UNITED STATES DISTRICT COURT
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-22-DC

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

This Court held that Plaintiffs have standing for their APA claims. Dkt. 44 at 18. Therefore, the test for the Court's continued jurisdiction, which Defendants (HHS) challenge, is not simple standing, but the significantly "higher" bar of mootness. *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 376 n.40 (5th Cir. 2022) (citation omitted). HHS "cannot automatically moot a case simply by ending its [allegedly] unlawful conduct once sued." *Id.* at 376. Instead, HHS must show it is "absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." *Id.* (quoting *Freedom From Religion Found. v. Abbott*, 955 F.3d 417, 425 (5th Cir. 2020)).

Here, the opposite is clear. As discussed in Plaintiffs' Supplemental Brief, the Revised Guidance continues to impose obligations on Plaintiffs' discretion to dispense drugs, make

suitability determinations, and end a growing unborn life, and it does so in violation of their right to notice and comment. Moreover, HHS continues to insist in every other surrounding element of this smurfed policy that it is committed to using sex and disability discrimination laws to mandate "access" to abortion. HHS did not repent of the plain abortion advocacy this Court correctly acknowledged was this mandate's intent. It did not eliminate that advocacy from the executive order or the press announcement for the Revised Guidance, and HHS's other guidance and statements imposing Section 1557 insist on using its enforcement authority to promote abortions. HHS merely tweaked this guidance in an attempt to barely moot this case, and failing at even that. Far from being "not reasonably [] expected to recur," the Revised Guidance already purports to override Texas law and force Mayo to end growing unborn lives.

With standing to challenge the original mandate, Plaintiffs were entitled to a Court order holding it "unlawful" for HHS to impose an abortion pharmacy mandate on them, and enjoining HHS from imposing such a mandate in the future with or without notice and comment. Plaintiffs are still entitled to that relief, because the Revised Mandate does not come close to giving Plaintiffs "the precise relief that petitioners requested." *Franciscan All.*, 47 F.4th at 374 (quoting *New York State Rifle & Pistol Ass'n, Inc. v. City of New York*, 140 S. Ct. 1525, 1526 (2020)).

I. Plaintiffs have Standing.

HHS contends that Plaintiffs "fail to demonstrate an actual or imminent injury in fact." Dkt. 55 at 12. This is not the standard. Since the Court has already found standing, the higher burden of mootness is what HHS must show. HHS has failed that burden.

A. The Revised Guidance injures Plaintiffs.

The Revised Guidance fails to give Plaintiffs the precise relief they requested or make it absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur. *Franciscan All.*, 47 F.4th at 376. The Revised Guidance imposes the same kinds of obligations on Plaintiffs after denying them notice and comment, and the Revised Guidance leaves its abortion context in place, affirming rather than repudiating HHS's commitment to impose pharmacy abortion mandates.

1. The Revised Guidance imposes obligations without notice and comment.

The Revised Guidance continues to impose unlawful obligations on Plaintiffs' regulated pharmacies. It even creates new and broader obligations of the same kind. Thus it does "not moot the case;" it merely "repeals the challenged action and replaces it with something substantially similar." *Franciscan All.*, 47 F.4th at 374. For this reason, Plaintiffs' claims against both the original and revised guidances remain live.

a. Restrictions on advising and making suitability determinations.

The Revised Guidance continues to burden pharmacy advice and suitability determinations. This Court already held its restriction on speech and on the exercise of professional duty imposes an injury. Dkt. 44 at 11. The Revised Guidance similarly stipulates 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 of civil rights laws. Dkt. 52-1 at 3.

HHS characterizes this as a retraction, but the text shows the opposite: it is simply a rephrasing of the same obligation. It does not walk back HHS OCR's position that it is "discrimination" under Section 1557 to raise concerns about dispensing drugs because they might cause abortion. For example, in another document issued shortly after *Dobbs*, HHS OCR says in the preamble of a pending proposed rule under Section 1557 that the law prohibits "termination of pregnancy discrimination," and OCR refuses to incorporate Title IX's statutory abortion-non-coercion clause into that proposal.[1] The Revised Guidance separately claims not to require "dispensing" drugs for abortion purposes, but that caveat conspicuously fails to say the guidance does not restrict giving advice and making suitability determinations based on a drug's possible abortion effects. The Revised Guidance is therefore a "substantially similar" mandate for mootness purposes. *Franciscan All.*, 47 F.4th at 374.

b. Requiring methotrexate to end a growing unborn life.

The Revised Guidance continues to oblige the Plaintiffs to dispense methotrexate to "halt" a pregnancy and end "the growing of cells." Dkt. 52-1 at 5. "The ultrasound indicates the fertilized egg is *growing* in a fallopian tube." *Id.* (emphasis added). Which is to say, the baby is still alive. Mayo Pharmacy specifically objected to this obligation. *See, e.g.*, Dkt. 49-2 ¶ 10, 17–18; Dkt. 49 at 15–16. The Revised Guidance therefore injures Mayo. In Texas, the removal of an ectopic pregnancy is not an abortion. Tex. Health & Safety Code § 245.002(1)(C). But this mandate nevertheless injures state sovereignty because it preempts state laws that give pharmacists "the exclusive authority to determine whether or not to dispense a drug." Tex. Occ. Code § 551.006.

[1] Nondiscrimination in Health Programs and Activities 87 Fed. Reg. 47,824, 47,844, 47,878–79 (Aug. 4, 2022).

Texas law also protects pharmacists' conscientious objections. *See* Tex. Occ. Code § 103.001. Preempting state laws injures the state. *Texas v. Becerra*, 623 F. Supp. 3d 696, 713 (N.D. Tex. 2022) (citing various cases). By keeping its methotrexate mandate, the Revised Guidance imposes "substantially similar" obligations as the original, and does not moot Plaintiffs' claims. *Franciscan All.*, 47 F.4th at 374.

HHS contends that its vague reference to the Religious Freedom Restoration Act (RFRA) somehow negates this obligation on Mayo, but that objection fails. HHS does not say religious pharmacies will be exempt—it says the opposite, reserving judgment "on a case-by-case basis." Dkt. 52-1 at 6. HHS's mere promise to comply with RFRA is empty because RFRA is a balancing test, which in some cases, lets the government coerce entities if it pursues a compelling interest by a least restrictive means. 42 U.S.C. § 2000bb-1. Mayo contends this mandate would fail RFRA, but here HHS reserves the ability to argue that RFRA *lets it* coerce Mayo. The reasonable expectation is that HHS will do exactly that—deny RFRA exemptions—since it retained this mandate and did not even exempt Mayo specifically, even after knowing Mayo's objection.

The Fifth Circuit has already held that when HHS OCR issues an abortion mandate under Section 1557 and merely nods vaguely towards RFRA, this fails to negate standing. In *Franciscan Alliance* OCR did exactly this, and with respect to RFRA merely said "it 'has not to date evaluated' whether it will enforce Section 1557 against" the plaintiffs. 47 F.4th at 376. "[I]n other words," the court concluded, HHS "concedes that it may." *Id.* The court of appeals held that HHS failed to negate standing because plaintiffs were "within the 'class whose [conduct] is arguably restricted,' and the defendant's promise was so vague that the scope of liability was both 'unknown by the [defendant] and unknowable to those regulated by it.'" *Id.* at 377 (quoting *Speech First, Inc.*

v. Fenves, 979 F.3d 319, 338 (5th Cir. 2020)). Likewise Mayo, and Texas pharmacists whose judgment is protected by state law, are obligated by the Revised Guidance's methotrexate mandate, and HHS's promise merely to comply with RFRA is so vague they cannot know whether they are in violation. The Fifth Circuit has "repeatedly" found standing in the face of "similar prosecutorial indecision." *Id.* at 376.

c. Requirement to dispense all "lawfully prescribed medication."

The Revised Guidance imposes a new legal obligation not found in the original: requiring pharmacies to dispense all "lawfully prescribed medication." Dkt. 52-1 at 4. The "rights of women and pregnant people in their ability to access care that is free from discrimination . . . includes their ability to access lawfully prescribed medication from their pharmacy free from discrimination. . . . Denying lawfully prescribed medication to customers can have negative health effects and may violate civil rights laws." *Id.*

This obligation does not exist in Sections 1557 or 504 (the laws on which HHS relies). Those laws ban sex and disability discrimination; they do not create an obligation to dispense all lawful medications. This is particularly important because in additional OCR guidance cited in the Revised Mandate, Dkt. 52-1 at 6, OCR takes an expansive view that *all abortion drugs are legal* because HHS agrees with *Roe* and its progeny.[2] The dates on these documents and HHS's reliance on them shows HHS maintains this view even after *Dobbs*. Replacing a mandate to dispense abortion drugs with a mandate to dispense all lawful medication, combined with the official view

[2] *Id.* (citing "Guidance on Nondiscrimination Protections under the Church Amendments" (Feb. 3, 2023) ("this includes abortions that are 'lawful' under federal law. Decades of precedent make clear that it is unconstitutional for a state to prohibit a patient from ending a pregnancy prior to fetal viability."), https://www.hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html.

that all abortion drugs are lawful, does not produce mootness—it "repeals the challenged action and replaces it with something substantially similar." *Franciscan All.*, 47 F.4th at 374. This mandate, too, infringes on Texas law reserving to pharmacists the right to determine whether or not to dispense a drug. Tex. Occ. Code § 551.006. Mayo, in turn, insists on its conscientious judgment and professional duty in deciding which drugs to dispense because of the potential effect on the patient including the unborn child. Dkt 49-2 ¶¶ 13–18.

2. The Revised Guidance unsuccessfully attempts to rewrite history.

The Revised Guidance also fails to negate the abortion obligations imposed by the original guidance because, as this Court held, these guidances cannot be taken "in isolation"—they must be interpreted within the guidance's overwhelming abortion-advocacy context. *See* Dkt. 44 at 13. HHS rolled out the original pharmacy mandate in "separate, seemingly unrelated and innocent pieces," including the press announcement, and the Executive Order.[3] Dkt. 44 at 2. HHS removed abortion from *none* of those other "pieces," and kept most of the Revised Guidance's connection to them. This is important because it answers the question in the negative, whether it is "absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur" in order to meet HHS's high burden to show mootness. *Franciscan All.*, 47 F.4th at 376.

The Revised Guidance fails to disavow this context or disclaim that HHS has "accomplished what President Biden[] . . . wanted to accomplish," Hearing Transcript 15:8–11,—namely, "to protect healthcare service delivery and promote access to critical reproductive healthcare services, including abortion." Executive Order, 87 Fed. Reg. at 42,053 (defining

[3] Executive Order 14,076, Protecting Access to Reproductive Healthcare Services, 87 Fed. Reg. 42,053 (July 13, 2022).

"reproductive healthcare" as including "the termination of a pregnancy"). Even though the Revised Guidance deletes its reference to *Dobbs* and "comprehensive reproductive health care," it is still accompanied by a press announcement now "updated 9/29/23".[4] That document still says it derives from the Executive Order, insists on the goal of ensuring access to "comprehensive reproductive health care," declares the Revised Guidance "includes access to prescription medications for reproductive health," and frames it alongside "actions HHS has taken in the days following the Supreme Court's ruling to ensure access to reproductive health care." *Id.*

HHS also attached several items purportedly establishing the "administrative record" in a further attempt to rewrite the history of this mandate. Dkt. 54. As cited in the separately filed Plaintiffs' Objections to Defendants' Notice of Administrative Record, this record is vastly underinclusive because it omits all the abortion-specific sources that are *explicitly* cited in the original *and revised* guidances and press announcements. These documents further dispel the notion that this guidance was or is only about conditions such as arthritis. These include:

- Executive Order 14,076.
- *Dobbs v. Jackson Women's Health Organization*, 2022 WL 2276808 (U.S. June 24, 2022), cited in the original guidance and referenced in both press announcements.
- HHS's ReproductiveRights.gov website, cited in the original and revised guidance press announcements. This website is overwhelmingly about abortion, and says reproductive health care includes access to abortion.
- "Remarks by Secretary Xavier Becerra at the Press Conference in Response to President Biden's Directive following Overturning of *Roe v. Wade*," insisting on access

[4] Dkt. 53-1 at 3.

to "medication abortion" "to the fullest extent possible," and ordering OCR "to ensure . . . nondiscrimination for patients seeking reproductive health care."[5]

- Multiple statements from OCR, cited in these guidances' press announcements, and insisting that access to abortion is part of access to reproductive health care services and that OCR considers all abortions "legal" despite state law and *Dobbs*.[6]
- Multiple other documents cited in both guidance press announcements, in which HHS declares that reproductive health services includes abortion access.[7]

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[5] https://www.hhs.gov/about/news/2022/06/28/remarks-by-secretary-xavier-becerra-at-the-press-conference-in-response-to-president-bidens-directive-following-overturning-of-roe-v-wade.html.

[6] HHS OCR, "Guidance on Nondiscrimination Protections under the Church Amendments" (insisting all abortions are "lawful"), https://www.hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html; HHS OCR's "Guidance to Protect Patient Privacy in Wake of Supreme Court Decision on Roe" (June 29, 2022) ("Secretary Xavier Becerra called on HHS agencies to take action to protect access to sexual and reproductive health care, including abortion"), https://www.hhs.gov/about/news/2022/06/29/hhs-issues-guidance-to-protect-patient-privacy-in-wake-of-supreme-court-decision-on-roe.html; HHS OCR, "HIPAA Privacy Rule and Disclosures of Information Relating to Reproductive Health Care" (June 29, 2022) ("Access to comprehensive reproductive health care services, including abortion care, is essential to individual health and well-being."), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/phi-reproductive-health/index.html.

[7] HHS, "Readout: Secretaries Becerra, Walsh meet with health insurers, employee benefit plan stakeholders to discuss birth control coverage" (Jun 27, 2022) ("Women's ability to control their reproductive health care include[es] abortion."), https://www.hhs.gov/about/news/2022/06/27/readout-secretaries-becerra-walsh-meet-with-health-insurers-employee-benefit-plan-stakeholders-to-discuss-birth-control-coverage.html; HHS, "HHS Announces New Grants to Bolster Family Planner Provider Training" (June 30, 2022) (characterizing abortion as "reproductive health care"), https://www.hhs.gov/about/news/2022/06/30/hhs-announces-new-grants-to-bolster-family-planner-provider-training.html; HHS, "Following President Biden's Executive Order to Protect Access to Reproductive Health Care, HHS Announces Guidance to Clarify that Emergency Medical Care Includes Abortion Services" (July 11, 2022) https://www.hhs.gov/about/news/2022/07/11/following-president-bidens-executive-order-protect-access-reproductive-health-care-hhs-announces-guidance-clarify-that-emergency-medical-care-includes-abortion-services.html; HHS, "Readout of Secretary Becerra's call with Governors in Wake of Supreme Court Decision on Roe" (June 30, 2022),

3. The Revised Guidance continues to threaten enforcement.

In its Motion, HHS fails to give weight to the fact that both guidances invite people to file complaints against pharmacies they believe are violating its terms. ("If you believe that your or another person's civil rights . . . have been violated, visit the OCR complaint portal to file a complaint online."). As HHS cites, "[a]ny person who believes himself or any specific class of individuals to be subjected to discrimination . . . may by himself or by a representative file with the responsible Department official or his designee a written complaint." Dkt. 55 at 3; 45 C.F.R. § 80.7(b). Upon receipt of a complaint, the "Department official or his designee will make a prompt investigation," including "the circumstances under which the possible noncompliance . . . occurred." *Id*. at § 80.7(c).

As the Supreme Court has held, a threat of enforcement "is bolstered by the fact that authority to file a complaint with the Commission is not limited to a prosecutor or agency" but that "'any person' with knowledge of the purported violation" may file a complaint. *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 164 (2014). "[L]ike arrest or prosecution," "administrative action . . . may give rise to harm sufficient to justify pre-enforcement review." *Id.* at 165.

4. The Revised Guidance's disclaimer is insufficient.

HHS contends the Revised Guidance's disclaimer that it "does not require pharmacies to fill prescriptions for medication for the purpose of abortion" disproves Plaintiffs' injuries. Dkt. 52-1 at 2–3; Dkt. 55 at 5. This argument ignores the fact that the Revised Guidance stipulates that it

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https://www.hhs.gov/about/news/2022/06/30/readout-of-secretary-becerras-call-with-governors-in-wake-of-supreme-court-decision-on-roe.html; HHS, "HHS Secretary Becerra's Statement on Supreme Court Ruling in Dobbs v. Jackson Women's Health Organization" (June 24, 2022), https://www.hhs.gov/about/news/2022/06/24/hhs-secretary-becerras-statement-on-supreme-court-ruling-in-dobbs-v-jackson-women-health-organization.html.

imposes "[o]bligations," and specifically imposes the ones described above. Dkt. 52-1 at 2–4. Despite HHS's protestations to the contrary, the Revised Guidance still requires the provision of "reproductive health care services,"—*i.e.*, abortion drugs according to Secretary Becerra and the Executive Order—on threat of enforcement action. With few changes from the original, the Revised Guidance retains the examples of situations in which HHS would exercise "vigorous enforcement of our civil rights laws." Dkt. 52-1 at 3. Like the Original Guidance, the Revised Guidance requires pharmacies to dispense methotrexate to a woman with rheumatoid arthritis, regardless of whether the woman is pregnant, and it threatens enforcement actions against pharmacies that do not fill prescriptions for or stock misoprostol. Dkt. 52-1 at 3–5.

Several of HHS's other changes are cosmetic. In Example 1, HHS replaced "mifepristone" and "misoprostol," an abortion regimen, with the word "medication"—but kept the obligation to dispense it. Dkt. 52-1 at 4. This makes no difference for the duty imposed on pharmacies because HHS considers those drugs to be medications. The Revised Guidance also continues to mandate stocking and dispensing misoprostol despite its abortion uses. *Id.* at 4. As this Court has previously held, "[t]ry as they might, Defendants cannot obscure the temporal and thematic relationship between the Pharmacy Guidance and the executive branch's policy goal." Dkt. 44 at 8.

II. Plaintiffs' claims are not moot.

HHS does not clear the high bar that mootness requires. Courts can only find an injury moot "where it is *absolutely clear* that the conduct [causing the injury] cannot reasonably be expected to recur. . . . The heavy burden of persuading the court that the challenged conduct cannot reasonably be expected to recur lies with the party asserting mootness." *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 170 (2000); *see also Franciscan All.*, 47 F.4th

at 376. This is a "stringent" requirement. *Tucker v. Gaddis*, 40 F.4th 289, 293 (5th Cir. 2022). "When a challenged rule is replaced with a new rule, the case is moot so long as the change gives the precise relief that petitioners requested. The change will not moot the case if the government repeals the challenged action and replaces it with something substantially similar." *Franciscan All.*, 47 F.4th at 374. (internal quotation marks omitted).

HHS contends the Original Guidance is defunct, but since the Revised Guidance fails to meet the mootness standard, Plaintiffs are still entitled to receive the original relief they requested to enjoin the Original Guidance's revival, to hold the Revised Guidance's similar obligations unlawful, and to set it aside.

A. HHS's disclaimer does not meet the "absolutely clear" mootness test.

HHS's Motion hinges almost entirely on the disclaimers in the Revised Guidance. As discussed above, this disregards both the Revised Guidance's own "obligations," imposed on Plaintiffs unlawfully and sustaining their APA challenges, and the Revised Guidance's failure to eliminate *any* of the abortion mandate context still referenced in the panoply of other documents the administration issued as part of the smurfing effort that promulgated the Original Mandate.

HHS's Motion also fails to seriously engage with the examples that continue to be listed in the Revised Guidance. Those examples make clear that the disclaimers do not apply, at the least, to the situations described within them. *See, e.g.*, *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (recognizing that the specific governs the general). They still constitute obligations on Plaintiffs. The Revised Guidance also invites people to make complaints about potential non-compliance with its terms, and HHS's Motion offers no assurance that Plaintiffs would not be subject to OCR's burdensome and costly investigations for refusing to stock

or fill abortion-inducing drugs. *See generally* Dkt. 55; *see also Tucker*, 40 F.4th at 293 ("But the government has not even bothered to give Tucker any assurance that will permanently cease engaging in the very conduct that he challenges."). "At this juncture, we cannot say the past is dead; we cannot even say it is past." *Zuckerman v. USPS*, 961 F.3d 431, 445 (D.C. Cir. 2020).

The Supreme Court has "treated the threat of future enforcement as case-and fact-specific, understanding that evaluating threats against our most cherished rights cannot be neatly reduced to a rigid formula. Different factors are weighed accordingly per the case-specific facts." *Braidwood Mmgt., Inc. v. EEOC*, 70 F.4th 914, 928 (5th Cir. 2023) (internal citation omitted); *see also Gulf Pub. Co., Inc. v. Lee*, 679 F.2d 44, 46 (5th Cir. 1982). In light of the higher burden needed for HHS to establish mootness now that the Court already held Plaintiffs have standing, this case-specific analysis shows Plaintiffs continue to face a credible threat of enforcement from HHS.

If there were any doubt that the Revised Guidance still threatens Plaintiffs, the context in which the Revised Guidance makes clear that Plaintiffs must stock and dispense abortion-inducing drugs without regard to state law or conscience rights. Despite HHS's improper attempt to erase history from the administrative record, the Revised Guidance is not written on a clean slate. Both guidances were issued in response to President Biden's Executive Order No. 14,076. Dkt. 14-1 (HHS press release announcing the Original Guidance); Dkt. 53-1 (HHS press release announcing the Revised Guidance). That Executive Order was promulgated in direct response to "a decision by the Supreme Court to overrule *Roe v. Wade*, 410 U.S. 113 (1973))." *Executive Order on Securing Access to Reproductive and Other Healthcare Services*, The White House, https://www.whitehouse.gov/briefing-room/presidential-actions/2022/08/03/executive-order-

on-securing-access-to-reproductive-and-other-healthcare-services/ (Aug. 3, 2022) (attached as Exh. 1).

The President specifically noted that "it remains the policy of my Administration to support women's access to reproductive healthcare services, including their ability to travel to seek abortion care in States where it is legal." *Id.* HHS's press release announcing the issuance of the Guidance "following President Biden's Executive Order ensuing access to reproductive health care" is still on its website.[8] The press release details the Revised Guidance, advertising it as "the latest step in HHS' response to protect reproductive health care." *Id.* It includes the Revised Guidance as part of a "list of actions HHS has taken in the days following the Supreme Court's ruling [in *Dobbs*] to ensure access to reproductive health care." *Id.* And in the hearing on HHS's Motion to Dismiss, HHS told the Court that HHS "believe[d] that they accomplished what President Biden's executive order wanted to accomplish with the guidance." Hearing Transcript at 15:8–11.

Now, in their briefing to this Court, HHS says it was not its "objective" to "ensure[] access to 'medication abortion' and 'reproductive healthcare services.'" Dkt. 55 at 24. This is a *post hoc* litigation rationale designed to evade judicial review. *See Yarls v. Bunton*, 905 F.3d 905, 910 (5th Cir. 2018) ("Essentially, the goal is to [decide] whether the defendant's actions are 'litigation posturing' or whether the controversy is actually extinguished.").

[8] Dkt. 53-1; *see also HHS Issues Guidance to the Nation's Retail Pharmacies Clarifying Their Obligations to Ensure Access to Comprehensive Reproductive Health Care Services*, U.S. Dep't of Health & Human Servs., https://www.hhs.gov/about/news/2022/07/13/hhs-issues-guidance-nations-retail-pharmacies-clarifying-their-obligations-ensure-access-comprehensive-reproductive-health-care-services.html (July 13, 2022) (last visited Nov. 2, 2023).

HHS has not given any assurance that it will never conduct investigations of Texas pharmacies or Mayo for failing to fill prescriptions for abortion-inducing drugs, or for "lawfully prescribed medication" generally (which OCR says it interprets to mean all abortion drugs). The Revised Guidance continues to burden pharmacies' provision of advice and making of suitability determinations concerning abortion drugs, a requirement that is not affected at all by the caveat not to require *dispensing* abortion drugs. HHS includes the Revised Guidance among the Biden Administration's list of "actions HHS has taken in the days following the Supreme Court's ruling" in *Dobbs* "to ensure access to *reproductive health care*"—not, as HHS adamantly maintains in its Motion, to ensure access to drugs to treat rheumatoid arthritis.[9] HHS's attempt to whitewash the Guidance's context does not render Plaintiffs' claims moot—particularly when the Revised Guidance is substantially similar to the Original Guidance as discussed above.

Both the Original Guidance and the Revised Guidance invoke Section 1557 of the Affordable Care Act as the basis for the mandates' prohibition on "discrimination" against "pregnant people." Dkt. 52-1 at 3. In its Motion, HHS notes that OCR is charged with enforcing Section 1557, which "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 . . . sex." Dkt. 55 at 12. In a footnote, HHS advises the Court that "HHS has issued a proposed rule to revise OCR's current regulations implementing Section 1557." *Id.* at 12 n.1. That proposed rule is also important context, because when OCR issued it in the same post-*Dobbs* context of this mandate, OCR took the view that Section 1557's prohibition on sex

[9] *Compare* Dkt. 53-1 at 1–3, *with* Dkt. 55 at 15–16, 32–33.

discrimination prohibits "termination of pregnancy" discrimination. 87 Fed. Reg. at 47,878–79. The proposed rule preamble therefore constitutes guidance that OCR continues to believe what it said in the Original Guidance—that Section 1557 requires pharmacies to dispense abortion drugs. *See Wilgar Land Co. v. Dir., Off. of Workers' Comp. Programs*, 2023 WL 7145340 at *5 (6th Cir. Oct. 31, 2023) (courts can use preamble language to a rule as guidance of the agency's view). Combined with the Original and Revised Guidances, HHS cannot meet the mootness standard to show it is "clear" that it will not revise the guidance yet again to impose a broader abortion drug dispensing mandate.

B. Courts do not permit bureaucratic gamesmanship to negate standing.

The Court should not let HHS game the system to avoid judicial review. The Supreme Court has held that unilateral bureaucratic changes do not moot a case or prevent the court from issuing injunctive relief. Like the Governor of New York in *Roman Cath. Diocese of Brooklyn v. Cuomo*, HHS "argue[s] that we should withhold relief because the relevant circumstances have now changed," and "would deny relief at this time but allow the [plaintiffs] to renew their requests if this recent reclassification is reversed." 141 S. Ct. 63, 68 (2020). But "[t]here is no justification for that proposed course of action." *Id.* HHS "regularly changes the classification . . . without prior notice." *Id.* This Guidance was issued and revised merely by HHS posting it to its website with no public comment process. When a bureaucracy gives itself power to move the goalposts, the court should not allow it to avoid judicial review. Once [t]he applicants have made the showing needed to obtain relief, [] there is no reason why they should bear the risk of suffering further irreparable harm in the event of another reclassification." *Id.* at 68–69.

This Court is "not required to exhibit a naivete from which ordinary citizens are free." *Dep't of Comm. v. New York*, 139 S. Ct. 2551, 2575 (2019) (quoting *United States v. Stanchich*, 550 F.2d 1294, 1300 (2d Cir. 1977)). An agency that violates its notice and comment duties by unilaterally posting mandates on its website should not receive the presumption that it will not do so again tomorrow just because it partially changed that website again. By making only cosmetic changes to the Revised Guidance, HHS is attempting to remove abortion from the interpretive context of the mandate, even as it maintains that view in every ancillary source still connected to the mandate.

HHS should not be allowed to evade judicial review in this way. "If defendants could eject plaintiffs from court on the eve of judgment, then resume the complained of activity without fear of flouting the mandate of a court, plaintiffs would face the hassle, expense, and injustice of constantly relitigating their claims without the possibility of obtaining lasting relief." *Sossamon v. Lone Star State of Tex.*, 560 F.3d 316, 324 (5th Cir. 2009). Taking the Original Guidance, proposed rule preamble, and Revised Guidance together, it is clear that OCR's settled position is that it will interpret and enforce the Rehabilitation Act and Section 1557 to include discrimination on the basis of pregnancy.

C. The Revised Guidance harms Texas.

HHS contends that Texas lacks an injury, because Texas Tech's declaration does not "establish[] that [it] ha[s] been forced to change [its] operations in any way as a result of the pharmacy guidance." Dkt. 55 at 7. That argument misses the mark. Texas has also asserted a sovereign injury. The Revised Guidance deprives pharmacies of their "exclusive authority to determine whether or not to dispense a drug." Tex. Occ. Code § 551.006. And it forces Texas

pharmacies to choose between compliance with state law and potential enforcement actions by HHS, which could have the effect of bankrupting pharmacies. Texas's sovereignty is injured by "putting them to that choice." *Texas v. Yellen*, 2022 WL 989733, at *5 (N.D. Tex. March 4, 2022) (quotation marks omitted). "If TTUHSC's retail pharmacies fail to comply with the Pharmacy Mandate, it could result in the significant loss of federal funds," requiring "the School of Pharmacy to allocate funds from other funding sources . . . and could result in closing the pharmacies." Dkt. 49-1 at 3; *see also Braidwood*, 70 F.4th at 926 ("Without resolution, potential penalties hang over plaintiffs' heads like Damocles's sword."). Texas has standing to assert claims against HHS when the Guidance encourages pharmacies "to deviate from state law when it conflicts with the Guidance" for the purpose of avoiding liability. *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019).

HHS further contends that Texas lacks standing because Texas Tech has not evidenced an intent to engage in activity proscribed by the Guidance. Dkt. 55 at 21. But "[t]he Supreme Court does not require plaintiffs challenging the constitutionality of a law to 'confess that [they] will in fact violate the law.'" *Yellen*, at *6 (quoting *Driehaus*, 573 U.S. at 163). "If a plaintiff is subject to the threat of enforcement, 'an actual . . . enforcement action is not a prerequisite to challenge the law.'" *Id.* (citing *Driehaus*, 573 U.S. at 158). What's more, Texas challenges the Guidance as violative of the Spending Clause, and "[p]re-enforcement standing [in] Spending Clause cases is common." *Id.* (citing *NFIB v. Sebelius*, 567 U.S. 519, 542 (2012); *New York v. United States*, 505 U.S. 144, 171–72 (1992); *South Dakota v. Dole*, 483 U.S. 203, 205–06 (10987)).

As this Court has already recognized, "Texas has clearly indicated that it intends to enforce its state laws and prevent Texas pharmacies from dispensing the drugs for abortion purposes." Dkt. 44 at 4, 15. "Texas's sovereign policy-making and enforcement powers have been impeded"

by the Guidance's threats. *Texas v. Becerra*, 2023 WL 2754350, at *7 (N.D. Tex. March 31, 2023). "It is not necessary that petitioner first expose himself to actual arrest or prosecution to be entitled to challenge a statute that he claims deters the exercise of his constitutional rights." *Steffel v. Thompson*, 415 U.S. 452, 459 (1974).

D. The Revised Guidance does not moot Mayo's injury at all.

This Court has already held that Mayo has standing to bring this suit. HHS advances two arguments against Mayo's standing, but neither meet HHS's high burden to show mootness.

HHS seems to suggest that the disclaimer about not requiring drugs to be dispensed for abortion purposes removes Mayo's injury. But aside from the discussion above showing that in context that mandate is still reasonably likely to occur, even the Revised Guidance on its own terms continues to impose the requirement that Mayo dispense methotrexate to end a growing unborn life. This alone forces Mayo to do something it objects to doing, sustaining its injury. Mayo objects to the mandate's requirement to dispense methotrexate, and its desire to preserve its advising and making determinations about the suitability of medications for patients. *See, e.g.*, Dkt 49-2 ¶ 10, 17–18; Dkt. 49 at 15–16. The fact that HHS once again omitted notice and comment also imposes a procedural injury on Mayo. *Texas v. EEOC*, 933 F.3d 433, 441 (5th Cir. 2019).

The Revised Guidance includes a nominal reference to RFRA, but as discussed above this fails to help Mayo or demonstrate mootness. In addition to the fact that *Franciscan Alliance* precludes a finding of mootness from HHS's vague promise about RFRA, under which it reserves the right to coerce Mayo anyway, HHS's approach improperly suggests that regulated entities must wait until they suffer enforcement actions and findings of violation before they may sue. This is incorrect. Mayo need not wait for HHS to bring an action against it so it can raise a RFRA

defense—this would read an exhaustion requirement into RFRA where none exists. *Patsy v. Bd. of Regents of Fla.*, 457 U.S. 496, 516 (1982) (holding that exhaustion of state administrative remedies in a Section 1983 claim is not required); *Doster v. Kendall*, 54 F.4th 398, 415 (6th Cir. 2022). (applying *Patsy* in holding that no exhaustion requirement should be read into RFRA). Mayo "likely can challenge a religiously discriminatory policy without receiving a formal" decision by the regulator. *Id.* at 417. Plaintiffs need not "wait[] for [the agency] to 'drop the hammer' in order to have their day in court." *U.S. Army Corps of Engineers v. Hawkes Co., Inc.*, 578 U.S. 590, 600 (2016); *accord Sackett v. EPA*, 556 U.S. 120 (2012). A generic promise to comply with the law in future enforcement action by government officials, where the government reserves the right to conclude that *coercion is legal*, is no barrier to Mayo's right to sue under the APA.

HHS also claims Mayo lacks standing because it has not cited a history of enforcement against religious pharmacies. But Mayo is not required to plead a pattern of past practice of enforcement of this mandate by HHS against religious pharmacies. The pharmacy mandate is new. Shallow enforcement history should be given little weight where the guidances were only recently released. See *Online Merchants Guild v. Cameron*, 995 F.3d 540 (6th Cir. 2021) (finding a lack of significant history of enforcement during a state of emergency is not dispositive). This family of mandates are less than two years old, and HHS does not publish files showing its ongoing investigations. Limited enforcement history of such a new policy cannot negate HHS's enforcement threat. *See Kay Elec. Co-op. v. City of Newkirk, Okla.*, 647 F.3d 1039, 1045 (10th Cir. 2011) (it is not "the place of a court to say" desuetude applies to a 14-year-old law); *Rhode Island Ass'n of Realtors, Inc. v. Whitehouse*, 199 F.3d 26, 32 (1st Cir. 1999) (rejecting desuetude argument against a law "only twenty years" old).

The Revised Guidance encourages private parties to file complaints with HHS OCR, and HHS has acknowledged many women had already done so in its press release concerning enforcement against CVS and Walgreens. *See* Dkt. 44 at 17. In *Kentucky v. Yellen*, a "credible threat" was established based solely upon a letter indicating an agency's intent to enforce penned by the Secretary of that agency but where no actual enforcement had begun. 54 F.4th 325, 337 (6th Cir. 2022). The Revised Guidance promises vigorous enforcement, and directly forces Mayo to dispense methotrexate to end a growing unborn life. This is a live injury.

III. The Original and Revised Guidances violate the APA.

Because HHS has not established mootness, Plaintiffs' claims run against both guidances, and they both violate the APA for similar reasons. The Court already held Plaintiffs are injured by the Original Guidance, and that suffices to support summary judgment for Plaintiffs to prevent any pharmacy abortion mandate as exceeding HHS's statutory authority, and to prevent the progeny of this anti-*Dobbs* guidance from being construed or reissued without notice and comment. "Plaintiffs are reasonably worried about the implications" of the Guidance, and "[t]hey are entitled to receive clarification from this court before stifling their constitutional practices or otherwise exposing themselves to punishment or enforcement action. That is a core purpose of a declaratory judgment." *Braidwood*, 70 F.4th at 927–28.

A. Both Guidances constitute final agency action.

Both Guidances constitute final agency actions subject to review under the APA. *See Texas v. EEOC*, 933 F.3d at 441 (explaining that agency action treated as binding is reviewable as final agency action). The Revised Guidance "has the effect of committing the agency itself to a view of the law that, in turn, forces the plaintiff either to alter its conduct, or expose itself to potential

liability." *Louisiana State v. United States Army Corp of Engineers*, 834 F.3d 574, 581 (5th Cir. 2016). As detailed above and in Plaintiffs' Supplemental Brief, the Revised Guidance includes several provisions that create new legal obligations and threaten substantial legal and monetary penalties. Dkt. 53.

This Court's analysis concluding that the Original Guidance is final agency action and that Plaintiffs have no alternative remedy applies to both guidances. Dkt. 44 at 19–22. The Revised Guidance is no less a consummation of agency deliberation. HHS's own motion depicts it as a reconsideration of the agency's position in light of this Court's order and a repromulgation of its view. *See, e.g.*, Dkt. 55 at 1. The Revised Guidance also imposes "the chilling threat of legal consequences," Dkt. 44 at 20, maintaining its insistence on "vigorous enforcement," Dkt. 52-1 at 3, and as discussed above, maintaining its posture of announcing "obligations." This is a threat of liability for failure to comply with its demands. *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (Kavanaugh, J.). And it is still the case that being able to object to enforcement after the fact is an inadequate remedy for a claim that a rule was illegally promulgated. Dkt. 44 at 21–22 (discussing *Hinojosa v. Horn*, 896 F.3d 305, 311 (5th Cir. 2018), and *Sackett*, 566 U.S. at 127). Leaving Plaintiffs to be targeted by enforcement also fails to remedy their notice and comment violation. The Court should decline HHS's invitation to reconsider its well-reasoned conclusion on these points. *See* Dkt. 55 at 18.

Though framed as guidance reminding pharmacies of only existing obligations, the agency's characterization of its own action is not dispositive. *McCarthy*, 758 F.3d at 252 (D.C. Cir. 2014) (Kavanaugh, J.); *Texas v. United States*, 787 F.3d at 764 (explaining that an agency's characterization of its own action as "guidance" or a "policy statement" is not determinative).

There is no pre-existing authority that imposes the obligation to dispense abortion-inducing drugs, or all lawfully prescribed medications, nor to restrict advising and making suitability determinations in relation to abortion concerns, nor to require pharmacies to dispense methotrexate to end a growing unborn life. The Guidances are not mere reminders. The Revised Guidance still constitutes one fulfillment of Secretary Becerra's promise to pull "every lever we have to protect access to abortion care." Dkt. 44 at 22 (citation omitted).

B. The Revised Guidance exceeds statutory authority and is not in accordance with law.

1. The Revised Guidance lacks statutory authority.

The Revised Guidance attempts to codify a legal duty to stock and dispense abortion-inducing drugs, and all lawfully prescribed medication, as an openly political reaction against *Dobbs*. The Revised Guidance offers only two statutory bases for its mandates: Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act. Dkt. 52-1 at 3. These laws prohibit discrimination; they do not prohibit pharmacy qualms about abortion, or make pharmacies into vending machines to dispense all lawfully prescribed medications. In its Motion, HHS does not contest that these statutes make no reference to abortion or to a broad requirement to dispense all lawfully prescribed medications. *See generally* Dkt. 55. Much less does HHS show that Congress gave it authority to impose OCR's view that all abortions are "lawful" — because HHS agrees with *Roe* and disagrees with *Dobbs*—and therefore pharmacies must dispense all abortion drugs as a consequence of the alleged obligation to dispense all lawfully prescribed medications. If Congress intended to confer HHS with authority to require pharmacies to stock and dispense abortion-inducing drugs, or all lawfully prescribed medication, even where State law either prohibits such dispensation or leaves it to pharmacists' own judgment, Congress would have spoken clearly on

that subject. *See West Virginia v. EPA*, 597 U.S. --, 142 S. Ct. 2587, 2609 (2022). HHS's promulgation of both iterations of the Pharmacy Mandate exceeds their statutory authority and should be set aside.

2. The Revised Guidance violates Texas' constitutional prerogatives.

The Revised Guidance is "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

The legitimacy of an exercise of the federal spending power "rests on whether the State voluntarily and knowingly accepts the terms of the 'contract.'" *Id.* at 577 (citing *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981)). The Revised Guidance threatens the withdrawal of federal funds against pharmacies who, for example, "do[] not stock misoprostol because of its" use in medication abortion. Dkt. 52-1 at 4. This is a condition on federal funds that is not imposed by any of the statutes Defendants invoke as the basis for their authority to promulgate the conditions of the Revised Guidance. This point is uncontested. *See* Dkt. 55 at 41. Defendants instead offer two reasons why they contend the Revised Guidance does not violate the Spending Clause, neither of which is persuasive. First, Defendants contend the Revised Guidance simply reiterates the federal prohibitions on discrimination on the bases of sex and disability. Dkt. 55 at 39. Second, Defendants contend the Revised Guidance does not require pharmacies to violate state law. Dkt. 55 at 41. None of the statutes on which Defendants rely require pharmacies to stock or dispense abortion-inducing drugs—or require them to stock or dispense any specific drug at all. And as explained above, the Revised Guidance still threatens Plaintiffs with investigations and enforcement actions if they fail to stock or dispense these drugs.

Defendants' reliance on Section 1557 of the ACA is futile. The ACA specifically rejects Defendants' interpretation of discrimination on the basis of sex: "Nothing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions." 42 U.S.C. § 18023(c)(1). Defendants also rely on Title IX's prohibition of discrimination on the basis of sex. But Title IX's prohibition of discrimination on the basis of sex does not extend to pregnancy discrimination, *see, e.g.*, *Franciscan Alliance, Inc. v. Becerra*, 47 F.4th 368, 374 (5th Cir. 2022), and Title IX specifically prohibits persons and entities from being required to "provide or pay for any benefit or service, including the use of facilities, related to an abortion." 20 U.S.C. § 1688. Nor does Section 504 of the Rehabilitation Act require pharmacies to stock or dispense any particular drug.

The Spending Clause confers Congress the authority to "lay and collect Taxes, Duties, Imposts, and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States." U.S. Const. art. I, § 8, cl. 1. While "Congress may exercise its spending power to incentive States to follow federal policies," it may not "use this authority to cross the line between persuasion and compulsion." *Yellen*, at *7 (citing *Coll. Savings Bank v. Fla. Prepaid Postsecondary Ed. Expense Bd.*, 527 U.S. 666, 686 (1999) and *Dole*, 483 U.S. at 207–08. The Supreme Court has recognized that when the federal government threatens to withhold Medicaid funding, as it does here, it has "crossed the line distinguishing encouragement from coercion." *Sebelius*, 567 U.S. at 579–80 (internal quotation marks omitted).

"[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so unambiguously." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 16 (1981). "There can, of

course, be no knowing acceptance if a State is unaware of the conditions or is unable to ascertain what is expected of it." *Id.* Texas could not have ascertained that its pharmacies could only receive Medicaid and Medicare funding if they agreed to violate state law—and Defendants do not dispute this. *See generally* Dkt. 55. While "Spending Clause programs do not pose [a] danger when a State has a legitimate choice whether to accept the federal conditions in exchange for federal funds," where, as here, there are *billions* of dollars at stake[10], Texas does not "have a genuine choice." *Sebelius*, 567 U.S. at 578, 588. The remedy for this constitutional violation is to preclude HHS from imposing this condition. *See id.* at 588.

C. HHS violated the APA in not subjecting the Guidances to notice and comment.

Both guidances impose obligations on Plaintiffs. As such, HHS *should* have complied with all of the APA's substantive provisions when promulgating each. *E.g., Sierra Club v. U.S. E.P.A.*, 939 F.3d 649, 663 (5th Cir. 2019). "[C]ourts have long looked to the *contents* of the agency's action, not the agency's self-serving *label*, when deciding whether statutory notice-and-comment demands apply." *Texas v. United States*, 50 F.4th 498, 522 (5th Cir. 2022) (emphasis in original) (internal quotation marks omitted). For reasons similar to the Court's analysis of the Original Guidance's imposition of determining "rights or obligations," Dkt. 44 at 18–19, the Guidances are also substantive or legislative rules that needed to be subjected to public notice and an opportunity to comment. *See also* Dkt. 49 at 14–15 (explaining why the Original Guidance is a legislative rule).

As discussed above, the Revised Guidance continues to impose specific obligations not

[10] Financial Management Report for FY 2022, *Expenditure Reports from MBES/CBES*, MEDICAID.GOV, available at https://www.medicaid.gov/medicaid/financial-management/state-expenditure-reporting-for-medicaid-chip/expenditure-reports-mbescbes/index.html (last visited Nov. 3, 2023).

found in Sections 1557 and 504 on which the Revised Guidance relies. These including restricting advise and suitability determinations, mandating dispensation of all lawfully prescribed medications, and mandating dispensing methotrexate to end a growing unborn life. Dkt. 52-1 at 3–5. HHS suggests that the Revised Guidance sufficiently softens the language surrounding these mandates to make them non-binding, but that is not convincing. The document is replete with "obligations" language, insisting pharmacies "may not" discriminate, specifies the abortion context and examples of those obligations, insists on "vigorous enforcement," and that HHS is "committed" to "ensuring nondiscriminatory access." *Id.* at 2–3.

HHS argues that the Revised Guidance is not a legislative rule and therefore not subject to notice and comment under *Mock v. Garland*, 75 F.4th 563, 580 (5th Cir. 2023). Dkt. 55 at 27–28. The opposite is true. Both guidances meet the relevant factors for being a legislative rule subject to notice and comment. In them, HHS "intended to speak with the force of law" by examination of the "language actually used by the agency." *Mock*, 75 F.4th at 580 (quoting *Cargill v. Barr*, 502 F. Supp. 3d 1163, 1184 (W.D. Tex. 2020)). Even in the Revised Guidance, HHS titled it as imposing "Obligations," and repeats its intent to impose "obligations" in the body of the document. Dkt. 52-1 at 1–2. The Revised Guidance also directs that pharmacies "may not" advise and make suitability determinations in ways it considers impermissible. *Id.* at 3. HHS repeats the same ominous threat of "vigorous enforcement" that this Court observed in concluding that the original guidance-imposed requirements. *Id.* Both guidances are therefore framed using "prospective, binding language." *Mock*, 75 F.4th at 581 (quoting *Cargill*, 502 F. Supp. 3d at 1184). Furthermore, by "provid[ing] specific information" about how to comply and not to comply, *id.*

at 580–81, in this case through examples including one mandating the dispensation of methotrexate, HHS further indicated its intent to speak with the force of law.

HHS labels this effort as merely reminding pharmacies of obligations, rather than imposing them. But "we are not bound by an agency's classification of its action." *Mock*, 75 F.4th at 580. The statutes cited—Sections 1557 and 504—contain no obligation to dispense abortion drugs as found in the original guidance, nor an obligation to dispense all lawful medications, restrict one's advice and suitability determinations, nor an obligation to dispense methotrexate to end a growing unborn life. These are new, and HHS cites no statutory language containing those mandates. Consequently the Court should reject HHS's conclusory label.

Although HHS did not publish the guidance in the Code of Federal Regulations or cite *Chevron* deference, HHS "explicitly invoke[d] its general legislative authority," *Mock*, 75 F.4th at 580. It centrally relies on Sections 1557 and 504 and its "enforcement" authority, Dkt. 52-1 at 3, just as the instrument found to be a rule in *Mock* "cites" statutes and regulations "and affirms that these provisions vest the responsibility for administering and enforcing" the underlying laws. *Mock*, 75 F.4th at 581 (cleaned up).

Finally, the guidances "will produce significant effects on private interests." *Id.* at 580 (cleaned up). As this Court held, "[t]he Pharmacy Guidance is also intended to carry the chilling threat of legal consequences." Dkt. 44 at 20. The guidance "reflects a 'settled agency position' that the entire agency intends to follow in its enforcement of its regulations, and that gives 'marching orders' to a regulated entity." *Id.* at 21 (quoting *Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1020–23 (D.C. Cir. 2000)). The Revised Guidance is no less impactful. Because it continues to contain binding language and insist on "vigorous" enforcement, it's chilling threat of

legal consequences remains. It not only continues to require dispensing methotrexate to end the growing life of a child, but now requires dispensing all lawfully prescribed medications, and continues to burden advising and making suitability determinations on drugs for patients.

Together, all of these factors show that the Revised Guidance is a rule no less than the Original Guidance was. Since there is no dispute the Guidances were not subjected to the notice and comment process, they violated Plaintiffs' rights under the APA. *See* Dkt. 49 at 14–16.

D. The Guidances are arbitrary and capricious.

Both the Original and Revised Guidance were promulgated by mere executive fiat in response to the Supreme Court decision in *Dobbs*. After the *Dobbs* decision, Secretary Becerra announced that Americans "can no longer trust" the Supreme Court, and HHS would "be aggressive and go all the way" to pushback against the Court's decision.[11] As the Fifth Circuit has held, "courts have an affirmative duty *not* to" "turn a blind eye to the statements" of those promulgating these extreme mandates. *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 614 (5th Cir. 2021) (emphasis in original). "The reasoned explanation requirement of administrative law . . . is meant to ensure that agencies offer genuine justifications for important decisions, reasons that can be scrutinized by courts and the interested public. Accepting contrived reasons would defeat the purpose of the enterprise." *Dep't of Comm.*, 139 S. Ct. at 2575–76.

The Revised Guidance does not acknowledge the agency's change in position from never having previously required pharmacies to stock and dispense abortion-inducing drugs under

[11] HHS Secretary Becerra talks women's future with abortion following Roe v. Wade decision (NBC NEWS broadcast June 25, 2022) https://www.nbcnews.com/video/women-s-future-withabortion-implementing-harm-reduction-with-addiction-142836293922, at 1:45 (last visited Nov. 3, 2023).

Section 1557 or the Rehabilitation Act; it offers no explanation of the interaction between its mandate and religious freedom and conscience laws; and it discusses no alternative approaches. It discusses no reliance interests by regulated entities or pro-life pharmacists. "Because it is generally arbitrary or capricious to depart from a prior policy *sub silentio*, agencies must typically provide a detailed explanation for contradicting a prior policy, particularly when the prior policy has engendered serious reliance interests." *BST Holdings*, 17 F.4th at 614.

HHS is hinging federal Medicare and Medicaid dollars on compliance with this mandate in an effort to subvert the Supreme Court's holding in *Dobbs* and gut the State's authority to regulate abortion. The Revised Guidance must be set aside and held unlawful.

CONCLUSION

Just as HHS attempted to smurf its original pharmacy abortion mandate, it attempts to smurf its purported walk-back of that mandate. It maintains the guidance's obligations, qualifies those only partly, and does not roll back any of the guidance's surrounding documents which continue to maintain HHS's insistence on access to medication abortion through HHS OCR's nondiscrimination authorities.

For the foregoing reasons, Plaintiffs respectfully ask the court to deny Defendants' Motion for Summary Judgment, grant Plaintiffs' Motion for Summary Judgment, and issue Plaintiffs' requested declaratory and permanent injunctive relief.

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing document was filed via CM/ECF, providing electronic service to all counsel of record.

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