's Article III standing. For all the reasons explained above, those arguments fail. *See supra*, part II.; *cf. Tex. Ass'n of Mfrs.*, 989 F.3d at 377 ("A high risk of economic injury is sufficiently real, immediate, and direct" to confer standing). Defendants also suggest that Dr. Tice-Harouff must identify a specific patient she may lose or a particular insurer who is likely to impose cost sharing for FABM counseling. *See* Docket No. 2 at 12 n.8. But Defendants cite no authority imposing this burden of specificity on a plaintiff seeking a preliminary injunction, and the Court finds none.

Accordingly, this factor supports injunctive relief.

C.

The final factors are the balance of the equities and the public interest. These factors also favor a preliminary injunction.

An injunction would not harm Defendants, who maintain that the 2021 Guidelines already require cost-free coverage for FABM counseling. *See* Docket No. 20 at 6; *see also* Docket Nos. 26; 28. Dr. Tice-Harouff's patients, however, will suffer irreparable harm when they lose the cost-free coverage for FABM counseling provided by the current Guidelines. Many will undoubtedly forego this care altogether due to cost—or at least reduce the number or extent of counseling sessions. Docket No. 1 ¶¶ 72–81. This harm to both Dr. Tice-Harouff and her patients is imminent and irreparable, as discussed above. Indeed, immediate relief is necessary

here because many health insurers are already formulating and seeking regulatory approval for health plans that will begin on January 1, 2023. *See id.* ¶ 66. An injunction that preserves the status quo, moreover, would benefit insurers who may be required to change their plans after a full trial on the merits. *Cf. Barber v. Bryant*, 833 F.3d 510, 511 (5th Cir. 2016) ("[T]he maintenance of the status quo is an important consideration in granting a stay." (citation omitted)).

Further, the public interest "always is served when public officials act within the bounds of the law and respect the rights of the citizens they serve." *Camacho v. Tex. Workforce Comm'n*, 326 F. Supp. 2d 794, 802 (W.D. Tex. 2004) (quoting *Finlan v. City of Dallas*, 888 F. Supp. 779, 791 (N.D. Tex. 1995)). As explained above, Defendants likely violated the law in eliminating cost-free coverage for FABM counseling. The public interest in an injunction thus outweighs whatever interest Defendants claim in the freedom to implement their own policies. *See Wages & White Lion*, 16 F.4th at 1143 ("[T]here is generally no public interest in the perpetuation of unlawful agency action." (quoting *Texas v. Biden*, 10 F.4th 538, 560 (5th Cir. 2021)).

* * *

In sum, all factors weigh in favor of a preliminary injunction delaying the effective date of the deletion of FABM counseling from the 2021 Guidelines.

IV.

Accordingly, Plaintiff Cami Jo Tice-Harouff's motion for a Temporary Restraining Order and Preliminary Injunction (Docket No. 4) is **GRANTED**.

IT IS ORDERED that the effective date of Defendants' deletion of the following sentence from the 2021 Guidelines is **DELAYED** until further order of the

Court, and as a consequence this sentence remains at the conclusion of the "Contraception" section of those guidelines:

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

IT IS FURTHER ORDERED that the Court enjoins Defendants, their officials, agents, employees, and all persons in active concert or participation with them, including their successors in office, from using or applying the 2021 Guidelines to delete the above language, thereby maintaining that current language unless and until it is changed through a final rule (not an interim final rule) issued after notice to the public and an opportunity to comment consistent with the Administrative Procedure Act. Unless otherwise dissolved by this Court, this Order shall remain in effect until Final Judgment has been issued in this matter.

So **ORDERED** and **SIGNED** this **12th** day of **August, 2022.**

JEREMY D. KERNODLE
UNITED STATES DISTRICT JUDGE