## 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.,	
D.I. 1. 1.00	

Plaintiffs;

Defendants.

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,

No. 7:23-cv-00022-DC

DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AND SUPPLEMENTAL OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

## **TABLE OF CONTENTS**

TABLE OF AUTHORITIESii			
Таі	BLE (	OF DOCKET ENTRIES CITED IN BRIEF	vi
INT	ROD	OUCTION	1
Arc	GUMI	ENT	2
I.	that	ntiffs Mischaracterize the Pharmacy Guidance: The Revised Guidance Makes Clear It Does Not Require Pharmacies to Fill Prescriptions for Medications for Ortions in Violation of State Law or Otherwise	2
II.	The	e Court Lacks Subject Matter Jurisdiction to Review the Superseded Guidance	10
	Α.	Plaintiffs' Challenge to the July 2022 Guidance Has Been Mooted by OCR's Issuance of the Revised Guidance	10
	В.	Plaintiffs Fail to Establish Standing at This Stage in the Litigation	13
	C.	The Court Lacks Jurisdiction to Review the Pharmacy Guidance Because It Is Not Final Agency Action	18
III.	Plai	ntiffs' Claims Fail on the Merits	19
	Α.	Defendants' Actions Do Not Exceed Statutory Authority	19
	В.	Notice And Comment Procedures Were Not Required	21
	C.	The Pharmacy Guidance Is Not Arbitrary and Capricious	24
	D.	The Pharmacy Guidance Does Not Violate the Spending Clause	24
	E.	Plaintiffs Have Not Established Entitlement to a Permanent Injunction	26
Coi	NCLI	ISION	27

## **TABLE OF AUTHORITIES**

## <u>Cases</u>

Benning v. Georgia, 391 F.3d 1299 (11th Cir. 2004)	26
California v. Texas, 141 S. Ct. 2104 (2021)	13, 14, 15, 16
Clapper v. Amnesty Int'l USA, 568 U.S. 398 (2013)	13
Daves v. Dallas Cnty., 64 F.4th 616 (5th Cir. 2023)	12
Department of Education v. Brown, 600 U.S. 551 (2023)	17, 18
Dobbs v. Jackson Women's Health Organization, 142 S. Ct. 2228 (2022)	5
eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388(2006)	27
Flight Training Int'l, Inc. v. Fed. Aviation Admin., 58 F.4th 234 (5th Cir. 2023)	22
Franciscan All., Inc. v. Becerra, 47 F.4th 368 (5th Cir. 2022)	12, 13
Freedom From Religion Found., Inc. v. Abbott, 58 F.4th 824 (5th Cir. 2023)	12
Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc., 528 U.S. 167 (2000)	12
Gaydar v. Sociedad Instituto Gineco-Quirurgico y Planificacion, 345 F.3d 15 (1st Cir. 2003)	6
Haaland v. Brackeen, 599 U.S. 255 (2023)	15
Herndon v. Upton, 985 F.3d 443 (5th Cir. 2021), cert. denied, 142 S. Ct. 82, 211 L. Ed. 2d 17 (2021)	
voive viviewing 1 12 0. On 02, 211 12. 114. 24 1/ (2021)	

# Case 7:23-cv-00022-DC Document 60 Filed 11/17/23 Page 4 of 36

Holz v. United States, 2009 WL 10704725 (N.D. Tex. Sept. 29, 2009)	27
Louisiana by & through Landry v. Biden, 64 F.4th 674 (5th Cir. 2023)	17
Lujan v. Defs. of Wildlife, 504 U.S. 555 (1992)	13, 15, 17
Mayweathers v. Newland, 314 F.3d 1062 (9th Cir. 2002)	26
Mock v. Garland, 75 F.4th 563 (5th Cir. 2023)	22, 23
Moore v. Brown, 868 F.3d 398 (5th Cir. 2017)	12
N.Y. State Rifle & Pistol Ass'n, Inc. v. City of N.Y., 140 S. Ct. 1525 (2020)	10, 11, 12, 13
National Minining Ass'n v. McCarthy, 758 F.3d 243 (D.C. Cir. 2014)	18, 19
Neese v. Becerra, 640 F. Supp. 3d 668 (N.D. Tex. 2022)	27
Peoples Nat'l Bank v. Off. of Comptroller of Currency of U.S., 362 F.3d 333 (5th Cir. 2004)	18
Professionals & Patients for Customized Care v. Shalala, 56 F.3d 592 (5th Cir. 1995)	23
Pugh v. Rainwater, 572 F.2d 1053 (5th Cir. 1978)	10
Spencer v. Texaco, Inc., 1996 WL 363540 (E.D. La. June 28, 1996)	27
Summers v. Earth Island Institute, 555 U.S. 488 (2009)	17, 18
Susan B. Anthony List v. Driehaus, 573 U.S. 149 (2014)	14, 16
Sw. Airlines Co. v. U.S. Dep't of Transp., 832 F.3d 270 (D.C. Cir. 2016)	19

Texas v. United States, 809 F.3d 134 (5th Cir. 2015)	18
Texas v. Equal Employment Opportunity Commission, 933 F.3d 433 (5th Cir. 2019)	17
Texas v. Yellen, 2022 WL 989733 (N.D. Tex. March 4, 2022)	15
United States v. Mississippi, 82 F.4th 387 (5th Cir. 2023)	19
W & T Offshore, Inc. v. Bernhardt, 946 F.3d 227 (5th Cir. 2019)	27
West Virginia v. EPA, 142 S. Ct. 2587 (2022)	20
Whitman v. Am. Trucking Ass'n, 531 U.S. 457 (2001)	19
Wilgar Land Co. v. Dir., Off. of Workers' Comp. Programs, 2023 WL 7145340 (6th Cir. Oct. 31, 2023)	19
<u>Statutes</u>	
5 U.S.C. § 704	18
5 U.S.C. § 706(2)	26
42 U.S.C. § 18116(a)	4
Regulations	
45 C.F.R. § 92.6(b)	17
State Statutes	
Tex. Health & Safety Code § 245.002(1)(C)	17
S.B. 2150, 68th Leg. Sess., Reg. Sess. (N.D. 2023)	6
Other Authorities	
Am. Assoc. of Pro-Life Obstetricians & Gynecologists, What is AAPLOG's Treatment of Ectopic Pregnancy?, https://perma.cc/9DMT-QKZP	

# 

Am. College of Obstetricians & Gynecologists, Facts Are Important: Understanding Ectopic Pregnancy, https://perma.cc/7LPU-AUPB	
Antonette T. Dulay, M.D., <i>Ectopic Pregnancy</i> , Merck Manual, https://perma.cc/3EDP-AR4L	6
Equitable Remedy, Black's Law Dictionary (10th ed. 2014)	27
Nondiscrimination in Health Programs & Activities, 87 Fed. Reg 47,824 (Aug. 4, 2022)	17, 19
Supersede, Black's Law Dictionary (11th ed. 2019)	11

## TABLE OF DOCKET ENTRIES CITED IN BRIEF

Doc. 14	Plaintiffs' Amended Verified Complaint
Doc. 44	Memorandum Opinion, July 12, 2023 (motion to dismiss decision)
Doc. 49-1	Declaration of Eric Bentley
Doc. 49-2	Declaration of Kevin Martian / Mayo Pharmacy, Inc.
Doc. 49-3	Plaintiffs' Proposed Order
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. 53	Plaintiffs' Supplemental Brief in Support of Plaintiffs' Motion for Summary Judgment
Doc. 55	Defendants' Motion for Summary Judgment and Opposition to Plaintiffs' Motion for Summary Judgment
Doc. 55-1	Ex. 1 to Defendants' Motion: OCR Closure Letter
Doc. 57	Plaintiffs' Response in Opposition to Defendants' Motion for Summary Judgment and Reply in Support of Plaintiffs' Motion for Summary Judgment

#### INTRODUCTION

Defendants respectfully submit this reply brief in support of their motion for summary judgment, and in response to plaintiffs' supplemental summary judgment brief. Plaintiffs claim to be injured by a requirement to dispense medications for abortion contained in guidance to pharmacies issued by the U.S. Department of Health and Human Services Office for Civil Rights ("OCR"). But OCR issued the Revised Guidance, which supersedes and replaces the guidance challenged in the Amended Complaint, to clarify that the guidance does not impose such a requirement. Plaintiffs misconstrue the Revised Guidance's language to argue that it requires pharmacists to dispense medications for abortion, but the language of the Revised Guidance is clear: 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 issuance of the Revised Guidance demonstrates that the Court lacks subject-matter jurisdiction. Plaintiffs' challenge to the Superseded Guidance is moot because defendants have given plaintiffs the precise relief they sought by revoking the Superseded Guidance and replacing it with Revised Guidance that makes clear that it contains no requirement to dispense medications for abortions. And because the guidance does not impose such a requirement, plaintiffs cannot meet their burden at the summary judgment stage to identify evidence showing that they are injured by the guidance. Furthermore, the issuance of the Revised Guidance reinforces that the Superseded Guidance was not and is not final agency action.

Should the Court reach the merits, each of plaintiffs' claims fail. Plaintiffs claim that OCR has acted in excess of statutory authority by requiring pharmacies to fill prescriptions for medications for abortion, but this argument rests on a mischaracterization of the guidance, which contains no such requirement. The pharmacy guidance was not required to go through notice and comment procedures

either, because it is not a legislative rule that imposes new obligations with the force of law; rather, it provides OCR's interpretation of the obligations that exist under existing civil rights laws. Plaintiffs argue that the guidance is arbitrary and capricious because it does not adequately explain a decision to impose a new abortion requirement, but because the guidance expressly does not impose such a requirement, no explanation of such a decision was required. Finally, the guidance does not violate the Spending Clause by interpreting pharmacies' obligations under federal civil rights laws that clearly condition federal funding on an obligation not to discriminate on the basis of sex or disability.

For these reasons, and as discussed further below and in defendants' opening brief, Doc. 55, the Court should grant defendants' motion for summary judgment and deny plaintiffs' motion.

#### **ARGUMENT**

I. Plaintiffs Mischaracterize the Pharmacy Guidance: The Revised Guidance Makes Clear that It Does Not Require Pharmacies to Fill Prescriptions for Medications for Abortions in Violation of State Law or Otherwise

The claims in plaintiffs' Amended Complaint<sup>1</sup> rely on the notion that the pharmacy guidance requires pharmacies to dispense drugs for abortion purposes. *See, e.g.*, Doc. 14 ¶ 57 (asserting that the "Pharmacy [Guidance] attempts to impose a legal duty on pharmacies and pharmacists in Texas and nationwide to dispense drugs for abortion purposes"); *id.* at ¶ 79 (asserting that the "Pharmacy [Guidance] substantively changes the conditions for payment for services by requiring pharmacies that receive federal funds to dispense drugs for abortions, notwithstanding their obligations under Texas law"); *id.* at ¶¶ 88, 90 (asserting that "[t]he Pharmacy [Guidance] . . . change[d] . . . the agency's position" because it interpreted federal civil rights laws "to require pharmacies to stock or dispense drugs for abortion purposes").

But the applicable guidance does not impose the requirements to which plaintiffs object. In

2

<sup>&</sup>lt;sup>1</sup> The pending claims here are Count 1, Count 2, and Count 3 of the Amended Complaint, Doc. 14. This Court transferred Count 4—Mayo's Religious Freedom Restoration Act ("RFRA") claim—to the District of North Dakota. Doc. 44 at 25.

September 2023, OCR issued the Revised Guidance, which supersedes and revises the July 2022 Guidance, "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." Doc. 52-1 at 2.

As shown on the redline document attached as Exhibit 1, the Revised Guidance made the following revisions to the Superseded Guidance:

- ➤ Changed the title to better reflect the content of the guidance and make clear that the guidance is about nondiscriminatory access to health care at pharmacies. This revision ensures that there could be no inference that the guidance was implicitly obligating pharmacies to dispense medication for abortion.
- Added an explanation of the Revised Guidance at the top of the document. The explanation states: "Revised guidance: On September 29, 2023, OCR revised this guidance to clarify that the guidance does not require pharmacies to fill prescriptions for medication for the purpose of abortion."
- Deleted reference to "comprehensive reproductive health care" in the first body paragraph, and replaced it with a more specific and precise description of the pharmacy guidance's focus. The revised sentence of the first paragraph states: "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." This language more specifically identifies the reproductive health care topics covered by the pharmacy guidance (miscarriages and early pregnancy loss, contraception, and

- fertility treatments), and also accounts for the fact that the guidance covers nonreproductive health care topics like access to rheumatoid arthritis drugs.
- Added a paragraph to the body of the pharmacy guidance, explaining the effect and purpose of the Revised Guidance. The new paragraph indicates that the Revised Guidance "supersedes and revises" the Superseded Guidance. And it states the purpose of the revision: "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."
  - Revised a previously unclear sentence that the Court had viewed as "prohibit[ing] pharmacies from 'making determinations regarding the suitability of a prescribed medication for a patient," Doc. 44 at 11. OCR had not intended to include such a prohibition in the pharmacy guidance. Therefore, OCR rephrased this sentence to describe more clearly what it was trying to convey. The new sentence says: "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." As revised, the sentence simply conveys that Section 1557 and Section 504 apply to activities of pharmacies that receive federal financial assistance. This position is not new, but rather reflects Congress's enactment of Section 1557, which is codified at 42 U.S.C. § 18116. See 42 U.S.C. § 18116(a) ("Except as otherwise provided for in this title (or an amendment made by this title), an individual shall not, on the ground prohibited under [various federal civil rights laws including Section 504] be

- excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance.").
- ➤ Deleted reference to *Dobbs v. Jackson Women's Health Organization*, 142 S. Ct. 2228 (2022), to avoid creating the misimpression that the guidance imposed obligations relating to abortion.
- Replaced the phrase "reproductive health care, including prescription medication" with the phrase "lawfully prescribed medication." The phrase "lawfully prescribed medication" indicates that the guidance is concerned with accessing medications that are prescribed in compliance with federal law and applicable state law. The pharmacy guidance recognizes that pharmacies are regulated by and operate within the confines of State and federal laws, and as it states explicitly, it does not intend to describe an obligation of pharmacies to fill prescriptions for medication in violation of State laws. The Revised Guidance uses the phrase "lawfully prescribed medication" in several places to capture this idea.
- ➤ In the first bullet point under "Examples," replaced specific names of medications with a more general reference to "medication." This bullet point pertains to treatment for early pregnancy loss (first-trimester miscarriage), not any specific medication.

- In the fourth bullet point under "Examples," added the word "ectopic" in two places to confirm that the example is limited to treatment for an ectopic pregnancy.<sup>2</sup>
- Edited the paragraph mentioning the Church Amendments so that it explicitly refers more broadly to "Federal religious freedom and conscience statutes including the Church Amendments" and to RFRA. The Revised Guidance confirms that OCR "complies with [RFRA]," and to the extent its civil rights enforcement activities implicate RFRA or other religious conscience statutes, "OCR will evaluate and apply these statutory protections on a case-by-case basis."

Defendants lay out these revisions because plaintiffs' supplemental and opposition briefs mischaracterize the Revised Guidance. Contrary to plaintiffs' assertion, *cf.* Doc. 53 at 2, the Revised Guidance does not impose new obligations on pharmacies. Indeed, it does not impose any obligations at all, but instead describes pharmacies' *existing* nondiscrimination obligations under Section 1557 and Section 504. Plaintiffs emphasize the guidance's use of the word "obligations," but they cannot explain how any "obligations" are created by the guidance, rather than the preexisting statutory scheme. The pharmacy guidance itself indicates that it is describing and summarizing "obligations of

<sup>&</sup>lt;sup>2</sup> "An ectopic pregnancy is a form of pregnancy in which implantation of the fertilized egg occurs outside of the uterus, oftentimes in one of the fallopian tubes." *Gaydar v. Sociedad Instituto Gineco-Quirurgico y Planificacion*, 345 F.3d 15, 19 n.2 (1st Cir. 2003). An ectopic pregnancy cannot lead to a live birth, and it can cause severe and life-threatening bleeding in the pregnant person if not promptly treated. *See, e.g.*, Antonette T. Dulay, M.D., *Ectopic Pregnancy*, Merck Manual, <a href="https://perma.cc/3EDP-AR4L">https://perma.cc/3EDP-AR4L</a>.

<sup>&</sup>quot;In Texas, the removal of an ectopic pregnancy is not an abortion." Doc. 57 at 4 (citing Tex. Health & Safety Code § 245.002(1)(C)). Likewise, treating an ectopic pregnancy is not an "abortion" under North Dakota law, S.B. 2150, 68th Leg. Sess., Reg. Sess. (N.D. 2023), and leading medical organizations as well as major pro-life groups do not consider treatment of ectopic pregnancy to be abortion, Am. College of Obstetricians & Gynecologists, Facts Are Important: Understanding Ectopic Pregnancy, <a href="https://perma.cc/7LPU-AUPB">https://perma.cc/7LPU-AUPB</a> ("indication and treatment for ectopic pregnancies is distinct from the indication and provision of induced abortion[]"); Am. Assoc. of Pro-Life Obstetricians & Gynecologists, What is AAPLOG's Position on Treatment of Ectopic Pregnancy?, <a href="https://perma.cc/9DMT-QKZP">https://perma.cc/9DMT-QKZP</a> ("[We] recognize[] the unavoidable loss of human life that occurs in an ectopic pregnancy, but do[] not consider treatment of ectopic pregnancy by standard surgical or medical procedures to be the moral equivalent of elective abortion, or to be the wrongful taking of human life.").

pharmacies *under federal civil rights laws*." Doc. 52-1 at 1 (emphasis added). The guidance "do[es] not have the force and effect of law and [is] not meant to bind the public in any way," *id.* at 5, and therefore it does not impose obligations.

Plaintiffs insist nonetheless that the Revised Guidance "creates a new obligation to dispense all lawful medications." Doc. 53 at 4. Not so. As discussed above, OCR added the modifier "lawfully prescribed" to the word "medication" in several places in the Revised Guidance to underscore OCR's pronouncement that the pharmacy 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. Rather than broadening the guidance, the phrase "lawfully prescribed medication" clarifies the narrowness of its impact, including that the guidance addresses medications that are prescribed in compliance with federal law and state law. Nothing in the Revised Guidance supports plaintiffs' contention that the guidance requires pharmacies to "dispense all lawful medications." The Revised Guidance and the underlying federal civil rights laws are concerned only with certain types of denials that are discriminatory on the basis of sex or disability.

Contrary to plaintiffs' assertion, the Revised Guidance does not "contain obligations preventing pharmacies from acting on their reluctance to facilitate abortion." *Cf.* Doc. 53 at 12. Again, the pharmacy guidance is concerned with scenarios in which individuals are treated differently because of their sex or disability. A pharmacist who advises a patient that a certain medication is contraindicated for pregnancy is not discriminating based on sex or disability. The Revised Guidance plainly states that the "guidance does not require pharmacies to fill prescriptions for medication for the purpose of abortion." Doc. 52-1 at 1. Further, none of the examples pertain to abortion. The examples are concerned with denials of a medication to a patient because of its possible alternative uses, not because the medication would cause an unintended (or intended) abortion for that patient.

Plaintiffs assert that the Revised Guidance "still regulates advising and making

determinations." Doc. 53 at 2. But as discussed above, *supra* at 4–5, the pharmacy guidance simply relays Section 1557's and Section 504's requirement that pharmacies that receive federal financial assistance must not discriminate on the basis of sex or disability. Pharmacy advice and determinations are implicated only to the extent that they discriminate on these statutory bases. The Revised Guidance rephrased the pertinent sentence in the guidance to more clearly convey this point. *See supra* at 4–5.

Plaintiffs argue that the Revised Guidance "maintain[s] [an] anti-*Dobbs* context." Doc. 53 at 3. Plaintiffs incorrectly point to the July 13, 2022 press release as demonstrating this proposition, merely because the webpage housing that press release was annotated on September 29, 2023 to note that the July 2022 Guidance had been superseded by the Revised Guidance. *Id.* at 3–4. Such annotation does not transform the July 13, 2022 press release into a "press announcement" for the Revised Guidance as plaintiffs contend. It merely reflects that across HHS's website, wherever the July 2022 Guidance was mentioned, HHS added language indicating that the former guidance had been superseded and replaced by the Revised Guidance. HHS did so to prevent confusion and clarify that the July 2022 Guidance was no longer in effect.

Defendants have explained, and the administrative record demonstrates, that the reason the guidance was issued close in time to *Dobbs* was because, in the period after the *Dobbs* decision issued, patients were reportedly being denied access to medications for non-abortion purposes such as treating rheumatoid arthritis. Doc. 55 at 15. 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. AR 00028–00041, 00168–00170. OCR also heard directly from disability advocates and state officials about such disruption. AR 00171–00177.

In addition to addressing non-reproductive health care topics, the pharmacy guidance also

addresses certain non-abortion reproductive health care topics, including fertility treatments, miscarriage management, and contraception. This does not mean that the pharmacy guidance was an attempt to countermand *Dobbs*' ruling on abortion. The comments made by defendants' counsel at the June 29, 2023 motion-to-dismiss hearing—which plaintiffs mischaracterize and only partially cite, Doc. 53 at 3 (citing Hearing Tr. 15:8–11)—make a similar point.<sup>3</sup> Counsel explained that the Superseded Guidance followed the Executive Order's general direction and strategy to "enhance access to reproductive healthcare" because it addressed "certain forms of non-abortion reproductive healthcare." Hearing Tr. 14:18–16:1; *see also id.* 13:5–14:12.

Plaintiffs also argue that the "Revised Guidance contains no relief for religious pharmacies," Doc. 53 at 5, and complain that the Revised Guidance does not sufficiently protect Mayo's RFRA rights. The Court has transferred Mayo's RFRA claim to the District of North Dakota, so this argument is not properly before this Court. But, in any event, the Revised Guidance specifically references not just RFRA but also Federal religious freedom and conscience statutes including the Church Amendments. The Revised Guidance makes clear that OCR will "apply" these statutory protections as warranted based on the particular circumstances in which religious objections arise. Doc. 52-1 at 5.

Plaintiffs are projecting onto the Revised Guidance policies that they believe to be objectionable. But the policies that Plaintiffs seek to contest are not the policies adopted by the Revised Guidance. Indeed, the Revised Guidance fully addresses the very concerns raised in plaintiffs' Amended Complaint. As noted above, the Amended Complaint asserted that the July 2022 Guidance

<sup>&</sup>lt;sup>3</sup> Plaintiffs cite the transcript lines that include the Court's question whether "HHS believe[s] that they accomplished what President Biden's executive order wanted to accomplish with this guidance," and defendants' counsel's response in the affirmative, while ignoring the fuller colloquy in which counsel explained that the purpose of the guidance was to "remind[]" pharmacies of their obligations under federal civil rights laws in light of the fact that "women were struggling to access certain forms of non-abortion" healthcare from pharmacies. Hearing Tr. 14:25-15:7.

improperly "attempt[ed] to impose a legal duty on pharmacies and pharmacists . . . to dispense drugs for abortion purposes." Doc. 14 ¶ 57; see also, e.g., id. at ¶¶ 79, 88, 90. The Revised Guidance—which superseded the July 2022 Guidance and is the only pharmacy guidance currently in effect and before this Court— was issued to clarify OCR's intent in this regard. It includes an explicit pronouncement confirming 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.

#### II. The Court Lacks Subject Matter Jurisdiction to Review the Superseded Guidance

# A. Plaintiffs' Challenge to the July 2022 Guidance Has Been Mooted by OCR's Issuance of the Revised Guidance

The Court's "review must be in the light of the [pharmacy guidance] as it now stands." *Pugh* v. Rainwater, 572 F.2d 1053, 1058 (5th Cir. 1978) (en banc). Where, as here, a superseding policy provides plaintiffs the "precise relief" they request, the challenge to the original policy is moot. N.Y. State Rifle & Pistol Ass'n, Inc. v. City of N.Y., 140 S. Ct. 1525, 1526 (2020).

To determine whether the Revised Guidance provides plaintiffs the "precise relief" they requested, the Court must consider what plaintiffs actually sought in their Amended Complaint and their Proposed Order accompanying their motion for summary judgment. *Herndon v. Upton*, 985 F.3d 443, 449 (5th Cir. 2021) (Oldham, J., concurring), *cert. denied*, 142 S. Ct. 82, 211 L. Ed. 2d 17 (2021) ("As the Supreme Court recently emphasized, mootness is a function of a party's requested relief—not the theoretical possibility that a party could request or receive something."). Plaintiffs challenged the July 2022 Guidance, and sought to have it "set aside." Doc. 49-3 at ¶ 2 (Pls.' Proposed Order); Doc. 14 at 22 (Am. Compl. Prayer for Relief). They also sought to enjoin HHS from "enforcing" the July 2022 Guidance, "either in the State of Texas or against Mayo Pharmacy." Doc. 49-3 at ¶ 3; *see also* Doc. 14 at 22. And they specifically challenged what they viewed as the July 2022 Guidance's

"interpretation that Section 1557 of the ACA or Section 504 of the Rehabilitation Act require pharmacies to dispense drugs for abortions." Doc. 49-3 at ¶ 4 (emphasis added); see also, e.g., Doc. 14 at 57 (characterizing and faulting the July 2022 Guidance as requiring pharmacies "to dispense drugs for abortion purposes"). The Revised Guidance provides all three forms of relief.

First, the Revised Guidance superseded the July 2022 Guidance, and thus voided the earlier guidance and took its place. Doc. 52-1 at 2 ("This guidance supersedes and revises OCR guidance . . . issued on July 13, 2022."). To supersede means "[t]o annul, make void, or repeal by taking the place of." *Supersede*, Black's Law Dictionary (11th ed. 2019). Plaintiffs had sought to "set aside" the July 2022 Guidance, and the Revised Guidance provided this "precise relief" because the Superseded Guidance has been annulled and made void, and is therefore of no effect, because the Revised Guidance replaced it. *See N.Y. State Rifle & Pistol Ass'n*, 140 S. Ct. at 1526. Defendants noted as much in their opening brief. Doc. 55 at 9–10. Plaintiffs' opposition brief does not counter defendants' contention that the July 2022 Guidance has been superseded and voided. To the contrary, plaintiffs implicitly concede as much by arguing that it is the Revised Guidance that causes them harm. *See* Doc. 57 at 3–11, 17–19.

Second, although defendants dispute that the non-binding July 2022 Guidance was ever enforceable, to the extent it were, the July 2022 Guidance is no longer being "enforced," nor can it be, as it has been replaced by the Revised Guidance. Again, this is the "precise relief" requested by plaintiffs. See N.Y. State Rifle & Pistol Ass'n, 140 S. Ct. at 1526.

Third, by making clear that it "does not require pharmacies to fill prescriptions for medication for the purpose of abortion," Doc. 52-1 at 2, the Revised Guidance also provides the precise relief that plaintiffs sought in their request to enjoin defendants "from enforcing the Pharmacy Mandate's interpretation that Section 1557 of the ACA or Section 504 of the Rehabilitation Act require

pharmacies to dispense drugs for abortions," Doc. 49-3 ¶ 4.4 See N.Y. State Rifle & Pistol Ass'n, 140 S. Ct. at 1526. Indeed, the Revised Guidance goes even further by making clear that 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.

Plaintiffs acknowledge that the appropriate standard for mootness where a challenged policy is replaced with a new policy is whether the new policy gives the plaintiffs the "precise relief" they requested. Doc. 57 at 12 (quoting Franciscan All., Inc. v. Becerra, 47 F.4th 368, 374 (5th Cir. 2022)). But they additionally contend that defendants must also show that "it is absolutely clear that the conduct [causing the injury] cannot reasonably be expected to recur." Doc. 57 at 11 (quoting Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc., 528 U.S. 167, 170 (2000)). That standard—the voluntary cessation doctrine—typically is inapplicable where, as here, plaintiffs challenge a former government policy that has been replaced by a new policy. See, e.g., Daves v. Dallas Cnty., 64 F.4th 616, 634 (5th Cir. 2023); see also N.Y. State Rifle & Pistol Ass'n., 140 S. Ct. at 1526. Further, the Fifth Circuit has made clear that to the extent the doctrine applies, it applies differently to the government than to private actors. See, e.g., Moore v. Brown, 868 F.3d 398, 406-07 (5th Cir. 2017) (a "government entity ... bears a lighter burden to prove that challenged conduct will not recur."). "[T]he government's ability to reimplement the [policy] at issue is insufficient to prove the voluntary-cessation exception [to mootness]." Freedom From Religion Found., Inc. v. Abbott, 58 F.4th 824, 833 (5th Cir. 2023).

In Franciscan Alliance, cited by plaintiffs, Doc. 57 at 11–12, the Fifth Circuit held that the plaintiffs' challenge to the agency's 2016 rule regarding Section 1557 was moot due to the 2020 rule that rescinded the 2016 rule. Franciscan All., Inc., 47 F.4th at 374–77. The 2020 Rule replaced the challenged rule and thus gave Franciscan Alliance the remedy they sought through their APA action.

<sup>&</sup>lt;sup>4</sup> Although plaintiffs' Proposed Order includes a request for permanent injunctive relief, Doc. 49-3¶4, they have not briefed the relevant factors for such relief, and thus have not pursued such relief. *See* Section III.E, *infra*.

Id. So too here, by voiding and replacing the July 2022 Guidance with the Revised Guidance, OCR has provided plaintiffs "the precise relief that [plaintiffs] requested." See id. (quoting N.Y. State Rifle & Pistol Ass'n, 140 S. Ct. at 1526). Plaintiffs' "claim for declaratory and injunctive relief with respect to the . . . old [guidance] is therefore moot." N.Y. State Rifle & Pistol Ass'n, 140 S. Ct. at 1526.

### B. Plaintiffs Fail to Establish Standing at This Stage in the Litigation

As the parties invoking federal jurisdiction, plaintiffs bear the burden of establishing standing. Lujan v. Defs. of Wildlife, 504 U.S. 555, 561 (1992). The elements of standing (injury, causation, and redressability) "are not mere pleading requirements but rather an indispensable part of the plaintiff's case," and at each stage of the litigation "each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." Id. Plaintiffs' contention that they need not demonstrate standing at the summary judgment stage because "the Court has already found standing" at the motion to dismiss stage, Doc. 57 at 2, ignores this well-settled principle. As defendants explained in their opening brief: at summary judgment, plaintiffs "can no longer rest on . . . mere allegations" to establish standing, "but must set forth . . . specific facts' that adequately support" standing. Doc. 55 at 11 (quoting California v. Texas, 141 S. Ct. 2104, 2117 (2021), which in turn quoted Clapper v. Annesty Int'l USA, 568 U.S. 398, 411–12 (2013)).

Defendants' opening brief analyzed the Bentley and Martian declarations submitted by plaintiffs with their opening brief (Docs. 49-1 and 49-2), and explained why they fail to demonstrate an actual or imminent injury in fact. Doc. 55 at 12–14. Plaintiffs ignore this too. Plaintiffs make no attempt to counter defendants' observations that 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. 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. 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. Neither declaration shows that plaintiffs have been the subject of an OCR investigation or enforcement action or that they face a substantial likelihood of future enforcement for failure to fill prescriptions for medications that could cause abortions. They fail to establish that the pharmacy guidance injures their actual operations. Defendants respectfully refer the Court to defendants' opening brief for a full analysis of the deficient evidence submitted by plaintiffs. See Doc. 55 at 12–14. In sum, plaintiffs fail to meet the standard for showing pre-enforcement injury at the summary judgment stage because they do not show that based on their specific conduct "the likelihood of future enforcement is 'substantial." California, 141 S. Ct. at 2114 (quoting Susan B. Anthony List v. Driehaus ("SBA List"), 573 U.S. 149, 164 (2014)).

Likewise, plaintiffs fully ignore the OCR closure letter that defendants attached as Exhibit 1 to their opening brief, Doc. 55-1. Defendants submitted this letter to show OCR's practice of complying with RFRA. The letter, sent from OCR to a religious hospital, communicated OCR's decision to close a discrimination investigation involving the hospital. As is its practice, OCR evaluated the discrimination complaint "in light of [OCR's] responsibilities under the Religious Freedom Restoration Act (RFRA)." *Id.* at 2. 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 "Section 1557's prohibition on sex discrimination as applied to the facts of [that] complaint was [not] the least restrictive means of achieving the government's compelling interest," and therefore, OCR closed the investigation against the hospital. *Id.* 

In the case at bar, plaintiffs accuse OCR of offering a "mere promise to comply with RFRA"—a promise that plaintiffs call "empty." Doc. 57 at 5. But it is both OCR's policy and its practice to comply with RFRA, as the OCR closure letter shows and defendants' opening brief demonstrated. Doc. 55 at 13–14 (citing OCR pronouncements across three separate presidential administrations, including the current administration).

Instead of relying on evidence at this stage—and indeed ignoring the evidence proffered by defendants—plaintiffs continue to push speculation and conjecture. They assert that the pharmacy guidance "forces Texas pharmacies to choose between compliance with state law and potential enforcement actions by HHS, which could have the effect of bankrupting pharmacies." Doc. 57 at 17–18. But as discussed above and in defendants' opening brief, the evidence submitted by plaintiffs does not demonstrate that Texas pharmacies are in fact forced to make such a choice. This is particularly so given that the Revised Guidance reiterates that the pharmacy guidance does not oblige pharmacies to fill prescriptions for medication in violation of State laws. Relying on an unpublished, out-of-district, district court decision from 2022, Texas advances a theory that Texas has standing based on a "sovereign interest." Id. (citing Texas v. Yellen, No. 2:21-cv-79, 2022 WL 989733, at \*5 (N.D. Tex. March 4, 2022). This theory is not legitimate, as the Supreme Court found in 2023 when rejecting Texas's attempt to advance this same theory in Haaland v. Brackeen, 599 U.S. 255, 295 (2023). Texas must still demonstrate a "concrete' and 'particularized' invasion of a legally protected interest' necessary to establish an 'injury in fact." Id. (quoting Lujan, 504 U.S. at 560); see also 599 U.S. at 295 ("Were it otherwise, a State would always have standing to bring constitutional challenges."). Texas has not done so here.

Nor has Mayo. It is not enough that a plaintiff is subject to a policy; the plaintiff must demonstrate a harm from that policy that can be redressed. *See California*, 141 S. Ct. at 2115. Mayo "stock[s] and dispense[s] the drugs methotrexate and misoprostol for non-abortion purposes, [but]

does not dispense such drugs for abortion purposes." Doc. 14 ¶ 45. This approach appears consistent with the pharmacy guidance, which describes examples of methotrexate and misoprostol used for non-abortion purposes. Doc. 52-1 at 3-4. Moreover, the Revised Guidance explicitly states that it "does not require pharmacies to fill prescriptions for medication for the purpose of abortion." Id. at 1. And the Revised Guidance includes specific reference to Federal religious freedom and conscience statutes (including RFRA), indicating that these protections will be considered on a case-by-case basis as they arise. Id. at 5. Plaintiffs' opposition brief indicates that Mayo specifically objects to medication treatment of ectopic pregnancies, see Doc. 57 at 4 (quoting the ectopic pregnancy example in the Revised Guidance); see also id. at 6, 19, 21 (all presenting a limited objection to using methotrexate to treat ectopic pregnancies),<sup>5</sup> and the Martian declaration states that Mayo objects "to instances where methotrexate is dispensed in the situation of an ectopic pregnancy where the baby's life has not been confirmed to have expired," Doc. 49-2 ¶ 10. But Mayo does not aver that it has ever been asked to dispense these drugs under this specific circumstance, nor does it provide a reason to think Mayo will likely be put in this position in the future. See supra at 13 (discussing Martian declaration). This is insufficient to show actual injury. To meet the test for pre-enforcement standing, Mayo needs to show a "credible threat," SBA List, 573 U.S. at 159, that OCR would penalize Mayo for refusing to dispense methotrexate to treat ectopic pregnancy on the basis of its religious objection. Mayo fails to make that showing particularly in light of the Revised Guidance's language regarding RFRA, Doc. 52-

\_

<sup>&</sup>lt;sup>5</sup> The pharmacy guidance's example regarding ectopic pregnancies describes a situation where an "ultrasound indicates the fertilized egg is growing in a fallopian tube" and a "medical provider orders methotrexate to halt the ectopic pregnancy." Doc. 52-1 at 4. The Revised Guidance notes that "[i]f a pharmacy refuses to fill the prescription because it will halt the growing of cells and end the ectopic pregnancy, it may be discriminating on the basis of sex." *Id.* Mayo's brief refers to this as a "methotrexate mandate," Doc. 57 at 5, but it is not a mandate. It merely describes a situation that *may* be sex discrimination, while not reaching a conclusion on that point for any given factual scenario and additionally indicating that where a provider asserts a religious objection such objection will be considered on a case-by-case basis, as RFRA requires. *See* Doc. 52-1 at 4, 5. The Revised Guidance also mentions methotrexate in its example regarding rheumatoid arthritis, *id.* at 4, but Mayo presents no specific objection to that example.

1 at 5; HHS's consistent acknowledgment that the agency must abide by RFRA when enforcing civil rights laws<sup>6</sup>; and HHS's actual practice in that regard, *see* Doc. 55-1 (OCR letter closing discrimination investigation into a religious hospital based on application of RFRA).

Finally, plaintiffs' assertion of a procedural injury merely because they could not comment on the pharmacy guidance before it was issued is "insufficient to create Article III standing," Louisiana by & through Landry v. Biden, 64 F.4th 674, 683 (5th Cir. 2023) (quoting Summers v. Earth Island Institute, 555 U.S. 488, 496 (2009)), as defendants demonstrated in their opening brief, Doc. 55 at 17. Plaintiffs cite Texas v. Equal Employment Opportunity Commission, to support their procedural-injury standing theory. Doc. 57 at 19 (citing 933 F.3d 433, 447 (5th Cir. 2019)). But that Fifth Circuit case was decided before the more recent Supreme Court case of Department of Education v. Brown, which clarified when a procedural injury can establish standing. The Supreme Court explained that "when a statute affords a litigant 'a procedural right to protect his concrete interests,' the litigant may establish Article III jurisdiction without meeting the usual 'standards for redressability and immediacy." 600 U.S. 551, 561 (2023). By way of example, the Court pointed to the National Environmental Policy Act's environmental impact statement procedural requirement that provides a procedural right to a person before a federal facility may be constructed next door to that person's house. Id. (citing Lujan, 504 U.S. at 572). The Court emphasized that "[r]egardless of the redressability showing [it] ha[s] tolerated in the procedural-rights context," the Supreme Court has "never held a litigant who asserts such a right is excused from demonstrating that it has a 'concrete interest that is affected by the deprivation' of the claimed right." 600 U.S. at 562. Consistent with this observation, the Court pointed to its prior

<sup>&</sup>lt;sup>6</sup> See, e.g., 45 C.F.R. § 92.6(b) ("Insofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided . . [], the Religious Freedom Restoration Act (42 U.S.C. 2000bb et seq.), . . [] or any related, successor, or similar Federal laws or regulations, such application shall not be imposed or required"); Nondiscrimination in Health Programs & Activities, 87 Fed. Reg 47,824 47,886 (Aug. 4, 2022) (notice of proposed rulemaking) ("OCR is thus committed to complying with RFRA and all other legal requirements").

decision in *Summers*, where it had held that failure to follow the APA's notice-and-comment rulemaking procedures was insufficient on its own to establish Article III standing. *Id.* (citing *Summers*, 555 U.S. at 497). The *Brown* case also involved claims for insufficient notice-and-comment under the APA—and as in *Summers*—the Supreme Court held that plaintiffs did not establish standing based solely on the agency's failure to provide opportunity for public comments. 600 U.S. at 567–69.

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

Although this Court determined in its motion to dismiss decision that the July 2022 Guidance constituted final agency action, Doc. 44 at 18–22, defendants have respectfully requested that the Court reconsider its determination in light of the revision of the guidance, which provides additional indicia that the July 2022 Guidance was nonfinal. If, as defendants contend, the pharmacy guidance does not constitute final agency action, then the Court lacks jurisdiction under the APA to entertain a challenge to the guidance. 5 U.S.C. § 704; *Peoples Nat'l Bank v. Off. of Comptroller of Currency of U.S.*, 362 F.3d 333, 336 (5th Cir. 2004).

An agency's characterization of its own action is one of several factors the Court should consider to determine whether an action is final agency action, *National Minining Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (Kavanaugh, J.). The Fifth Circuit has instructed that courts should "give some deference" (albeit "not overwhelming" deference) to the agency's characterization of its own action. *Texas v. United States*, 809 F.3d 134, 171 n.125 (5th Cir. 2015), *as revised* (Nov. 25, 2015). Here, the pharmacy guidance itself states that its contents "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. To be sure, the pharmacy guidance "may signal" potential future enforcement; if so, that enforcement "can be challenged at that time," and OCR "will not be able to rely on the [pharmacy guidance] in defending" an enforcement decision.

<sup>&</sup>lt;sup>7</sup> Plaintiffs cite this case, but ignore this point. Doc. 57 at 22.

See Nat'l Min. Ass'n, 758 F.3d at 252. This weighs against a finding that the pharmacy guidance constitutes final agency action. Id.

The most important factor for determining whether agency guidance constitutes final agency action is "the actual legal effect (or lack thereof) of the agency action in question on regulated entities." *Id.* The pharmacy guidance uses conditional language like "may" to describe situations that, depending on actual factual scenarios, might constitute sex or disability discrimination. But it does not reach a final, legally binding conclusion about any of them. The guidance "is intended only to provide clarity to the public regarding existing requirements under the law or [HHS's] policies," Doc. 52-1 at 5, and thus "has no legal impact," *Nat'l Min. Ass'n*, 758 F.3d at 252, 253. The fact that the pharmacy guidance did not undergo notice-and-comment rulemaking further indicates that the guidance is non-binding and non-final. *United States v. Mississippi*, 82 F.4th 387, 393 (5th Cir. 2023). As plaintiffs acknowledge, Doc. 57 at 15–16, HHS is separately undertaking notice-and-comment rulemaking to establish binding policies regarding Section 1557. *See* 87 Fed. Reg. at 47,824.

Moreover, the July 2022 Guidance was not the agency's "last word on the matter," as the agency superseded that document with the Revised Guidance. Whitman v. Am. Trucking Ass'n, 531 U.S. 457, 478 (2001). This further indicates that the pharmacy guidance is not final agency action. See id.; Sw. Airlines Co. v. U.S. Dep't of Transp., 832 F.3d 270, 276 (D.C. Cir. 2016).

#### III. Plaintiffs' Claims Fail on the Merits

### A. Defendants' Actions Do Not Exceed Statutory Authority

As defendants showed in their opening brief, the sole basis of plaintiffs' claim that defendants' actions exceed statutory authority is their argument that the pharmacy guidance imposes a duty on

<sup>&</sup>lt;sup>8</sup> Plaintiffs incorrectly assert that the preamble of the proposed Section 1557 rule itself "constitutes guidance," Doc. 57 at 16. But they lack authority for the proposition that a proposed rule that is undergoing notice-and-comment rulemaking should itself be treated as a final rule, and instead cite to a case holding that courts can use preamble language in a *final rule* as guidance of an agency's views. *See id.* (citing *Wilgar Land Co. v. Dir., Off. of Workers' Comp. Programs*, No. 22-cv-3709, 2023 WL 7145340 at \*5 (6th Cir. Oct. 31, 2023)).

pharmacies to dispense medication for the purpose of abortion. Because the pharmacy guidance imposes no such duty, plaintiffs fail to show that defendants exceeded statutory authority. Doc. 55 at 19–25.

Plaintiffs' opposition brief confirms that their statutory authority claim hinges solely on a purported requirement to dispense drugs for purposes of abortion. Plaintiffs argue that the Revised Guidance exceeds statutory authority because it "attempts to codify a legal duty to stock and dispense abortion-inducing drugs," and that such a duty exceeds statutory authority because Congress did not "confer HHS with authority to require pharmacies to stock and dispense abortion-inducing drugs." Doc. 57 at 23. But for the reasons explained in this brief and defendants' opening brief, the pharmacy guidance does not impose such a requirement. *See supra*; Doc. 55 at 14–16, 19–25.9

Plaintiffs distort the meaning of the Revised Guidance in contending that it requires pharmacies "to dispense all lawfully prescribed medications," which plaintiffs assert includes "all abortion drugs," based on OCR's purported "view that all abortions are 'lawful." Doc. 57 at 23. The Revised Guidance notes that OCR is responsible for protecting people "in their ability to access care that is free from discrimination," which "includes their ability to access lawfully prescribed medication from their pharmacy free from discrimination." Doc. 52-1 at 3. But this does not mean that pharmacies must dispense all lawfully prescribed medication, only that pharmacies must not engage in discrimination when dispensing lawfully prescribed medication. Indeed, the Revised Guidance makes clear that pharmacies are permitted to make suitability determinations (which includes the ability to make determinations that a prescription is not suitable for a patient) provided they do not

<sup>&</sup>lt;sup>9</sup> Because the pharmacy guidance does not impose a requirement on pharmacies to fill prescriptions for medications for abortions, the Court need not and should not address whether such a requirement would implicate the major questions doctrine. *See* Doc. 57 at 24 (citing *West Virginia v. EPA*, 142 S. Ct. 2587, 2609 (2022)).

do so on a basis prohibited by civil rights laws such as Section 1557 or Section 504. *Id.* at 2.<sup>10</sup>

Furthermore, the Revised Guidance's reference to "lawfully prescribed medication" means medication that is prescribed in compliance with federal law *and* state law. If filling a prescription would violate state law, including state abortion law, then the medication was not lawfully prescribed. Nothing in either guidance document expresses or attempts to impose a "view that all abortions are 'lawful." Doc. 57 at 23. That was not the law before *Dobbs* and it is not the law after *Dobbs*. Plaintiffs' assertion that the Revised Guidance requires pharmacies to dispense all medications for abortion (even when prohibited by state law) cannot be squared with the guidance's unambiguous language stating 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.

Beyond plaintiffs' incorrect argument that the pharmacy guidance imposes an abortion mandate, plaintiffs do not argue or show that the pharmacy guidance exceeds statutory authority in any way. Because plaintiffs' statutory authority arguments rest on a mischaracterization of the pharmacy guidance, this claim fails, and the Court should grant summary judgment to defendants.

#### B. Notice And Comment Procedures Were Not Required

The pharmacy guidance was not required to go through notice and comment because it is not a substantive rule or legislative rule creating new obligations with the force of law. Rather, it explained OCR's view of preexisting obligations under the federal civil rights laws. Therefore, to the extent the pharmacy guidance is any kind of a rule, it is an interpretive rule exempt from notice and comment. Doc. 55 at 25–28.

Plaintiffs concede that two of the five factors articulated by the Fifth Circuit for identifying

<sup>&</sup>lt;sup>10</sup> For example, a federally funded pharmacy would clearly engage in discrimination prohibited by Section 1557 if it determined on the basis of racial animus that certain medications were unsuitable for patients of certain races.

legislative rules, see Mock v. Garland, 75 F.4th 563, 580 (5th Cir. 2023), weigh against the conclusion that the guidance required notice and comment, because defendants "did not publish the guidance in the Code of Federal Regulations or cite *Chevron* deference." Doc. 57 at 28. Plaintiffs' arguments that the other three factors weigh in favor of classifying the guidance as a legislative rule are unpersuasive.

First, plaintiffs are incorrect that defendants "intended to speak with the force of law." Doc. 57 at 27 (quoting Mock, 75 F.4th at 580). Plaintiffs reason that the guidance must intend to carry the force of law because it discusses "obligations" and contains mandatory language. Doc. 57 at 27. But the Fifth Circuit has "reject[ed] the proposition that a rule cannot be interpretive if it . . . uses binding language." Flight Training Int'l, Inc. v. Fed. Aviation Admin., 58 F.4th 234, 242 (5th Cir. 2023). That is because "interpretive rules explain what an agency thinks a statute or regulation actually says." Id. "If the law is mandatory, then it is natural for an agency's restatement of the law to speak in mandatory terms as well." Id. On its face, the pharmacy guidance does not impose obligations, but rather describes OCR's interpretation of obligations that are imposed under the civil rights laws. It "covers the nondiscrimination obligations of pharmacies under federal civil rights laws." Doc. 52-1 at 1 (emphasis added). It identifies the specific statutes—Section 1557 and Section 504—that obligate federally funded pharmacies not to discriminate on the basis of sex or disability, id. at 2, before describing circumstances in which a pharmacy's refusal to dispense non-abortion medication "may be discriminat[ion] on the basis of disability" or "sex" in violation of those statutes, id. at 3-4. Plaintiffs argue that the pharmacy guidance cannot be an interpretation of Section 1557 and Section 504 because those statutes purportedly do not "contain" the "obligation[s]" described in the pharmacy guidance. Doc. 57 at 28. But that is not an argument that the pharmacy guidance does not interpret federal civil rights laws. Rather, it is an argument that the pharmacy guidance's interpretation of federal civil rights

laws is incorrect.11

Further showing that the guidance is not intended to speak with the force of law, the guidance states that it "do[es] not have the force and effect of law" and "is intended only to provide clarity to the public regarding existing requirements under the law." *Id.* at 6. Although plaintiffs are correct that this disclaimer is not dispositive, it is afforded "some deference," *Professionals & Patients for Customized Care v. Shalala*, 56 F.3d 592, 595 (5th Cir. 1995). Here, the text and structure of the pharmacy guidance is consistent with and reinforces the disclaimer's statement that the guidance describes OCR's view of existing legal requirements rather than purporting to impose new requirements.

Second, plaintiffs are incorrect that "HHS 'explicitly invoke[d] its general legislative authority" in the guidance. Doc. 57 at 28 (quoting Mock, 75 F.4th at 580). Plaintiffs cite no invocation of HHS's or OCR's legislative authority, and cite only the guidance's reference to "enforcement" of civil rights laws. Doc. 57 at 28; see Doc. 52-1 at 2. But an agency's enforcement authority is not its general legislative authority. Enforcement authority is the authority to enforce the law (i.e., require someone to obey a law or impose consequences for violation of the law), while an agency's general legislative authority is the authority to promulgate regulations carrying the force of law. See Enforce, Black's Law Dictionary (11th ed. 2019) ("[t]o give force or effect to (a law, etc.); to compel obedience to"); Legislate, Black's Law Dictionary (11th ed. 2019) ("[t]o make or enact law"). That OCR cited its authority to enforce existing laws but not its authority to promulgate new rules reinforces that the pharmacy guidance is interpretive, not legislative.

Third, plaintiffs fail to show that "the guidance[] 'will produce significant effects on private interests." Doc. 57 at 28 (quoting *Mock*, 75 F.4th at 580). Plaintiffs argue that the pharmacy guidance

<sup>&</sup>lt;sup>11</sup> For the reasons stated above, plaintiffs' arguments that the pharmacy guidance describes obligations that go beyond Section 1557 and Section 504 are incorrect. *See supra*, Part III.A.

significantly affects private interests because it "now requires dispensing all lawfully prescribed medications," Doc. 57 at 29, which plaintiffs construe to include medications for abortion, Doc. 57 at 23, but that interpretation of the pharmacy guidance is incorrect. *See supra*. And as shown above, none of the pharmacies involved in this case (Mayo and the Texas Tech pharmacies) show that they are injured by the pharmacy guidance. *See supra*, Part II.B.

In sum, the pharmacy guidance did not need to go through notice and comment because it describes existing obligations under OCR's interpretation of preexisting law but does not purport to impose new legal obligations carrying the force of law.

#### C. The Pharmacy Guidance Is Not Arbitrary and Capricious

Plaintiffs fail to show that the pharmacy guidance is arbitrary and capricious. Plaintiffs' closing brief confirms that their arguments supporting this claim hinge on the premise that the pharmacy guidance purportedly "gut[s] the State's authority to regulate abortion." Doc. 57 at 30. But the pharmacy guidance does not do so. To the contrary, it makes absolutely clear 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." Doc. 52-1 at 2. Therefore, the pharmacy guidance cannot be arbitrary and capricious for failing to adequately explain a supposed abortion "mandate," Doc. 57 at 30, or for failing to justify a supposed "change in position" to impose such a mandate, *id.* at 29–30, for it imposes no such mandate.

#### D. The Pharmacy Guidance Does Not Violate the Spending Clause

OCR did not violate the Spending Clause by issuing guidance that interprets the federal civil rights laws that clearly and unambiguously require recipients of federal funding not to discriminate on the basis of sex or disability. Doc. 55 at 30–32. Texas does not dispute that it is well established under Supreme Court and Fifth Circuit case law that federal civil rights laws that condition federal funding on a requirement not to discriminate are valid exercises of Congress's Spending Clause power. *Id.* at

30–31. Nor does Texas offer any basis to conclude that OCR violated the Spending Clause by interpreting the scope of federally funded pharmacies' obligations not to discriminate on the basis of sex or disability under Section 1557 and Section 504, which are undisputedly valid Spending Clause statutes.

Texas argues that the pharmacy guidance violates the Spending Clause because it purportedly "require[s]" pharmacies "to provide . . . an abortion," and requires pharmacies "to violate state law[]" as a condition of federal funding. Doc. 57 at 25, 26. But as explained above, Texas misinterprets the pharmacy guidance. *See supra*. The Revised Guidance 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.

Texas gets no further in arguing that the pharmacy guidance violates the Spending Clause because Section 1557 and Section 504 do not contain language "requir[ing] [pharmacies] to stock or dispense any specific drug at all." Doc. 57 at 24.<sup>12</sup> These statutes unsurprisingly do not contain specific language about drugs and pharmacies because they are general civil rights laws prohibiting discrimination on the basis of sex and disability. Furthermore, the pharmacy guidance does not require federally funded pharmacies to stock or dispense any drug in all circumstances, but it does explain that under certain circumstances, withholding prescribed medication may constitute discrimination. That

Doc. 52-1 at 3.

<sup>&</sup>lt;sup>12</sup> To the extent Texas contends that the pharmacy guidance purports to require pharmacies to stock or dispense misoprostol for "use in medication abortion," Doc. 57 at 24, that is incorrect. The example in the pharmacy guidance cited by Texas addresses prescriptions of misoprostol to treat chronic stomach ulcers:

An individual experiences severe and chronic stomach ulcers, such that their condition meets the definition of a disability under civil rights laws. Their gastroenterologist prescribes misoprostol to decrease risk of serious complications associated with ulcers. If the pharmacy refuses to fill the individual's prescription or does not stock misoprostol because of its alternate uses, it may be discriminating on the basis of disability.

is correct. For example, it would almost surely constitute unlawful discrimination if a federally funded pharmacy adopted a general practice of dispensing methotrexate to men who needed the drug to treat rheumatoid arthritis, but not to non-pregnant women who needed the drug to treat rheumatoid arthritis.

Texas misconceives the Spending Clause inquiry by suggesting that it violates the Spending Clause to apply a federal civil rights law in a circumstance that is not expressly listed in the text of the statute. "Congress is not required to list every factual instance in which a state will fail to comply with a condition. Such specificity would prove too onerous, and, perhaps, impossible. Congress must, however, make the existence of the condition itself—in exchange for the receipt of federal funds—explicitly obvious." *Benning v. Georgia*, 391 F.3d 1299, 1307 (11th Cir. 2004) (quoting *Mayneathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002)). Section 1557 and Section 504 unambiguously condition federal funding on nondiscrimination obligations, and OCR did not violate the Spending Clause by describing those obligations.

#### E. Plaintiffs Have Not Established Entitlement to a Permanent Injunction

In their opposition brief, plaintiffs indicate that notwithstanding the Revised Guidance, they continue to seek a permanent injunction "enjoining HHS from imposing [what plaintiffs call 'an abortion pharmacy mandate'] in the future with or without notice and comment." Doc. 57 at 2; see also id. at 30. Plaintiffs have made no attempt, however, to meet the standard for obtaining such equitable relief. As discussed above and in defendants' opening brief, the Court should deny plaintiffs' motion and enter judgment in favor of defendants. Yet were the Court to conclude—contrary to defendants' arguments—that plaintiffs are entitled to summary judgment, the Court should limit their relief to "hold[ing] unlawful and set[ting] aside" the pharmacy guidance as to Mayo Pharmacy and any state-owned pharmacies in Texas that establish injury from the guidance. See 5 U.S.C. § 706(2).

Equitable remedies, including injunctions, "are typically affirmatively sought and 'obtained

when available legal remedies . . . cannot adequately redress the injury." W & T Offshore, Inc. v.

Bernhardt, 946 F.3d 227, 240 (5th Cir. 2019) (quoting Equitable Remedy, Black's Law Dictionary (10th

ed. 2014)). Here, plaintiffs have not attempted to explain why the legal remedies available under § 706

of the APA would be insufficient. Nor have they made any attempt to brief the factors relevant to

the appropriateness of injunctive relief. Thus, the Court should decline to assess the appropriateness

of injunctive relief. See, e.g., Neese v. Becerra, 640 F. Supp. 3d 668, 684 (N.D. Tex. 2022) (declining to

assess injunctive relief where plaintiffs did not brief the relevant factors). "It is not the court's job to

divine the applicable law for the parties,' nor is it the Court's job 'to manufacture every possible

argument [the plaintiffs] could conceivably make." Id. at 684-85 (quoting Spencer v. Texaco, Inc., No.

96-cv-0228, 1996 WL 363540, at \*2 (E.D. La. June 28, 1996)); Holz v. United States, No. 3:09-cv-1568,

2009 WL 10704725, at \*2 n.4 (N.D. Tex. Sept. 29, 2009); see also, e.g., eBay Inc. v. MercExchange, L.L.C.,

547 U.S. 388, 391(2006) (detailing injunction requirements).

CONCLUSION

For the above-stated reasons, and those discussed in defendants' opening brief, Doc. 55, 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.

Dated: November 17, 2023

Respectfully submitted,

BRIAN M. BOYNTON

Principal Deputy Assistant Attorney General

MICHELLE R. BENNETT

Assistant Director, Federal Programs Branch

/s/ Lisa Zeidner Marcus

LISA ZEIDNER MARCUS (N.Y. Bar # 4461679)

JEREMY S.B. NEWMAN (D.C. Bar. # 1024112)

Trial Attorneys

U.S. Department of Justice, Civil Division

Federal Programs Branch

27

# 

1100 L St., NW, Twelfth Floor Washington, DC 20530 Tel: (202) 514-3336 Fax: (202) 616-8470 lisa.marcus@usdoj.gov

Counsel for Defendants

#### **Certificate of Service**

I certify that on November 17, 2023, I served the foregoing Defendants' Reply in Support of Motion for Summary Judgment and Supplemental Opposition to Plaintiffs' Motion for Summary Judgment via the Court's CM/ECF system upon plaintiffs via their counsel as follows:

Ryan L. Bangert
Alliance Defending Freedom
Resaca Plaza
11701 FM2244
Bee Cave, TX 78738
Email: rbangert@adflegal.org
Counsel for Plaintiff Mayo Pharmacy

Matthew S. Bowman Alliance Defending Freedom 440 First Street NW, Suite 600 Washington, DC 20001 Email: mbowman@adflegal.org Counsel for Plaintiff Mayo Pharmacy

Andrea Regan Dill Alliance Defending Freedom 440 First Street NW Washington, DC 20001 Email: adill@adflegal.org Counsel for Plaintiff Mayo Pharmacy Amy Snow Hilton
Office of the Attorney General of Texas
P.O. Box 12548, Capital Station
Austin, TX 78711-2548
Email: amy.hilton@oag.texas.gov
Counsel for Plaintiff the State of Texas

Christopher D. Hilton
Office of the Attorney General of Texas
P.O. Box 12548, Capital Station
Austin, TX 78711-2548
Email: christopher.hilton@oag.texas.gov
Counsel for Plaintiff the State of Texas

William D. Wassdorf
Office of the Attorney General of Texas
P.O. Box 12548, Capital Station
Austin, TX 78711-2548
Email: will.wassdorf@oag.texas.gov
Counsel for Plaintiff the State of Texas

/s/ Lisa Zeidner Marcus LISA ZEIDNER MARCUS (N.Y. Bar # 4461679) JEREMY S.B. NEWMAN (D.C. Bar. # 1024112)

Counsel for Defendants