IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
MIDLAND / ODESSA DIVISION

STATE OF TEXAS, AND MAYO PHARMACY INC., A NORTH DAKOTA CORPORATION., *Plaintiffs*; v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE FOR CIVIL RIGHTS, *Defendants*.	No. 7:23-cv-00022-DC

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT
AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Constitution

Federal Statutes

Regulations

Rules

State Statutes

Other Authorities

Table of Docket Entries Cited in Brief

Doc. 14	Plaintiffs' Amended Verified Complaint
Doc. 14-1	Amended Complaint Ex. 1: "HHS Issues Guidance to the Nation's Retail Pharmacies Clarifying Their Obligations to Ensure Access to Comprehensive Reproductive Health Care Services," U.S. Department of Health and Human Services (July 13, 2022 press release)
Doc. 14-2	Amended Complaint Ex. 2: *Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services* (July 13, 2022) (the "July 2022 Guidance" or "Superseded Guidance")
Doc. 44	Memorandum Opinion, July 12, 2023 (motion to dismiss decision)
Doc. 46	Defendants' Answer
Doc. 49	Plaintiffs' Motion for Summary Judgment
Doc. 49-1	Declaration of Eric Bentley
Doc. 49-2	Declaration of Kevin Martian / Mayo Pharmacy, Inc.
Doc. 52-1	*Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies* (Sept. 29, 2023) (the "September 2023 Guidance" or "Revised Guidance")
Doc. 54	Administrative Record

INTRODUCTION

Defendants issued the now-superseded guidance challenged in plaintiffs' Amended Complaint and Motion for Summary Judgment, *see* Doc. 14-2 (the "July 2022 Guidance" or "Superseded Guidance"), in the wake of reports that in the aftermath of the Supreme Court decision in *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), patients (primarily women and girls) were having difficulty accessing medications for various non-abortion purposes, because those medications could also be used for the purpose of abortion. The Superseded Guidance was meant to address this then-urgent concern. Although Defendants never intended for the Superseded Guidance to impose or state a requirement for pharmacies to dispense medication for purposes of abortion, in its Memorandum Opinion on defendants' Motion to Dismiss, this Court interpreted the Superseded Guidance as "requir[ing] pharmacies to dispense drugs for abortion purposes." Mem. Op. (July 12, 2023), Doc. 44, at 13.

Because defendants did not want to leave in place a guidance document that a federal court had construed as imposing a requirement that they did not intend to impose, defendant U.S. Department of Health and Human Services Office for Civil Rights ("OCR") revoked the Superseded Guidance and replaced it with the Revised Guidance, which makes clear that it "does not require pharmacies to fill prescriptions for medication for the purpose of abortion; nor does the guidance suggest or imply an obligation of pharmacies to fill prescriptions for medication in violation of State laws, including those banning or restricting abortion." Doc. 52-1, at 2 (the "September 2023 Guidance" or "Revised Guidance"). All of plaintiffs' claims revolve around the perceived requirement to dispense medication for purposes of abortion. Because, as the Revised Guidance (the only guidance now in effect) makes abundantly clear, no such requirement is in effect (and indeed OCR never intended to impose such a requirement), plaintiffs cannot establish subject-matter jurisdiction, and all of their claims fail on the merits.

Subject-matter jurisdiction is lacking for several reasons. Any challenge to the Superseded Guidance, based on an alleged threat of future enforcement of the Superseded Guidance, was mooted when that guidance was superseded and replaced by the Revised Guidance. Moreover, plaintiffs cannot meet their burden to demonstrate standing at the summary judgment stage. All of plaintiffs' alleged injuries derive from their fears of being required by the Superseded Guidance to dispense medication for purposes of abortion. But OCR issued the Revised Guidance to make even clearer going forward that the guidance does not impose such a requirement.

Should the Court reach the merits of plaintiffs' claims, they fail as a matter of law. Plaintiffs' claim that defendants have exceeded their statutory authority by requiring pharmacies to dispense medication for purposes of abortion fails because the pharmacy guidance does not impose such a requirement, as the Revised Guidance makes clear. The pharmacy guidance did not need to undergo notice and comment procedures because it describes and illustrates existing legal requirements; it is not a legislative rule that imposes new requirements with the force of law. The pharmacy guidance survives deferential arbitrary and capricious review, as all of plaintiffs' contrary arguments rest on the incorrect premise that the guidance requires pharmacies to dispense medication for purposes of abortion. Finally, the pharmacy guidance does not transgress any limitations in the Spending Clause by interpreting federal civil rights laws in which Congress has clearly required recipients of federal funding not to discriminate on the basis of sex or disability as a condition of that funding.

For these reasons, and as discussed further below, the Court should deny plaintiffs' motion for summary judgment and grant defendants' cross-motion for summary judgment.

FACTUAL BACKGROUND

A. HHS Office for Civil Rights ("OCR") and Its Enforcement Process

OCR is the agency within the U.S. Department of Health and Human Services ("HHS" or "the Department") that enforces federal civil rights laws; conscience and religious freedom laws;

Health Insurance Portability and Accountability Act ("HIPAA") rules regarding health privacy and security; and the confidentiality requirements of the Patient Safety Act. These laws together protect Americans' fundamental rights of nondiscrimination, conscience, religious freedom, and health information privacy.

Among the laws enforced by OCR are two statutes particularly relevant here prohibiting recipients of federal financial assistance from discriminating based on certain protected grounds. Section 504 of the Rehabilitation Act ("Section 504") prohibits funding recipients and HHS from discriminating on the basis of disability. 29 U.S.C. § 794(a); *see also* 45 C.F.R. pt. 84. Section 1557 of the Affordable Care Act ("Section 1557") prohibits health programs and activities that receive federal financial assistance from discriminating on the basis of grounds prohibited under other civil rights laws, including on the basis of race, color, national origin, age, disability, or sex. 42 U.S.C. § 18116(a); *see also* 45 C.F.R. pt. 92.[1]

OCR conducts investigations using enforcement procedures outlined in HHS's regulations implementing Title VI of the Civil Rights Act of 1964 ("Title VI"), which prohibits discrimination on the basis of race, color, or national origin by recipients of federal financial assistance. *See* 45 C.F.R. §§ 80.1–80.13. OCR uses the same procedures to enforce other civil rights laws, including Section 504 and Section 1557, except for with respect to claims of age discrimination. *See* 45 C.F.R. § 84.61 (procedures for HHS's Section 504 regulations); 45 C.F.R. § 92.5 (providing that "[t]he enforcement mechanisms provided for, and available under, Title VI" and other civil rights laws, "shall apply" to violations of the statutory grounds laid out in 45 C.F.R. § 92.2, which is within 45 C.F.R. pt. 92—HHS's regulations implementing Section 1557).

If an OCR investigation indicates a failure to comply with the law, "the matter will be resolved

[1] HHS has issued a proposed rule to revise OCR's current regulations implementing Section 1557. *See Nondiscrimination in Health Programs & Activities*, 87 Fed. Reg. 47,824 (Aug. 4, 2022).

by informal means whenever possible." *Id.* § 80.7(d)(1); *see also id.* § 80.8(a). If informal means cannot correct the issue, OCR may take various actions within its discretion to effect compliance, including but not limited to referral to the Department of Justice for enforcement. *Id.* § 80.8. If OCR determines that suspension or termination of a recipient's federal financial assistance may be warranted, it may not do so without first providing notice and a formal administrative hearing. *Id.* § 80.8(c); *id.* § 80.9. Additionally, OCR must file reports with appropriate House and Senate committees, providing a "full written report of the circumstances and the grounds" for any determination to suspend or terminate funding, and then wait at least thirty days before such order becomes effective. *Id.* § 80.8(c). Administrative determinations revoking funding are subject to judicial review in district court, *id.* § 80.11, and are also subject to post-termination administrative proceedings to restore funding, *id.* § 80.10(g).

OCR also carries out its enforcement responsibilities by providing technical assistance and guidance to funding recipients to help them comply with the civil rights laws. *Id.* § 80.6.

B. The Pharmacy Guidance

On July 13, 2022, OCR issued a since-superseded guidance document to retail pharmacies that receive federal financial assistance from the Department. Doc. 14-2. The guidance, entitled "Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services," reviewed the nondiscrimination obligations of covered pharmacies under civil rights laws—and particularly Section 504 and Section 1557.[2] The pharmacy guidance was not intended to require pharmacies to fill prescriptions for medication for purposes of abortion; nor was it intended to suggest or imply an obligation of

[2] As recipients of federal financial assistance, including Medicare and Medicaid, covered pharmacies are prohibited from discriminating on the basis of race, color, national origin, sex, age, and disability in their programs and activities under a range of federal civil rights laws, including Section 504 and Section 1557.

pharmacies to fill prescriptions for medication in violation of State law. After this Court issued a decision interpreting the guidance otherwise, OCR issued the Revised Guidance, entitled "Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies." Doc. 52-1. The Revised Guidance supersedes and revises the July 2022 guidance in order "to clarify that the guidance does not require pharmacies to fill prescriptions for medication for the purpose of abortion; nor does the guidance suggest or imply an obligation of pharmacies to fill prescriptions for medication in violation of State laws, including those banning or restricting abortion." *Id.* at 2. The Revised Guidance is now posted on OCR's website along with other educational materials.[3]

The Revised Guidance states that "[w]hile pharmacies regularly dispense medications, make determinations regarding the suitability of a prescribed medication for a patient, and advise patients about medications and how to take them, pharmacies that receive federal financial assistance may not discriminate against pharmacy customers on the bases prohibited by Section 1557 and Section 504 when they do so." *Id.*

The guidance lists several examples of circumstances in which a pharmacy "may be discriminating" on the basis of sex or disability if it refuses to dispense certain medication for certain purposes. For instance, one of the examples states that a pharmacy may be discriminating on the basis of disability if it refuses to dispense methotrexate as an immunosuppressive treatment for rheumatoid arthritis, because of its alternate uses. *Id.* at 4. Although the pharmacy guidance discusses reproductive health issues including pregnancy, miscarriage, and contraception, *id.* at 2–3, it does not address dispensing medication for purposes of abortion. Instead, the guidance covers the refusal to dispense

[3] The Revised Guidance is posted to the same location on HHS's website where the now-superseded July 2022 Guidance was previously posted; the July 2022 Guidance has been removed. *See* Doc. 14 ¶ 17 n.9; https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html.

medication prescribed for purposes *other than abortion*. *Id.* at 3–4.

C. Response to Plaintiffs' Statement of Facts

In the factual background section of their summary judgment brief, plaintiffs assert that their Amended Verified Complaint, Doc. 14, "constitutes evidence in support of Plaintiffs' motion." Pls.' Mot., Doc. 49 at 4. This is true only as to those factual allegations for which plaintiffs have personal knowledge, and which they have verified. *See Hart v. Hairston*, 343 F.3d 762, 765 (5th Cir. 2003) ("On summary judgment, factual allegations set forth in a verified complaint may be treated the same as when they are contained in an affidavit."); *see also King v. Dogan*, 31 F.3d 344, 346 (5th Cir. 1994) ("A plaintiff's verified complaint can be considered as summary judgment evidence to the extent that it comports with the requirements of [Rule 56 of the Federal Rules of Civil Procedure]."); Fed. R. Civ. P. 56(c)(4) (affidavits used to support a motion for summary judgment must be made on personal knowledge). The only verified paragraphs in plaintiffs' Amended Complaint are enumerated paragraphs 2 and 34–53.[4] *See* Doc. 14 at 26 (declaration of Kevin Martian, "declar[ing] under penalty of perjury pursuant to 28 U.S.C. § 1746 that paragraphs 2 and 34-53 in the … Amended Complaint are true and correct to the best of my knowledge"). Thus, those are the only paragraphs that properly may be considered evidence at the summary judgment stage, but only to the extent that they contain factual allegations not legal conclusions.[5] *See Hart*, 343 F.3d at 765.

Plaintiffs submitted two declarations with their motion for summary judgment, the declaration of Eric Bentley, Vice Chancellor and General Counsel of the Texas Tech University System ("TTUS"),

[4] Amended Complaint ¶ 2 states: "Plaintiff Mayo Pharmacy, Inc. (Mayo Pharmacy) is a North Dakota corporation located at 303 North 4th Street, Bismarck, North Dakota 58501." Paragraphs 34–53 of the Amended Complaint describe Mayo Pharmacy's operation and religious beliefs.

[5] Paragraphs 46–53 of the Amended Complaint, though purportedly "verified," contain legal conclusions that cannot be considered factual allegations constituting evidence. *See* Defs.' Answer, Doc. 46 at ¶¶ 46–53; *see also, e.g.*, *Ghedi v. Mayorkas*, 16 F.4th 456, 467–68 (5th Cir. 2021) (distinguishing between "legal conclusions" and "factual allegations").

Doc. 49-1, and the declaration of Kevin Martian, owner of Mayo Pharmacy, Inc. ("Mayo"), Doc. 49-2. Mr. Bentley's declaration outlines the Medicare and Medicaid funds received by the Texas Tech University Health Sciences Center ("TTUHSC") and provides figures representing the approximate amounts of Medicare and Medicaid funding received by TTUHSC for the current and past two fiscal years. Doc. 49-1 ¶¶ 6–7. Mr. Martian's declaration states the approximate numbers and percentages of prescriptions filled by Mayo Pharmacy during the past fiscal year that were filled for patients paying with Medicare or Medicaid. Doc. 49-2 ¶¶ 3–7. It also describes Mr. Martian's religious and ethical opposition, both for himself and for Mayo Pharmacy, to "dispensing drugs in circumstances where they could cause the demise of an unborn human life after conception/fertilization (including in the zygotic or embryonic stage)." *Id.* ¶ 9. Neither declaration states or otherwise establishes that plaintiffs have been forced to change their operations in any way as a result of the pharmacy guidance. Doc. 49-1; Doc. 49-2. Nor do the declarants state how, if at all, their pharmacy operations are inconsistent with the pharmacy guidance. Plaintiffs' declarations do not contend that plaintiffs were investigated by OCR while the Superseded Guidance was in place, or that they anticipate enforcement actions being taken against them. *Id.*

D. Procedural History

Texas initially filed this action on February 7, 2023. On February 28, 2023, Texas filed an amended complaint, adding co-plaintiff Mayo, a privately owned pharmacy located in Bismarck, North Dakota. Doc. 14 ¶ 34. Plaintiffs assert several claims under the Administrative Procedure Act ("APA"), alleging that the now-superseded July 2022 guidance document (Doc. 14-2) and July 13, 2022 press release (Doc. 14-1): (a) exceed statutory authority and are not in accordance with law, specifically the Affordable Care Act, Title IX, the Hyde Amendment, the Department of Justice's

appropriation act, and the Constitution's Spending Clause, *id.* ¶¶ 54–75;[6] (b) were required to be issued pursuant to notice-and-comment rulemaking procedures, *id.* ¶¶ 76–81; and (c) are arbitrary and capricious, *id.* ¶¶ 82–90.

On July 12, 2023, this Court denied in part and granted in part defendants' motion to dismiss. Doc. 44. The Court denied defendants' motion to dismiss under Rule 12(b)(1) of the Federal Rules of Civil Procedure. The Court granted in part defendants' motion to dismiss under Rule 12(b)(3) and ordered that Mayo's Religious Freedom Restoration Act ("RFRA") claim be transferred to the District of North Dakota. The Court ordered that defendants' motion to dismiss under 12(b)(6) be denied as moot.

Defendants issued the Revised Guidance on September 29, 2023, superseding and revising the pharmacy guidance at issue in this case.

LEGAL STANDARD

"If the court determines at any time that it lacks subject-matter jurisdiction," including at the summary judgment stage, "the court must dismiss the action." Fed. R. Civ. P. 12(h)(3); *see also*, *e.g.*, *de Sanchez v. Banco Central de Nicaragua*, 770 F.2d 1385, 1386 (5th Cir. 1985) (affirming the district court's dismissal for lack of subject-matter jurisdiction at the summary judgment stage). "The party invoking federal jurisdiction"—plaintiffs—bears the burden of proof in establishing subject-matter jurisdiction. *Ford v. NYLCare Health Plans of Gulf Coast, Inc.*, 301 F.3d 329, 332 (5th Cir. 2002).

To the extent that subject-matter jurisdiction exists and agency action is challenged pursuant to the APA, "summary judgment is the proper mechanism for deciding, as a matter of law, whether [the] agency's action is supported by the administrative record and consistent with the APA standard of review." *Nat'l Ass'n of Mfrs. v. SEC*, 644 F. Supp. 3d 342, 347 (W.D. Tex. 2022) (Counts, J.)

[6] Texas alone brings the Spending Clause claim. Doc. 14 ¶¶ 69–75.

(citations omitted). "'When assessing a summary judgment motion in an APA case, the district judge sits as an appellate tribunal,' and '[t]he entire case on review is a question of law.'" *Id.* (quoting *Permian Basin Petrol. Ass'n v. U.S. Dep't of the Interior*, 127 F. Supp. 3d 700, 706 (W.D. Tex. 2015)).

ARGUMENT

I. The Court Lacks Subject-Matter Jurisdiction to Review the Superseded Guidance

The Court can—and must—dismiss plaintiffs' claims at the summary judgment stage if the Court lacks subject-matter jurisdiction. *See de Sanchez*, 770 F.2d at 1386; Fed. R. Civ. P. 12(h)(3). Plaintiffs have not met their burden to establish subject-matter jurisdiction. Their challenge to the July 2022 Guidance is moot due to the intervening issuance of the Revised Guidance in September 2023, which clarifies that the guidance does not mean and is not intended to mean what Plaintiffs say it does. Plaintiffs also have failed to establish standing because they have not shown that they are injured by the pharmacy guidance. Further, the Court lacks jurisdiction to review the Superseded Guidance because it is not final agency action.

A. The Issue of the Validity of the Superseded Guidance Is Moot

To the extent plaintiffs seek to challenge the Superseded Guidance, that challenge is moot. The Revised Guidance "supersedes and revises" the Superseded Guidance. Doc. 52-1 at 2. To supersede means "[t]o annul, make void, or repeal by taking the place of." *Supersede*, Black's Law Dictionary (11th ed. 2019). The Revised Guidance therefore makes clear that the Superseded Guidance has been annulled and made void, and is therefore of no effect, by virtue of having been replaced by the Revised Guidance. Consequently, plaintiffs can no longer assert that the July 2022 Guidance is affecting their rights. *See Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477 (1990) ("Article III denies federal courts the power 'to decide questions that cannot affect the rights of litigants in the case before them,' and confines them to resolving 'real and substantial controvers[ies] admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising

what the law would be upon a hypothetical state of facts.'") (quoting *North Carolina v. Rice*, 404 U.S. 244, 246 (1971)); *Princeton University v. Schmid*, 455 U.S. 100, 103 (1982) (*per curiam*) (holding that where a challenged policy was superseded by a new policy, "the issue of the validity of the old regulation is moot, for this case has 'lost its character as a present, live controversy of the kind that must exist if we are to avoid advisory opinions on abstract questions of law'") (quoting *Hall v. Beals*, 396 U.S. 45, 48 (1969) (*per curiam*)). To rule on the validity of the July 2022 Guidance at this point "would constitute no more than an advisory opinion," which is impermissible. *Daves v. Dallas Cnty., Texas*, 64 F.4th 616, 634 (5th Cir. 2023) (*en banc*) (case challenging state's bond procedures mooted by passage of amended state law revising those procedures).

The Revised Guidance supersedes the July 2022 Guidance, and clarifies that the pharmacy guidance does not require pharmacies to fill prescriptions for medication purposes of abortion; nor does it preempt state laws. This is the exact relief requested by plaintiffs, and therefore their challenge to the July 2022 Guidance is moot. *See N.Y. State Rifle & Pistol Ass'n, Inc. v. City of New York*, 140 S. Ct. 1525, 1526 (2020) (*per curiam*) (case became moot due to State ordinance amendment accomplishing what plaintiffs sought in litigation). The "crux of this case is now whether the new [Revised Guidance] … measures up" to plaintiffs' proffered concern regarding a requirement that pharmacies fill prescriptions for medication for abortion. *See Daves*, 64 F.4th at 635. Plainly, it does. The Revised Guidance makes clear that "the guidance does not require pharmacies to fill prescriptions for medication for the purpose of abortion; nor does the guidance suggest or imply an obligation of pharmacies to fill prescriptions for medication in violation of State laws, including those banning or restricting abortion." Doc. 52-1 at 2. Plaintiffs' challenge to the July 2022 Guidance is moot by virtue of the Revised Guidance that supersedes and revises it and clarifies that it does not contain "the complained-of defect." *Freedom From Religion Found., Inc. v. Abbott*, 58 F.4th 824, 832 (5th Cir. 2023) ("'When a plaintiff's complaint is focused on a particular statute, regulation, or rule and seeks only

prospective relief, the case becomes moot when the government repeals, revises, or replaces the challenged law and thereby removes the complained-of defect.'" (quoting *Ozinga v. Price*, 855 F.3d 730, 734 (7th Cir. 2017))).

B. Plaintiffs Lack Standing; They Do Not Face a Substantial Risk of Enforcement for Failing to Fill Prescriptions for Abortion Purposes, as Confirmed by the Revised Guidance

The Court lacks subject-matter jurisdiction for another reason as well: plaintiffs have not met their burden to establish standing at the summary judgment stage. At summary judgment, plaintiffs "'can no longer rest on . . . mere allegations'" to establish standing, "'but must set forth . . . specific facts' that adequately support" standing. *California v. Texas*, 141 S. Ct. 2104, 2117 (2021) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 411–12 (2013)). Plaintiffs must demonstrate that they have suffered a concrete injury, or that such an injury is "imminent" or "certainly impending." *Clapper*, 568 U.S. at 409. Plaintiffs challenging a law or government policy when no enforcement action has been taken against them satisfy the injury-in-fact requirement by establishing "'an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and there exists a credible threat of prosecution thereunder.'" *Susan B. Anthony List v. Driehaus* ("*SBA List*"), 573 U.S. 149, 159 (2014) (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). But "[i]n the absence of contemporary enforcement, . . . a plaintiff claiming standing must show that the likelihood of future enforcement is 'substantial.'" *California*, 141 S. Ct. at 2114 (quoting *SBA List*, 573 U.S. at 164). Here, plaintiffs have not submitted sufficient evidence to establish that they have suffered or face a substantial likelihood of suffering harm as a result of the pharmacy guidance. And the Revised Guidance further confirms the lack of any injury by reiterating that the pharmacy guidance does not require pharmacies to fill prescriptions for medications for abortion, does not oblige pharmacies to fill prescriptions for medication in violation of State laws, and affirms the application of Federal religious freedom and conscience statutes including RFRA.

The Bentley and Martian declarations submitted by plaintiffs fail to demonstrate an actual or imminent injury in fact. While Mr. Bentley and Mr. Martian establish that their pharmacies receive Medicare and Medicaid funds—and discuss the potential financial consequences were they to lose those federal funds—they do not assert that the plaintiffs have already suffered harm or are on the brink of suffering harm as a result of the pharmacy guidance. Doc. 49-1 at 6–7; Doc. 49-2 at 3–8. Neither declaration asserts that the plaintiffs' pharmacies have been forced to change their operating procedures or to fill prescriptions that they otherwise would not fill as a result of the pharmacy guidance. They do not show an "intention to engage in a course of conduct … proscribed" by the pharmacy guidance. *SBA List*, 573 U.S. at 159. Plaintiffs point to no specific circumstances in which they refused to dispense a medication and believe that refusal to have been prohibited under their reading of the guidance. Nor do they offer any evidence to support the inference that such circumstances are imminently likely to arise. Mr. Bentley's declaration does not discuss TTUHSC's practices with regard to filling prescriptions at all. Doc. 49-1. Mr. Martian describes his and Mayo Pharmacy's practices and objections to dispensing medication in circumstances where it could cause abortions, but he does not demonstrate that these practices conflict with the pharmacy guidance, which does not require pharmacies to fill prescriptions for medication for the purpose of abortion and which further provides that religious freedom objections will be considered on a case-by-case basis, *see* Doc. 52-1 at 2, 5. Neither declaration shows that plaintiffs have been the subject of an OCR investigation or enforcement action under the pharmacy guidance,[7] or that they face a "substantial likelihood of future enforcement" for failure to fill prescriptions for medications that could cause abortions. *See California*, 141 S. Ct. at 2114. Indeed, plaintiffs fail to cite a single instance of OCR

[7] There is no likelihood of "enforcement" of the pharmacy guidance, let alone a "substantial" likelihood, *California*, 141 S. Ct. at 2114, because the pharmacy guidance "do[es] not have the force and effect of law," Doc. 14-2, at 4, and merely describes a pharmacy's nondiscrimination obligations under existing civil rights laws.

taking enforcement action against any pharmacy—theirs or others—for refusing to dispense medication for abortion purposes. And the Revised Guidance confirms the lack of any credible threat of enforcement by reiterating that "the guidance does not require pharmacies to fill prescriptions for medication for the purpose of abortion." Doc. 52-1. As such, plaintiffs' assertion that "Mayo and pharmacies in Texas face enforcement actions and devastating loss of federal fundings," Doc. 49 at 9, is "'purely speculative' and thus, insufficient to provide the 'injury in fact' required for Article III standing." *Consumer Data Indus. Ass'n v. Texas through Paxton*, No. 21-51038, 2023 WL 4744918, at *4 (5th Cir. July 25, 2023).

Mayo also fails to show a credible threat of enforcement for an additional reason: Under RFRA, the federal government cannot substantially burden a person's exercise of religion unless it shows that doing so is the least restrictive means of advancing a compelling government interest.[8] 42 U.S.C. § 2000bb-1. HHS has consistently maintained that it will abide by RFRA in any enforcement of civil rights laws. *See*, *e.g.*, *Nondiscrimination in Health Programs & Activities*, 81 Fed. Reg. 31,376, 31,466 (May 18, 2016) ("application" of requirements of rule implementing Section 1557 "shall not be required" where it "would violate applicable Federal statutory protections for religious freedom and conscience"); *Nondiscrimination in Health & Health Educ. Programs or Activities, Delegation of Auth.*, 85 Fed. Reg. 37,160, 37,207 (June 19, 2020) (HHS "is bound to enforce Section 1557 in compliance with RFRA"); *Nondiscrimination in Health Programs & Activities*, 87 Fed. Reg at 47886 (notice of proposed rulemaking) ("OCR is thus committed to complying with RFRA and all other legal requirements").[9]

[8] While this Court transferred Mayo's RFRA claim to the District of North Dakota, Doc. 44 at 25, Mayo continues to press religious objections in connection with its APA claim. *See* Doc. 49 at 8–9 (arguing that Mayo faces enforcement actions due to its religious beliefs); *id.* at 16–17 (arguing that the pharmacy guidance "contains no discussion of RFRA, much less discussion of how it will impact religiously-run pharmacies, such as Mayo").

[9] Further, the agency's recent notice of proposed rulemaking implementing Section 1557 proposes a procedure under which, if a covered entity asserts rights under a federal conscience or religious freedom law, HHS will not take action unless and until HHS makes a determination on the entity's

It is not just OCR's policy to comply with RFRA, but also OCR's practice. For example, attached as Exhibit 1 is a closure letter that OCR recently sent informing a religious hospital of OCR's decision to close a discrimination investigation involving the hospital because "OCR evaluated the complaint in light of its responsibilities under the Religious Freedom Restoration Act (RFRA)." Ex. 1 at 2. The letter explains that "OCR determined that [the hospital] ha[d] adequately asserted its sincerely held religious beliefs to establish a substantial burden under RFRA as a matter of federal law," and that "the Department was unable to conclude that Section 1557's prohibition on sex discrimination as applied to the facts of [that] complaint was the least restrictive means of achieving the government's compelling interest." *Id.* The Revised Guidance likewise explicitly acknowledges that HHS complies with RFRA, and indicates that religious freedom and conscience objections will be evaluated and applied "on a case-by-case basis," as RFRA requires. Doc. 52-1 at 5. Mayo has not cited any examples of HHS taking enforcement action to require a pharmacy to dispense a drug for the purpose of abortion (or any other drug for any other purpose) over a religious objection. That underscores that Mayo has failed to show a credible threat of enforcement.

Moreover, plaintiffs' declarations make no causal link between the pharmacy guidance and any harm actually suffered or anticipated. The declarations do not connect the pharmacy guidance's specific provisions or OCR's actions to the harm in question; they merely say that the plaintiffs' pharmacies would suffer harm if they lost federal financial assistance, without establishing that the pharmacy guidance would cause them to lose such federal financial assistance.

OCR's issuance of the Revised Guidance in September 2023 countenances a different conclusion regarding standing than the one the Court reached at the motion to dismiss stage. The Court observed that plaintiffs' "standing in this case turns on the answer to a single question: does the

entitlement to an exemption. *See* 87 Fed. Reg. at 47,918-19.

Pharmacy Guidance require pharmacies to dispense drugs for abortion purposes?" Doc. 44 at 9. The Court found that a "temporal and thematic relationship" existed between the pharmacy guidance and the executive branch's policy goals—as stated in President Biden's Executive Order No. 14,076[10]—"in reaction to *Dobbs's* holding on abortion rights." Doc. 44 at 10. The Court observed that the "Executive Order instructed HHS to 'identify potential actions (A) to protect and expand access to abortion care, *including medication abortion*; and (B) to otherwise protect and expand access to the full range of *reproductive healthcare services*[.]'" *Id.* (emphasis in original) (quoting Exec. Order No. 14,076). The Court concluded that the pharmacy guidance was issued in response to the Executive Order, which in turn responded to the Supreme Court's decision in *Dobbs*. *Id.* at 12. The Court further concluded, therefore, that the pharmacy guidance necessarily serves the agency's goal to "ensure[] access to 'medication abortion' and 'reproductive healthcare services,'" *id.*, and that it "requires pharmacies to dispense drugs for abortion purposes," *id.* at 13.

Yet, this was not OCR's objective. The Administrative Record indicates that the reason the guidance was issued close in time to *Dobbs* was because, in the period after the *Dobbs* decision issued, news outlets reported that patients were being denied access to medications for *non-abortion* purposes such as treating rheumatoid arthritis. *See* AR 00028–00041. Additionally, after this Court issued its motion to dismiss decision, OCR issued the Revised Guidance. OCR had not intended in the Superseded Guidance to impose a requirement to dispense medication for purposes of abortion, and accordingly, "OCR revised this guidance to clarify that the guidance does not require pharmacies to fill prescriptions for medication for the purpose of abortion." Doc. 52-1 at 1. The Revised Guidance makes clear that it "does not require pharmacies to fill prescriptions for medication for the purpose of abortion; nor does the guidance suggest or imply an obligation of pharmacies to fill prescriptions

[10] Protecting Access to Reproductive Healthcare Services, Exec. Order No. 14,076, 87 Fed. Reg. 42053, 42053 (July 8, 2022).

for medication in violation of State laws, including those banning or restricting abortion." *Id.* at 2. Regardless, then, of the proper interpretation of the July 2022 guidance, Plaintiffs cannot now show a credible threat of prosecution for failure to fill prescriptions for medication abortions because OCR has confirmed and further clarified that the pharmacy guidance does not require pharmacies to fill such prescriptions. Moreover, OCR has not taken any action to enforce either guidance document on the basis that any pharmacy violated any requirement in either guidance document by not dispensing medication for purposes of abortion, and plaintiffs have not contended or provided evidence otherwise. Plaintiffs do not face a credible threat of prosecution for failure to dispense medications for abortion purposes.

Plaintiffs proffer three arguments why they are injured; none has merit. First, plaintiffs argue that the pharmacy guidance "conflicts with Texas's Human Life Protection Act, which states that '[a] person may not knowingly perform, induce, or attempt an abortion,'" Doc. 49 at 7 (quoting Act of May 25, 2021, 87th Leg., R.S., ch. 800, 2021 Tex. Sess. Law Serv. 1887 (H.B. 1280) (codified at Tex. Health & Safety Code Ch. 170A)), and with Texas statutes predating *Roe v. Wade*, 410 U.S. 113 (1973), that address abortion, Doc. 49 at 7. But there is no conflict between the pharmacy guidance and these state laws. The Revised Guidance could not be more plain: the guidance does not "suggest or imply an obligation of pharmacies to fill prescriptions for medication in violation of State laws, including those banning or restricting abortion." Doc. 52-1 at 2.

Second, plaintiffs assert that they are "objects" of the pharmacy guidance "because they receive federal funds through Medicare and Medicaid," Doc. 49 at 8; plaintiffs contend that receiving federal funds suffices to establish injury, *id.* It does not. The Supreme Court recently encountered a similar argument in *California*, 141 S. Ct. at 2115. The plaintiffs in that case "emphasize[d] the [Supreme] Court's statement in *Lujan* that, when a plaintiff is the 'object' of a challenged Government action, 'there is ordinarily little question that the action ... has caused him injury, and that a judgment

preventing ... the action will redress it.'" *Id.* (quoting respondent's brief, which in turn quoted *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992)). The Supreme Court rejected that argument and emphasized that plaintiffs must show that unlawful Government action "fairly traceable" to a challenged policy "caused the plaintiffs' … *harm*." *Id.* (emphasis added). In other words, it is not enough that the plaintiffs are subject to a policy; they must demonstrate a harm from that policy that can be redressed. The "dispute must 'be real and substantial' and 'admit of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *Id.* (quoting *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 126–127 (2007)).

Third, plaintiffs argue that they suffer a procedural injury of having been deprived of the opportunity to provide comment on the pharmacy guidance. Notice and comment procedures were not required here because the pharmacy guidance is not a legislative rule, as discussed further below in section II(B). Plaintiffs' procedural injury argument fails in any event because "deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing." *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009). Here, plaintiffs do not identify an affected "concrete interest" for the reasons discussed above: the pharmacy guidance, including as confirmed by the Revised Guidance, does not require filling prescriptions for abortion purposes. And their assertion of "[m]erely being 'denied the ability to file comments' is 'insufficient to create Article III standing.'" *Louisiana by & through Landry v. Biden*, 64 F.4th 674, 683 (5th Cir. 2023) (quoting *Summers*, 555 U.S. at 496).

C. The Court Lacks Jurisdiction to Review the Superseded Guidance Because It Is Not Final Agency Action

The Court has jurisdiction to entertain a challenge to the Superseded Guidance only if the guidance constitutes final agency action under the APA. 5 U.S.C. § 704; *Peoples Nat'l Bank v. Office of Comptroller of Currency of U.S.*, 362 F.3d 333, 336 (5th Cir. 2004). This Court has correctly observed

that "'[a]n action is either final or not, and the *mere* fact that the agency could—or actually does—reverse course in the future does not change that fact." Doc. 44 at 19–20 (quoting *Data Mktg. P'ship, LP v. DOL*, 45 F.4th 846, 854 (5th Cir. 2022) (emphasis added)). Yet, the fact that a guidance document is subject to revision, and actually revised, can provide indicia that the guidance was not "final agency action." *See Whitman v. Am. Trucking Ass'n*, 531 U.S. 457, 478 (2001) (court should consider whether agency "has rendered its last word on the matter" to determine whether an action is "final" and thus reviewable) (quotations omitted); *Sw. Airlines Co. v. U.S. Dep't of Transp.*, 832 F.3d 270, 276 (D.C. Cir. 2016) (where an agency actually institutes a process to revise initial guidance, it confirms that the earlier guidance "is not the agency's final word on the issues at hand").

Although the Court determined in its motion to dismiss decision that the July 2022 Guidance constituted final agency action, Doc. 44 at 18–22, defendants ask the Court to reconsider that determination in light of the revision of the guidance, which provides additional indicia that the July 2022 Guidance was nonfinal. *See Whitman*, 531 U.S. at 478; *Sw. Airlines Co.*, 832 F.3d at 276. The pharmacy guidance's statement that "[t]he contents of this document do not have the force and effect of law and are not meant to bind the public in any way," Doc. 52-1 at 5, provides another indication of the non-binding, non-final nature of the guidance, *see United States v. Mississippi*, No. 21-60772, – F.4th –, 2023 WL 6138536, at *5 (5th Cir. Sept. 20, 2023) ("Non-binding disclaimers are 'relevant to the conclusion that a guidance document is non-binding.'" (quoting *Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 228 (D.C. Cir. 2007)), as does the fact that the guidance did not undergo "notice and comment under the APA to become a binding regulation," *id.* The guidance document provides tentative guidance regarding situations that "may" constitute discrimination but is "not binding … with respect to any particular factual situation" and therefore constitutes non-final agency action. *See Data Mktg. P'ship*, 45 F.4th at 855 (citation omitted).

II. Defendants Are Entitled to Summary Judgment on The Merits

A. Defendants' Actions Do Not Exceed Statutory Authority or Violate the Law

The sole basis for plaintiffs' claim that defendants have exceeded their authority and violated the law is their contention that the pharmacy guidance, in conjunction with the July 13, 2022 press release, "impose[s] a legal duty on pharmacies to dispense drugs for abortions," a purported duty that plaintiffs contend defendants "lack[] any statutory authority to impose." Doc. 49 at 11; *see also* Doc. 14 ¶¶ 65–67. This claim fails because, as explained above, the pharmacy guidance does not impose a duty on pharmacies to dispense medication for the purpose of abortion. *See supra*, Part I.

Defendants acknowledge that at the pleading stage, this Court concluded that the Superseded Guidance "requires pharmacies to dispense drugs for abortion purposes." Doc. 44 at 13. That conclusion is not controlling at the merits stage, where: (1) plaintiffs are no longer entitled to the assumption of truth of their allegations, *see id.* at 7 ("In deciding a 12(b)(6) motion, a court accepts all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff.") (quotations omitted); (2) this Court has the benefit of considering the administrative record, *see* 5 U.S.C. § 706 (in deciding APA claims, "the court shall review the whole record or those parts of it cited by a party"); and (3) circumstances have changed materially with the revocation of the Superseded Guidance and issuance of the Revised Guidance that clarifies that the pharmacy guidance does not require pharmacies to dispense medication for purposes of abortion.

In any event, regardless of the Court's interpretation of the Superseded Guidance before it was superseded (that is, revoked and replaced), neither the Superseded Guidance nor the Revised Guidance requires pharmacies to dispense medication for abortions. The Superseded Guidance has been superseded and does not require anything. *See* Doc. 52-1 at 2 (explaining that the Revised Guidance "supersedes and revises" the Superseded Guidance); *Supersede*, Black's Law Dictionary ("To

annul, make void, or repeal by taking the place of").[11] And the Revised Guidance makes clear that it "does not require pharmacies to fill prescriptions for medication for the purpose of abortion." Doc. 52-1 at 2.

OCR revoked the Superseded Guidance and replaced it with the Revised Guidance precisely because OCR did not want to leave in place a guidance document that a court had interpreted (and that, therefore, members of the public may interpret upon viewing the court's opinion) as requiring pharmacies to dispense medication for purposes of abortion. To that end, OCR revised the language that led the Court to construe (and, in OCR's respectful view, misconstrue) the Superseded Guidance as requiring pharmacies to dispense medication for purposes of abortion.

For example, the Superseded Guidance stated: "Pharmacies, therefore, may not discriminate against pharmacy customers on the bases prohibited by Section 1557 and Section 504—including with regard to supplying medications; making determinations regarding the suitability of a prescribed medication for a patient; or advising patients about medications and how to take them." Doc. 14-2 at 1. The Court interpreted that language as "prohibit[ing] pharmacies from 'making determinations regarding the suitability of a prescribed medication for a patient.' In other words, pharmacies have no discretion to withhold dispensing medication even if they believe dispensing such medication in a given circumstance would violate the law." Doc. 44 at 11. OCR did not intend to state or suggest that pharmacies are prohibited from making suitability determinations, and certainly did not intend to state or suggest that pharmacies were required to dispense medication in violation of state abortion law. Therefore, OCR revised that portion of the guidance to clarify that pharmacies can and do make suitability determinations, but they just cannot discriminate in violation of civil rights laws when they

[11] Underscoring that it is the only pharmacy guidance document in effect, only the Revised Guidance is displayed on HHS's website, in the location where HHS formerly displayed the Superseded Guidance. *See supra*, n. 3.

do so:

> While pharmacies regularly dispense medications, make determinations regarding the suitability of a prescribed medication for a patient, and advise patients about medications and how to take them, pharmacies that receive federal financial assistance may not discriminate against pharmacy customers on the bases prohibited by Section 1557 and Section 504 when they do so.

Doc. 52-1 at 2. Underscoring this point, the Revised Guidance states that it does not "suggest or imply an obligation of pharmacies to fill prescriptions for medication in violation of State laws, including those banning or restricting abortion," *id.*, thus making absolutely clear that it does not require pharmacies to dispense medication in violation of state abortion laws.

The Court also believed that the title of the Superseded Guidance, "Obligations under Federal Civil Rights Laws to Ensure Access to Comprehensive Reproductive Health Care Services," tended to show that the guidance required pharmacies to dispense medication for purposes of abortion. *See* Doc. 44 at 12. OCR referred to reproductive health care services in the title of the Superseded Guidance because several (but not all) of the examples covered in the guidance address non-abortion forms of reproductive health care. *See* Doc. 14-2 at 3–4 (first, third, fourth, sixth, and seventh bullets addressing miscarriage care, ectopic pregnancy, and contraception). But to more fully reflect the contents of the guidance, OCR changed the title of the Revised Guidance to "Guidance to Nation's Retail Pharmacies: Obligations under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies." Doc. 52-1 at 1.

OCR similarly revised language in the first paragraph of the guidance to reflect the purpose of the guidance more precisely. The first paragraph of the Superseded Guidance stated: "this guidance is to remind the roughly 60,000 retail pharmacies in the United States of the unique role pharmacies play in ensuring access to comprehensive reproductive health care services." Doc. 14-2 at 1. That language was an accurate, but incomplete, summary of the guidance's content, because the guidance addresses both (non-abortion) reproductive health care and non-reproductive health care.

Accordingly, the Revised Guidance describes the forms of reproductive health care and non-reproductive health care addressed by the guidance in more detail, revising that sentence to read as follows:

> The purpose of this guidance is to remind the roughly 60,000 retail pharmacies in the United States of the unique role pharmacies play in ensuring nondiscriminatory access to health care services and supporting persons with disabilities, women experiencing miscarriages and early pregnancy loss, and those seeking access to contraceptives and fertility treatments.

Doc. 52-1 at 1.

In its Memorandum Opinion, the Court also pointed to the fact that the Superseded Guidance was issued with an accompanying press release stating that the guidance was issued "following President Biden's Executive Order on ensuring access to reproductive health care," in concluding that the Superseded Guidance imposed a requirement to dispense medication for purposes of abortion. Doc. 44 at 10. That Executive Order directed the Secretary to "(i) identify[] potential actions: (A) to protect and expand access to abortion care, including medication abortion; and (B) to otherwise protect and expand access to the full range of reproductive healthcare services, including actions to enhance family planning services such as access to emergency contraception." Exec. Order No. 14,076 § 3. The Superseded Guidance served the purposes of the Executive Order, in part (specifically § 3(i)(B), but not § 3(i)(A)), because it addressed access to several forms of reproductive health care, including access to emergency contraception, a reproductive healthcare service specifically identified in the Executive Order. *See* Doc. 14-2 at 4. In any event, in light of the fact that OCR revoked the Superseded Guidance and issued the Revised Guidance "to clarify that the guidance does not require pharmacies to fill prescriptions for medication for the purpose of abortion," Doc. 52-1 at 2, the press release does not support an inference that the Superseded Guidance required or that the Revised Guidance requires pharmacies to dispense medication for purposes of abortion.

The administrative record confirms that the focus of the guidance is addressing access to

medication for non-abortion purposes, not imposing a requirement to dispense medication for abortion. OCR considered several reports showing alarm among patients, doctors, and patient advocacy groups at widespread disruption in patients' access to medication for non-abortion purposes, where the medication could also be used for purposes of abortion.

For example, on June 30, 2022, the Arthritis Foundation published a report indicating that "[t]he reversal of Roe v. Wade . . . is having unforeseen consequences for some people who take methotrexate for arthritis and those who prescribe it. In some states where laws banning or severely restricting abortion have already taken effect, some patients are reporting difficulty getting their prescriptions for methotrexate." *See* Linda Rath, Arthritis Foundation, *New Barrier to Methotrexate for Arthritis Patients* (June 30, 2022), AR 00039. The report explained that "[m]ethotrexate is one of the most commonly prescribed drugs for inflammatory forms of arthritis," and is "often the first medication prescribed for rheumatoid arthritis, psoriasis, psoriatic arthritis, lupus and juvenile idiopathic arthritis (JIA)." *Id.* However, the Arthritis Foundation reported that "arthritis patients who rely on methotrexate are reporting difficulty accessing it" because the drug can also have the effect of terminating a pregnancy. *Id.* at AR 00040. In particular, the report explains that Texas "allows pharmacists to refuse to fill prescriptions for misoprostol and methotrexate, which together can be used for medical abortions. Already there are reports that people in Texas who miscarry or take methotrexate for arthritis have trouble getting their prescriptions filled." *Id.*

Similarly, an article published on July 6, 2022 in the medical journal The BMJ reported that "[p]atients are reporting trouble accessing drugs for autoimmune diseases in light of some US states banning abortion inducing drugs." Elizabeth Mahase, *US Anti-Abortion Laws May Restrict Access to Vital Drug for Autoimmune Diseases, Patient Groups Warn*, BMJ 2022 (July 6, 2022), AR 00038. The article explained that state abortion bans

> have already begun causing problems for people trying to access drugs that are considered 'abortion inducing' for other conditions, patient groups have reported.

> One key example is methotrexate, which can be used to terminate a pregnancy but is also approved for the treatment of rheumatoid arthritis, lupus, and cancer. Additionally, it is used to treat patients after an early pregnancy loss, including ectopic pregnancy and miscarriage.

Id. In addition to describing the above report from the Arthritis Foundation, the article notes that the Lupus Foundation of America had reported: "We are aware of reports that some people are having difficulty accessing methotrexate in the wake of the Supreme Court's ruling." *Id.*

And a Los Angeles Times article published on July 11, 2022, reported widespread disruption in patients' access to methotrexate to treat a variety of rheumatic illnesses in the aftermath of *Dobbs*. Sonja Sharp, L.A. Times, *Post-Roe, Autoimmune Patients Lose Access to 'Gold Standard' Drug* (July 11, 2022), AR 00028. For example, one "lupus patient" received a notice six days after *Dobbs* that her healthcare provider was "pausing all prescriptions and subsequent refills of methotrexate . . . in response to the reversal of Roe v. Wade." *Id.* at AR 00029. The article reported that "[s]ince [*Roe v. Wade*'s] reversal, many patients have been delayed or denied methotrexate, which is a 'gold-standard' treatment for conditions that have nothing to do with pregnancy." *Id.* at AR 00030. The article described how a pharmacist in Texas refused to dispense methotrexate to an 8-year-old girl with juvenile arthritis, citing "state abortion laws." *Id.* at AR 00031. The fact that "[m]any pharmacists have . . . refused to fill methotrexate prescriptions . . . led to panic for many patients who rely on the drug." *Id.* at AR 00034.

These materials explain the temporal relationship between *Dobbs* and the Superseded Guidance. OCR issued the Superseded Guidance shortly after *Dobbs* in order to address what was then an urgent and widespread issue concerning collateral disruption to medication for non-abortion purposes that arose in the wake of *Dobbs*.

At the pleading stage, the Court concluded that defendants had passed up "the opportunity to put their money where their mouth is" by not agreeing that the Court should issue "a declaratory judgment in Texas's favor." Doc. 44 at 16. Defendants opposed such a judgment based on their view that Texas lacks standing, and therefore the Court lacks subject-matter jurisdiction, because the

pharmacy guidance does not impose a requirement to dispense medication for abortion. As the Supreme Court has held, "[w]ithout jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) (quoting *Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 514 (1868)). Defendants' opposition to a judgment in Texas's favor reflected this Supreme Court precedent that a court without subject-matter jurisdiction lacks authority to enter a judgment in a plaintiff's favor.

Yet defendants have now superseded the Superseded Guidance by revoking it and replacing it with the Revised Guidance, which makes clear that it "does not require pharmacies to fill prescriptions for medication for the purpose of abortion" and does not "suggest or imply an obligation of pharmacies to fill prescriptions for medication in violation of State laws, including those banning or restricting abortion." Doc. 52-1 at 2. Accordingly, there can now be no doubt that the pharmacy guidance does not require pharmacies to dispense medication for purposes of abortion, and the Court should hold as such in rejecting plaintiffs' claims.

Because defendants' actions do not impose a requirement on pharmacies to dispense medication for purposes of abortion, plaintiffs' claim that defendants have exceeded statutory authority or violated the law by imposing such a requirement necessarily fails.

B. Notice And Comment Procedures Were Not Required

Plaintiffs' claim that the guidance violated the APA for not going through notice and comment fails because the pharmacy guidance is not a legislative rule for which notice and comment is required. Although the APA generally requires agencies to follow notice and comment procedures when issuing rules, notice and comment is not required for "interpretative rules, general statements of policy, or

rules of agency organization, procedure, or practice."[12] 5 U.S.C. § 553(b). Rules required to go through notice and comment "are often referred to as 'legislative rules' because they have the 'force and effect of law.'" *Perez*, 575 U.S. at 96 (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302–03 (1979)). By contrast, "the critical feature of interpretive rules," which do not need to go through notice and comment, "is that they are 'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'" *Id.* at 97 (quoting *Shalala v. Guernsey Mem. Hosp.*, 514 U.S. 87, 99 (1995)).

As the Fifth Circuit summarized, "[g]enerally speaking, it seems to be established that 'regulations,' 'substantive rules,' or 'legislative rules' are those which create law; whereas interpretive rules are statements as to what the administrative officer thinks the statute or regulation means." *Shell Offshore Inc. v. Babbitt*, 238 F.3d 622, 628 (5th Cir. 2001) (quoting *Brown Express Inc. v. United States*, 607 F.2d 695, 700 (5th Cir. 1979)). In distinguishing "substantive rules from nonsubstantive rules," the key issue is whether the rule constitutes a "binding norm"—i.e., whether it has a "binding effect on agency discretion or severely restricts it." *See Pros. & Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995). In this inquiry, "the starting point is 'the agency's characterization of the rule,'" *id.* at 596 (quoting *Metro. Sch. Dist. of Wayne Twp. v. Davila*, 969 F.2d 485, 489 (7th Cir. 1992)), which, although not dispositive, is afforded "some deference," *id.* at 595.

Plaintiffs' argument that the pharmacy guidance is a substantive rule rests on the assertion that it "added a new legal norm," meaning a requirement to dispense medication for purposes of abortion. Doc. 49 at 15; *see also* Doc. 14 ¶ 79. But as explained above, that is incorrect. The pharmacy guidance does not impose such a requirement. *See supra*, Part I. Once it is understood that the pharmacy guidance does not impose a requirement to dispense medication for abortion, it becomes clear that to

[12] Courts commonly refer to what the APA calls "interpretative rules" as "interpretive rules." *See Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 96 & n.1 (2015).

the extent the guidance is any kind of a "rule" under the APA, it is an interpretive rule exempt from notice and comment requirements. The guidance sets forth OCR's interpretation of civil rights laws and describes certain scenarios (all involving refusing to dispense medication for purposes other than abortion) under which, depending on all the facts, a pharmacy "may be discriminating" in violation of civil rights laws. Doc. 52-1 at 3–4.

The Fifth Circuit recently set forth a five-factor test for differentiating legislative rules from interpretive rules:

> The five factors are, first, whether the agency intended to speak with the force of law. We examine the language actually used by the agency. Second, we see whether the agency published its rule in the Code of Federal Regulations. Third, we examine whether the agency explicitly invoked its general legislative authority. Fourth, we note whether the agency claimed *Chevron* deference. Finally, in the Fifth Circuit, courts scrutinize whether the rule will produce significant effects on private interests.

Mock v. Garland, 75 F.4th 563, 580 (5th Cir. 2023) (cleaned up).

Each of these factors supports the conclusion that the guidance is interpretive, rather than legislative. First, the language of the guidance shows that the agency did not intend to speak with the force of law. It contains a disclaimer that "[t]he contents of this document do not have the force and effect of law and are not meant to bind the public in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or the Departments' policies." Doc. 52-1 at 5. Consistent with that disclaimer, the guidance states that it concerns "obligations of pharmacies under federal civil rights laws," *id.* at 1, reflecting that the guidance describes obligations under distinct statutes and regulations rather than imposing new obligations.

Plaintiffs may argue that the guidance intends to speak with the force of law because it uses some mandatory language, such as stating that "pharmacies that receive federal financial assistance may not discriminate against pharmacy customers on the bases prohibited by Section 1557 and Section 504." Doc. 52-1 at 2. But the Fifth Circuit has "reject[ed] the proposition that a rule cannot be interpretive if it limits discretion or uses binding language," reasoning that "interpretive rules explain

what an agency thinks a statute or regulation actually says. If the law is mandatory, then it is natural for an agency's restatement of the law to speak in mandatory terms as well." *Flight Training Int'l, Inc. v. Fed. Aviation Admin.*, 58 F.4th 234, 242 (5th Cir. 2023). As the passage quoted above shows, the guidance uses mandatory language to "explain what [OCR] thinks [Section 1557 and Section 504] actually say[]," and it is therefore "natural" for the guidance's "restatement of" federal civil rights statutes "to speak in mandatory terms." *Id.*

Second, the guidance was not published in the Code of Federal Regulations.

Third, OCR did not invoke its general authority to make legislative rules as authority for the guidance. Invoking such authority was unnecessary because, on its own terms, the guidance explains existing requirements rather than imposing new ones.

Fourth, OCR did not claim *Chevron* deference.

Fifth, because the guidance does not require pharmacies to dispense medication for purposes of abortion, plaintiffs cannot show that it will produce significant effects on private interests. Notably, plaintiffs have not claimed that the guidance harms pharmacies in any way other than by imposing a purported abortion requirement. *See* Doc. 14 ¶¶ 29–33, 46–53.

These factors all demonstrate that the guidance is not a legislative rule and therefore did not need to go through notice and comment.

C. The Pharmacy Guidance Is Not Arbitrary and Capricious

Review under the APA to determine whether agency action is arbitrary and capricious "is narrow and a court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The Fifth Circuit has stressed: "Under this highly deferential standard of review, a reviewing court has the 'least latitude in finding grounds for reversal.'" *Sabine River Auth. v. U.S. Dep't of Interior*, 951 F.2d 669, 678 (5th Cir. 1992) (citation omitted). Agency action must be upheld if the action "is rational, based on consideration of the relevant factors

and within the scope of the authority delegated to the agency." *State Farm*, 463 U.S. at 42. Reviewing courts "uphold an agency's action if 'its reasons and policy choices satisfy minimum standards of rationality.'" *10 Ring Precision, Inc. v. Jones*, 722 F.3d 711, 723 (5th Cir. 2013) (citation omitted).

The pharmacy guidance easily satisfies this standard. All of plaintiffs' arguments for why the guidance is arbitrary and capricious rest on the premise that the guidance imposes a requirement to dispense medication for purposes of abortion. As explained above, it does not. *See supra*, Part I. Therefore, all of plaintiffs' arbitrary and capricious arguments necessarily fail.

For example, plaintiffs argue that defendants arbitrarily failed to acknowledge and explain "a change in position" to impose a "new" "mandate to dispense drugs for abortions." Doc. 49 at 16; *see also* Doc. 14 ¶ 88. But the pharmacy guidance does not impose such a mandate, and accordingly there is no need to explain a change in position to impose such a mandate.

Plaintiffs also argue that defendants failed to consider pharmacies' "reliance interests" in a "lack of any federal mandate to dispense drugs for abortions." Doc. 49 at 16–17; *see also* Doc. 14 ¶ 88. But the pharmacy guidance does not implicate any such reliance interests because it does not impose such a mandate. Indeed, it has been well over a year since OCR issued the Superseded Guidance, and OCR has not once relied on either the Superseded Guidance or the Revised Guidance to require any pharmacy to dispense medication for purposes of abortion (and plaintiffs do not assert or demonstrate otherwise). Likewise, because the guidance does not impose the abortion mandate claimed by plaintiffs, there is no need to "discuss alternative approaches to issuing" such a mandate. Doc. 49 at 17.

Finally, plaintiffs argue that the guidance is arbitrary and capricious because the Superseded Guidance did not discuss RFRA. Doc. 49 at 17. But HHS has repeatedly acknowledged that all of its civil rights enforcement is subject to RFRA and has stated repeatedly that it enforces civil rights statutes in compliance with RFRA. *See supra*, p. 13 (citing examples).

The fact that the Superseded Guidance did not specifically mention RFRA does not detract from HHS's ongoing commitment, expressed consistently over many years, to comply with RFRA. Furthermore, to the extent there was any doubt, the Revised Guidance confirms that OCR "complies with [RFRA]," and to the extent its civil rights enforcement implicates RFRA or other religious conscience statutes, "OCR will evaluate and apply these statutory protections on a case-by-case basis." Doc. 52-1 at 5.[13]

In sum, plaintiffs fail to show any way in which the pharmacy guidance is arbitrary and capricious.

D. The Pharmacy Guidance Does Not Violate the Spending Clause

The pharmacy guidance does not violate the Constitution's Spending Clause, which authorizes Congress to "provide for the common defense and general welfare of the United States." U.S. Const., Art. I, § 8, cl. 1. As explained above, the pharmacy guidance describes the obligations of pharmacies under statutes enacted pursuant to the Spending Clause: Section 1557, Section 504, and Title IX. *See* Doc. 52-1 at 2 & 6 n.3. It is well-established that federal civil rights laws such as these, which require recipients of federal funding not to discriminate on certain bases (including sex and disability) as a condition of receiving federal funding, are valid exercises of authority under the Spending Clause. *See, e.g.*, *Franklin v. Gwinnett Cnty. Pub. Sch.*, 503 U.S. 60, 74–75 (1992) (concluding that Title IX, which "was enacted pursuant to Congress' Spending Clause power," validly "placed on [a school system receiving

[13] As noted above, *supra* p. 14, OCR recently closed an investigation concerning a religious hospital on the basis that the hospital was protected by RFRA. A complainant alleged that a hospital had discriminated in violation of Section 1557 by refusing to provide a (non-abortion) service, and the hospital informed OCR that it refused to provide the service in accordance with its religious beliefs. OCR evaluated the complaint in light of RFRA, determining after a factual investigation that the hospital had adequately asserted that providing the service would substantially burden the hospital's sincerely held religious beliefs, and that applying Section 1557 to require the hospital to provide the service was not the least restrictive means of achieving the government's compelling interests. A redacted copy of the letter announcing the closure of this investigation is attached as Exhibit 1. This letter shows that OCR takes RFRA seriously and applies the civil rights laws in compliance with RFRA.

federal funding] the duty not to discriminate on the basis of sex," and authorized damages actions for intentional sex discrimination); *Pederson v. Louisiana State Univ.*, 213 F.3d 858, 876 (5th Cir. 2000) ("The Supreme Court has noted that Congress in enacting Title IX 'condition[ed] an offer of federal funding on a promise by the recipient not to discriminate, in what amounts essentially to a contract between the Government and the recipient of funds.'") (quoting *Gebser v. Lago Vista Indep. School Dist.,* 524 U.S. 274, 286 (1998)).

Although, as plaintiffs point out, the Supreme Court has stated that the validity of Spending Clause legislation turns on whether a state "voluntarily and knowingly" accepted conditions on federal funding, *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981), the federal civil rights statutes here are crystal clear in imposing requirements not to discriminate on the bases of sex and disability. *See* 42 U.S.C. § 18116(a) (prohibiting discrimination "on the ground prohibited under . . . title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.), . . . or section 794 of title 29"); 20 U.S.C. § 1681(a) ("[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance"); 29 U.S.C. § 794(a) ("[n]o otherwise qualified individual with a disability in the United States, . . . shall, solely by reason of her or his disability, be excluded from the participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance"); *see also Pederson*, 213 F.3d at 876. Because the federal civil rights laws unambiguously prohibit recipients of federal funding from discriminating on the bases of sex and disability,[14] OCR did not violate the Spending Clause by issuing guidance interpreting those prohibitions. *See Benning v. Georgia*, 391 F.3d 1299, 1306 (11th Cir. 2004) ("[S]o long as a spending

[14] Indeed, HHS regulations require applicants for federal financial assistance through HHS to provide written assurances in their applications that they do not discriminate in violation of federal civil rights laws, including Section 1557, Section 504, and Title IX. *See* 45 C.F.R. §§ 80.4, 84.5, 86.4, 91.33, 92.3.

condition has a clear and actionable prohibition of discrimination, it does not matter that the manner of that discrimination can vary widely.").

Moreover, Texas's Spending Clause arguments rest on the assertion that defendants are imposing a condition on federal funding to "provid[e] drugs for abortions" that Texas claims is not imposed by statute. Doc. 14 ¶¶ 71–72; *see also* Doc. 49 at 19 (guidance violates Spending Clause because it "compel[s] [Texas pharmacies] to violate State [abortion] law"). But as explained above, the guidance does not impose this requirement or condition on Texas's federal funding. *See supra*, Part I. Rather, the guidance interprets federal civil rights laws and explains circumstances in which refusing to dispense medication for certain non-abortion purposes may constitute discrimination. Therefore, the Court need not address whether agency guidance would create a problem under the Spending Clause if it purported to impose a requirement that a plaintiff contended was not contained within a statute enacted under the Spending Clause, because the guidance is not imposing the purported requirement about which Texas complains.

CONCLUSION

For the above-stated reasons, the Court should dismiss plaintiffs' claims for lack of subject-matter jurisdiction and/or enter summary judgment in defendants' favor. The Court should deny plaintiffs' motion for summary judgment.

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Respectfully submitted,

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Certificate of Service

I certify that on October 20, 2023, I served Defendants' Motion for Summary Judgment and Opposition to Plaintiffs' Motion for Summary Judgment via the Court's CM/ECF system upon plaintiffs via their counsel as follows:

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