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

CAMI JO TICE-HAROUFF, on behalf of herself and her patients, *Plaintiff,* v. **CAROLE JOHNSON** in her official capacity as Administrator of the Health Resources and Services Administration of the United States Department of Health and Human Services; **HEALTH RESOURCES AND SERVICES ADMINISTRATION OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**; **XAVIER BECERRA**, in his official capacity as Secretary of the United States Department of Health and Human Services; and **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,** *Defendants.*	No. _____ **VERIFIED COMPLAINT** **Jury Trial Demanded**

PLAINTIFF'S VERIFIED COMPLAINT

Plaintiff, Dr. Cami Jo Tice-Harouff, DNP, APRN, FNP-C, on behalf of herself and her patients, for her verified complaint against Defendants, states:

INTRODUCTION

1. This case is a challenge under the Administrative Procedure Act to the federal government's final decision to change a health insurance coverage mandate under the Affordable Care Act (ACA) without using the notice-and-comment rulemaking process to issue the change.

2. The ACA requires most health plans to provide coverage, without cost sharing, of women's preventive services as set forth in guidelines by Defendant Health Resources and Services Administration (HRSA), *see* 42 U.S.C. § 300gg-13(a)(4). Since 2016 that requirement has included coverage of instruction in fertility

awareness-based methods of family planning. But in December 2021, the government issued a decision to delete the language requiring coverage of that service.

3. This final agency action harms women and their healthcare professionals who depend on these insurance benefits. Plaintiff Dr. Cami Jo Tice-Harouff, a Family Nurse Practitioner in Longview, Texas, regularly instructs patients in fertility awareness-based methods of family planning both locally and by telehealth, and she bills her patients' health insurance plans for those services.

4. The government should have considered many important issues before deleting coverage of these services, including their importance to women and to their health professionals. But the government not only failed to consider those issues—it made this change without using the notice-and-comment process at all, despite the Administrative Procedure Act's mandate that notice-and-comment rulemaking be used before changing a requirement that binds external parties. Women should not have to fear losing their doctor and their medical treatment as a result of backroom government decisions.

5. Dr. Tice-Harouff thus challenges the government's action on two grounds under the Administrative Procedure Act. *First*, the government unlawfully failed to follow notice-and-comment rulemaking procedures. *Second*, the government's action was arbitrary and capricious, and not the product of reasoned decision-making.

6. A temporary restraining order, and preliminary and permanent injunctive relief, are necessary to prevent women and health professionals from being harmed by this change, which goes into effect for health plan years starting after December 30, 2022. Health plan issuers in Texas and around the country are already in the process of obtaining approval of plans set to take effect in January 2023.

JURISDICTION & VENUE

7. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because this action arises under the U.S. Constitution and federal law.

8. This Court also has jurisdiction under 28 U.S.C. § 1346(a) because this is a civil action against the United States.

9. Additionally, this Court has jurisdiction under 28 U.S.C. § 1361 to compel an officer of the United States or any federal agency to perform his or her duty.

10. This Court has jurisdiction to review Defendants' unlawful actions and enter appropriate relief under the Administrative Procedure Act, 5 U.S.C. §§ 553, 701–06.

11. This court has jurisdiction to issue equitable relief to enjoin ultra vires agency action. *Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689–91 (1949).

12. This case seeks declaratory and other appropriate relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202, 5 U.S.C. § 705–06, Federal Rule of Civil Procedure 57, and the Court's inherent equitable powers.

13. This Court may award costs and attorneys' fees under the Equal Access to Justice Act, 28 U.S.C. § 2412.

14. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims occurred in this district, and a substantial part of property that is the subject of the action is situated here, because this district and this division is where Plaintiff is situated and is regulated by Defendants' actions. Defendants are United States agencies or officers sued in their official capacities. A substantial part of the events or omissions giving rise to the Complaint occurred within the Eastern District of Texas.

PARTIES

15. Plaintiff Cami Jo Tice-Harouff, DNP, APRN, FNP-C, is a family nurse practitioner whose home and office are each located in Longview, Texas, and Gregg County, Texas. She sues on her own behalf and on behalf of her current and future patients.

16. Defendant Carole Johnson is Administrator of the Health Resources and Services Administration of the United States Department of Health and Human Services. She is responsible for the overall operations of HRSA, including HRSA's implementation of the women's preventive services mandate at 42 U.S.C. § 300gg-13(a)(4). Defendant Johnson is sued in her official capacity. Her address at HRSA is 5600 Fishers Lane Rockville, MD 20857.

17. Defendant Health Resources and Services Administration (HRSA) is a federal agency within the executive branch of the U.S. government, including under 5 U.S.C. § 551 and 701(b)(1). HRSA is an operating division of the United States Department of Health and Human Services. Its address is 5600 Fishers Lane Rockville, MD 20857

18. Defendant Xavier Becerra is the Secretary of the U.S. Department of Health and Human Services (HHS), and is sued in his official capacity. He is responsible for the overall operations of the Department, including of the Health Resources and Services Administration. His address at HHS is 200 Independence Ave SW, Washington, DC 20201.

19. Defendant U.S. Department of Health and Human Services (HHS) is a federal agency within the executive branch of the U.S. government, including under 5 U.S.C. § 551 and 701(b)(1). Its address is 200 Independence Ave SW, Washington, DC 20201.

20. Collectively and as applicable, all defendants are referred to herein as "the government."

FACTUAL ALLEGATIONS

I. The government removed fertility awareness-based methods of family planning from its contraceptive mandate.

21. Under the Affordable Care Act (ACA):

> 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 for . . .
>
> . . .
>
> (4) with respect to women, such additional preventive care and screenings . . . 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) (also referred to as section 2713 of the Public Health Service Act).

22. Although the statute refers to these as "guidelines," they are mandatory by virtue of the prefatory language of 42 U.S.C. § 300gg-13(a), which says plans and issuers "shall" provide coverage and "shall not" impose cost sharing for the items listed in the guidelines.

23. Using that authority, Defendants HRSA and its Administrator, and upon information and belief Defendants HHS and its Secretary by virtue of their authority over HRSA, have issued guidelines describing which women's preventive services must be covered without cost sharing under § 300gg-13(a)(4).

24. According to HRSA, since guidelines published at least as far back as 2016, the women's preventive care and screenings coverage requirements under § 300gg-13(a)(4) have required group health plans and health insurance issuers to offer coverage without cost-sharing of "instruction in fertility awareness-based methods"

of family planning. HRSA's website lists the coverages that were set forth in its "2016 Guidelines."[1]

25. But in December 2021, the government changed these guidelines to delete the sentence requiring coverage without cost sharing of "instruction in fertility awareness-based methods" of family planning. *See* Exhibit A at 2–3, under "Contraception," comparing "Current Guidelines" to "Updated Guidelines Beginning With Plan Years Starting in 2023."[2]

26. This agency action at Exhibit A is hereinafter referred to as the "2021 Guidelines," and its deletion of this language is the subject of this lawsuit.

27. Under the 2021 Guidelines, applicable health plans and coverages "are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market policy year) that begins on or after December 30, 2022." 2021 Guidelines at note *.

28. The one-year timeframe for the 2021 Guidelines effective date is mandated by § 300gg-13(b)(2).

29. Thus the government issued the 2021 Guidelines as a final matter in December 2021, with an effective date on plans that start after December 30, 2022.

30. HRSA refers to its issuance of the 2021 Guidelines as "the formal action by the Administrator under Section 2713." Ex. A at 7–8.

31. HRSA also calls its issuance of the 2021 Guidelines "the decision to update the Guidelines." Update to the Women's Preventive Services Guidelines, Update to the Women's Preventive Services Guidelines, 87 Fed. Reg. 1,763 (Jan. 12, 2022).

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[1] HRSA, *Women's Preventive Services Guidelin*es (2016), https://bit.ly/3NBpi3x (last visited May 24, 2022).

[2] Also available at HRSA, *Women's Preventive Services Guidelin*es (2021), https://bit.ly/3GcDLkc (last visited May 24, 2022). HRSA subsequently published this change in the Federal Register at Update to the Women's Preventive Services Guidelines, 87 Fed. Reg at 1,763 (noting the December date of the change).

32. The 2021 Guidelines are HRSA's final, post-deliberative decision about what coverages are required under § 300gg-13(a)(4).

33. Issuance of the 2021 Guidelines is a final agency action.

34. Under the guidelines that existed previous to the 2021 Guidelines, applicable health plans and issuers were required to cover "instruction in fertility awareness-based methods" of family planning with no cost sharing.

35. The effect of the December 2021 Guidelines' deletion of language that had required coverage of "instruction in fertility awareness-based methods" is that applicable health plans and issuers will no longer be required to cover those services under the guidelines authorized by § 300gg-13(a)(4).

II. Dr. Tice-Harouff bills insurance for fertility awareness-based methods of family planning.

36. Plaintiff Dr. Cami Jo Tice-Harouff, DNP, APRN, FNP-C, is a health professional who provides patients with instruction in fertility awareness-based methods of family planning.

37. Dr. Tice-Harouff bills patients' health insurance plans for providing this instruction.

38. Dr. Tice-Harouff has a Doctor of Nursing Practice degree in Advanced Practice Nursing from Samford University, a Master of Science in Nursing from Bellarmine University, and an undergraduate degree in Theology and Psychology from The Baptist College of Florida.

39. Dr. Tice-Harouff is a member of the American Association of Nurse Practitioners, Texas Nurse Practitioners, the East Texas Nurse Practitioner Association, the National League for Nursing, the Catholic Medical Association, Fertility Appreciation Collaborative to Teach the Science (FACTS), BOMA-USA (Billings Ovulation Method), and the National Association of Catholic Nurses.

40. Dr. Tice-Harouff has often taught academic courses to nursing students through various universities.

41. Dr. Tice-Harouff has worked in many community settings, including in nonprofit health programs for vulnerable populations and as a Registered Nurse, Sexual Assault Nurse Examiner.

42. Dr. Tice-Harouff currently practices as a family nurse practitioner.

43. Since March 2021, Dr. Tice-Harouff has served as the executive director of Hesed Health Clinic, a 501(c)(3) nonprofit charitable health clinic in Longview, Texas.

44. Dr. Tice-Harouff sees patients in person and by telehealth.

45. Dr. Tice-Harouff is licensed to practice in Texas. She is also licensed to provide telehealth on a full basis to patients in Delaware, Connecticut, Florida, and Nevada, and on a limited basis to patients in Kentucky and California. She is seeking to expand her licensure for telehealth to other states soon, such as Rhode Island, to address the shortage of healthcare providers.

46. As part of her practice, Dr. Tice-Harouff provides general women's health, which includes medical management of women's reproductive health needs, and instruction in fertility awareness-based methods of family planning.

47. Dr. Tice-Harouff offers instruction and medical support in several fertility awareness-based methods of family planning, including NaProTechnology care, Creighton Model FertilityCare education, and the Marquette Method of family planning. She also plans to add FEMM Medical Management to her services.

48. These fertility awareness-based methods of family planning help patients avoid or achieve pregnancy in many situations, including while breastfeeding.

49. Dr. Tice-Harouff's instruction of patients in these fertility awareness-based methods of family planning has been covered by the HRSA guidelines issued under § 300gg-13(a)(4) for several years, but will no longer be covered when the 2021 Guidelines go into effect.

50. Many women have medical, philosophical, or religious reasons for choosing fertility awareness-based methods of family planning. Birth control, for instance, sometimes creates harmful side effects, like blood clots, weight gain, or increased anxiety and depression in some women. That makes fertility awareness-based methods of family planning some women's only option without serious endangerment to their health. Fertility awareness-based methods of family planning are also the method many women chose based on their philosophical, moral, or religious beliefs.

51. Dr. Tice-Harouff's fertility-affirming family planning thus allows patients to live according to healthy living practices and their core principles while seeking to choose the best care for their families

52. Dr. Tice-Harouff's appointments providing instruction in fertility awareness-based methods of family planning are minimally one hour long and often last ninety to one hundred twenty minutes.

53. Dr. Tice-Harouff sees such patients about six times in the first five months that she begins providing them instruction in fertility awareness-based methods of family planning.

54. Dr. Tice-Harouff bills and receives payment from many of her patients' insurance plans for her instruction in fertility awareness-based methods of family planning.

55. For patients who have insurance coverage, Dr. Tice-Harouff's instructional sessions are reimbursed by about $300 to $450 per encounter from insurance coverage for her provision of instruction in fertility awareness-based methods of family planning.

56. In the last six months, Dr. Tice-Harouff's instruction in fertility awareness-based methods of family planning have generated at least $20,000 thousand dollars in health insurance reimbursement payments.

57. As a service to the needy, Dr. Tice-Harouff volunteers for Hesed Health Clinic, and she arranges for her health care reimbursement payments to go to Hesed Health Clinic in order to benefit that nonprofit organization and the people for whom the clinic provides care.

58. Standardized coding exists to bill insurance companies for instruction in fertility awareness-based methods of family planning (also referred to as "natural family planning"), as an item that has heretofore been covered by the HRSA Guidelines.[3]

59. Dr. Tice-Harouff receives referrals to provide care to patients around the country, and she cares for patients in various states where she is licensed or is authorized to work with a medical doctor in that state.

60. Dr. Tice-Harouff is an in-network provider for many large, well-known, and commonly carried group health plans and health insurance issuers.

61. The state where a patient's plan was issued is often not the only state in which the patient may receive care. For example, many plans provided by employers are issued in one state but cover employees of that company who live in many other states, and those plans give patients in-network and out-of-network options for care in those states, including for no-cost-sharing preventive care, or through telehealth.

62. Dr. Tice-Harouff accepts health insurance issued in any state. She provides care and bills insurance for a patient so long as she is licensed to provide care to the patient based on the patient's physical location during treatment, is recognized as a provider by their plan or issuer, and other applicable conditions are met.

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[3] American College of Obstetricians and Gynecologists, *Women's Preventive Services Initiative (WPSI), 2021 Coding Guide* at 4, 26 (2021), https://bit.ly/3z0axmX (last visited May 24, 2022) (listing "Coding for Natural Family Planning" as "Z30.02 Counseling and instruction in natural family planning to avoid pregnancy.")

63. Some of Dr. Tice-Harouff's patients change or may change insurance plans during a year or annually, either due to life changes, open enrollment opportunities, or for other reasons, such as premium increases.

64. Uniform mandatory coverage of instruction in fertility awareness-based methods of family planning without cost sharing allows patients to continue to receive uninterrupted care despite different changes that can occur to their health insurance coverage.

65. Issuers revise benefits each year, and state health regulators approve coverage for health insurance plans each year.

66. Group health plans and health insurance issuers are already in the process of applying for approval for their plan years that would begin on January 1, 2023.[4]

III. Dr. Tice-Harouff and her patients will be harmed by the government's removal of fertility awareness-based methods from the women's preventive services guidelines.

67. Without insurance coverage and without cost-sharing for fertility-awareness-based methods of family planning, Dr. Tice-Harouff and her patients will suffer both financially and in their health outcomes.

68. Upon information and belief, without the explicit requirement in HRSA's women's preventive services guidelines for several years, many health insurance plans would not have covered instruction in fertility awareness-based methods of family planning, either at all or without cost-sharing.

69. Upon information and belief, many health insurance plans will not cover instruction in fertility awareness-based methods of family planning at all, or will cover it but impose cost-sharing, in coverage subject to the 2021 Guidelines.

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[4] *See, e.g*, Texas Department of Insurance, *Life/Fraternal, Accident and Health Insurers and Group Hospital Service Corporations, 2021/2022 Filing Smart*, https://bit.ly/3Gdxch8 (last visited May 24, 2022) (setting forth multiple deadlines beginning in March 2022 for health insurers to file documents for their next plan year).

70. Insurance coverage, and coverage without cost-sharing, is key to access to care. In the past, HHS has acknowledged that research shows that "cost sharing can be a significant barrier" to obtaining family planning services. Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725, 8,728 (Feb. 15, 2012) (to be codified at 26 C.F.R. 54).

71. HHS has concluded that including services in the women's preventive care guidelines—specifically in the "contraception" category where HRSA previously included language on fertility awareness-based methods—has increased coverage of those services for tens of millions of women, has decreased their costs, and has increased their use of those services, especially concerning services that would cost hundreds of dollars, such as for patients in high deductible health plans.[5]

72. In Dr. Tice-Harouff's experience, patients are less likely to pursue medical care, and instruction in fertility awareness-based methods of family planning in particular, if that care is not covered or is not covered without cost-sharing.

73. For example, Dr. Tice-Harouff has patients whose coverage of fertility awareness-based methods of family planning would be subject to a high deductible, and her care would cost them hundreds of dollars each month, if this service was not covered without cost-sharing as mandated by the Guidelines. Dr. Tice-Harouff also has other patients who face financial difficulties and would struggle to pay for instruction in fertility awareness-based methods of family planning without coverage or if cost-sharing is imposed.

74. If health insurance plans choose not to cover instruction in fertility awareness-based methods of family planning, either at all or without cost-sharing,

[5] 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 at 1, 9–10 (Jan. 11, 2022), https://bit.ly/3lEHWM5.

Dr. Tice-Harouff's current and future patients would be unable or less able to pay for her instruction, and would suffer negative health outcomes as a result.

75. Dr. Tice-Harouff will face reduced demand for and compensation for her instruction in fertility awareness-based methods of family planning under the 2021 Guidelines.

76. She 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.

77. Fewer of Dr. Tice-Harouff's current and future patients will likely know that they have the option of fertility awareness-based methods of family planning from her, fewer patients will avail themselves of it, and fewer patients will be able to afford it, under the 2021 Guidelines.

78. Women who practice fertility awareness-based methods make serious personal and financial decisions in seeking to choose the best care for their families consistent with their philosophical or religious views. Removing mandatory insurance coverage of these services under the 2021 Guidelines will impose serious harm to these families.

79. Some patients who decline to use other methods of family planning for health, philosophical, or religious reasons will have access to no acceptable methods of family planning under the 2021 Guidelines.

80. Under the 2021 Guidelines' changes to fertility awareness-based methods instruction coverage, fewer patients will be able to maximize their individual health goals as under previous guidelines.

81. Dr. Tice-Harouff and her patients will likely experience reduced societal support for fertility awareness-based methods of family planning under the 2021 Guidelines.

82. HHS is imposing its own preferred method of family planning on all women by deleting language requiring coverage of instruction in fertility awareness-based methods from the 2021 Guidelines.

83. Dr. Tice-Harouff and her current and future patients are in danger of serious financial loss because of the 2021 Guidelines.

84. Because the government required insurers to cover instruction in fertility awareness-based methods of family planning under the previous Guidelines (which govern current coverage until plan years beginning after December 30, 2022), Dr. Tice-Harouff and her patients have a current, direct, and legally protected interest in the Guidelines' mandate of coverage of instruction in fertility awareness-based methods of family planning.

85. The 2021 Guidelines violate the APA rights of Dr. Tice-Harouff and her current and future patients.

86. The 2021 Guidelines cause legal wrongs to Dr. Tice-Harouff and her current and future patients.

87. Dr. Tice-Harouff and her current and future patients are adversely affected and aggrieved by the 2021 Guidelines.

88. The agency's lack of clarity and transparency in its process created confusion and disruption for Dr. Tice-Harouff, her patients, insurance plans, and the public.

89. Had the agency undergone a notice and comment process under the Administrative Procedure Act, Dr. Tice-Harouff and the public would have had proper notice of the change and the opportunity to submit public comments, which the agency would have had to consider and rationally discuss if it wished to finalize the change properly.

90. But the agency did not undergo the notice and comment process under the Administrative Procedure Act, and so Dr. Tice-Harouff and the public lost that

opportunity. She and others had no chance to urge the agency to keep its current mandate.

91. If the agency undergoes a future notice and comment process under the Administrative Procedure Act, Dr. Tice-Harouff intends to submit comments (1) raising reasons not to cut fertility awareness-based methods, (2) discussing her reliance interests in continued coverage for her services, and (3) suggesting possible alternatives to cutting instruction in fertility awareness-based methods.

92. There is a reasonable chance that the agency would make a different decision if the change challenged here is delayed, enjoined, and remanded unless and until the agency complies with the APA.

IV. The government's removal of fertility awareness-based methods from the contraceptive mandate is a final agency action and a binding rule.

93. HRSA's action to issue the 2021 Guidelines mandates or withdraws mandates of what insurance companies must or must not cover, and is a final agency action reviewable under the Administrative Procedure Act.

94. The 2021 Guidelines are an improperly issued rule.

95. HRSA's announcement of the 2021 Guidelines as "supported" by the agency consummated the agency decision process and issued them in final form.

96. HRSA's guidelines delineate the scope of obligations, rights, and benefits for the public, including for employers, insurers, providers, consumers, and insured women for the years specified, because HRSA intends its announcement of each set of guidelines to impose a mandate on insurance providers to cover the listed contraceptive services without cost-sharing.

97. HRSA insists on the binding nature of its Guidelines: "According to Section 2713 of the Public Health Service Act [42 U.S.C. § 300gg-13], private health insurers *must provide coverage* without cost sharing for the screenings and services in the guidelines. These guidelines *make sure* children and women receive a comprehensive

set of preventive services without having to pay a co-payment, co-insurance, or deductible."[6] (emphasis added).

98. HRSA's guidelines are not labeled as optional or advisory, either for the agency's officials or for the public.

99. In both its previous guidelines, which included coverage of "instruction in fertility awareness-based methods" of family planning, and its 2021 Guidelines which do not, HRSA insists that applicable health coverage plans "are required" to cover the items "specified" in such guidelines.[7]

100. Any non-exempt plan or issuer that fails to comply with the 2021 Guidelines, or previous guidelines, will face various and significant legal consequences.[8]

101. Issuers, plans, and employer plan sponsors thus must alter their coverage to include services specified for coverage in the Guidelines or face significant legal and financial liability.

102. Those parties do not face that same liability if they remove coverage of "instruction in fertility awareness-based methods" of family planning under the 2021 Guidelines.

V. The government did not meet the Administrative Procedure Act's requirements in issuing the 2021 Guidelines.

A. Inadequate Notice

103. The 2021 Guidelines were not preceded by a notice of proposed rulemaking.

104. The 2021 Guidelines do not purport to be an interim final rule.

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[6] HRSA, *Preventive Guidelines and Screenings for Women, Children, and Youth*, https://bit.ly/3NwssFU.

[7] *See* 2016 Guidelines (https://bit.ly/3amHmAj); 2019 Guidelines (https://bit.ly/3MXmsG8) and 2021 Guidelines (Exhibit A; *see also* https://bit.ly/3wLtebi).

[8] *See, e.g.*, *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 696–98 (2014) (describing penalties for employers who fail to offer coverage outlined in the guidelines).

105. The government did not purport to rely on "good cause" to fail to pursue notice-and-comment rulemaking in issuing the 2021 Guidelines.

106. In October 2021, HRSA had announced draft changes to recommendations that influence the Guidelines (hereinafter "the October 2021 notice").[9]

107. The October 2021 notice does not purport to be a proposed rule.

108. The October 2021 notice does not inform the public that HRSA planned to delete language that had required coverage of fertility awareness-based methods of family planning.

109. Instead, in describing draft changes to recommendations that influence the guidelines, the October 2021 notice described only three draft changes: "to clarify the terminology from contraceptive methods to contraceptives," to "remove[] the term 'female-controlled contraceptives' to allow women to purchase male condoms for pregnancy prevention," and to "further define[] the existing components of contraceptive follow-up care to include the management and evaluation of and changes to—including the removal, continuation, and discontinuation of—the contraceptive." 86 Fed. Reg. at 59,742.

110. The October 2021 notice did not provide any rationale for deleting language requiring coverage of instruction in fertility awareness-based methods of family planning.

111. The October 2021 notice left the public to guess whether it proposed cutting coverage of instruction in fertility awareness-based methods from the guidelines altogether, or merely that the language concerning those methods was not mentioned or discussed in the notice because there was no plan to change that part of the contraceptive mandate.

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[9] HRSA, *Updated HRSA-Supported Women's Preventive Services Guidelines: Contraception and Screening for HIV Infection*, 86 Fed. Reg. 59,741 (Oct. 28, 2021).

112. The October 2021 notice therefore did not adequately notify the public of a proposed change to fertility awareness-based methods of family planning coverage, or any reason for making that change, so as to adequately give the public an opportunity to comment on that change.

B. Irregular Public Comment Process

113. The October 2021 notice did not allow the public to submit comments about these changes to the responsible government agency, and the submission process did not use a public docket on the government website Regulations.gov.

114. Instead the October 2021 notice only allowed the public to submit comments to HRSA's private contractor, the Women's Preventive Services Initiative (WPSI).

115. The October 2021 notice was styled as an opportunity to comment to WPSI on what WPSI would *recommend*, concerning issues not inclusive of fertility awareness methods coverage. It was not an opportunity to comment to HRSA at all, and it was not an opportunity to comment on fertility awareness methods coverage specifically. HRSA stated that WSPI would "review the comments" on its recommendations," then, "[a]fter review, if approved, the HRSA Administrator accepts the proposed guidelines."[10] The notice did not mention or discuss fertility awareness methods.

116. Nevertheless, some organizations, fearful that the current administration was hostile to fertility awareness-based methods of family planning, submitted comments to WPSI in response to the October 2021 notice, expressing concern and objection to any removal of coverage for those services.[11]

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[10] HRSA, *Preventive Guidelines and Screenings for Women, Children, and Youth*, *supra*.

[11] *See, e.g.*, Catholic Medical Association, *Public Comments Submitted to WPSI Nov-21 Re: Possible Changes to Fertility-Awareness Based Methods* (Nov. 21, 2021),

117. The government did not respond to those comments in issuing the 2021 Guidelines.

118. In issuing the 2021 Guidelines, the government did not respond to any comments submitted to WPSI from the October 2021 notice.

119. Upon information and belief, the government did not even read comments concerning fertility awareness methods coverage before issuing the final 2021 Guidelines.

120. Upon information and belief, those comments concerning fertility awareness methods coverage were never even in HRSA's or HHS's possession before issuing the 2021 Guidelines.

121. Comments submitted to WPSI in response to the October 2021 notice are not available for the public to access.

122. None of WPSI's own statements, recommendations, or implementation considerations constitute "part of the formal action by the Administrator under Section 2713," that is, the issuance of the 2021 Guidelines. *See* Exhibit A note *.

123. The government never solicited comments to HRSA or HHS itself about any change to the Guidelines.

124. The lack of response to any comments submitted to WPSI suggests that the government did not meaningfully consider those comments in issuing the Guidelines.

125. The agency cannot delegate its duty to collect public comments, review them, and respond to significant public comments, to an outside agency.

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https://bit.ly/3PIMLSg & https://bit.ly/3MLMpbT (last visited May 24, 2022) (comments on behalf of U.S. Conference of Catholic Bishops, the National Catholic Bioethics Center and The Catholic Medical Association); Natural Womanhood, *Comments on Insurance Coverage for FAMs* (Nov. 21, 2021), https://bit.ly/3NQVIaL (last visited May 24, 2022) (comments of a non-profit women's health organization); FACTS, *Comment for the Women's Preventive Health Initiative Contraception Proposal*, https://bit.ly/38H28u5 (last visited May 24, 2022).

126. The government cannot issue a binding final agency action without responding to significant public comments on the legal theory that its non-governmental contractor considered those comments so no response by the government was necessary.

127. Yet the 2021 Guidelines did not even purport to rely on such a legal theory.

128. WPSI, too, disclaims any practice of responding to public comments or obligation to do so: "At the present time, WPSI cannot provide responses to individual comments."[12]

129. The government made no changes to the 2021 Guidelines in response to public comments.

130. The government did not meaningfully consider public comments, or consider them at all, in issuing the 2021 Guidelines.

C. No Reasoned Decision Making

131. In issuing the 2021 Guidelines, the government did not explain the substantive decision-making surrounding the change to fertility awareness methods coverage.

132. Instead, the agency simply published the group's draft recommendations as its own supported guidelines, the 2021 Guidelines, on the HRSA website, without explanation or rationale with respect to fertility awareness methods coverage.[13]

133. In issuing the 2021 Guidelines, the government (1) gave no reason for its deletion of language covering fertility awareness-based methods of family planning; (2) discussed no reliance interests of health professionals and patients in such coverage being included in the Guidelines; and (3) discussed no alternatives to deleting this language.

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[12] Women's Preventive Services Initiative, *Public Comment*, https://www.womenspreventivehealth.org/public-comment/ (last visited May 24, 2022).

[13] Ex. A, 2021 Women's Preventive Services Guidelines at 7–8.

134. The agency did not show in any other way its awareness of the change in the guidelines language concerning fertility awareness-based methods of family planning.

135. The agency cannot delegate its duty to make its own reasoned decision, and so any action by an outside group cannot substitute for the agency's own decision and judgment to be issued under the agency's own name and authority.

136. In any event, the agency did not purport to do so.

137. The agency did not state good cause for omitting any such procedure.

VI. Judicial relief is necessary and appropriate to halt the government's removal of fertility awareness-based methods from its contraceptive mandate.

138. Judicial relief is thus necessary and appropriate to hold unlawful and set aside the 2021 Guidelines' removal of language requiring coverage of fertility awareness-based methods of family planning.

139. Injunctive relief (temporary, preliminary, and permanent) is necessary to maintain the status quo in time for health plans and issuers to write and obtain government regulatory approval for their coverage to include this coverage, rather than to omit it based on this illegal change.

140. Injunctive relief is necessary to avoid patients' loss in health insurance benefits and surprise billing based on this illegal change.

141. Injunctive relief is necessary to avoid Dr. Tice-Harouff and other health professionals in the burgeoning field of fertility awareness-based methods instruction, from losing current and future patients and from losing financial compensation based on this illegal change.

142. Upon information and belief, health insurance issuers and government insurance regulators are already undergoing the planning and approval processes for plan or policy years that will begin after December 30, 2022.

143. Upon information and belief, it would cause significant confusion and hardship to health insurance issuers and plans to delay providing the injunctive relief requested here.

144. The relief requested must encompass the 2021 Guidelines' removal of coverage of fertility awareness-based methods of family planning, because Dr. Tice-Harouff's current and future patients span many states and individual health coverage situations, and plans will omit the required coverage and cause injury from the 2021 Guidelines if relief against the deletion itself is not afforded.

145. The government would suffer no harm from the relief requested, because with respect to fertility awareness-based methods instruction, the Guidelines would simply revert to language that has included for several years, and the 2021 Guidelines would not otherwise be affected.

146. Because health insurers around the country have already started their process of seeking approval for plan years beginning in January 2023, *see supra* note 4, Dr. Tice-Harouff and her patients will suffer irreparable harm unless this court issues a temporary restraining order delaying for one year the effective date of the 2021 Guidelines' change to language concerning fertility awareness-based methods instruction for one year, under 5 U.S.C. § 705 which explicitly authorizes that relief, so that plans, issuers, and state regulators can promptly become aware that this coverage cannot be dropped in these policies.

147. Dr. Tice-Harouff and her patients have no adequate remedy available at law.

CLAIMS FOR RELIEF

CLAIM ONE

ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706)

WITHOUT PROCEDURE REQUIRED BY LAW & CONTRARY TO LAW

148. Plaintiff re-alleges and incorporates herein, as though fully set forth, paragraphs 1–147 of this complaint.

149. Under the Administrative Procedure Act, agencies must follow public notice-and-comment procedures before they make final, binding actions.

150. Under the APA, a reviewing court must "hold unlawful and set aside agency action" if the agency action is "without observance of procedure required by law," and "not in accordance with law." 5 U.S.C. § 706(2)(A) & (D).

151. Under the APA, the court may issue temporary and preliminary injunctive relief and any other "necessary and appropriate process . . . to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705.

152. ***Notice requirement.*** The removal of instruction in fertility awareness-based methods of family planning from the 2021 Guidelines was not clearly set forth or adequately described, as to their nature or as to the agency's reasons, in the October 2021 notice.

153. The public had no clear way to know that the government planned to eliminate this coverage language rather than simply make the listed changes alongside the longstanding language.

154. The public had no adequate notice of why the government would remove this language or what doing so might mean, and thus no adequate opportunity to comment on such a proposal and the government's rationale for it, much less to comment on the impacts of such a change.

155. Thus the government violated the requirement that an agency must publish a general notice of proposed rulemaking in the Federal Register, including "a

statement of the time, place, and nature of public rule making proceedings" and "either the terms or substance of the proposed rule or a description of the subjects and issues involved," or else find good cause to omit these procedures on the record. 5 U.S.C. § 553(b).

156. ***Comment requirement.*** The removal of instruction in fertility awareness-based methods of family planning from the 2021 Guidelines was not the subject of an opportunity for public comment to the government, either to HRSA or HHS.

157. The government did not collect, review, or consider public comments before issuing the 2021 Guidelines.

158. The comments solicited for submission to WPSI were not clearly for commenting to the government itself on its changes, rather than to WPSI for what changes it might recommend.

159. There was no specific request for comment on deleting language concerning fertility awareness methods coverage language, even while there were requests specifying other changes made in the notice.

160. The government did not treat the comments as public comments to it, nor did it receive, review, meaningfully consider, or consider at all those comments before issuing the 2021 Guidelines.

161. Thus the government violated the requirement for a legislative or substantive rule that "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments . . . ." 5 U.S.C. § 553(c).

162. The government made no finding of good cause for omitting either the notice or the comment procedures, nor did it purport to make such a finding.

163. Therefore the 2021 Guidelines' removal of language requiring coverage of fertility awareness-based methods of family planning must be held unlawful, set aside, and preliminarily and permanently enjoined under the APA.

CLAIM TWO

ADMINISTRATIVE PROCEDURE ACT (5 U.S.C. § 706)

ARBITRARY, CAPRICIOUS, & AN ABUSE OF DISCRETION

164. Plaintiff re-alleges and incorporates herein, as though fully set forth, paragraphs 1–147 of this complaint.

165. Under the APA, a reviewing court must "hold unlawful and set aside agency action" if the agency action is "arbitrary, capricious, [or] an abuse of discretion . . . ." 5 U.S.C. § 706(2)(A).

166. The 2021 Guidelines, as to the removal of language requiring coverage of instruction in fertility awareness-based methods of family planning, are arbitrary, capricious, and an abuse of discretion.

167. The government failed to offer any rationale in its October 2021 notice describing why it was removing this coverage language, or even acknowledging that it planned to do so.

168. Likewise in the final 2021 Guidelines the government failed to offer any rationale for this change, or even an acknowledgement that it had made the change.

169. The government failed to describe any rational connection between the change made and some set of facts or problems.

170. The government failed to address, much less consider or adequately consider important aspects of the problem that led to or would be caused by removal of this language, such as the disruption caused by removing benefits or the degree of regulatory uncertainty that the new guidelines create.

171. The government completely failed to respond to multiple significant comments, submitted in the only comment process provided via HRSA's contractor, which raised concerns and objections about deletion of this language.

172. In making this change, the government relied on facts, studies, and recommendations only from one side of the issue, and it ignored other evidence and experts.

173. The government failed to consider or adequately consider reliance interests of patients and health care professionals in maintaining the coverage language at issue.

174. In particular, the government failed to adequately consider the impact on health professionals and patients with medical, ethical, conscientious, and religious objections to other forms of family planning.

175. The government failed to consider or adequately consider alternatives to the deletion of this language, such as not deleting it.

176. The government's inadequate thought process reveals that it made an error of judgment.

177. The government itself has a non-delegable duty must publish adequate notices, accept comments, respond to comments, and engage in reasoned decision making.

178. Therefore the 2021 Guidelines' removal of language requiring coverage of fertility awareness-based methods of family planning must be held unlawful, set aside, and preliminarily and permanently enjoined under the APA.

PRAYER FOR RELIEF

For these reasons, Plaintiff Dr. Cami Jo Tice-Harouff, DNP, APRN, FNP-C, on behalf of herself and her patients, respectfully requests that this Court enter judgment against Defendants, and provide the following relief:

A. That this Court declare unlawful, set aside, and vacate the 2021 Women's Preventive Service Guidelines as to the removal of the language requiring coverage of "instruction in fertility awareness-based methods" of family planning;

B. That this Court render a declaratory judgment stating that the current Women's Preventive Service Guidelines *status quo ante* the 2021 Guidelines will remain in effect as to language requiring coverage of "instruction in fertility awareness-based methods" of family planning, including for plan and policy years beginning after December 30, 2022;

C. That this Court render a declaratory judgment stating that HRSA's adoption or support of the 2021 Women's Preventive Service Guidelines, as to the removal of language requiring coverage of instruction in fertility awareness-based methods of family planning, is without observance of procedure required by law, and arbitrary, capricious, an abuse of discretion, and not in accordance with law under the Administrative Procedure Act;

D. That this Court issue a temporary restraining order and preliminary injunction order under 5 U.S.C. § 705 to delay the effective date of the 2021 Guidelines' elimination of the language requiring coverage of instruction in fertility awareness-based methods of family planning until at least one year after the conclusion of this Court's review of this case;

E. That this Court issue a temporary restraining order and preliminary and permanent injunction against Defendants, their officials, agents, employees, and all persons in active concert or participation with them, including their successors in office, using or applying the 2021 Guidelines to delete language requiring coverage of instruction in fertility awareness-based methods of family planning from the Women's Preventive Services Guidelines issued under 42 U.S.C. § 300gg-13, thereby maintaining that current language as set forth in previous Guidelines;

F. That this Court vacate and remand the 2021 Guidelines to the government for further consideration, as to their deletion of language requiring coverage of instruction in fertility awareness-based methods of family planning.

G. That this Court grant to Plaintiff reasonable costs and expenses of this action, including attorneys' fees, under any applicable law, including 28 U.S.C. § 2412;

H. That this Court adjudge, decree, and declare the rights and other legal relations of the parties to the subject matter here in controversy so that such declarations will have the force and effect of final judgment;

I. That this Court retain jurisdiction of this matter to enforce this Court's order; and

J. That this Court grant such other relief as this Court deems just and proper.

Respectfully submitted this 25th day of May, 2022.

/s/ Matthew S. Bowman

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DECLARATION UNDER PENALTY OF PERJURY

I, Cami Jo Tice-Harouff, a citizen of the United States and a resident of Texas, and as Plaintiff, declare under penalty of perjury under 28 U.S.C. § 1746 that the above is true and correct to the best of my knowledge.

Executed this 23rd day of May, 2022, at Longview, Texas

/s/ Cami Jo Tice-Harouff

Cami Jo Tice-Harouff

[Signature filed electronically with original maintained by counsel]

EXHIBIT A

Women's Preventive Services Guidelines

Affordable Care Act Expands Prevention Coverage for Women's Health and Well-Being

The Affordable Care Act (ACA) – the health insurance reform legislation passed by Congress and signed into law by President Obama on March 23, 2010 – helps make prevention services affordable and accessible for all Americans by requiring most health insurance plans to provide coverage without cost sharing for certain recommended preventive services. Preventive services that have strong scientific evidence of their health benefits must be covered and plans can no longer charge a patient a copayment, coinsurance or deductible for these services when they are delivered by a network provider.

Under the ACA, most private health insurers must provide coverage of women's preventive health care – such as mammograms, screenings for cervical cancer, prenatal care, and other services –with no cost sharing. Under section 2713 of the Public Health Service Act, as modified by the ACA, non-grandfathered group health plans and non-grandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose.

The law recognizes and HHS understands the unique health needs of women across their lifespan. The purpose of WPSI is to improve women's health across the lifespan by identifying preventive services and screenings to be used in clinical practice and, when supported by HRSA, incorporated in the Guidelines.

HRSA-Supported Women's Preventive Services Guidelines: Background

The HRSA-supported Women's Preventive Services Guidelines (Guidelines) were originally established in 2011 based on recommendations from a Department of Health and Human Services' commissioned study by the Institute of Medicine (IOM), now known as the National Academy of Medicine (NAM).

Since the establishment of the Guidelines, there have been advancements in science and gaps identified in clinical practice. To address these, in 2016, the Health Resources and Services Administration (HRSA) awarded a five-year cooperative agreement, the Women's Preventive Services Initiative (WPSI), to the American College of Obstetricians and Gynecologists (ACOG) to convene a coalition of clinician, academic, and consumer-focused health professional organizations to conduct a scientifically rigorous review to develop recommendations for updated Guidelines in accordance with the model created by the NAM Clinical Practice Guidelines We Can Trust. The American College of Obstetricians and Gynecologists (ACOG) formed an expert panel, also called the WPSI, for this purpose.

In March 2021, ACOG was awarded a subsequent cooperative agreement to review and recommend updates to the Guidelines. Under ACOG, WPSI reviews existing Women's Preventive Services Guidelines biennially, or upon the availability of new evidence, as well as new preventive services topics. New topics for future consideration can be submitted on a rolling basis at the Women's Preventive Services Initiative website.

HRSA-Supported Women's Preventive Services Guidelines

Learn More

- HRSA/MCHB Preventive Guidelines and Screening for Women, Children, and Youth
- Historical Files
- 2019 Guidelines
- 2016 Guidelines
- Institute of Medicine: *Clinical Preventive Services for Women* (2011)
- Bright Futures
- Advisory Committee on Heritable Disorders in Newborns and Children

For Further Information

Contact wellwomancare@hrsa.gov.

HRSA supports the Guidelines listed below that address health needs specific to women. In December 2021, HRSA approved a new guideline on obesity prevention for midlife women and updates to five existing preventive services guidelines: Well-Women Preventive Visits, Breastfeeding Services and Supplies, Counseling for Sexually Transmitted Infections (STIs), Screening for Human Immunodeficiency Virus (HIV) Infection, and Contraception.*

New and Updated Guidelines

Type of Preventive Service	Current Guidelines	Updated Guidelines Beginning With Plan Years Starting in 2023
Obesity Prevention in Midlife Women		(NEW) WPSI recommends counseling midlife women aged 40 to 60 years with normal or overweight body mass index (BMI) (18.5-29.9 kg/m2) to maintain weight or limit weight gain to prevent obesity. Counseling may include individualized discussion of healthy eating and physical activity.
Breastfeeding Services and Supplies	WPSI recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.	WPSI recommends comprehensive lactation support services (including consultation; counseling; education by clinicians and peer support services; and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to optimize the successful initiation and maintenance of breastfeeding. Breastfeeding equipment and supplies include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be a priority to optimize breastfeeding and should not be predicated on prior failure of a manual pump. Breastfeeding equipment may also include equipment and supplies as clinically indicated to support dyads with breastfeeding difficulties and those who need additional services.
Contraception **, ***	WPSI recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth	WPSI recommends that adolescent and adult women have access to the full range of contraceptives and contraceptive care to prevent

Type of Preventive Service	Current Guidelines	Updated Guidelines Beginning With Plan Years Starting in 2023
	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) 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.	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. 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) 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.

Type of Preventive Service	Current Guidelines	Updated Guidelines Beginning With Plan Years Starting in 2023
Counseling for Sexually Transmitted Infections (STIs)	WPSI recommends directed behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for STIs. WPSI recommends that health care providers use a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors may include age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgment.	WPSI recommends directed behavioral counseling by a health care clinician or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for STIs. WPSI recommends that clinicians review a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors include, but are not limited to, age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgment.

Type of Preventive Service	Current Guidelines	Updated Guidelines Beginning With Plan Years Starting in 2023
Screening for Human Immunodeficiency Virus Infection (HIV)	WPSI recommends prevention education and risk assessment for HIV infection in adolescents and women at least annually throughout the lifespan. All women should be tested for HIV at least once during their lifetime. Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection. Screening for HIV is recommended for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.	WPSI recommends all adolescent and adult women, ages 15 and older, receive a screening test for HIV at least once during their lifetime. Earlier or additional screening should be based on risk, and rescreening annually or more often may be appropriate beginning at age 13 for adolescent and adult women with an increased risk of HIV infection. WPSI recommends risk assessment and prevention education for HIV infection beginning at age 13 and continuing as determined by risk. A screening test for HIV is recommended for all pregnant women upon initiation of prenatal care with rescreening during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.

Type of Preventive Service	Current Guidelines	Updated Guidelines Beginning With Plan Years Starting in 2023
Well-Woman Preventive Visits	WPSI recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services, including preconception and many services necessary for prenatal and interconception care, are obtained. The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors.	WPSI recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure the provision of all recommended preventive services, including preconception and many services necessary for prenatal and interconception care, are obtained. The primary purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors. These services may be completed at a single or as part of a series of visits that take place over time to obtain all necessary services depending on a woman's age, health status, reproductive health needs, pregnancy status, and risk factors. Well-women visits also include prepregnancy, prenatal, postpartum and interpregnancy visits.

Existing Guidelines

Type of Preventive Service	Current Guidelines
Breast Cancer Screening for Average-Risk Women	WPSI recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening. These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.
Screening for Anxiety	WPSI recommends screening for anxiety in adolescent and adult women, including those who are pregnant or postpartum. Optimal screening intervals are unknown and clinical judgement should be used to determine screening frequency. Given the high prevalence of anxiety disorders, lack of recognition in clinical practice, and multiple problems associated with untreated anxiety, clinicians should consider screening women who have not been recently screened.

Type of Preventive Service	Current Guidelines
Screening for Cervical Cancer	WPSI recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Cotesting with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years.
Screening and Counseling for Interpersonal and Domestic Violence	WPSI recommends screening adolescents and women for interpersonal and domestic violence, at least annually, and, when needed, providing or referring for initial intervention services. Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services.
Screening for Diabetes Mellitus after Pregnancy	WPSI recommends women with a history of gestational diabetes mellitus (GDM) who are not currently pregnant and who have not previously been diagnosed with type 2 diabetes mellitus should be screened for diabetes mellitus. Initial testing should ideally occur within the first year postpartum and can be conducted as early as 4–6 weeks postpartum (see Table 1). Women with a negative initial postpartum screening test result should be rescreened at least every 3 years for a minimum of 10 years after pregnancy. For women with a positive postpartum screening test result, testing to confirm the diagnosis of diabetes is indicated regardless of the initial test (e.g., oral glucose tolerance test, fasting plasma glucose, or hemoglobin A1c). Repeat testing is indicated in women who were screened with hemoglobin A1c in the first 6 months postpartum regardless of the result.
Screening for Gestational Diabetes Mellitus	WPSI recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100-g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity. WPSI suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices.
Screening for Urinary Incontinence	WPSI recommends screening women for urinary incontinence annually. Screening should ideally assess whether women experience urinary incontinence and whether it impacts their activities and quality of life. The Women's Preventive Services Initiative recommends referring women for further evaluation and treatment if indicated.

Implementation Considerations

While not included as part of the HRSA-supported guidelines, the Women's Preventive Services Initiative, through ACOG, also developed implementation considerations, available at the Women's Preventive Services Initiative website, which provide additional clarity on implementation of the guidelines into clinical practice. The implementation considerations are

separate from the clinical recommendations, are informational, and are not part of the formal action by the Administrator under Section 2713.

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* Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market policy year) that begins on or after December 30, 2022. Before that time, non-grandfathered plans are generally required to provide coverage without cost sharing consistent with the guidelines as previously updated in 2019.

** (I)(a) Objecting entities—religious beliefs.

(1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:
(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (I)(a)(2) of this note. Such non-governmental plan sponsors include, but are not limited to, the following entities:
(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order;
(B) A nonprofit organization;
(C) A closely held for-profit entity;
(D) A for-profit entity that is not closely held; or
(E) Any other non-governmental employer;
(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (I)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to “plan participants and beneficiaries” will be interpreted as references to student enrollees and their covered dependents; and
(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (I)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (I)(a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.

(2) The exemption of this paragraph (I)(a) will apply to the extent that an entity described in paragraph (I)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.
(b) Objecting individuals—religious beliefs. These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (I)(b), and nothing in 45 CFR 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(II)(a) Objecting entities—moral convictions.

(1) These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration exempts from any Guidelines requirements issued under 45 CFR 147.130(a)(1)(iv) that relate to the provision of contraceptive services:
(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as

specified in paragraph (II)(a)(2) of this note:
(A) A nonprofit organization; or
(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);
(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (II)(a)(2) of this note. In the case of student health insurance coverage, section (I) of this note is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and
(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (II)(a)(2) of this note. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (II)(a)(1)(iii), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under these Guidelines unless it is also exempt from that requirement.

(2) The exemption of this paragraph (II)(a) will apply to the extent that an entity described in paragraph (II)(a)(1) of this note objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.
(b) Objecting individuals—moral convictions. These Guidelines do not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (II)(b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715-2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.

(III) Definition. For the purposes of this note, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of these Guidelines.

See Federal Register Notice: Religious Exemptions and Accommodations for Coverage of Certain Preventive Services under the Affordable Care Act (PDF - 488 KB).

*** General Notice
On July 29, 2019, the District Court for the Northern District of Texas issued an injunction preventing the enforcement of "the Contraceptive Mandate, codified at 42 U.S.C. § 300gg–13(a)(4), 45 C.F.R. § 147.130(a)(1)(iv), 29 C.F.R. § 2590.715–2713(a)(1)(iv), and 26 C.F.R. § 54.9815–2713(a)(1)(iv), against any group health plan, and any health insurance coverage provided in connection with a group health plan, that is sponsored by an Employer Class member[,]" to the extent that such coverage conflicts with the Employer Class member's sincerely held religious objections to such coverage, in connection with DeOtte v. Azar, No. 4:18-CV-00825-O, 2019 WL 3786545 (N.D. Tex. July 29, 2019). The injunction also prevents the enforcement of "the Contraceptive Mandate" to the extent it requires an "Individual Class member[] to provide coverage or payments for contraceptive services" to which the individual objects based on sincerely held religious beliefs, if a health insurance issuer and, if applicable, a sponsor of a group health plan, is willing to offer the Individual Class member a separate policy or plan that omits such contraceptive coverage. On December 17, 2021, the Fifth Circuit vacated the injunction in DeOtte v. Nevada, No. 19-10754 (5th Cir. Dec. 17, 2021). However, as of the date of this publication, the Fifth Circuit has yet to issue a mandate in connection with its order, and the injunction remains in place.

**** FDA's Birth Control Guide
This refers to FDA's Birth Control Guide (PDF - 450 KB) as posted on December 22, 2021 with the exception of sterilization surgery for men, which is beyond the scope of the WPSI.

Date Last Reviewed: January 2022

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JS 44 (Rev. 04/21)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Tice-Harouff, Cami Jo, on behalf of herself and her patients

(b) County of Residence of First Listed Plaintiff Gregg County
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Matthew S. Bowman
Alliance Defending Freedom [see attached for more]

DEFENDANTS

Johnson, Carole; and [see attached for full list]

County of Residence of First Listed Defendant
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*
Attorney General of the United States
[see attached for more information]

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☒ 2 U.S. Government Defendant
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
5 U.S.C. §§ 553, 701-706

Brief description of cause:
Administrative Procedure Act challenge to agency action for improper procedure and lack of reasoned decision making

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
May 25, 2022

SIGNATURE OF ATTORNEY OF RECORD
/s/ Matthew S. Bowman

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

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

CAMI JO TICE-HAROUFF,

Plaintiff,

v.

CAROLE JOHNSON in her official capacity as Administrator of the Health Resources and Services Administration of the United States Department of Health and Human Services; **HEALTH RESOURCES AND SERVICES ADMINISTRATION OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**; **XAVIER BECERRA**, in his official capacity as Secretary of the United States Department of Health and Human Services; and **UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,**

Defendants.

No. _____

ATTACHMENT TO CIVIL COVER SHEET

I. Plaintiff's Attorneys

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Alliance Defending Freedom
440 First Street NW, Suite 600
Washington, DC 20001
Telephone: (202) 393-8690

Ryan L. Bangert
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Scottsdale, AZ 85260
Telephone: (480) 444-0020

I. Defendants

CAROLE JOHNSON in her official capacity as Administrator of the Health Resources and Services Administration of the United States Department of Health and Human Services;

HEALTH RESOURCES AND SERVICES ADMINISTRATION OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES;

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; and

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. Defendants' Attorneys

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Washington, DC 20530-0001

Brit Featherston
U.S. Attorney for the Eastern District of Texas
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