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

CAMI JO TICE-HAROUFF, *Plaintiff* v. CAROLE JOHNSON, *et al.*, *Defendants.*	Case No. 6:22-cv-00201-JDK

RESPONSE IN OPPOSITION TO MOTION FOR
TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

INTRODUCTION

Beginning in 2016, health insurers were required to provide no-cost coverage for fertility awareness-based methods ("FABM") of contraceptive counseling, pursuant to section 2713 of the Public Health Service Act and comprehensive guidelines supported by the Health Resources and Services Administration ("HRSA"). The premise of Plaintiff's suit is that changes to these guidelines made in 2021 and effective at the end of this year (the "2021 Guidelines") mean that health insurers will no longer have this obligation. Plaintiff claims that she stands to lose at least some part of the "tens of thousands of dollars [she receives] every year from private insurance company reimbursements for her fertility awareness instruction," Mot. 6, ECF No. 4, if insurers are no longer required to provide no-cost coverage. Plaintiff also claims that her patients (on whose behalf Plaintiff asserts third-party standing) "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." *Id.*

Plaintiff is wrong. Health insurers are currently required to provide no-cost coverage for FABM *and will be required to do so after the 2021 Guidelines take effect*. Nothing in the 2021 Guidelines alters or changes the responsibility of insurers to provide no-cost coverage for FABM.

To make this clear, the Defendants have attached to this Response the declaration of a senior official within HRSA stating exactly this. Exhibit A to this motion is the Declaration of Lee Wilson, a Division Director within HRSA ("Declaration"). Paragraph 6 of this Declaration states that "FABM instruction is included in the 2021 Guidelines, as part of contraceptive counseling and education. Pursuant to Section 2713 of the PHS Act, all preventive services included in the 2021 Guidelines are required to be covered by Subject Health Insurers, without cost-sharing." Ex. A at ¶ 6.

Put plainly, after the effective date of the 2021 Guidelines, Plaintiff will continue to receive private insurance company reimbursements for her FABM counseling just as before, and her patients can receive this counseling knowing that insurers will be required to provide that coverage at no cost to the patient just as before. Because Plaintiff will not suffer financial harm and her patients will not be required to share the costs of FABM counseling, neither Plaintiff nor her patients have suffered an injury. Without an injury, Plaintiff lacks standing to bring suit, and is also unable to demonstrate

irreparable harm—the first element this Court considers when deciding whether to grant injunctive relief.

Plaintiff also cannot demonstrate a likelihood of success on the merits of her claims. Plaintiff claims that HRSA violated the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 551–559, when it failed to provide an opportunity for notice and comment prior to (allegedly) revising the Guidelines to remove no-cost coverage for FABM counseling and moreover, the (purported) decision to remove no-cost coverage for FABM counseling was arbitrary and capricious. But as stated above (and as will be emphasized through this Response), the 2021 Guidelines do not remove the obligation of health insurers to provide no-cost coverage.

Finally, the balance of the equities and the public interest favor the Defendants. Injunctive relief would prevent HRSA from complying with the Congressional directive, set forth in the Affordable Care Act, to support guidelines setting forth "preventive care and screenings" for which insurers are required to provide no-cost coverage. 42 U.S.C. § 300gg-13(a)(4). By contrast, Plaintiff has no equity in having her incorrect argument delay the effective date of the 2021 Guidelines.

Plaintiff's motion for injunctive relief should be denied.

BACKGROUND

The Patient Protection and Affordable Care Act, P.L. 111-148 (the "Affordable Care Act") added section 2713 of the Public Health Service Act, 42 U.S.C. § 300gg-13, to require non-grandfathered group health plans and non-grandfathered group and individual health insurance issuers[1] to provide coverage, without cost-sharing, for certain "preventive care and screening" for women. 42 U.S.C. § 300gg-13(a)(4); *see also* 45 C.F.R. § 147.130(a)(iv). What constitutes "preventive care and screenings" is determined by "comprehensive guidelines supported by [HRSA]." 42 U.S.C. § 300gg-13(a)(4).

[1] For ease of reference, Defendants refer to entities subject to this requirement as insurers or health insurers. The terms used in this Response are not intended to expand or limit the entities subject to section 2713.

The guidelines originate with recommendations made by the Women's Preventive Services Initiative (WPSI) through which the American College of Obstetricians and Gynecologists (ACOG) engages a coalition of national health professional organizations and consumer patient advocates with expertise in women's health across their lifespan, and are reviewed and accepted by HRSA. Decl. of Lee Wilson, Ex. A. at ¶ 3–5. Since the Affordable Care Act's enactment, three sets of guidelines have been issued. This present litigation involves the second and third set of guidelines: the guidelines issued in 2016 (the "2016 Guidelines"); and the 2021 Guidelines.[2]

A. The 2016 Guidelines

On December 20, 2016, HRSA supported WPSI's recommended updates to the Women's Preventive Services Guidelines. The 2016 Guidelines are available at HRSA's website. https://www.hrsa.gov/womens-guidelines-2016/index.html (last visited June 22, 2022). The introduction to the 2016 Guidelines state that "HRSA is supporting the Women's Preventive Services Initiative clinical recommendations listed below for preventive services that address health needs specific to women and fill gaps in existing guidelines." *Id.* Put together with the terms of the Affordable Care Act, this means that for a recommendation listed in the 2016 Guidelines (*e.g.*, "cervical cancer screening for average-risk women aged 21 to 65 years"), a health insurer must provide coverage "without a copayment, coinsurance, deductible, or other cost sharing" *Id.*

The 2016 Guidelines include a section entitled Contraception. This section is reproduced here in its entirety.

> The Women's Preventive Services Initiative 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.

[2] The 2011 Guidelines did not address FABM counseling.

> 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) 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.*

Id. (emphasis added). Thus, the 2016 Guidelines required health insurers to provide FABM instruction "without a copayment, coinsurance, deductible, or other cost sharing." *Id.*

Plaintiff agrees with this statement; indeed, her suit is premised on it. In the Complaint, Plaintiff states: "The ACA requires most health plans to provide coverage, without cost sharing, of women's preventive services as set forth in guidelines by [HRSA]. Since 2016 that requirement has included coverage of instruction in fertility awareness-based methods of family planning." ECF No. 1, at ¶ 2 (citation omitted); *see also* Mot. 4, ECF No. 4 ("Since 2016, those guidelines have explicitly included 'instruction in fertility awareness-based methods' of family planning.").

B. <u>The 2021 Guidelines</u>

In March 2021, HRSA awarded a second 5-year cooperative agreement to ACOG to continue WPSI. https://www.hrsa.gov/womens-guidelines/index.html (last visited June 22, 2022). That same month, WPSI made a public request on its website and to stakeholders for input on new preventive service guideline topics to be considered and for suggested changes or edits to existing guidelines. WPSI collected comments, cataloged them by topic, and assessed them. WPSI also provided this information to HRSA.

WPSI completed its review and submitted preliminary recommendations on contraception guideline revisions to HRSA. HRSA sought a second round of public comment by publishing the draft guidelines in the Federal Register on October 28, 2021. 86 Fed. Reg. 59,741. In the notice, HRSA provided WPSI's proposed language and solicited comments. *Id.* Following the 30-day comment period, WPSI deliberated on the merits of the comments, including supporting evidence offered by

commenters. WPSI submitted final recommendations following those deliberations without further changes. HRSA accepted the guidelines recommended by WPSI on December 30, 2021. Decl. of Lee Wilson, Ex. A. at ¶ 5. The 2021 Guidelines become effective at the end of 2022. *Id.*

The 2021 Guidelines, as accepted by HRSA, are available at https://www.hrsa.gov/womens-guidelines/index.html (last visited June 22, 2022).[3] As in 2016, the 2021 Guidelines are divided by topic. Thus, for example, the 2021 Guidelines include topics such as "Obesity Prevention in Midlife Women," "Breastfeeding Services and Supplies," and, as relevant here, "Contraception." *Id.*

In the Contraception topic, the 2021 Guidelines begin by stating that "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." *Id.* (emphasis added). The 2021 Guidelines then define "contraceptive care" to include "screening, *education*, *counseling*, and provision of contraceptives (including in the immediate postpartum period)." *Id.* (emphasis added). This is substantially the same definition of "contraceptive care" as in the 2016 Guidelines. *See* https://www.hrsa.gov/womens-guidelines-2016/index.html.[4]

The divergence between the 2016 and 2021 Guidelines occurs in the final paragraph of each set of guidelines. In 2016, this paragraph listed 18 "*contraceptive methods* for women currently identified by the U.S. Food and Drug Administration:" *Id.* (emphasis added). The 2016 Guidelines then go on to add an additional "contraceptive method" in a final sentence: FABM.

The 2021 Guidelines' final paragraph references not "contraceptive methods" but instead "contraceptives" and identifies 17 contraceptives "currently listed in the FDA's Birth Control Guide." https://www.hrsa.gov/womens-guidelines/index.html. The 2021 Guidelines do not include the final sentence discussing FABM counseling. But FABM counseling is not a form of contraception listed by

[3] Plaintiff has also attached a printout of this website as Exhibit A to her Complaint.

[4] If anything, the 2021 Guidelines are more explicit. Whereas the 2016 Guidelines provide that "[c]ontraceptive care *should* include contraceptive counseling, initiation of contraceptive use, and follow-up care," https://www.hrsa.gov/womens-guidelines-2016/index.html (emphasis added), the 2021 Guideline state that "[c]ontraceptive care *includes* screening, education, counseling, and provision of contraceptives" removing the "should." https://www.hrsa.gov/womens-guidelines/index.html.

the FDA and thus it would be misplaced to include it in a paragraph dedicated to identifying FDA approved forms of contraception.[5]

The implication drawn by Plaintiff from the absence of the 2016 Guidelines' final sentence is that insurers are not required to provide no-cost coverage. But this is not correct. FABM counseling is exactly that: counseling. And as discussed above, the 2021 Guidelines state that women are entitled to the "to the *full range* of contraceptives and contraceptive care" and "contraceptive care is defined to include "screening, *education*, *counseling*, and provision of contraceptives." *Id.* (emphases added). The "full range" of "contraceptive care" includes FABM "counseling."

Attached as Exhibit A to this filing is a Declaration of Lee A. Wilson. Mr. Wilson serves as a Division Director within HRSA. Ex. A at ¶ 1. Specifically. Mr. Wilson's "duties include, but are not limited to, advising HRSA's Maternal and Child Health Bureau and HRSA regarding the HRSA-supported Women's Preventive Services Guidelines." *Id.* In his Declaration, Mr. Wilson makes clear that after the effective date of 2021 Guidelines, health insurers will continue to be required to provide no-cost coverage for FABM:

> FABM instruction is included in the 2021 Guidelines, as part of contraceptive counseling and education. Pursuant to Section 2713 of the PHS Act, all preventive services included in the 2021 Guidelines are required to be covered by Subject Health Insurers, without cost-sharing.

Id. at ¶ 6.

ARGUMENT

I. Plaintiff lacks standing to challenge the 2021 Guidelines.

In her motion, Plaintiff asserts that she has standing on her own behalf and on behalf of her patients through third-party standing. Mot. 5, ECF No. 4. Plaintiff is wrong on both counts.

As the party invoking federal jurisdiction, Plaintiff bears the burden of demonstrating she has standing. *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2207 (2021). "To establish Article III standing,

[5] The FDA's regulatory mandate extends to, *inter alia*, drugs and medical devices. Plaintiff correctly does not suggest that a form of instruction or counseling such as FABM would be subject to FDA oversight.

a plaintiff must allege that [she] has '(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.'" *Cont'l Auto. Sys., Inc. v. Avanci, L.L.C.*, 27 F.4th 326, 332 (5th Cir. 2022). To show an injury in fact, a plaintiff must prove that she has suffered "an invasion of a legally protected interest [that] is concrete and particularized and actual or imminent, not conjectural or hypothetical." *Kitty Hawk Aircargo, Inc. v. Chao*, 418 F.3d 453, 459 (5th Cir. 2005).

Plaintiff claims that she will suffer a financial injury if the 2021 Guidelines do not provide no-cost coverage for FABM counseling. According to Plaintiff, she "generates tens of thousands of dollars every year from private insurance company reimbursements for her fertility awareness instruction." Mot. 6, ECF No. 4 (*citing* Compl. ¶¶ 55–56, ECF. No. 1). The implication is that if, after the effective date of the 2021 Guidelines, insurers are not required to provide no-cost coverage of FABM counseling, insurers will not cover it at all or will impose cost-sharing with patients. According to Plaintiff, patients will, in turn, not seek (or seek less often) such counseling. The combined effect in Plaintiff's view will deprive Plaintiff of some unspecified portion of the reimbursements she received from health insurers for FABM counseling.

Plaintiff also claims that her patients will suffer financial injuries and injuries to their health. According to Plaintiff, her "patients possess a right under the pre-2021 Guidelines to insurance coverage of fertility awareness instruction, which is enforceable, for example, under ERISA. Without that coverage guarantee, and its protection from co-pays and deductibles, [Plaintiff'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." Mot. 6, ECF No. 4. (citations omitted).

Contrary to Plaintiff's assertion, the remuneration she receives and the financial and medical well-being of her patients are not at risk. As discussed above, the 2021 Guidelines do not change or alter the requirement of health insurers to provide no-cost coverage for FABM counseling. Plaintiff has not suffered and will not suffer any injury. Likewise, and for the same reason, Plaintiff's patients have not and will not suffer any injury.

Even if for the purposes of this Motion, the Court determines that Plaintiff has identified potential injuries, the analysis is not complete. Ultimately, Plaintiff's claims of injuries are too speculative. Plaintiff is forecasting—without support—what two different groups of third parties not before the Court, private insurers and patients, will do in the future. The Fifth Circuit has held, however, that "[a] claim of injury generally is too conjectural or hypothetical to confer standing when the injury's existence depends on the decisions of third parties not before the court." *Avanci*, 27 F.4th at 332 (quoting *Little v. KPMG LLP*, 575 F.3d 533, 540 (5th Cir. 2009)).

Even assuming the 2021 Guidelines alter the obligations of health insurers, Plaintiff does not know what the response of insurers will be. Any prediction by Plaintiff is simply a guess. Insurers may continue to provide coverage of FABM without cost-sharing. Nor does Plaintiff know what the response of patients to any (already speculative) change in policy by insurers will be. Patients may choose to continue seeking FABM counseling. And of course, Plaintiff's *future* patients may choose not to avail themselves of FABM counseling for reasons having nothing to do with insurance coverage. Plaintiff has no way of knowing.

To support her claim of standing on her own behalf, Plaintiff cites this Court's recent decision in *Texas Medical Association v. United States Department of Health & Human Services*, No. 6:21-CV-425-JDK, 2022 WL 542879 (E.D. Tex. Feb. 23, 2022). In that case, this Court held that a physician and trade association representing physicians had standing to bring an APA challenge[6] to an interim final rule concerning an arbitration process for resolving payment disputes between out-of-network

[6] This Court's holding in *Texas Medical Association* is applicable in one respect. Even where a plaintiff brings an APA notice and comment challenge, the plaintiff must allege an *injury* brought about by a new rule. Thus, in *Texas Medical Association*, the plaintiffs argued that the substance of the IFR issued by the defendants would harm the plaintiffs. The alleged injury is not simply that a plaintiff was deprived of an opportunity to comment. Were this the case, every American would have standing in theory to bring a challenge. A plaintiff must allege they were deprived of an opportunity to comment *and* the product of the regulatory process (*i.e.*, the new rule) injured the plaintiff. *See, e.g., Texas Ass'n of Manufacturers v. United States Consumer Prod. Safety Comm'n*, 989 F.3d 368 (5th Cir. 2021) (plaintiff had standing to bring an APA challenge alleging lack of opportunity for comment where the "threat of reduced sales to companies that manufacture children's toys and child care articles" was a cognizable injury to at least one plaintiff that conferred standing).

providers and group health plans or health insurance issuers. The Court found standing because the "[p]laintiffs submit detailed affidavits with specific facts establishing that their injuries are not only likely and imminent, but inevitable." *Id.* at *5. Here, Plaintiff has done nothing of the sort. Instead, Plaintiff relies solely on her unsupported speculation of future injury.

This Court's decision in *Texas Medical Association* is also distinguishable on the facts. In that case, the rule at issue was held to have a direct impact on the plaintiffs. As out-of-network providers, this Court reasoned, the plaintiffs would presumably take part in the arbitration process set forth in the rule. Thus, this Court concluded that the rule applied directly to the physician-plaintiff and members of the trade association-plaintiff. Here, Plaintiff is not the immediate subject of the 2021 Guidelines. The 2021 Guidelines dictate what preventive services an *insurer* is obligated to cover without cost sharing by *patients*. Plaintiff is neither of these. Providers such as Plaintiff are impacted by any change in the guidelines only to the extent that private insurers and/or patients, two parties not before the Court, alter their behavior in response to the putative change.

Plaintiff's claim of third-party standing is equally unavailing. To support her claim of third-party standing, Plaintiff relies on the Supreme Court's holding in *June Medical Services LLC v. Russo*, 140 S. Ct. 2103 (2020). Mot. 5, ECF No. 4. According to Plaintiff, the Court's decision stands for the broad proposition that a physician may bring claims "on behalf of her patients." *Id.*

June should not be read so broadly, however. As the Supreme Court noted, that case lay "at the intersection of . . . two lines of precedent," cases where "abortion providers . . . invoke the rights of their actual or potential patients in challenges to abortion-related regulations, and cases where "plaintiffs . . . assert third-party rights in cases where the enforcement of the challenged restriction *against the litigant* would result indirectly in the violation of third parties' rights." 140 S. Ct. at 2118–19 (internal citations omitted and emphasis in the original).

The present case does not lie at the same intersection. The Supreme Court described *June* as involving "abortion providers challenging a law that regulates their conduct." *Id.* at 2119. According to the Court, "[t]he threatened imposition of governmental sanctions for noncompliance eliminates any risk that their claims are abstract or hypothetical." *Id.* (internal quotation omitted). This case

obviously does not involve abortion providers. Nor do the Guidelines regulate Plaintiff's conduct: she may continue to provide the relevant services exactly as before, whether or not insurance companies are required to cover them. Finally, this case does not involve enforcement of restrictions on Plaintiff's practice or "threatened imposition of sanctions for noncompliance" against Plaintiff.

The appropriate analysis of Plaintiff's third-party standing thus does not begin with *June*, but rather the Supreme Court's decision in *Kowalski v. Tesmer*, 543 U.S. 125 (2004). In *Kowalski*, the Court reiterated its rule "that a party 'generally must assert his own legal rights and interests, and cannot rest his claim to relief on the legal rights or interests of third parties.'" 543 U.S. at 128 (quoting *Warth v. Seldin*, 422 U.S. 490, 499 (1975)). The Court did recognize that, in limited circumstances, a third party could vindicate the rights of another party and set forth two showings that a third party must make. First, a third party must show "the party asserting the right has a 'close' relationship with the person who possesses the right." *Id.* at 130 (citing *Powers v. Ohio*, 499 U.S. 400, 411 (1991)). Second, the third party must show "there is a 'hindrance' to the possessor's ability to protect his own interests." *Id.*[7]

Plaintiff, misreading *June*, made no effort to make these showings. It is as well she did not try, as she cannot satisfy either requirement. While a particular physician-patient relationship may very well qualify as a close relationship, the physician-patient relationship asserted here is abstract and hypothetical. Plaintiff's relation is to unidentified and future patients of Plaintiff who after the alleged change in guidelines seek coverage for FABM counseling and their insurers deny coverage without cost-sharing. As such, this case bears striking resemblance to *Kowalski*. There, plaintiffs asserted third-party standing on behalf of "a future attorney-client relationship with as yet unascertained Michigan criminal defendants 'who will request, but be denied, the appointment of appellate counsel, based on the operation' of the statute." *Id.* The Supreme Court declined to find that a close relationship existed. Although "an attorney-client relationship as sufficient to confer third-party standing," an "*existing*

[7] Plaintiff's use of *June* rather than *Kowalski* is particularly notable with respect to this second showing. If the Plaintiff is correct that *June* confers standing on doctors to bring claims in the names of their patients this would effectively eliminate the need for the second showing at least insofar as doctors are concerned. But *June* does no such thing. As discussed above, *June* concerns standing for abortion providers where the challenged actions also carry a threat of sanctions to the providers. This is not such a case.

attorney-client relationship is, of course, quite distinct from the hypothetical attorney-client relationship posited here." *Id.* at 130–31 (emphasis in the original).

Plaintiff also cannot make the second showing. There is no reason that Plaintiff's patients or other parties would be hindered from bringing their own challenges to the 2021 Guidelines such that Plaintiff or physicians generally are necessary third parties. If prospective patients are concerned that the 2021 Guidelines will inhibit insurance coverage or that HRSA failed to comply with the APA, they may bring an appropriate challenge—provided of course they meet all requisite elements of standing. There is no hindrance to such potential plaintiffs that requires Plaintiff to bring this challenge.

II. Plaintiff fails to establish the elements necessary for preliminary injunctive relief.

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008) (citation omitted). The party seeking relief bears the burden to show: (1) "a substantial threat of irreparable injury," (2) "a substantial likelihood of success on the merits," (3) "that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted," and (4) "that the grant of an injunction will not disserve the public interest." *Jordan v. Fisher*, 823 F.3d 805, 809 (5th Cir. 2016) (citation omitted). A preliminary injunction should not be "granted unless the party seeking it has clearly carried the burden of persuasion on all four requirements." *Id.*

A. Plaintiff Cannot Demonstrate an Irreparable injury.

For all the reasons Plaintiff failed to establish an injury to establish standing to bring this case, Plaintiff cannot establish an irreparable injury sufficient to justify injunctive relief. To establish irreparable harm, a party must show that the harm is certain and so imminent as to necessitate immediate equitable relief. "Speculative harm" or the mere "possibility of irreparable harm" is not enough. *Winter*, 555 U.S. at 22; *United States v. Emerson*, 270 F.3d 203, 262 (5th Cir. 2001) ("Speculative injury is not sufficient; there must be more than an unfounded fear on the part of the applicant . . . *A presently existing actual threat must be shown.*") (emphasis in original); *see also Adams v. Cantwell*, Case No. 6:20-cv-11, 2022 WL 453544, at *2 (E.D. Tex. Jan. 10, 2022), *report and recommendation adopted*, Case No.

6:20-cv-11, 2022 WL 446756 (Feb. 12, 2022) (Kernodle, J.) ("To the extent that Plaintiff is expressing fear of future harm, the speculative nature of such claim does not satisfy the heightened burden necessary for the extraordinary relief of a preliminary injunction.").

Neither Plaintiff nor her patients have suffered, or will suffer, an injury. The premise supporting Plaintiff's claimed injury—the 2021 Guidelines no longer require health insurers to provide no-cost coverage for FABM counseling—is wrong. As set forth in the Wilson Declaration, "FABM instruction is included in the 2021 Guidelines, as part of contraceptive counseling and education. Pursuant to Section 2713 of the PHS Act, all preventive services included in the 2021 Guidelines are required to be covered by Subject Health Insurers, without cost-sharing." Wilson Decl. ¶ 6. Therefore, the 2021 Guidelines will not impose any injury, irreparable or otherwise, on Plaintiff or her patients.[8] As such, Plaintiff fails to carry her burden of demonstrating a *substantial* likelihood of irreparable injury.

B. Plaintiff Cannot Demonstrate a Likelihood of Success on the Merits.

1. Because Plaintiff's assumption that the 2021 Guidelines will not require no-cost coverage for FABM counseling is wrong, her claims lack merit.

Both of Plaintiff's claims—that she was deprived of the opportunity to comment and that the alleged changes in the 2021 Guidelines were arbitrary and capricious—rest on the unavoidable assumption the 2021 Guidelines will not require no-cost coverage for FABM counseling. In other words, the entirety of Plaintiff's lawsuit, her alleged injuries, her legal theory, and the relief she seeks, begins with the assumption that after the effective date of the 2021 Guidelines, insurers will not be

[8] To the extent the Plaintiff argues insurers may refuse to cover FABM without cost-sharing, the Complaint fails to establish more than a speculative fear of future harm by third parties not before the Court. The Complaint expresses the Plaintiff's opinion—generally on information and belief—that insurers may not cover FABM at all or without cost sharing. Compl. ¶¶ 68–69, ECF No. 1. From this possibility, the Plaintiff alleges "if" it happens, she "will likely" lose business and unidentified patients "will likely" not be able to afford the care. *Id.* ¶¶ 69, 74, 76. Of course, the Plaintiff's predictions about the potential future actions of third parties are speculative and should be disregarded altogether as conclusory. Plaintiff fails to identify any patient or private insurer who has indicated that her divination is accurate, let alone likely.

required to provide no-cost coverage for FABM counseling. With this incorrect assumption removed, Plaintiff's claims plainly lack merit.

2. The 2021 Guidelines are not subject to the APA's notice-and-comment requirements.

Even assuming this Court chooses to read the 2021 Guidelines to eliminate the requirement that insurers provide no-cost coverage for FABM counseling, Plaintiff is unlikely to prevail on her APA claims because HRSA's guidelines are not subject to notice-and-comment requirements. The APA's notice-and-comment requirements apply only to rulemaking, 5 U.S.C. § 553(b), and a "rule" is defined in the APA, in relevant part, as being "designed to implement, interpret, or prescribe law or policy." *Id.* § 551(4). The Guidelines do not constitute a "rule" within the meaning of the APA; they are HRSA-supported clinical recommendations from a scientific body. The substantive obligations imposed on group health insurance issuers were imposed by Congress in 42 U.S.C. § 300gg-13(a), as well in corresponding provisions of ERISA and the Internal Revenue Code, which expressly and automatically imported the content of various guidelines—including these HRSA-supported Guidelines. In the same provision, Congress also imports by reference clinical recommendations of the United States Preventive Services Task Force and the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention. *Id.* These clinical recommendations are not generally subject to notice and comments, and there is no suggestion that Congress intended otherwise here for any referenced recommendations.[9]

3. Even if the Court reaches the merits of Plaintiff's APA claims, HRSA satisfied all requirements relating to notice and comment.

Even assuming the 2021 Guidelines are "rules" subject to the APA, HRSA complied with all statutory procedures mandated by the APA. The APA requires government agencies to publish a notice of proposed rulemaking in the Federal Register before promulgating a rule that has legal force.

[9] In contrast, other provisions of the ACA use clear language when referring to the promulgation of substantive rules. *See, e.g.,* 42 U.S.C. § 300gg-1(b)(3) ("The Secretary shall promulgate regulations with respect to enrollment periods under paragraphs (1) and (2)."); *id.* § 300gg-14(b) ("The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subjection (a).").

Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2384 (2020) (citing 5 U.S.C. § 553(b)). Pursuant to the APA, a notice must contain "reference to the legal authority under which the rule is proposed" and "either the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id.* (quoting §§ 553(b)(2)-(3)). In addition, the APA also requires an agency to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," *id.* (citing § 553(c)); and requires that final rules be published 30 days before they become effective, *id.* (citing § 553(d)). The Supreme Court has explained that whether an agency has satisfied the APA requirements is determined by the substance of the notice and not by formal labels. *Little Sisters of the Poor*, 140 S. Ct. at 2384. The object of notice and comment is one of fair notice, and this object is met when an agency explains its position in detail and provides the public with an opportunity to comment. *Id.* at 2385.

HRSA met this standard when, on October 28, 2021, it published a Federal Register notice titled, "Updated HRSA-Supported Women's Preventive Services Guidelines: Contraception and Screening for HIV Infection" (the "Notice"). 86 Fed. Reg. 59,741. In the Notice, HRSA identifies 42 U.S.C. § 300gg-13 as the basis of its legal authority for updating the Guidelines, which states in relevant part,

> A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements . . . with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

42 U.S.C. § 300gg-13(a)(4). The Notice explained to the public the history of the establishment of the Guidelines and explained that HRSA had entered into a cooperative agreement with ACOG to convene a coalition representing clinicians, academics, and health professional organizations to review scientific evidence and make recommendations to HRSA regarding the Guidelines, WPSI. The Notice sought comments on updated draft recommendations for providing contraception from WPSI and explained that HRSA would then decide whether to support the recommended updates to the

Guidelines. Second, HRSA both included the substance of the proposed Guidelines update and described the issue involved. The Notice includes the full text of the recommended update to the Guidelines regarding Contraceptives. 86 Fed. Reg. at 59,742. The Committee recommended that the full range of FDA-approved contraceptives, "effective family planning practices," and sterilization procedures be available as part of contraceptive care. *Id.* Third, HRSA gave interested parties an opportunity to participate in the rulemaking process by soliciting comments for a period of at least 30 days until November 29, 2021. Finally, on January 12, 2022, HRSA published a notice titled, "Update to the Women's Preventive Services Guidelines" explaining that HRSA approved updates to the Guidelines on December 30, 2021. 87 Fed. Reg. 1763-1. Although the 2021 Guidelines became effective immediately, insurers and group health plans are not required to implement them until plan years starting on January 1, 2023.

4. Assuming the APA's notice-and-comment requirements applied, any error in adopting the 2021 Guidelines was harmless.

In any event, any procedural error was harmless. *See City of Arlington v. FCC*, 668 F.3d 229, 243 (5th Cir. 2012), *aff'd*, 569 U.S. 290 (2013); *see also* 5 U.S.C. § 706 (in reviewing agency action, "due account shall be taken of the rule of prejudicial error"). "The harmless error rule requires the party asserting error to demonstrate prejudice from the error." *City of Arlington*, 668 F.3d at 243 (internal quotation omitted). Plaintiff makes a half-hearted attempt to allege a procedural harm by claiming that she and her patients were "deprived of the right to participate in a meaningful notice-and-comment process." Mot. 6, ECF. No. 4. However, Plaintiff fails to show that she or any of her patients would have submitted a comment regarding the 2021 Guidelines. Without this information, Plaintiff cannot establish she was prejudiced by HRSA's process. *See Am. Bankers Ass'n v. NCUA*, 38 F.Supp. 2d 114, 140 (D.D.C. 1999) (finding harmless error where the plaintiff "did not explain what it would have said had it been given an opportunity to respond").

Regardless, Plaintiff cannot satisfy her burden to show prejudice. "In conducting the harmless error inquiry, [the court informs its] analysis with a number of potentially relevant factors, including … 'a hesitancy to generalize too broadly about particular kinds of errors when the specific factual

circumstances in which the error arises may well make all the difference.'" *City of Arlington*, 668 F.3d at 244 (quoting *Shinseki v. Sanders*, 556 U.S. 396, 411-12 (2009)). Here, there is no prejudice to Plaintiff because as explained *supra*, the 2021 Guidelines do not alter insurers obligation to provide no-cost coverage for FABM counseling. Additionally, although Plaintiff fails to offer any evidence that she or her patients participated in the process of updating the guidelines, the Catholic Medical Association (CMA), of which Plaintiff is a member, has done so. *See* Compl. 18 n.11, ECF. No. 1. CMA's comment expresses similar concerns Plaintiff expresses in this case.

5. *The 2021 Guidelines are neither arbitrary nor capricious.*

Plaintiff cannot demonstrate a likelihood of success on her second claim because HRSA's adoption of the 2021 Guidelines is not arbitrary and capricious. Pursuant to the APA's "deferential standard," this Court "may not substitute its own policy judgement for that of the agency" and simply "ensures that the agency has acted within a zone of reasonableness." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021); *City of Abilene v. EPA*, 325 F.3d 657, 664 (5th Cir. 2003) (an agency need only provide "minimal standards of rationality"). The 2021 Guidelines easily meet this standard.

Plaintiff offers a grab bag of conclusory allegations as to how the 2021 Guidelines are arbitrary and capricious: HRSA does not acknowledge it was changing its position by deleting language covering FABM; it offered no rationale or explanation for deleting the language covering FABM; it failed to respond to comments objecting to this deletion; and it failed to address significant issues associated with such a change such as reliance interests of women like Plaintiff's patients. *See* Mot. 12–13, ECF No. 4. These arguments, however, fail because the 2021 Guidelines did not change insurers' obligation to provide coverage, without cost-sharing, for FABM counseling. Wilson Decl. ¶ 6. As a result, Plaintiff cannot carry her burden of showing the adoption of the 2021 Guidelines is arbitrary or capricious.

Given the lack of impact on substantive rights or obligations, Plaintiff's only remaining complaint is with the deletion of one sentence concerning fertility instruction. Compl. 12, ECF No. 4. But the APA does not provide all citizens the right to red-line regulations, or in this case guidelines, supported by an agency such as HRSA and the Court should not create such a right in this case.

In any event, contrary to Plaintiff's claims, the 2021 Guidelines are well supported. HRSA relied on WPSI's clinical recommendations of updates to the Women's Preventive Services Guidelines. *See* 87 Fed. Reg. 1763-01 (Jan 12, 2022). This is consistent with HRSA's practice, dating back to the inception of the Guidelines, which were established in 2011 based on recommendations of the National Academy of Sciences, Engineering, and Medicine (formerly the IOM). Compl. Ex. A 1, ECF No. 1-1. HRSA supported updates to the Guidelines in 2016, 2017, and 2019, including the addition of FABM counseling, which was not addressed in the 2011 guidelines, based on review and recommendations under the WPSI cooperative agreement. The 2021 Guidelines are merely the latest update based on recommendations from medical experts. HRSA has had a consistent explanation for revisions to the Guidelines for over 10 years, including the 2021 Guidelines—HRSA follows the recommendations of experts in the field and the 2021 Guidelines reflect those recommendations.

The deletion of the language covering FABM counseling is consistent with the 2021 Guidelines' revised description of covered contraceptive care. As explained, *supra*, the current version of the Guidelines is framed in terms of "contraceptive methods," whereas the 2021 Guidelines' recommendation is framed in terms of "contraceptives." *See* Compl. Ex. A 2–3, ECF No. 1-1. It is reasonable for HRSA to rely on expert recommendations regarding the proper description of contraceptive care. "A reviewing court must be most deferential" in this context, where a "decision is based upon [an agency's] evaluation of complex scientific data within its technical expertise." *Sierra Club v. EPA*, 939 F.3d 649, 680 (5th Cir. 2019) (citation omitted); *Nuclear Energy Institute, Inc. v. EPA*, 373 F.3d 1251, 1289 (D.C. Cir. 2004) ("We are 'extremely deferential, however, to an agency evaluating scientific data within its expertise.") (cleaned up); *Stewart v. Potts*, 996 F. Supp. 668, 678 n.8 (S.D. Tex. 1998) (APA does not permit a court to "evaluate [agency's] scientific methods"). And as discussed above, clarifying the language based on WPSI's recommendations does not alter coverage for FABM. Wilson Decl. ¶ 6.

Plaintiff's final argument—that HRSA failed to address reliance interests—fares no better. Citing *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S.Ct. 353 (2020), Plaintiff argues HRSA failed to address the impact on reliance interests or consider alternatives. This could not be further

from the truth, especially since the 2021 Guidelines do not change coverage for FABM counseling. Given the fact FABM is still covered in the 2021 Guidelines, Plaintiff's complaint that HRSA failed to consider alternatives not only falls flat, it is also simply incorrect.

In any event, the Court need not consider the impact on reliance interests, because Plaintiff fails to establish any reliance interests potentially affected by the 2021 Guidelines since mandatory coverage, without cost-sharing, continues to be required. In *Regents*, the reliance interests consisted of DACA recipients who "enrolled in degree programs, embarked on careers, started businesses, purchased homes, and even married and had children, all in reliance on the DACA program." *Regents*, 140 S. Ct. at 1914. Plaintiff has provided no evidence of similar reliance interests with respect to FABM coverage. Plaintiff attempts to manufacture a reliance interest in "patients who currently receive no-cost-sharing coverage" for FABM counseling. (*See* Mot. 12–13, ECF No. 4. But unlike DACA recipients, it does not appear these patients will be affected *at all* by the 2021 Guidelines since they do not change the obligation to provide no-cost-sharing coverage for FABM.[10]

C. The Balance of Equities and the Public Interest Weigh in Favor of Denying Injunctive Relief.

Because Plaintiff here seeks to enjoin the action of a government agency, the third factor in assessing whether injunctive relief is appropriate, the balance of equities, and the fourth factor, the public interest, merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). In the present case both factors weigh in favor of denying injunctive relief.

"[A]ny time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012)

[10] Additionally, based on the Verified Complaint, it appears patients receiving FABM education only need that care for a limited period and presumably all of Plaintiff's current patients will complete their "education" prior to January 1, 2023. *See* Compl. ¶ 53, ECF No. 1 (explaining Plaintiff sees patients 5 times in the first 6 months). Surely FABM cannot require indefinite education and in any event, Plaintiff fails to offer evidence that it does. Thus, the only patients potentially affected by the 2021 Guidelines are *future* patients who have not yet elected to receive FABM education and therefore lack any reliance interest on the current coverage regime.

(Roberts, Circuit Justice, in chambers) (quoting *New Motor Vehicle Bd. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (Rehnquist, Circuit Justice, in chambers)). Here, injunctive relief would prevent HRSA from complying with the Congressional directive, set forth in the Affordable Care Act, to support guidelines setting forth "preventive care and screenings" for which insurers are required to provide no-cost coverage. 42 U.S.C. § 300gg-13(a)(4).

This is not, however, the limit of the public interest in denying injunctive relief here. The public has an undoubted interest in the ongoing review of preventive care and screenings such that insurers provide no-cost coverage of only preventive services that qualified medical professionals, after a scientifically rigorous review, deem appropriate and effective.

What is more, the 2021 Guidelines do not change the requirement of insurers to provide no-cost coverage of FABM counseling. By contrast and as discussed above, the interests of Plaintiff are limited and the potential injury speculative, at best. As noted with respect to standing and Plaintiff's alleged irreparable injury, Plaintiff does not provide any support for her claim that, even if the 2021 Guidelines did eliminate the requirement of no-cost coverage, insurance companies would cease to provide no-cost coverage or, perhaps more importantly, that prospective patients of Plaintiff would opt to undergo FABM counseling in the absence of full insurance coverage. Plaintiff's interest is predicated on two different sets of third parties not before this Court, insurers and patients, both responding in a particular manner that results in an economic injury to Plaintiff.

What is more, Plaintiff has not demonstrated that her interest will be served only by the extraordinary remedy of injunctive relief rather than through the course of ordinary litigation. In *Texas Medical Association v. United States Department of Health & Human Services*, No. 6:21-CV-425-JDK, 2022 WL 542879 (E.D. Tex. Feb. 23, 2022), this Court considered an APA challenge asserting a lack of notice and comment in the ordinary course. There remains at least six months prior to the effective date of the 2021 Guidelines. Plaintiff provides no reason for asserting that her interests cannot be vindicated during that time in regular litigation.

CONCLUSION

For the reasons set forth above, this Court should deny Plaintiff's motion for injunctive relief.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify on this 22nd day of June, 2022, a true and correct copy of this document was served electronically by the Court's CM/ECF system to all counsel of record.

/s/ James Gillingham
JAMES GILLINGHAM