Nos. 20-15398, 20-15399, 20-16045, and 20-35044

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

COUNTY OF SAN FRANCISCO, *Plaintiff-Appellee*,
v.
ALEX M. AZAR II, et al., *Defendants-Appellants*.

COUNTY OF SANTA CLARA, et al., *Plaintiffs-Appellees*,
v.
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,
Defendants-Appellants.

STATE OF CALIFORNIA, *Plaintiff-Appellee*,
v.
ALEX M. AZAR II, et al., *Defendants-Appellants*.

STATE OF WASHINGTON, *Plaintiff-Appellee*,
v.
ALEX M. AZAR II, et al., *Defendants-Appellants*.

On Appeal from the United States District Courts for the
Northern District of California and the Eastern District of Washington

ANSWERING BRIEF OF PLAINTIFFS-APPELLEES COUNTY OF SANTA CLARA, LOS ANGELES LGBT CENTER, WHITMAN-WALKER CLINIC, INC. D/B/A WHITMAN-WALKER HEALTH, BRADBURY SULLIVAN LGBT COMMUNITY CENTER, CENTER ON HALSTED, HARTFORD GYN CENTER, MAZZONI CENTER, MEDICAL STUDENTS FOR CHOICE, AGLP: THE ASSOCIATION OF LGBTQ+ PSYCHIATRISTS, AMERICAN ASSOCIATION OF PHYSICIANS FOR HUMAN RIGHTS D/B/A GLMA: HEALTH PROFESSIONALS ADVANCING LGBT EQUALITY, COLLEEN MCNICHOLAS, ROBERT BOLAN, WARD CARPENTER, SARAH HENN, AND RANDY PUMPHREY

James R. Williams
Greta S. Hansen
Laura S. Trice
Mary E. Hanna-Weir
Susan P. Greenberg
H. Luke Edwards
OFFICE OF THE COUNTY COUNSEL
COUNTY OF SANTA CLARA
70 West Hedding St., East Wing
San José, CA 95110
Tel: (408) 299-5900

Counsel for County of Santa Clara

Nicole A. Saharsky
Miriam R. Nemetz
Megan E. Stride
Peter B. Baumhart
MAYER BROWN LLP
1999 K Street NW
Washington, DC 20006
Tel: (202) 263-3000
nsaharsky@mayerbrown.com

Counsel for all Plaintiffs

(continued on inside cover)

Richard B. Katskee
Kenneth D. Upton, Jr.
AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE
1310 L Street NW, Suite 200
Washington, DC 20005
Tel: (202) 466-3234

Camilla B. Taylor
Omar Gonzalez-Pagan
LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC.
105 West Adams, 26th Floor
Chicago, IL 60603
Tel: (312) 663-4413

Genevieve Scott
Rabia Muqaddam
CENTER FOR REPRODUCTIVE RIGHTS
199 Water Street, 22nd Floor
New York, NY 10038
Tel: (917) 637-3605

Counsel for Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association of LGBTQ+ Psychiatrists, American Association of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey

RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Plaintiffs-Appellees Los Angeles LGBT Center, Whitman-Walker Clinic, Inc., d/b/a Whitman-Walker Health, Bradbury-Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students for Choice, AGLP: The Association of LGBTQ+ Psychiatrists, and American Association of Physicians for Human Rights d/b/a GLMA: Health Professionals Advancing LGBTQ Equality are non-profit corporations. Hartford Gyn Center's parent corporation is Humedco Corp. None of the other listed entities has a parent corporation, and no publicly traded corporation owns 10% or more of the stock of any of the listed entities.

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

Cases

TABLE OF AUTHORITIES
(continued)

Cases (continued) **Page(s)**

TABLE OF AUTHORITIES
(continued)

Cases (continued) **Page(s)**

TABLE OF AUTHORITIES
(continued)

Cases (continued) **Page(s)**

Federal Statutes, Regulations, and Rule

TABLE OF AUTHORITIES
(continued)

Federal Statutes, Regulations, and Rule (continued) **Page(s)**

TABLE OF AUTHORITIES
(continued)

Federal Statutes, Regulations, and Rule (continued) **Page(s)**

State Statutes and Regulations

TABLE OF AUTHORITIES
(continued)

State Statutes and Regulations (continued) **Page(s)**

Legislative Materials

TABLE OF AUTHORITIES
(continued)

Other Authorities

INTRODUCTION

The Department of Health and Human Services has promulgated a sweeping new regulation that greatly expands religious objections in healthcare, to the point of permitting healthcare workers to deny life-saving care to patients in emergencies. The Rule goes beyond anything Congress ever has authorized, and HHS adopted it without seriously grappling with the many severe harms it will cause.

The Rule "upsets the balance drawn by Congress between protecting conscientious objections versus protecting the uninterrupted effective flow of health care to Americans." ER35.[1] By adding definitions of key statutory terms, the Rule greatly expands both the universe of healthcare workers who may object to serving patients, and the activities to which they may object. The Rule contains no exceptions for emergencies. Put simply, if the Rule goes into effect, patients will be denied necessary healthcare, and patients will die.

The Rule's enforcement provisions are draconian. The Rule threatens to punish noncompliance with loss of all federal funding. Then it makes

[1] This brief refers to the Excerpts of Record (Dkt. 17-1 and 17-2) with the prefix "ER" and to the Supplemental Excerpts of Record (Dkt. 46) with the prefix "SER."

compliance exceedingly difficult, by inviting far more religious objections than Congress ever contemplated, while severely limiting providers' ability to accommodate objections while still maintaining the standard of care. Providers will be forced to make dramatic policy and staffing changes to attempt to comply with the Rule. Providers who focus on providing reproductive healthcare and serving LGBT patients cannot comply with the Rule without violating standards of care and medical ethics, and without compromising their missions and the health and lives of their patients.

The Rule exceeds HHS's authority, is contrary to law, and is arbitrary and capricious. It also violates the Spending Clause and the separation of powers. Whether to uphold the Rule is not a close call. In addition to the court below, two other district courts have invalidated it. This Court should affirm the district court's grant of summary judgment to Plaintiffs.

STATEMENT OF JURISDICTION

Defendants-Appellants' jurisdictional statement, Br. 2, is correct.

ISSUES PRESENTED

1. Whether the Rule violates the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* (APA), because it exceeds HHS's statutory authority and is contrary to law.

2. Whether the Rule violates the APA because it is arbitrary and capricious.

3. Whether the Rule violates the Spending Clause and the separation of powers.

4. Whether vacatur of the entire Rule is the appropriate remedy.

STATEMENT OF THE CASE

A. The Statutory And Regulatory Framework That Applies To Healthcare Providers

1. Healthcare providers' obligations to provide competent, nondiscriminatory care

The core mission of healthcare providers is to provide high-quality care to patients who need it. In carrying out that mission, providers are subject to a web of state and federal laws, medical-ethics requirements, and professional standards that ensure that patients receive competent, nondiscriminatory care.

For example, state laws require providers to meet the standard of care – to use the care and skill of a reasonably prudent practitioner. *See*, *e.g.*, *Barris v. County of Los Angeles*, 972 P.2d 966, 971 n.1 (Cal. 1999).[2] State

[2] Medical associations also have established standards of care applicable to the treatment of particular conditions. *See, e.g.*, SER1233, 1238 (describing standards of care promulgated by the World Professional Association of Transgender Health for the treatment of persons with gender dysphoria,

laws also prohibit discrimination in healthcare,[3] require providers to obtain patients' informed consent for medical procedures,[4] and require providers to ensure continuity of treatment for patients in need of care.[5] Medical-ethics rules require providers to empower patients to make informed decisions about their medical treatment, to prioritize patient needs, and to provide care in emergencies.[6] Congress has been careful not to displace "quintessentially state-law standards of reasonable medical care," *Roach v. Mail Handlers Ben. Plan*, 298 F.3d 847, 850 (9th Cir. 2002), or state informed-consent requirements, *see* 42 U.S.C. §§ 1396u-2(b)(3)(B), 18114.

Many federal laws focus on increasing access to healthcare and thereby improving the public health. Medicare, Medicaid, the Patient Protection and Affordable Care Act (ACA), the Children's Health Insurance

---

and protocols issued by the American Medical Association and the American Psychological Association, among others).

[3] *See, e.g.*, Cal. Gov. Code § 11135 (prohibiting discrimination in access to state programs, including healthcare programs).

[4] *See*, *e.g.*, *Brownfield v. Daniel Freeman Marina Hosp.*, 256 Cal. Rptr. 240, 245 (Ct. App. 1989); *Logan v. Greenwich Hosp. Ass'n*, 465 A.2d 294, 300 (Conn. 1983).

[5] *See*, *e.g.*, Cal. Prob. Code § 4736; Conn. Gen. Stat. § 19a-580a; D.C. Code § 3-1205.14(a)(30); 225 Ill. Comp. Stat. 60/22(A)(16); N.Y. Comp. Codes R. & Regs. tit. 8, § 29.2; 49 Pa. Code § 16.61(a)(17).

[6] *See*, *e.g.*, SER117-18, 128-29, 137-38, 156.

Program, the Ryan White HIV/AIDS Treatment Program, the Maternal and Child Health Block Grant, and Centers for Disease Control funding laws all reflect this important congressional purpose.

State and federal laws ensure that patients will be able to receive prompt treatment in emergencies. The federal Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. § 1395dd, requires federally funded hospitals with emergency departments to screen every patient to determine whether the patient needs emergency care, and to treat the patient until he or she is stable. *Id.* § 1395dd(a), (b)(1). A hospital may not transfer a patient in an emergency to another facility unless the patient requests transfer in writing, or the patient has been stabilized, the transfer is medically warranted, and the benefits of transfer outweigh its risks to the patient. *Id.* § 1395dd(b)-(c). State laws likewise require healthcare providers to treat patients in emergencies.[7]

[7] *See, e.g.*, Cal. Health & Safety Code § 123420; 210 Ill. Comp. Stat. 70/1; 210 Ill. Comp. Stat. 80/1; 745 Ill. Comp. Stat. 70/6; Ill. Admin. Code tit. 77, § 545.35; Mass. Gen. Laws ch. 111, § 70E; Nev. Rev. Stat. § 439B.410; N.Y. Pub. Health Law § 2805-b; Wis. Stat. § 256.30(2). EMTALA does not preempt state laws requiring emergency care. *See* 42 U.S.C. § 1395dd(f).

2. Laws and provider policies that accommodate conscience objections

Against that backdrop, Congress has enacted statutes that require recipients of federal funds to accommodate religious or moral objections to certain healthcare procedures or training. Those statutes include the Weldon Amendment, Pub. L. No. 116-94, div. A., § 507(d)(1), 133 Stat. 2534, 2607 (2019), which prohibits discrimination based on whether a healthcare professional is willing to participate in abortion care; the Coats-Snowe Amendment, 42 U.S.C. § 238n(a)(1)-(2), which prohibits discrimination in training to provide abortion care; and the Church Amendments, 42 U.S.C. § 300a-7, which address objections to participation in abortions or sterilizations and other specified healthcare activities, *id.* §§ 300a-7(c)(1)-(2), (d), (e). The government relies on those conscience statutes as the basis for the Rule.

Each statute was adopted to address a particular situation, and each is narrowly worded to accommodate conscience objections while ensuring that patients continue to receive care. The statutes are limited in scope, and they do not override state laws requiring adherence to the standard of care, requiring emergency treatment, requiring informed consent, and

prohibiting discrimination.[8] Indeed, when the statutes were enacted, the sponsors provided assurances that they would not impede access to care by willing providers.[9] Further, the statutes were enacted on top of the Title VII framework for accommodating religious objections, where employers must provide reasonable accommodations for employees' religious practices as long as the accommodations do not impose undue hardships. *See* 42 U.S.C. §§ 2000e(j), 2000e-2.

Significantly, none of the conscience statutes delegates broad rulemaking authority to HHS. *See* ER59-60. The Weldon Amendment and the Church Amendments delegate no rulemaking authority at all, and the Coats-Snowe Amendment delegates rulemaking authority to HHS only with respect to accreditation standards for post-graduate physician training programs. *See* 42 U.S.C. § 238n.

---

[8] *See* 119 Cong. Rec. 9603 (1973) (statement of Sen. Church) ("Nothing in this amendment undertakes to preempt or interfere with State law.").

[9] *See* 151 Cong. Rec. 754-755 (2005) (statement of Rep. Weldon) ("My amendment in no way infringes on a woman's ability to seek and receive elective abortions . . . Hyde-Weldon allows any health care entity to participate in abortions in any way they choose."); 142 Cong. Rec. 5160 (1996) (statement of Sen. Coats) ("[W]e do not want to prevent those who voluntarily elect to perform abortions from doing so. Nobody is prevented in this legislation from voluntarily receiving abortion training or from voluntarily offering that training . . . .").

Healthcare providers across the country, including Plaintiffs, have adopted policies to accommodate religious objections while maintaining the standard of care and complying with other state and federal laws. *See, e.g.*, SER138-39, 145, 161, 168, 274, 410, 422-23, 684-85. The policies require medical staff to provide advance notice of objections, so that management can develop staffing policies and practices designed to ensure efficient, continuous, and competent patient care while accommodating objections. SER1341-42, 1370-71, 1373, 1586-87, 1590-93. The policies also require medical staff to treat patients during emergencies, SER1373, 1591-92, because refusing to provide life-saving care would violate the standard of care and would be unethical, *see* SER112-13, 117-18, 133, 156, 320-21.

B. The HHS Rule At Issue

1. Promulgation of the Rule

In January 2018, HHS set out the draft Rule in a notice of proposed rulemaking. *See* Protecting Statutory Conscience Rights in Health Care, 83 Fed. Reg. 3880 (Jan. 26, 2018). HHS stated that the proposed Rule was designed to "provide for the implementation and enforcement" of dozens of "Federal health care conscience and associated anti-discrimination laws." 83 Fed. Reg. at 3892.

But from the beginning, the draft Rule went well beyond those laws. It did so by defining key statutory terms in ways that greatly expand the statutes' reach, 83 Fed. Reg. at 3892-95, and by adding draconian enforcement provisions, including termination and clawback of all federal funding, *id.* at 3891.

More than 242,000 comments were filed by medical associations, medical providers, civil-rights organizations, state and local governments, and others. *See* 84 Fed. Reg. 23,170, 23,180 & n.41 (May 21, 2019). Commenters explained that providers would not be able to accommodate religious objections while ensuring continuity of care and complying with state and federal laws and medical-ethics requirements. *See*, *e.g.*, SER117-18, 132, 684-85. They expressed particular concern that the Rule does not include any exceptions for emergencies. *See, e.g.*, SER111-12, 133, 245, 276. And they documented how the Rule will harm patients, especially patients seeking reproductive care and LGBT patients. *See, e.g.,* SER153, 245-46, 276-78, 383-85.

In May 2019, HHS published the final Rule, without addressing most of the serious concerns raised during the comment period. *See* Protecting Statutory Conscience Rights in Health Care, 84 Fed. Reg. 23,170 (May 21,

2019) (to be codified at 45 C.F.R. Pt. 88). HHS did not deny that the Rule will disproportionately affect vulnerable communities and will cause more patients to be refused care, even life-saving care. *Id.* at 23,188, 23,251, 23,253. HHS also did not provide guidance about how providers could comply with the Rule while meeting their treatment and nondiscrimination obligations under state and federal law. *Id.* at 23,183, 23,191-92.

2. Key provisions in the final Rule

As the district court explained, the Rule "expands the[] protections" in the Conscious Statutes well "beyond what Congress intended." ER35.

a. Expansion of individuals and conduct covered by the conscience statutes

The Rule copies the substantive provisions in the underlying statutes, then provides new definitions of various terms in those statutes, thereby expanding the statutes' substantive reach. ER44. The new definitions expand the scope of people who can make objections and the procedures to which they can object. For example, the Rule defines the phrase "[a]ssist in the performance," a key term in the Church Amendments, to include taking almost any action related to a healthcare procedure, including "counseling, referral, training, or otherwise making arrangements for the procedure." 84 Fed. Reg. at 23,263, § 88.2. The Church Amendments were intended to give

medical professionals the ability to opt out of performing abortions and sterilizations, but the Rule permits all staff, including non-medical staff, to refuse to perform tasks even tangentially related to medical procedures.

Similarly, certain conscience statutes protect healthcare providers or medical staff who decline to provide "referrals" for abortion care. Weldon Amendment, § 507(d)(1), 133 Stat. at 2607; 42 U.S.C. § 238n(a)(1)-(2). The Rule defines "referral" expansively to mean giving a patient any type of information that could result in the patient's receiving care, 84 Fed. Reg. at 23,264, § 88.2, rather than using the ordinary meaning of "referral" in the medical context (directing a patient to another healthcare professional for care), ER59.

Further, the Rule defines "healthcare entity" and "entity" to include healthcare facilities and personnel beyond those specified by Congress. For example, the Coats-Snowe Amendment concerns physicians and participants in healthcare training programs, 42 U.S.C. § 238n(c)(2), but the Rule expands "health care entity," a phrase used in that statute, to include any healthcare professional, staff member, pharmacist, or facility, including a hospital, pharmacy, or medical laboratory, 84 Fed. Reg. at 23,264, § 88.2.

Together, those provisions allow virtually anyone who works for a healthcare provider to decline to perform any task related to a medical procedure to which he or she objects, such as scheduling appointments, cleaning a room before a patient's appointment, or handling insurance billing.

b. Displacement of existing methods for accommodating religious objections

The Rule places new requirements on healthcare providers' ability to accommodate objecting employees, while limiting their ability to ensure that patients receive needed care. The Rule does this by first defining "discriminate" broadly to include virtually any action directed at a religious objector, and then strictly limiting when providers may ask individuals about their potential objections and how they may make accommodations to ensure that patients continue to receive care. 84 Fed. Reg. at 23,263, § 88.2.

The Rule gives objectors a near-total say in how their views must be accommodated. For example, it requires that an employer make the objector's preferred accommodation even if it would impose an "undue hardship" on the provider. 84 Fed. Reg. at 23,263, § 88.2 (objector must "voluntarily" accept any accommodation); *id.* at 23,191. The result is to

allow the individual objector, not the provider, to determine the appropriate accommodation – no matter how unworkable or dangerous for patients.

c. No emergency exception

The Rule contains no exceptions for emergencies. *See* 84 Fed. Reg. at 23,263, § 88.2. As a result, an employer cannot have a policy that requires an employee to assist with a life-saving procedure when there is no alternative employee available. Under the Rule, an ambulance driver could refuse to transport a woman suffering from an ectopic pregnancy, *see id.* at 23,188, and a doctor could turn away a woman hemorrhaging from a miscarriage, *see id.* at 23,248 (citing *Means v. U.S. Conf. of Catholic Bishops*, No. 15-1779 (6th Cir. 2016)).

Commenters pointed out that providers have legal obligations to provide emergency treatment, and that some patients will die if they are denied emergency care. But HHS refused to include an emergency exception in the Rule. Instead, it said that it will review application of the Rule in emergency circumstances on a case-by-case basis. 84 Fed. Reg. at 23,188; *see* 83 Fed. Reg. at 3888. That gives providers no guidance on when they may require employees to provide life-saving care, and it provides cold comfort to patients who are denied that care.

d. Targeting of patients seeking reproductive healthcare and LGBT patients

The Rule targets reproductive healthcare by permitting even non-medical staff to object to tasks and communications even tangentially related to abortion or contraception. Through its examples of procedures to which individuals can object, the Rule makes clear that it considers treatment of ectopic pregnancies and miscarriages to be abortions, even though those procedures are not abortions and are not covered by the underlying statutes. *See* 84 Fed. Reg. at 23,186-88.

The Rule also invites discrimination against transgender patients. It repeatedly misuses the term "sterilization" – a procedure mentioned in the Church Amendments – to describe medically necessary healthcare procedures for transgender patients to treat gender dysphoria. *See* 84 Fed. Reg. at 23,178 (citing *Minton v. Dignity Health*, No. 17-558259 (Cal. Super. Ct. Apr. 19, 2017)); *see also id*. at 23,205. Treatment for medical conditions like gender dysphoria or cancer may incidentally affect reproductive function, but that treatment is not sought for the purpose of preventing reproduction. *See* SER1244, 1561-62, 1621. Indeed, some courses of treatment for gender dysphoria do not prevent a patient from having children, and many transgender patients take steps to preserve their

fertility as they undergo treatment for gender dysphoria. SER1244. The Rule will permit any staff member, from the first point of patient contact onward, to deny assistance to patients seeking medically necessary treatment such as hormone therapy or emergency care for complications resulting from gender-affirming surgery.

e. New certification requirements and enforcement provisions

The Rule confers on HHS's Office for Civil Rights (OCR) broad new enforcement authority, even though none of the underlying statutes gives the agency that authority. The Rule requires funding recipients to certify compliance with the Rule. *See* 84 Fed. Reg. at 23,269, § 88.4(a). At the same time, the Rule provides scant guidance on how providers can comply with it without violating other state and federal laws and medical-ethics rules. So the Rule places funding recipients in a no-win position from the start.

Then the Rule threatens covered entities with severe penalties for noncompliance. OCR can withdraw and even claw back federal funding from providers that violate the Rule, 84 Fed. Reg. at 23,180; *see id.* at 23,270, § 88.6(a); *id.* at 23,271, § 88.7(a); *id.* at 23,272 § 88.7(i)(3)(iv), before even giving them a chance to take corrective action, *see id.* at 23,271-72, § 88.7(i)(2).

C. The Rule's Impacts On Healthcare Providers And Patients

Plaintiffs represent providers and medical students from across the country who are committed to providing healthcare to vulnerable and underserved populations. Plaintiffs are the County of Santa Clara, a political subdivision of the State of California responsible for providing safety-net healthcare and public health services for almost two million residents; providers and national organizations focused on reproductive health services; and providers and national and community organizations serving the LGBT community.

1. Impacts on the County

The County operates three public hospitals, numerous satellite clinics and pharmacies, a local public health department covering 15 cities, a behavioral health department, and a public health maintenance organization. It is the second largest safety-net healthcare provider in the State, and the sole safety-net provider and sole accreditor of emergency responders in the County. SER1368, 1421. It receives more than one billion dollars in HHS funding annually, and it depends on that funding for its facilities' continued operation. SER1374-75.

The Rule will require the County to either forgo that critical federal funding or implement policies that permit staff to turn patients away, refuse to help during an emergency, and otherwise stigmatize and harm patients. The Rule will frustrate the County's ability to budget, plan, and carry out its mission to provide care to millions of people. SER1373-74.

Under the County's current policies, staff must make their managers aware of objections in advance, so managers can make staffing arrangements that avoid compromising patient care. Staff can raise objections only to the direct provision of care, not to ancillary activities. SER1370-71, 1377-79. And an objecting staff member must provide assistance in an emergency if no one else is available. SER1341-42, 1373, 1591-92.

The Rule will shift the burden to providers to ask essentially every employee (rather than just medical and nursing staff) about any objections that the employee might have to any job duties. *See* 84 Fed. Reg. at 23,186-88. That will interfere with the County's operations and impose significant costs. *See* SER1371-75.

Even with the information that the County is allowed to obtain under the Rule, providers may not be able to address religious objections through

accommodations and reassignments, due to the breadth of the activities covered by the Rule and the requirement that employees voluntarily agree to any accommodation. *See* SER1342-43, 1372-74, 1586-88. As a result, the County may not be able to ensure that its staff can provide competent care in an emergency. SER1341-42.

2. Impacts on Plaintiffs specializing in reproductive healthcare and healthcare for LGBT patients

The Rule will frustrate the missions of Plaintiffs specializing in reproductive healthcare and healthcare for LGBT people. It will be difficult, if not impossible, for those mission-driven healthcare providers to accommodate staff who refuse to provide basic services, without compromising the providers' missions, the quality of patient care, and the health of their patients. SER902, 1543, 1545.

The Rule will frustrate the missions of providers dedicated to providing reproductive healthcare. SER899-90. The Rule prevents them from asking potential employees about possible objections before hiring, meaning that providers could be put to the choice of losing all federal funding or accommodating individuals who object to their very missions. SER910, 912-14, 916. Further, if the Rule goes into effect, fewer large medical institutions will provide abortions and teach students and residents

about abortion and contraception. SER902, 1514. Although abortion is a common and safe medical procedure, SER1401-02, there is a national shortage of abortion providers in the United States, and their numbers are shrinking, SER894, 1398-99. Many patients already must travel long distances to obtain care. SER1510. The Rule will lead to delays in obtaining an abortion, which substantially increase the health risks to patients. SER1401-02, 1510. And some patients may not be able to receive abortion care at all. SER1404.

Plaintiff LGBT-focused providers cannot accommodate objections to basic services such as treatment for gender dysphoria, mental healthcare that affirms a patient's sexual orientation or gender identity, and HIV-prevention counseling without harming patients. SER1543, 1545, 1562. Those providers are providers of last resort – they treat patients who have experienced discrimination and been refused treatment by other healthcare providers, including severely ill patients who were denied care in life-threatening circumstances. SER945-48, 1360-63. The Rule will make it harder for LGBT-focused providers to ensure quality care, including in emergencies. SER1220-24, 1543-45, 1566-69.

Mission-driven providers like the Los Angeles LGBT Center and Whitman-Walker Health work hard to maintain trust with their patients, given that those providers tend to be the only options available for some patients who have already faced discrimination in healthcare. SER1217-18, 1562. The Rule will erode community members' confidence in the healthcare system, impeding LGBT-focused providers' efforts to build trust so that patients will seek healthcare when they need it. SER1198-99, 1542-43, 1579, 1622-23. Patients who fear discrimination and humiliation at the hands of healthcare providers delay or decline necessary care, including check-ups, screenings, and testing, resulting in health conditions that worsen and become more difficult to treat. SER920-21, 948-50, 1363. When LGBT patients do seek care, the Rule will make them reluctant to disclose their sexual orientations or gender identities, even though that information can be relevant and even vital to treatment. SER1360. Not only is this delay or denial of healthcare likely to cause those patients avoidable pain and injury, it will also increase providers' costs and frustrate their ability to fulfill their missions. SER920, 1359-60, 1543-45, 1562, 1569-70.

In an effort to comply with the Rule, Plaintiff healthcare providers will be forced to institute costly workarounds and duplicative staffing, to

unfairly burden non-objecting employees, to reduce services, or even to close programs. SER913, 1223-25, 1365-66, 1389-90, 1400-01, 1563-66, 1578-79, 1622-26. Some hospitals and facilities will be forced to forgo providing abortion, contraception, or LGBT services entirely. SER1400-01, 1513-14, 1565-66. That will increase the financial burdens on providers that continue to provide full reproductive and LGBT healthcare services, because patients will look to them to serve needs previously met elsewhere. *See* SER1223-24, 1513-14, 1569-70, 1577. The Rule also will frustrate the Plaintiff medical associations' missions of promoting training in abortion care, SER895, 897, and nondiscriminatory care for LGBT patients, SER1345-51, 1629-34.

D. Proceedings Below

Plaintiffs brought this lawsuit, arguing that the Rule violates the APA, the Spending Clause, the separation of powers, the Establishment Clause, and patients' constitutional rights to substantive due process, equal protection, and free speech. ER145-218. Plaintiffs moved for a preliminary injunction to prevent immediate enforcement of the Rule. ECF No. 36 (No. 3:19-cv-02916-WHA). The government agreed to delay the effective date of the Rule until November 22, 2019. ER78-80. The case was consolidated

with two other cases challenging the Rule, filed by the State of California and by the City and County of San Francisco. ER81.

On cross-motions for summary judgment, the district court held that the Rule violates the APA and vacated it. ER34, 65. The court concluded that the Rule exceeds statutory authority and is contrary to law because it "upset[s] the balance drawn by Congress between protecting conscientious objections versus facilitating the uninterrupted provision of health care in America." ER44, 63. The Rule does so by "set[ting] forth new definitions of statutory terms that conflict with the statutes themselves." ER44. The court explained how the Rule's definitions of "assist in the performance," "referral," "health care entity," and "entity" "significantly expand[] the scope of protected conscientious objections," ER45-59 – even though HHS "does not have rulemaking authority to change, add to, or subtract from" the underlying statutes, ER60.

As a remedy, the district court set aside the entire Rule. ER63. The court deemed the Rule "so saturated with error" that "there is no point in trying to sever the problematic provisions" – "[t]he whole rule must go." *Id.* The court rejected the government's argument that relief should be limited to the parties, explaining that when a court has "determined that a rule is

facially invalid," the appropriate remedy is vacatur. *Id.* Because the court vacated the rule "in its entirety" on statutory grounds, it did not reach the constitutional claims. ER64; *see* ER6.

Meanwhile, two other district courts (in New York and Washington) also invalidated the Rule. *See New York v. HHS*, 414 F. Supp. 3d 475, 523 (S.D.N.Y. 2019), appeal filed, Nos. 19-4254 et al. (2d Cir. Dec. 18, 2019); ER8-33 (Washington decision).

The government appealed, and the California cases were consolidated on appeal with the Washington case.

SUMMARY OF ARGUMENT

Over a period of decades, Congress has adopted context-specific statutes to address individuals and entities that do not wish to participate in certain medical procedures or research based on religious or moral objections. Hospitals and other healthcare organizations have complied with those laws for decades by carefully crafting policies that accommodate religious objections while ensuring that patients receive care.

The Rule completely upends the existing regime by elevating religious objections over the obligation to provide care, even in emergencies. The Rule greatly expands both the universe of healthcare workers who may

object to serving patients based on religious objections, and the activities to which they may object. The Rule severely limits providers' ability to accommodate employees' religious objections without compromising patient care. And the Rule authorizes HHS to impose draconian penalties for noncompliance. If HHS believes that a provider (or any contractor or subrecipient of federal funding) has violated the Rule, it can cut off and claw back all of the provider's federal funding.

HHS lacked the statutory authority to impose this new regime on providers and patients. The Rules' broad definitions of "assist in the performance," "referral," "health care entity," and "entity" vastly expand conscience rights beyond what Congress intended. The new definition of "discrimination" makes it nearly impossible for providers to accommodate those objections while ensuring that patients will receive needed care. And the Rule is contrary to law, because it directly conflicts with EMTALA by preventing providers from ensuring treatment of patients in emergencies, as EMTALA requires.

The Rule also is a paradigmatic example of arbitrary and capricious agency action. Many commenters pointed out that the Rule will make it more likely that patients will be refused needed healthcare, even in

emergencies. They demonstrated that the Rule is impracticable and costly, that it conflicts with providers' legal and ethical obligations, and that it undermines the well-established framework for accommodating religious objections. HHS impermissibly brushed these concerns aside, insisting without support that the harms caused by *the Rule* are the result of *Congress's* policy choices. Further, the record does not support HHS's claims about the need for the Rule or the Rule's supposed benefits.

Because Congress has not authorized HHS to withhold healthcare funding based on violations of the Rule, the Rule violates the separation of powers. And if Congress had delegated that authority to HHS, the Rule would violate the Spending Clause, because it imposes funding conditions that are coercive, ambiguous, retroactive, and unrelated to the purposes of the funding.

The district court correctly vacated the entire Rule. This Court should affirm the grant of summary judgment to Plaintiffs.

ARGUMENT

I. THE RULE VIOLATES THE APA BECAUSE IT EXCEEDS HHS'S STATUTORY AUTHORITY AND IS CONTRARY TO LAW

A final agency action must be set aside if it is "in excess of" the agency's statutory authority or otherwise "not in accordance with law." 5 U.S.C. § 706(2). As the district court correctly held, the Rule goes well beyond the statutes Congress enacted, disrupting the balance Congress struck between accommodating religious objections and ensuring that patients receive healthcare. ER44. And the Rule directly conflicts with EMTALA, because it prevents providers from treating patients in emergencies.

A. The Rule Goes Far Beyond The Underlying Statutes Through Its Expansive Definitions

The Rule significantly broadens the reach of the conscience statutes by adopting new definitions of certain key words and phrases, contrary to Congress's intent.

1. "Assist in the performance"

The Church Amendments protect from discrimination those individuals who "perform" abortions and sterilizations, and those who "assist in the performance" of those procedures. 42 U.S.C. § 300a-7. In that

context, "assist in the performance" was "intended to cover only those individuals in the operating room who actually assisted the physician in carrying out the abortion or sterilization procedure." ER46.

Yet the Rule defines "assist in the performance" much more broadly, as "tak[ing] an action that has a specific, reasonable, and articulable connection to furthering" a medical procedure or research activity. 84 Fed. Reg. at 23,263, § 88.2. That definition includes not only helping perform medical procedures, but "counseling, referral, training, or otherwise making arrangements for the procedure." *Id.* Then (as explained below), the Rule separately defines "referral" to include giving any information that could lead to a patient obtaining a procedure. *Id.* at 23,264, § 88.2.

That broad definition of "assist in the performance" extends the right to object to individuals and activities only tangentially connected with medical procedures. For example, objections can be raised by a receptionist who schedules appointments; an ambulance driver who transports a patient to the hospital; a janitor who prepares an operating room; a phlebotomist who routinely draws blood from patients; an orderly who escorts patients to treatment areas; or an administrative clerk who collects billing and insurance forms. ER48; *see New York*, 414 F. Supp. 2d at 515.

HHS acknowledges the definition's very broad scope. *See* 84 Fed. Reg. at 23,186-88 (noting that the Rule would cover an individual who "[s]chedul[es] an abortion or prepar[es] a room and the instruments for an abortion" and someone who "driv[es] a person to a hospital or clinic"). Indeed, at oral argument in this case, the government conceded that the Rule would allow an ambulance driver to kick out a patient in the middle of an ambulance ride across Central Park. SER1869-77; *see* ER47-48 (same in New York case).

This new definition goes well beyond the underlying statute. "[T]he phrase 'assist in the performance' is a term of art" that "refers to a doctor, nurse, medical assistant or other medical professional who physically helps the treating doctor, either by physically handling necessary instruments or by physically handling the patients." SER1191-92, SER1643.

To attempt to justify its new definition, the government relies on dictionary definitions of "assist" and "performance." *See* Br. 30. But those definitions do not account for the medical context here, and they actually support Plaintiffs' view, not the government's view. "Performance" means "the execution of an action," and to "assist" means "to give support or aid," such as when "another surgeon [assisted] on the operation." *Merriam-*

Webster's Collegiate Dictionary 70, 863 (10th ed. 1996). By using the terms "perform" and "assist," Congress required that the person objecting must have a close and direct connection to the procedure at issue.

The legislative history confirms that the Rule's definition of "assist in the performance" is way too broad. The sponsor of the Church Amendments explained that "[t]here is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal to perform what would otherwise be a legal operation." 119 Cong. Rec. 9597 (1973). The government objects to reliance on legislative history, Br. 32, but of course a court may look to legislative history as an indication of congressional intent, *see, e.g., Mt. Graham Red Squirrel v. Madigan*, 954 F.2d 1441, 1453-55 (9th Cir. 1992) – especially where, as here, it confirms the plain meaning of a statutory phrase.

2. "Refer for" and "referral"

The Coats-Snowe Amendment, the Weldon Amendment, the ACA, and various Medicare and Medicaid laws exempt providers or individuals from providing "referral[s]" for certain procedures to which they object. *See* 42 U.S.C. §§ 238n(a)(1), 1395w-22(j)(3)(B), 18023(b)(4); Weldon Amendment, § 507(d)(1), 133 Stat. at 2607. Those statutes reflect the

common understanding of "referral" in the medical context – helping a patient get care from another healthcare provider. *See* XIII *Oxford English Dictionary* 467 (2d ed. 1989) (definition of "referral").

Yet the Rule defines "referral" and "refer for" much more broadly, to include virtually anyone providing any type of information that results in a person obtaining a procedure. It covers the "provision of information" in any form "where the purpose or reasonably foreseeable outcome . . . is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure." 84 Fed. Reg. at 23,264, § 88.2.

The result is that an individual could object to providing basic information if doing so may help the patient obtain a procedure to which the individual objects. The district court recognized that broad scope when it noted that an entity could violate the Rule "if it fired a hospital front desk employee for refusing to tell a woman seeking" emergency treatment "for an ectopic pregnancy which floor she needed to go to for her procedure." ER58.

That was not Congress's intent. Congress intended the word "referral" to have its ordinary meaning in the healthcare setting – directing a patient to another healthcare provider for care. *See New York*, 414 F.

Supp. 3d at 526 ("a common understanding of the term 'referral' in the context of the health care industry would include sending a patient to another physician or provider"). HHS's definition of "referral" "goes beyond the meaning of the term, as understood by the very industry HHS purports it is trying to protect," because it covers even the "informal provision of general information" that could lead to a person obtaining care. ER59. The legislative history confirms that Congress did not intend that broad scope for "referral." ER58-59 (reviewing legislative history).

HHS claims that Congress's use of "refer for" in the Coats-Snowe Amendment shows an intent to cover not only "providing a particular referral document," but also "sending or directing a person for abortions or training in a more general sense." Br. 40. But the Rule's definition is not limited to "directing or sending" a patient for an abortion; it encompasses "providing any information that could help the patient obtain" a service or procedure. *New York*, 414 F. Supp. 3d at 526. The government's argument does not come close to justifying the expansive definition in the Rule.

3. "Discriminate" and "discrimination"

The Weldon Amendment, Coats-Snowe Amendment, and Church Amendments prohibit "discrimination" against religious objectors in

specified contexts. *See* Weldon Amendment, § 507(d)(1), 133 Stat. at 2607; 42 U.S.C. § 238n(a)(1)-(2); *id.* § 300a-7(c)(1)-(2), (e). As commonly understood, "discrimination" is "a failure to treat all persons equally when no reasonable distinction can be found between those favored and those not favored." *Discrimination, Black's Law Dictionary* (11th ed. 2019). That understanding is well established: The ACA, for example, prohibits "discrimination" in healthcare on the basis of race, color, national origin, age, sex, or disability. 42 U.S.C. § 18116.

The Rule goes far beyond that well-established definition and is inconsistent with what Congress intended. The Rule defines "[d]iscrimination" to mean any change to the objecting employee's "position," "status," "benefit[s]," or "privilege[s]" in employment, as well as use of any "policies[] or procedures" that subject the objector to "any adverse treatment." 84 Fed. Reg. at 23,263, § 88.2. Then, the Rule places unprecedented restrictions on providers' ability to accommodate objections in a manner that still ensures patient health and safety.

First, the Rule limits employers' ability to identify potential objections in advance. An employer can inquire about objections only "after . . . hiring"

the worker and "once per calendar year thereafter, unless supported by a persuasive justification." 84 Fed. Reg. at 23,263, § 88.2.

Second, when the employer offers an accommodation, the objecting employee must "voluntarily accept[]" it. 84 Fed. Reg. at 23,263, § 88.2. That means that the employer cannot impose reasonable accommodations over an employee's objections, even when necessary to protect patients' health. *Id.* An employer must provide an employee's preferred accommodation even if it would impose an "undue hardship." *Id.* at 23,191.[10]

Third, an employer cannot even require objectors to cooperate in ensuring that patients receive appropriate care from someone else. *See* 84 Fed. Reg. at 23,192 (a covered entity may "use alternate staff or methods to provide or further any objected-to conduct" only if the entity "does not require any additional action by" the objector).

Together, those provisions put providers to a terrible choice – either attempt to accommodate religious objections in the manner required by the Rule, no matter how impracticable and regardless of the effect on patients, or violate the Rule and potentially lose all federal funding.

---

[10] The district court suggested that the Rule could be read to include a "persuasive justification" defense for providers, ER57, but the government pointedly rejects that view, *see* Br. 43-44.

The district court here did not "criticize the rule based on its definition of 'discriminate.'" ER57. As the New York court recognized, however, the Rule's novel definition of discrimination "cannot be defended" as a "mere recapitulation of the terms of an existing statutory provision." 414 F. Supp. 3d at 524. No federal statute defines discrimination so expansively. On the contrary, federal law recognizes rationales and defenses that may justify adverse employment actions, including that an employer need not accommodate an employee's religious beliefs when the accommodation would cause undue hardship to the employer. *See* 42 U.S.C. § 2000e(j); *EEOC v. Abercrombie & Fitch Stores, Inc.*, 135 S. Ct. 2028, 2032 (2015); *Peterson v. Hewlett-Packard Co.*, 358 F.3d 599, 607 (9th Cir. 2004). The Rule's new definition of "discrimination" is "game-changing," because "it would materially expand the right of employees articulating objections to covered procedures, and correspondingly enhance the duties of health care employers in this area." *New York*, 414 F. Supp. 3d at 524.

4. "Health care entity" and "entity"

Both the Coats-Snowe and Weldon Amendments define "health care entity," but the Rule significantly expands the term in both contexts, "add[ing] a host of individuals and organizations." ER53.

The Coats-Snowe Amendment protects a "health care entity" that declines to provide abortions or abortion training. 42 U.S.C. § 238n(a), (c)(2). It was designed to "protect doctors, residents, and medical students in the context of training." ER51; *see* 142 Cong. Rec. 5160-61 (1996). It therefore defines "health care entity" to cover "an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." 42 U.S.C. § 238n(c)(2).

The Rule goes many steps further, to "add[] several new persons and entities" never contemplated by Congress. ER50. The new definition includes "a health care professional, a pharmacist, health care personnel, an applicant for training or study in the health professions, a hospital, medical laboratory, an entity engaging in biomedical or behavioral research, a pharmacy, or any other health care provider or health care facility." *Id.* As the district court explained, Congress never meant to reach entities and individuals like "medical laboratories" or "pharmacies and pharmacists." ER50-51. Rather, "the statute consistently includes only those engaging in or needing to engage in the actual performance of a procedure in question or assisting in the procedure, such as doctors and nurses." ER50.

The Rule makes a similar impermissible move in redefining "health care entity" under the Weldon Amendment. The Weldon Amendment was intended to ensure that doctors are not required to perform abortions and sterilizations and that insurance companies are not required to pay for them. ER52-53 (citing 150 Cong. Rec. 25,044-45 (2004)). Accordingly, the statute defines "health care entity" to include "an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." Weldon Amendment, § 507(d)(2), 133 Stat. at 2607.

The Rule adds a long list of individuals and programs to the definition, including, for example, "a pharmacist"; any person "training in the health professions"; any "applicant for training or study in the health professions"; a "medical laboratory"; a "pharmacy"; and any "health care personnel" and "any other health care provider or health care facility." 84 Fed. Reg. at 23,264. Again, "none of these additions are defined or contemplated in the underlying statute." ER53. By adding them, HHS completely overwrote the definition Congress provided. HHS does not have the authority to do that.

HHS's only response is that the statutory definitions use the word "include." Br. 37. True, the word "include" sometimes signifies that a list is "illustrative, rather than conclusive." *Id.* at 51. But when a list is illustrative, the "list still cannot be inflated with terms lacking the defining essence of those in the list." ER51 (citing *Russell Motor Car Co. v. United States*, 261 U.S. 514, 519 (1923)). That is the problem here: The Rule adds people and organizations materially dissimilar from those chosen by Congress, and the legislative history confirms that Congress did not intend the long lists included in the Rule. *Id.*

Finally, the Church Amendments use the terms "entity" and "individual," to "consistently . . . distinguish" between organizations and people. ER54. But the Rule defines "entity" to include "a 'person' as defined in 1 U.S.C. § 1," which includes "corporations, companies . . . [and] individuals." 84 Fed. Reg. at 23,263, § 88.2; *see* 1 U.S.C. § 1. The Rule thus conflates organizations and people – "exactly what the Church Amendment avoided" – in order to expand the Rule's reach. ER54.

B. The Rule Cannot Be Upheld As A Merely Interpretive Rule

The government contends that the Rule may be upheld on the ground that the new definitions are merely interpretive. Br. 27. That is wrong for several reasons.

First, whether characterized as an interpretive rule or a legislative rule, the Rule is impermissible because it goes beyond what Congress authorized. As the New York court explained, "the Rule relocates the metes and bounds – the who, what, when, where, and how – of conscience protection under federal law." 414 F. Supp. 3d at 516. HHS is not allowed to do that. If viewed as legislative, the Rule "is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). As the government acknowledges, Congress did not expressly delegate to HHS the authority to enact rules that expand the reach of the underlying statutes. SER1866-67. Further, no statute gives HHS the authority to adopt the Rule's enforcement provisions. If the Rule is viewed as merely interpretive, it fails because the definitions are not a faithful or permissible interpretation of the underlying statutes. ER44. Either way, the Rule exceeds HHS's authority under the conscience statutes.

Second, both in this case and in the New York case, the government admitted that the Rule is not merely interpretive. When asked point blank below whether the rule was interpretative, the government lawyer said it was not. SER1865. The district court pushed back, saying that the underlying statutes have "zero words that give[] you the authority to issue a legislative rule"; the government lawyer admitted that "there is no language in the statute itself that explicitly delegates authority" to HHS, but then continued to insist that the Rule is legislative and attempted to rely on some kind of "implicit authority" in the statutes. SER1866-67. The government took the same position in the New York case, stating unequivocally that "the rule is substantive" and "it does impose obligations on regulated entities." SER1818.

Third, it is clear from the face of the Rule that it is not merely interpretive, because it not only expands the substantive reach of the underlying statutes, but also imposes new certification requirements and enforcement provisions. "[I]nterpretive rules merely explain, but do not add to, the substantive law that already exists in the form of a statute or legislative rule," while legislative rules "create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by

Congress." *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1087 (9th Cir. 2003). The Rule on its face confers new privileges on objectors and imposes new obligations on providers. Without the new definitions, there would be no basis for requiring providers to allow objections by nonmedical staff to performing tasks only tangentially related to medical care, or for requiring providers to change their policies specifying that all personnel must assist patients in emergencies. That makes the Rule legislative. *See, e.g.*, *id.*; *Alameda Health Sys. v. Centers for Medicare & Medicaid Servs.*, 287 F. Supp. 3d 896, 915-19 (N.D. Cal. 2017).

Further, the Rule is the sole basis for the new enforcement scheme. It is the Rule – not the statutes – that requires providers to certify compliance with both the statutes and the Rule and threatens termination or clawback of all federal funding for violations. *See New York,* 414 F. Supp. 3d at 475, 526. The government's argument (Br. 28) that the Rule "has no effects independent of a statute" blinks reality.

C. HHS Lacked Authority To Adopt The Rule's Enforcement Provisions

Even if HHS permissibly adopted new definitions to interpret the statute (and it did not), the Rule has an independent problem, which is that HHS did not have statutory authority to confer on OCR powerful new tools

for enforcing the underlying statutes and the Rule. The government relies on three potential sources of enforcement authority, Br. 20-26, but none of them is sufficient.

1. Conscience statutes

First, the conscience statutes themselves do not support the Rule's enforcement provisions. The government concedes that the statutes do not "specify[] a consequence for violations," Br. 24, but suggests that "termination of the relevant funding is a natural consequence for violations," *id.* The two decisions that it cites for that proposition are inapposite, because they concern statutes that expressly provide that funding termination is a consequence for noncompliance. *See United States v. Marion Cty. Sch. Dist.*, 625 F.2d 607, 611-12 (5th Cir. 1980); *United States v. Mattson*, 600 F.2d 1295, 1299 n.6 (9th Cir. 1979). They do not hold that an agency administering critical public-health programs has implicit authority to terminate funding for a violation, without even giving the recipient a chance to cure.

Further, the funding conditions imposed by the statutes have a limited scope. The Church Amendments tie their nondiscrimination requirements to particular funding sources. 42 U.S.C. § 300a-7(c). The

Coats-Snowe Amendment imposes obligations only with respect to physicians, medical residents, and other health professional trainees with respect to refusals to perform, or to learn how to perform, abortions. 42 U.S.C. § 238n. The Weldon Amendment affects a particular funding stream, and imposes conditions relating only to certain entities and only with respect to abortion. Weldon Amendment, § 507(d), 133 Stat. at 2607. But the Rule authorizes HHS to terminate *all* federal funding for any violation. 84 Fed. Reg. at 23,272, § 88.7(i)(3). None of the statutes goes that far.

2. Uniform Administrative Requirements

The government also relies on the Uniform Administrative Requirements (UAR), but they also do not support the Rule's enforcement provisions. The UAR establish "administrative requirements, cost principles, and audit requirements for Federal awards to non-Federal entities." 45 C.F.R. § 75.100(a)(1). By their terms, they permit an agency to take specified enforcement actions only with respect to the particular "Federal award," "activity," "action," "project," or "program" affected by noncompliance. *Id.* § 75.371. The Rule goes much further, to authorize termination of all federal funding, regardless of its connection to the violation. *See* 84 Fed. Reg. at 23,272, § 88.7(i)(3).

Also, the UAR do not permit termination as a matter of course. HHS must determine whether noncompliance may "be remedied by imposing additional conditions," 45 C.F.R. § 75.371, and it must give the funding recipient "an opportunity to object and provide information and documentation challenging the suspension or termination action" before it cuts off funds, *id.* § 75.374. The Rule incorporates neither safeguard. Instead, despite the government's assertion that HHS will terminate funding only "where voluntary resolutions are not possible," Br. 9, the Rule expressly permits HHS to terminate funding even while the recipient undertakes voluntary, good-faith compliance efforts, 84 Fed. Reg. at 23,271-72, § 88.7(i)(2).

Finally, the UAR say nothing about clawing back funds, which the Rule expressly allows. *See* 84 Fed. Reg. at 23,180 (stating that enforcement mechanisms include "funding claw backs to the extent permitted by law"). The UAR thus cannot justify the Rule's enforcement provisions.

3. Housekeeping Statute

The Housekeeping Statute is straightforward and narrow: "The head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its

employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." 5 U.S.C. § 301. The statute authorizes only internal rules of agency governance – "regulations to conduct the business of the department." *In re Estate of Covington*, 450 F.3d 917, 920 (9th Cir. 2006). It does not authorize an agency to promulgate "substantive rules." *Exxon Shipping Co. v. U.S. Dep't of Interior*, 34 F.3d 774, 777 (9th Cir. 1994).

HHS has admitted that the Rule imposes substantive obligations, SER1865-67, and that is clear from the Rule's face. Indeed, HHS acknowledges that covered entities will spend $46.9 million per year just to satisfy the Rule's new certification requirements. *See* 84 Fed. Reg. at 23,260. The government's contention that the Rule only "govern[s] HHS's own conduct," Br. 21, clearly is wrong.

D. The Rule Is Contrary To Law Because It Conflicts With EMTALA

The Rule directly conflicts with EMTALA, because it prevents providers from ensuring that patients receive emergency treatment. Although the court below did not reach the question, the New York court held that the Rule conflicts with EMTALA, 414 F. Supp. 3d at 537-39, and

this Court may affirm on that ground, *see Atel Fin. Corp. v. Quaker Coal Co.*, 321 F.3d 924, 926 (9th Cir. 2003).

The conflict is stark. EMTALA requires hospitals participating in the federal Medicare and Medicaid programs that have emergency rooms to screen patients to determine "whether or not an emergency medical condition . . . exists" and, if it does, to stabilize the patient or transfer him or her to another facility. 42 U.S.C. §§ 1395dd(a), (b)(1), (c)(1). Transfer is allowed only if the patient requests transfer in writing, or the treating physician certifies that transfer is medically appropriate and its benefits to the patient outweigh its risks. *Id.* § 1395dd(c). That is, the transfer decision is focused on the interests of the patient, not the provider.

Hospitals that fail to comply with EMTALA face penalties of up to $50,000 per violation and litigation by patients who have been harmed. 42 U.S.C. § 1395dd(d)(1)-(2). EMTALA includes no exceptions for religious or moral objections to providing emergency care. *See, e.g.*, *Matter of Baby K*, 16 F.3d 590, 597 (4th Cir. 1994).[11]

[11] The government argues that *Baby K* does not "address the conscience statutes or any analogous statutory right," Br. 46, but that is incorrect; the hospital claimed an exemption based on analogous state law, *see Baby K*, 16 F.3d at 595.

Yet the Rule authorizes healthcare workers to refuse to provide emergency care, making it difficult, if not impossible, for providers to comply with EMTALA. An agency may not create a regulatory exception to a statutory mandate – especially an exception that will deprive people in medical emergencies of life-saving care. The whole point of EMTALA was to provide for equal access to emergency care, so low-income and other individuals would not be turned away from emergency rooms. *See Bryant v. Adventist Health System/West*, 289 F.3d 1162, 1165 (9th Cir. 2002) (recognizing that EMTALA's purpose is to impose a duty to treat "to ensure that individuals . . . receive adequate emergency medical care" when they arrive at the hospital). It would be contrary to EMTALA's entire purpose to say that healthcare providers can treat some patients in emergencies, but not others, based on conscience objections.

The government contends that the Rule is consistent with EMTALA because EMTALA requires providers to use "staff and facilities available at the hospital" to treat patients in emergencies, 42 U.S.C. §§ 1395dd(b)(1), and a staff member with an objection is not "available," Br. 35. But that definition of "available" would eviscerate EMTALA's protections for patients: The duty to provide stabilizing treatment set forth in EMTALA

applies not only to participating hospitals but also to treating physicians in participating hospitals, 42 U.S.C. § 1395dd(d)(1)(B), and "EMTALA does not provide an exception for stabilizing treatment physicians may deem medically or ethically inappropriate," *Baby K*, 16 F.3d at 597. Interpreting "available" to permit those exceptions would "conflict[] with the provisions of EMTALA that require stabilizing treatment to be provided." *Id.* The government basically admits that: It states that, in its view, *every staff member* at a hospital could raise an objection, so the patient could be refused all care at that facility. Br. 35.

None of the underlying statutes was intended to give providers or staff a right to deny patients life-saving care. *See* 151 Cong. Rec. 755 (2005) (statement of Rep. Weldon) (referencing EMTALA and clarifying that Weldon Amendment "simply prohibits coercion in nonlife-threatening situations"); 119 Cong. Rec. 9601 (1973) (statement of Sen. Church) ("[I]n an emergency situation – life or death type – no hospital, religious or not, would deny such services."). Further, the ACA expressly provides that nothing in it, including its conscience provisions, "relieve[s] any health care provider from providing emergency services as required by State or Federal law, including . . . 'EMTALA.'" 42 U.S.C. § 18023(d).

The government claims that any conflict with EMTALA must be judged in an as-applied challenge, and that "possibility" of harm in "uncommon particular applications" does not justify invalidating the Rule. Br. 44. But the Rule sets up a conflict with EMTALA on its face, and the record demonstrates that real patients will be harmed. SER226-27, 277, 283, 389-96, 551, 888. That is not speculative; the Rule itself admits that patients can be denied care in emergencies. *See* 84 Fed. Reg. at 23,188, 23,248; ER47-48. Because the Rule lacks any exception for emergency medical situations, the Rule conflicts with EMTALA and is contrary to law.

II. THE RULE VIOLATES THE APA BECAUSE IT IS ARBITRARY AND CAPRICIOUS

The APA "requires agencies to engage in reasoned decisionmaking, and directs that agency action be set aside if it is arbitrary or capricious." *DHS v. Regents of the Univ. of Calif.*, 140 S. Ct. 1891, 1905 (2020) (internal citations and quotation marks omitted); *see* 5 U.S.C. § 706(2)(A). An agency acts arbitrarily and capriciously when it "entirely fail[s] to consider an important aspect of the problem" or "offer[s] an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983). "For an agency's decisionmaking to be rational, it must respond to significant

points raised during the public comment period." *Allied Local & Reg'l Mfrs. Caucus v. EPA*, 215 F.3d 61, 80 (D.C. Cir. 2000).

The government flunked that standard here. Although the district court invalidated the Rule on other grounds, the Rule fails for the independent reason that it is arbitrary and capricious. *See New York*, 414 F. Supp. 3d at 546, 554, 558; ER31-32 (Washington decision).

A. HHS Failed To Consider Important Aspects Of The Problem And Did Not Respond To Significant Comments

1. HHS failed to address evidence that the Rule will harm patients

HHS's stated mission is to "enhance the health and well-being of all Americans." HHS, *Introduction: About HHS*, http://www.hhs.gov/about/strategic-plan/introduction/index.html. But in promulgating the Rule, HHS "disregarded the comments and evidence showing the Rule would severely and disproportionately harm certain vulnerable populations, including women; . . . LGBT individuals[]; individuals with disabilities; and people living in rural areas." ER30-31. When an agency responsible for public health ignores evidence that its proposed regulation will severely harm patients, its decision is arbitrary and capricious. *See Regents of the Univ. of Calif.*, 140 S. Ct. at 1913-14 (agency's failure to address harms to DACA

recipients caused by DACA's rescission rendered the decision arbitrary and capricious).

Many commenters explained that the Rule will make it more likely that patients will be refused care or denied critical information, SER168-69, 306-07, 333-34, 589-91, 617-18, 671-72, 718-20, 730-35, causing them harm, SER300-01, 342-43, 595-96, 888-89. Those commenters observed that, under the Rule, more individuals and entities will assert religious objections to more types of care, especially reproductive healthcare (including reproductive assistance for same-sex partners), care for transgender patients, and HIV/AIDS treatment. SER203-04, 293, 306-07, 326-27, 383-85, 489-92, 568-71, 583-86, 731-32.

Commenters showed that religious objections have been asserted to deny rape survivors emergency contraception, to refuse to provide emergency contraception in time to prevent pregnancy, and to deny care to complete miscarriages even when women's lives were in danger. SER226-27, 351-52, 652. The Rule will invite staff members to object to care in a much wider variety of circumstances, SER194-95, 306-07, 417-18, 596, and it will hamstring providers' efforts to accommodate objections while ensuring adequate and timely care, SER132, 597, 685. As a result, the Rule

will make it more difficult for healthcare entities to offer reproductive healthcare and training, which will exacerbate national shortages caused by hospital mergers and restrictive laws. SER243-45, 248-50, 462-65, 551-53, 637-38. Having fewer providers available will increase patients' risks of injury and death. SER152, 248-49, 487-88, 551-53, 596-97.

Commenters also pointed out that the Rule will disproportionately burden individuals who already experience discrimination and other obstacles when seeking healthcare, such as LGBT patients. SER190, 228-29, 277-78, 460-67, 481-86. Providers have refused to treat LGBT patients and their children, even in emergencies. SER211-15, 277-78, 283, 331, 888. Many LGBT people and people living with HIV have reported providers refusing to touch them or using excessive precautions, using harsh or abusive language, being physically abusive, or blaming them for medical conditions. SER310-11. Under the Rule, some of those patients will be deterred from seeking care and some will be denied care altogether. SER326-27, 484, 603-04.

The Rule will be especially harmful to patients seeking reproductive healthcare and LGBT patients in rural communities, SER153, 374, 431-34, 462, 522-24, 620-21, 629, 691-92, who often have few if any alternatives if

a provider refuses to provide care, SER263, 462, 724. Economically disadvantaged patients, who lack resources to seek alternate providers, also will suffer disproportionately. SER227-29, 234, 249-50, 689-90, 717.

In the Rule itself, HHS admitted that those harms will occur. It stated that "[d]ifferent types of harm can result from denial of a particular procedure," including that a "patient's health might be harmed if an alternative is not readily found, depending on the condition." 84 Fed. Reg. at 23,251. It expressly contemplated that individuals would object to reproductive and LGBT healthcare. *Id.* at 23,176 & n.27. It also recognized that a patient denied care likely will incur additional costs searching for an alternative; that "the patient may experience distress associated with not receiving a procedure he or she seeks"; and that the patient ultimately may not receive care. *Id.* at 23,251. And it conceded that the Rule will adversely affect "rural communities, underprivileged communities, or other communities that are primarily served by religious healthcare providers or facilities," and that patients in those areas will be more likely to "suffer adverse health outcomes as a result." *Id.* at 23,180, 23,253. Yet it adopted the Rule anyway.

The government offers three possible justifications, but none passes muster. First, it admits that some patients will be harmed but asserts that Congress deemed religious refusals "worth protecting even if they impact . . . access to a particular service, such as abortion" or cause patients "emotional distress." 84 Fed. Reg. at 23,182, 23,251. But none of the purported authorizing statutes contemplates or requires harm to patients. When Congress established limited protections for religious objectors, it did so against the backdrop of federal and state statutes expanding and prioritizing patient care, including EMTALA. The *Rule*, not the statutes, elevates religious objections over the health of patients.

Second, the government relies (Br. 55) on the Rule's assertion that it will "increase, not decrease, access to care" by attracting providers who otherwise supposedly would not practice medicine because of religious objections. 84 Fed. Reg. at 23,180; *see id.* at 23,247 (same). HHS's principal support for this assertion was a small, outdated, and unreliable political poll. *See* pp. 61-62, *infra*. HHS contends that its judgments about "access-to-care issues" are entitled to "'deferential review.'" Br. 54 (quoting *California ex rel. Becerra v. Azar*, 950 F.3d 1067, 1096 (9th Cir. 2020)). But HHS made clear that it is relying on one limited poll; it is not using its

expertise to make its own judgment about likely effects of the Rule, and so no deference is due. *See McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1190 (D.C. Cir. 2004) (refusing to defer where the agency "provided no actual evidence, nor did it claim special knowledge based upon its experience, to support" its conclusion). HHS also ignored the fact that attracting new providers who refuse to provide certain medical treatments or to serve certain classes of patients will do nothing to help those patients, who already are underserved.

Third, HHS suggested that it could not quantify "the impact of this rule on access to care" because there were "too many confounding variables" and "not enough reliable data." 84 Fed. Reg. at 23,252. But HHS acknowledged that the harms will result, including harms to "the patient's health." *Id.* at 23,251. As the Washington court observed, it is "particularly glaring" that HHS refused to rely on what it considered "'anecdotal accounts of discrimination from LGBT' people," but was more than willing to rely on "anecdotes of bias and animus in the health care section against individuals with religious beliefs and moral convictions." ER32 (quoting 84 Fed. Reg. at 23,552). There was no question that the Rule will harm patients, and it was arbitrary and capricious for the agency charged with protecting

Americans' health to refuse to address and attempt to ameliorate those harms.

2. HHS failed to address concerns about the lack of an emergency exception

Many commenters sounded the alarm that the lack of an emergency exception created an unacceptable risk that patients will not be able to obtain care in emergencies. *See*, *e.g.*, SER111-12, 133, 147, 171, 245, 416-17, 559, 610-11, 672-73. All HHS said in response is that it will consider specific emergency scenarios on a case-by-case basis. 84 Fed. Reg. at 23,188. That does nothing to help providers determine how to ensure care in emergencies, or how to comply with state and federal laws and medical-ethics requirements that they provide emergency treatment. SER1343. And it certainly cannot bring back the patients who die because they are denied care.

As the New York court explained, the comments regarding the need for an emergency exception "should have yielded a thoughtful response from the federal agency responsible for health care, one that engaged with these important questions." 414 F. Supp. 3d at 556. Instead, HHS provided only "generalized conclusions and inadequate responses" that "virtually define

the APA term arbitrary and capricious." *Id.* (internal quotation marks and citations omitted).

3. HHS failed to respond meaningfully to concerns that the Rule will harm providers

HHS also ignored comments from major medical associations, provider groups, academics, and experts, who raised concerns that providers cannot reasonably follow the Rule's commands while fulfilling their duties to patients.

Commenters explained that hospitals and other healthcare organizations already have policies that allow individuals to opt out of certain procedures on religious or moral grounds while still ensuring that patients will receive care. *See, e.g.,* SER123, 132, 167-68, 198-99, 274, 406-07, 410, 684-85. They showed that these policies are more effective than the Rule in protecting patients while still allowing for religious objections. *See, e.g.*, SER132, 145-46, 161, 168, 274, 410, 422-23, 684-85. They also pointed to evidence that the Rule will be expensive and time-consuming to implement, undermining efforts to reduce the costs of healthcare and diverting time and energy away from patient care. *See, e.g.*, SER170, 200, 278-80, 407-08.

Further, commenters stressed that the policy changes required by the Rule will violate state and federal laws and codes of ethics. *See*, *e.g.*, SER87-91, 100-01, 129-30, 215-17. The Rule makes providers unable to comply with EMTALA, state laws mandating the standard of care, and their obligation to protect patients from discriminatory treatment by staff. *See, e.g.*, SER132-33. Commenters warned that the Rule will interfere with the relationship of trust between providers and their patients. *See, e.g.*, SER396. HHS's response is that the Rule does not prohibit a doctor or healthcare entity from caring for patients "if they feel they have a duty to do so." Br. 56. But the Rule will prevent healthcare providers from ensuring that healthcare workers carry out *the providers'* duty to deliver competent and nondiscriminatory care to patients. SER99-100. HHS ignored that problem.

HHS did not even try to craft a rule that addressed and resolved commenters' well-founded concerns about overriding well-established policies and procedures for management of religious objections. Nor did it attempt to balance the costs identified by commenters against the Rule's supposed benefits. That is arbitrary and capricious. *See Regents of the Univ. of Calif.*, 140 S. Ct. at 1915.

4. HHS failed to justify its rejection of the existing religious-accommodation framework

HHS also failed to respond adequately to commenters' concerns about the Rule's departure from the familiar religious-accommodation framework in Title VII. Under Title VII, an employer is required to reasonably accommodate an employee's religious exercise unless doing so would constitute an undue hardship, meaning that it would impose "more than a de minimis cost" on the employer. 42 U.S.C. § 2000e(j); *Ansonia Bd. of Educ. v. Philbrook*, 479 U.S. 60, 68-69 (1986). But the Rule rejects Title VII's reasonable-accommodation framework and undue-hardship defense and gives the objecting employee a near-total veto over any proposed accommodation. *See* 84 Fed. Reg. at 23,191 (employee must "voluntar[ily] accept[]" an accommodation).

Although "numerous commenters raised questions about the conflict" between the draft Rule and the Title VII framework, HHS failed to adequately address that issue. As the New York court explained, "the agency did not seriously engage with the implications of having differing sets of standards govern the accommodation of objectors – one set by Title VII and the other by the 2019 Rule." 414 F. Supp. 3d at 557. Further, HHS failed to provide even the "minimal level of analysis" to explain how the new

accommodation process will work. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

In response, the government asserts that the conscience statutes are "entirely distinct from Title VII," and "[i]f Congress intended to provide Title VII-like defenses, then it would have placed such defenses in the conscience statutes themselves." Br. 42. That misses the point. "[W]hen an agency rescinds a prior policy its reasoned analysis must consider the 'alternative[s]' that are 'within the ambit of the existing [policy].'" *Regents of the Univ. of Calif.*, 140 S. Ct. at 1913 (quoting *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 51). HHS had an obligation to consider obvious alternatives, such as Title VII's framework. Indeed, when HHS promulgated an earlier rule addressing the conscience statutes, it did not define "discrimination" at all, concluding that "the term . . . is widely understood," 73 Fed. Reg. 78,072, 78,077 (Dec. 19, 2008), and did not otherwise attempt to dictate how healthcare providers address objections, *id.* at 78,083.

HHS's refusal to consider the Title VII alternative, as well as its failure to grapple with the serious questions about the practicability of its new religious-accommodation regime, underscores that the Rule is arbitrary and capricious.

B. HHS's Explanation For Its Decision Runs Counter To The Evidence

HHS asserted that the Rule was necessary because of an increase in complaints about violations of the conscience statutes, and it contended that the Rule will increase the number of healthcare providers overall. Neither claim is supported by the record.

1. HHS's assertion about an increase in complaints was false

HHS explained the need for the Rule by pointing to a "significant increase" in the complaints alleging violations of the conscience statutes. *See* 84 Fed. Reg. at 23,175. But between 2008 and January 26, 2018 – a ten-year period – OCR received only 44 complaints alleging violations of conscience rights. 83 Fed. Reg. at 3886. HHS says that it received 343 complaints in fiscal year 2018, 84 Fed. Reg. at 23,229, but the vast majority of those complaints concern state vaccination mandates, which the Rule does not address, SER963.

Reviewing the complaints on which HHS relies, the New York court concluded that "virtually none address the Conscience Provisions at all, let alone indicate a deficiency in the agency's enforcement capabilities as to these laws." 414 F. Supp. 3d at 541. Because "HHS's central factual claim of a significant increase of complaints of Conscience Provision violations is

flatly untrue," that "alone makes the agency's decision to promulgate the Rule arbitrary and capricious." *Id.* (internal quotation marks omitted).

2. HHS's contention that the Rule will increase the number of healthcare providers is not supported by data

In explaining the supposed benefits of the Rule, HHS relied heavily on its supposition that the Rule would increase the number of healthcare providers overall. *See* 84 Fed. Reg. at 23,246-47; *see also* Br. 55. But the agency admitted that it had no "data enabling it to quantify any effect the Rule may have on increasing" providers. 84 Fed. Reg. at 23,247. It merely "assume[d]" that the Rule will attract more providers. *Id.*

That "assumption" is based primarily on polling conducted in 2009 and 2011 by a political polling company on behalf of the Christian Medical and Dental Associations. SER882-85. HHS cites that poll a dozen times in the Rule. *See*, *e.g.*, 84 Fed. Reg. at 23,246 n.309; *id.* at 23,247 nn.316-18. But that dated, nonrepresentative poll does not support HHS's conclusion that the Rule will increase the number of healthcare providers. The poll consisted of two phone surveys of American adults and an online survey of members of faith-based medical organizations. SER876-80, 882-85. The participants in the online survey were "self-selecting," and the poll was "not

intended to be representative of the entire medical profession [or even] of the entire membership rosters of these organizations." SER885.

This poll simply cannot bear the weight placed on it by HHS. It does not show that the Rule will lead to an increase in providers. At the same time, other evidence belies HHS's conclusion, including evidence that religiously affiliated healthcare institutions are thriving and growing in the absence of the Rule. 84 Fed. Reg. at 23,248. The government argues (Br. 54) that the Court should defer to the agency's speculation about how "health care entities" will respond to the Rule, but courts "do not defer to the agency's conclusory or unsupported suppositions." *McDonnell Douglas Corp.*, 375 F.3d at 1187; *Occidental Petroleum Corp. v. SEC.*, 873 F.2d 325, 342 (D.C. Cir. 1989). In short, HHS's asserted principal benefit of the Rule is not supported by competent evidence and "do[es] not suffice to explain its decision." *Encino Motorcars*, 136 S. Ct. at 2127.

III. THE RULE VIOLATES THE SPENDING CLAUSE AND THE SEPARATION OF POWERS

As the Washington and New York courts held, the Rule violates the separation of powers and the Spending Clause by imposing funding

conditions that Congress did not authorize and could not require. SER2203, 2247; *New York*, 414 F. Supp. 3d at 561-72.[12]

"The United States Constitution exclusively grants the power of the purse to Congress," not to the Executive Branch. *City & Cty. of S.F. v. Trump*, 897 F.3d 1225, 1231 (9th Cir. 2018). HHS therefore "does not have unilateral authority to refuse to spend . . . funds" that have been appropriated by Congress "for a particular project or program." *In re Aiken Cty.*, 725 F.3d 255, 261 n.1 (D.C. Cir. 2013). The Rule violates that principle, because it gives OCR the power to withhold federal funds allocated to healthcare programs if Plaintiffs fail to comply with the Rule. Because Congress has not authorized that regime, the Rule violates the separation of powers.

If Congress had authorized the Rule, the Rule would violate the Spending Clause. Congress may not impose conditions that are coercive, ambiguous, retroactive, or unrelated to the federal interest in a particular program. *See Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 572 (2012)

[12] This brief incorporates by reference the separation of powers and Spending Clause arguments of San Francisco (Br. 52-56) and the Spending Clause arguments of California (Br. 47-63). *See* Fed. R. App. P. 28(j).

(*NFIB*). The Rule violates these strictures in a manner that directly affects the County.

The Rule coerces the County to make an impossible choice – forgo federal funding that it needs to provide healthcare to its residents, SER1200-05, or implement policies that allow its staff to turn patients away or refuse to help during an emergency, *New York*, 414 F. Supp. 3d at 571. The County relies on roughly one billion dollars in federal funding to support critical local healthcare and public health services. SER1374-75. Loss of that funding would impede the County's ability to provide a wide range of services and would interfere with the County's fulfillment of state-law duties to protect public health and safety, prevent transmission of communicable disease, and care for the indigent. SER1375. The Rule threatens these core local functions to advance concerns unrelated to the federal interest in programs being funded, which is to increase access to healthcare. *See NFIB*, 567 U.S. at 580.

The Rule places the County (and its residents) at risk of losing those critical funds based on unanticipated, after-the-fact, and confusing requirements. *See id.* at 581-84. Without clarity regarding the County's legal obligations under the Rule, the County "cannot adequately plan or

budget" and "will not know what [it] must do in order to be able to certify [its] compliance" with the Rule. SER1373-74. The Rule therefore exceeds Congress's authority under the Spending Clause.[13]

IV. VACATUR OF THE ENTIRE RULE IS THE APPROPRIATE REMEDY

The district court correctly vacated the entire Rule.

A. The District Court Appropriately Vacated The Rule Rather Than Limiting Relief To The Parties

When, as here, a rule is unlawful, the APA provides the remedy: A court must "set aside" the "agency action." 5 U.S.C. § 706(2)(A). That is the "ordinary result" in those circumstances. *Empire Health Found. for Valley Hosp. Med. Ctr. v. Azar*, 958 F.3d 873, 886 (9th Cir. 2020) (internal quotation marks omitted); *see Alliance for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1121 (9th Cir. 2018) ("Ordinarily when a regulation is not promulgated in compliance with the APA, the regulation is invalid." (alteration and internal quotation marks omitted)). The district court correctly followed that established practice by vacating the Rule.

---

[13] Plaintiffs also raised other constitutional claims, ECF No. 113 at 42-52 (No. 3:19-cv-02769-WHA), but the district court did not reach them. If this Court does not affirm the judgment on any of the grounds addressed in this brief, it should remand for the district court to consider Plaintiffs' constitutional claims in the first instance.

The government argues that the district court should have limited relief only to Plaintiffs. Br. 65-67. But that cannot be squared with the APA, which not only permits but requires a court to "set aside" an "unlawful" rule. 5 U.S.C. § 706(2)(A). It also makes no sense: Plaintiffs include nationwide organizations that include thousands of medical professionals. Even if limited to Plaintiffs, the relief would need to be nationwide. Further, the relief is invalidation of a Rule, not an injunction that could apply to particular parties. It is a difficult to imagine how the Rule would work if it existed for some providers and not others.

For one thing, it is not clear how the Court could go about effectuating a remedy that leaves this comprehensive federal regulation in place, but permanently exempts Plaintiffs. *See O.A. v. Trump*, 404 F. Supp. 3d 109, 153 (D.D.C. 2019) ("What would it mean to 'vacate' a rule as to some but not other members of the public? What would appear in the Code of Federal Regulations?"), appeal filed, No. 19-5272 (D.C. Cir. Oct. 11, 2019). A geographical limitation is not possible, because Plaintiffs "do not operate in a fashion that permits neat geographic boundaries." *East Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1282-83 (9th Cir. 2020). They include healthcare providers across the country and three national associations of

medical professionals whose members work in hundreds, if not thousands, of healthcare facilities nationwide. SER893, 909, 1345, 1387, 1393, 1617, 1629. To limit relief to Plaintiffs could therefore only "be a source of confusion," because there would be two sets of requirements applying indefinitely across the entire regulated community. *Desert Survivors v. U.S. Dep't of the Interior*, 336 F. Supp. 3d 1131, 1135 (N.D. Cal. 2018) (rejecting geographical limit on vacatur).

The government has not cited a single decision where a court reached such an incongruous result, and courts that have considered similar requests have rejected them as "both at odds with settled precedent and difficult to comprehend." *O.A.*, 404 F. Supp. 3d at 153.[14] The decisions on which the government relies (Br. 65-70) do not concern vacatur under the

[14] One district court recently granted statewide "vacatur," explaining that the plaintiff (Baltimore) had not asked for nationwide relief before entry of judgment and that a statewide remedy would "afford the City complete relief." *Mayor of Baltimore v. Azar*, No. RDB-19-1103, 2020 WL 1873947, at *6 (D. Md. Apr. 15, 2020). On appeal, the Fourth Circuit rejected HHS's argument that the remedy should have been limited to Baltimore. *See Mayor of Baltimore v. Azar*, 973 F.3d 258, 293-94 (4th Cir. 2020), petition for cert. pending, No. 20-454 (filed Oct. 7, 2020). The Fourth Circuit did not address Baltimore's argument that the district court should have granted nationwide relief because it concluded that Baltimore had not preserved the issue. *Id.* at 294-95. Here, Plaintiffs sought complete vacatur of the Rule from the start, ER217, and a statewide remedy would be inappropriate because Plaintiffs are located nationwide.

APA. To the extent that they address remedies at all, they consider injunctions – often preliminary injunctions issued without the benefit of a full record.[15] Injunctive relief and vacatur are distinct remedies; whatever limitations the government's cases might impose on injunctive relief, they offer no basis to depart from the APA's clear language or the line of cases holding that vacatur is the appropriate remedy for an "unlawful" rule. If relief were limited to the parties, then multiple lawsuits would be required to invalidate unlawful federal regulations. That has never been the law.

B. The District Court Correctly Held That The Rule Is Not Severable

The district court also correctly declined to sever any part of the Rule. First, the court did not find any part of the Rule to be valid; the defects that the district court identified infected the entire Rule. ER63. There was (and is) nothing to sever.

[15] *See DHS v. New York*, 140 S. Ct. 599 (Mem.) (2020) (staying preliminary injunction pending appeal); *Trump v. Hawaii*, 138 S. Ct. 2392 (2018) (reversing preliminary injunction); *California v. Azar*, 911 F.3d 558, 584 (9th Cir. 2018) (limiting scope of preliminary injunction). Because the district court had a full summary judgment record before it, the government's concern about "rushed," "low-information decisions" is misplaced. Br. 67 (internal quotation marks omitted).

Even if some portion of the Rule were valid, severance would still be inappropriate here. "Whether the offending portion of a regulation is severable depends upon the intent of the agency and upon whether the remainder of the regulation could function sensibly without the stricken provision." *MD/DC/DE Broads. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001). HHS's desire that invalid parts of the Rule be severed, 84 Fed. Reg. at 23,272, § 88.10, does not settle the matter because the remaining parts still must be able to function, *Whole Women's Health v. Hellerstedt*, 136 S. Ct. 2292, 2319 (2016), and they could not do so here.

The district court concluded that the Rule's definitions are invalid because they exceed HHS's authority. ER62. The Rule could not function without those definitions, because they define the substantive requirements on funding recipients. Excising them would thus "severely distort" the obligations that the Rule tries to impose on funding recipients. *MD/DC/DE*, 236 F.3d at 23.

That would lead to a cascading effect for the rest of the Rule, such as the certification requirements and HHS's enforcement authority, because everything is tied to those requirements and prohibitions. *See* 84 Fed. Reg.

at 23,269-72, §§ 88.4, 88.6-88.7. And the enforcement provisions are independently invalid, so those parts of the Rule could not stand, either.

Severance therefore would "produce a rule strikingly different from any the [agency] has ever considered or promulgated." *MD/DC/DE*, 236 F.3d at 23. Any "isolated shards of the Rule" that might be left would not only be meaningless, but would "ignore the big picture: that the rulemaking exercise here was sufficiently shot through with glaring legal defects as to not justify a search for survivors." *New York*, 414 F. Supp. 3d at 577. This Court should not attempt to "fashion a valid regulation from the remnants of the old rule." *East Bay Sanctuary Covenant*, 950 F.3d at 1283 (quoting *Harmon v. Thornburgh*, 878 F.2d 484, 494 (D.C. Cir. 1989)).

CONCLUSION

The judgment below should be affirmed.

By: /s Nicole A. Saharsky

James R. Williams
Greta S. Hansen
Laura S. Trice
Mary E. Hanna-Weir
Susan P. Greenberg
H. Luke Edwards
OFFICE OF THE COUNTY COUNSEL
COUNTY OF SANTA CLARA
70 West Hedding St., East Wing
San José, CA 95110
Tel: (408) 299-5900

Counsel for County of Santa Clara

Nicole A. Saharsky
Miriam R. Nemetz
Megan E. Stride
Peter B. Baumhart
MAYER BROWN LLP
1999 K Street NW
Washington, DC 20006
Tel: (202) 263-3000
nsaharsky@mayerbrown.com

Counsel for all Plaintiffs

Richard B. Katskee
Kenneth D. Upton, Jr.
AMERICANS UNITED FOR
SEPARATION OF CHURCH
AND STATE
1310 L Street NW, Suite 200
Washington, DC 20005
Tel: (202) 466-3234

Camilla B. Taylor
Omar Gonzalez-Pagan
LAMBDA LEGAL DEFENSE
AND EDUCATION FUND,
INC.
105 West Adams, 26th Floor
Chicago, IL 60603
Tel: (312) 663-4413

Genevieve Scott
Rabia Muqaddam
CENTER FOR REPRODUCTIVE
RIGHTS
199 Water Street, 22nd Floor
New York, NY 10038
Tel: (917) 637-3605

Counsel for Los Angeles LGBT Center, Whitman-Walker Clinic, Inc. d/b/a Whitman-Walker Health, Bradbury Sullivan LGBT Community Center, Center on Halsted, Hartford Gyn Center, Mazzoni Center, Medical Students For Choice, AGLP: The Association of LGBTQ+ Psychiatrists, American Association of Physicians For Human Rights d/b/a GLMA: Health Professionals Advancing LGBT Equality, Colleen McNicholas, Robert Bolan, Ward Carpenter, Sarah Henn, and Randy Pumphrey

Dated: October 13, 2020

STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, appellees state that they know of no related cases pending in this Court beyond those consolidated with this case, which are listed in the appellants' Statement of Related Cases.

s/Nicole A. Saharsky
Nicole A. Saharsky
MAYER BROWN LLP

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and Circuit Rule 32-1 because:

   ☒ this brief contains 13,820 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii) and Fed. R. App. P. 32(f), *or*

   ☐ this brief uses a monospaced typeface and contains _____ lines of text, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because:

   ☒ this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 and is set in Century Schoolbook font in a size equivalent to 14 points or larger, *or*

   ☐ this brief has been prepared in a monospaced spaced typeface using *(state name and version of word processing program)* _____ with *(state number of characters per inch and name of type style)* _____ _____.

s/ Nicole A. Saharsky
Nicole A Saharsky
Attorney for Plaintiffs County of Santa Clara, et al.

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on October 13, 2020.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

s/ Nicole A. Saharsky
Nicole A. Saharsky
MAYER BROWN LLP