

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

**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

State of Washington,

Plaintiff-Appellee,

v.

Alex M. Azar II, et al.,

Defendants-Appellants.

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON AT YAKIMA

No. 2:19-cv-00183-SAB
The Honorable Stanley A. Bastian
United States District Court Judge

ANSWERING BRIEF

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TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	STATEMENT OF JURISDICTION	4
III.	STATEMENT OF THE ISSUES	4
IV.	STATEMENT OF THE CASE	4
	A. Statutory Background.....	4
	1. Federal Statutes Addressing Patients’ Timely Access to Care and Providers’ Conscience Rights	4
	2. Washington’s Laws Balancing Conscience Rights and Patient Access to Timely Care.....	9
	B. Regulatory Background.....	10
	C. Procedural Background.....	12
V.	SUMMARY OF THE ARGUMENT	14
VI.	STANDARD OF REVIEW	17
VII.	ARGUMENT	17
	A. The Rule Exceeds HHS’s Statutory Authority and Is Contrary to Law	17
	1. The Rule’s definitions exceed HHS’s authority and are contrary to law	19
	a. “Discriminate or discrimination”	21
	(1) The Rule’s definition breaks with the common legal definition.....	22

(2) The Rule’s definition impermissibly expands what conduct is actionable under the conscience statutes	27
b. “Assist in the performance”	33
c. “Health care entity”	37
d. “Referral or refer for”	40
2. The Rule’s new enforcement powers exceed HHS’s statutory authority and the Rule conflicts with EMTALA	43
B. The Rule is Arbitrary and Capricious	43
1. HHS’s stated rationales for the Rule are contradicted by the administrative record	45
a. The administrative record does not support HHS’s sweeping expansion of conscience rights in health care.....	46
(1) Conscience-Related Complaints	46
(2) Evidence of Discrimination and Coercion	49
(3) Evidence of Confusion	50
b. The record does not support HHS’s claimed need for new enforcement tools.....	52
2. HHS failed to consider or meaningfully address evidence of severe harms the Rule will inflict	53
a. Patient harm.....	54
b. Impact on emergency medical services.....	56
c. Harm to vulnerable populations	58

d. Abandonment of Title VII framework	61
C. The Rule is Unconstitutional.....	62
1. The Rule violates the Spending Clause	62
a. Washington’s Spending Clause argument is ripe.....	62
b. The Rule violates the Spending Clause by imposing new conditions on federal funds and threatening to terminate all HHS-administered funding.....	65
2. The Rule Violates Separation of Powers Principles	66
D. The District Court Properly Vacated the Rule Against All Persons and in Its Entirety.....	67
VIII. CONCLUSION.....	68

TABLE OF AUTHORITIES

Cases

<i>Abbott Labs. v. Gardner</i> , 387 U.S. 136 (1967)	63
<i>AEP Texas N. Co. v. Surface Transp. Bd.</i> , 609 F.3d 432 (D.C. Cir. 2010)	58
<i>Am. Postal Workers Union, San Francisco Local v. Postmaster Gen.</i> , 781 F.2d 772 (9th Cir. 1986).....	29
<i>Ass’n of Am. Med. Colleges v. United States</i> , 217 F.3d 770 (9th Cir. 2000).....	64
<i>Bennett v. Kentucky Dep’t of Educ.</i> , 470 U.S. 656 (1985)	65
<i>Bowen v. Am. Hosp. Ass’n</i> , 476 U.S. 610 (1986)	46
<i>Burwell v. Hobby Lobby Stores, Inc.</i> , 573 U.S. 682 (2014)	36
<i>California v. United States</i> , No. C 05-328, 2008 WL 744840 (N.D. Cal. Mar. 18, 2008).....	65
<i>City of Kansas City, Mo. v. Dep’t of Hous. & Urban Dev.</i> , 923 F.2d 188 (D.C. Cir. 1991)	45
<i>Connecticut v. United States</i> , No. 09-cv-054 (D. Conn.)	11
<i>Davis Next Friend LaShonda D. v. Monroe Cty. Bd. of Educ.</i> , 526 U.S. 629 (1999)	66
<i>Dep’t of Commerce v. New York</i> , 139 S. Ct. 2551 (2019)	48, 52

Dep’t of Homeland Sec. v. MacLean,
574 U.S. 383 (2015) 24, 25

Dep’t of Homeland Sec. v. Regents of the Univ. of California,
140 S. Ct. 1891 (2020) 44, 48, 62

Dioxin/Organochlorine Ctr. v. Clarke,
57 F.3d 1517 (9th Cir. 1995)..... 45

E.E.O.C. v. Abercrombie & Fitch Stores, Inc.,
575 U.S. 768 (2015) 28

Empire Health Found. for Valley Hosp. Med. Ctr. v. Azar,
958 F.3d 873 (9th Cir. 2020)..... 67

Encino Motorcars, LLC v. Navarro,
136 S. Ct. 2117 (2016) 44, 53, 56, 62

F.C.C. v. Fox Television Stations, Inc.,
556 U.S. 502 (2009) 44, 51, 56

Gill v. United States Dep’t of Justice,
913 F.3d 1179 (9th Cir. 2019)..... 17

Guedes v. Bureau of Alcohol, Tobacco, Firearms, & Explosives,
920 F.3d 1 (D.C. Cir. 2019) 19, 20

Gutierrez v. Ada,
528 U.S. 250 (2000) 40

Heller v. EBB Auto Co.,
8 F.3d 1433 (9th Cir. 1993)..... 28, 29

Louisiana Pub. Serv. Comm’n v. F.C.C.,
476 U.S. 355 (1986) 41

Lujan v. Nat’l Wildlife Fed’n,
497 U.S. 871 (1990) 63, 64

McDonnell Douglas Corp. v. Green,
411 U.S. 792 (1973) 31

Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm Mut. Auto. Ins. Co.,
463 U.S. 29 (1983) 44, 53

Nat. Res. Def. Council v. U.S. Nuclear Regulatory Comm’n,
879 F.3d 1202 (D.C. Cir. 2018) 60

Nat. Res. Def. Council, Inc. v. Rauch,
244 F. Supp. 3d 66 (D.D.C. 2017) 52

Nat’l Family Planning & Reprod. Health Ass’n, Inc. v. Gonzales,
468 F.3d 826 (D.C. Cir. 2006) 31, 65

Nat’l Fed’n of Indep. Bus. v. Sebelius,
567 U.S. 519 (2012) 66

Nat’l Fuel Gas Supply Corp. v. F.E.R.C.,
468 F.3d 831 (D.C. Cir. 2006) 50

New Prime Inc. v. Oliveira,
139 S. Ct. 532 (2019) 22

New York v. United States Dep’t of Health & Human Servs.,
414 F. Supp. 3d 475 (S.D.N.Y. 2019)..... passim

Pennhurst State Sch. & Hosp. v. Halderman,
451 U.S. 1 (1981) 65

PPL Wallingford Energy LLC v. F.E.R.C.,
419 F.3d 1194 (D.C. Cir. 2005) 58

Rittmann v. Amazon.com, Inc.,
971 F.3d 904 (9th Cir. 2020)..... 22

Roe v. Wade,
410 U.S. 113 (1973) 6

Samantar v. Yousuf,
560 U.S. 305 (2010) 39

Sandifer v. U.S. Steel Corp.,
571 U.S. 220 (2014) 22

Shelton v. University of Medicine & Dentistry,
223 F.3d 200 (3d Cir. 2000)..... 26, 29, 30

State v. United States Bureau of Land Mgmt.,
277 F. Supp. 3d 1106 (N.D. Cal. 2017) 51

Stormans, Inc. v. Selecky,
586 F.3d 1109 (9th Cir. 2009)..... 64

Sullivan v. Stroop,
496 U.S. 478 (1990) 42

Taylor v. St. Vincent’s Hosp.,
523 F.2d 75 (9th Cir. 1975)..... 6

The Wilderness Soc’y v. U.S. Fish & Wildlife Serv.,
353 F.3d 1051 (9th Cir. 2003)..... 36

Thomas v. Review Bd. of Indiana Employment Sec. Div.,
450 U.S. 707 (1981) 36

Trans World Airlines, Inc. v. Hardison,
432 U.S. 63 (1977) 23

United States v. Lemus,
582 F.3d 958 (9th Cir. 2009)..... 18

Washington State Dep’t of Soc. & Health Servs. v. Guardianship Estate of Keffeler,
537 U.S. 371 (2003) 40

Watkins v. Mercy Med. Ctr.,
364 F. Supp. 799 (D. Idaho 1973), *aff’d*, 520 F.2d 894 (9th Cir. 1975)..... 6

Yott v. N. Am. Rockwell Corp.,
602 F.2d 904 (9th Cir. 1979)..... 29

Statutes

42 U.S.C. § 1395dd..... 8, 56

42 U.S.C. § 1395dd(e)(1)..... 56

42 U.S.C. § 18113(a) 5

42 U.S.C. § 2000e(j) 8, 23

42 U.S.C. § 2000e-2(a)(1) 8

42 U.S.C. § 238(a)(2)..... 37

42 U.S.C. § 238n..... 7

42 U.S.C. § 238n(a) 7

42 U.S.C. § 238n(a)(1)..... 37

42 U.S.C. § 238n(a)(3)..... 40

42 U.S.C. § 238n(b)(1) 7

42 U.S.C. § 238n(c)(2)..... 7, 37

42 U.S.C. § 300a-7..... 6, 33

42 U.S.C. § 300a-7(a) 34

42 U.S.C. § 300a-7(b)..... 6, 34, 35

42 U.S.C. § 300a-7(c) 35

42 U.S.C. § 300a-7(c)(1) 7

42 U.S.C. § 300a-7(c)(1)(B) 22

42 U.S.C. § 300a-7(c)(2)	59
42 U.S.C. § 300a-7(d).....	35, 59
5 U.S.C. § 706(2).....	17, 67
5 U.S.C. § 706(2)(A).....	14, 18, 45
5 U.S.C. § 706(2)(B).....	16
5 U.S.C. § 706(2)(C).....	14, 18
Wash. Rev. Code § 48.43.065(2)(a)	9
Wash. Rev. Code § 48.43.065(2)(b).....	9
Wash. Rev. Code § 7.7.050	10
Wash. Rev. Code § 70.41.350	10
Wash. Rev. Code § 70.47.160(2)(a)	9
Wash. Rev. Code § 70.47.160(2)(b).....	9
Wash. Rev. Code § 74.09.875(1).....	10

Rules

Fed. R. App. P. 28(i).....	20
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Regulations

<i>Protecting Statutory Conscience Rights in Health Care: Delegations of Authority</i> , 84 Fed. Reg. 23,170 (May 21, 2019) (codified at 45 C.F.R. pt. 88).....	passim
45 C.F.R. § 88.1	12
45 C.F.R. § 88.2	passim

45 C.F.R. § 88.2(4) 27, 28, 29, 31

45 C.F.R. § 88.2(5) 31

45 C.F.R. § 88.4 12, 43

45 C.F.R. § 88.5 12, 43

45 C.F.R. § 88.6 12, 43

45 C.F.R. § 88.7 12, 43

45 C.F.R. § 88.7(3)(i)..... 65

45 C.F.R. § 88.7(4) 65

45 C.F.R. § 88.7(i)(2)..... 65

73 Fed. Reg. 78,072 (Dec. 19, 2008)..... passim

74 Fed. Reg. 10,207 (Mar. 10, 2009)..... 11

76 Fed. Reg. 9968, 9969 (Feb. 23, 2011) 11

83 Fed. Reg. 3880 (Jan. 26, 2018)..... 11, 45

Other Authorities

119 Cong. Rec. 9,595 (Mar. 27, 1973) 6

119 Cong. Rec. S9597 (daily ed. Mar. 27, 1973) (statement of
Sen. Church)..... 35, 36

142 Cong. Rec. 5165 (daily ed. Mar. 19, 1996) 38

142 Cong. Rec. S2264 (daily ed. Mar. 19, 1996) (statement of Sen. Coats) 7

Act of September 28, 2018, Pub. L. No. 115-245, 132 Stat. 2981
§ 507(d)(1)..... 38, 39

Civil Rights Act § VII.....	3, 8
<i>Consolidated Appropriations Act of 2010</i> , Pub. L. No. 111-117, § 508(d)(1), 123 Stat. 3034	40
Department of Health and Human Services Office of Civil Rights, <i>Fiscal Year 2019 Justification of Estimates for Appropriations Committee</i> at 30, https://www.hhs.gov/sites/default/files/fy2019-ocr-congressional- justification-accessible.pdf (last visited Oct. 12, 2020)	48
Emergency Medical Treatment and Labor Act	3, 8
<i>Medical Definition of Referral</i> , Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/referral (last visited Oct. 12, 2020)	41
Pub. L. No. 115-245, § 507(d)(1), 132 Stat. 2981, 3118 (Sept. 28, 2018).....	8
<i>Refer</i> , Merriam-Webster’s Medical Dictionary, https://www.merriam- webster.com/dictionary/refer#medicalDictionary (last visited Oct. 12, 2020).....	41

I. INTRODUCTION

Federal agencies are supposed to administer the law, not create it. In May 2019, the U.S. Department of Health and Human Services (HHS) issued a Rule dramatically expanding statutory protections for conscience objections for any person whose work even remotely touches on health care. *Protecting Statutory Conscience Rights in Health Care: Delegations of Authority*, 84 Fed. Reg. 23,170 (May 21, 2019) (codified at 45 C.F.R. pt. 88) (the “Rule”). The Rule upends the careful balance achieved by Congress and the states to ensure that providers can raise religious objections while still protecting patients’ access to care. The Rule conflicts with the statutes it purports to construe, violates federal statutes protecting patients in emergencies and governing the health care workplace, and was premised on facts the district court found to be “demonstrably false.”

Under the guise of “clarifying” federal law, the Rule made fundamental changes to existing law, including:

- Redefining “discrimination” to give health care employees a right to refuse a reasonable accommodation, regardless of the hardships such refusal might impose on Washington’s hospitals and their patients, and eliminating the undue burden defense for health care employers;

- Redefining the term “assist in the performance” to allow individuals entirely uninvolved in the performance of an actual procedure to refuse to perform essential functions of their job, including ambulance drivers transporting pregnant patients with life-threatening complications;
- Jettisoning the accepted medical definition of “referral” and redefining it to include providing any information where a “foreseeable outcome” is to assist a person in receiving an objected-to procedure, thereby drastically expanding the conduct to which the conscience statutes apply and allowing, for example, an insurance representative to refuse to disclose whether a procedure is covered; and
- Expanding HHS’s enforcement power to allow it to terminate *all* of a recipient’s HHS funding, including Medicare and Medicaid payments, for a single violation of the Rule—in Washington’s case, jeopardizing \$10.5 billion in health care funding per year.

Washington has a carefully constructed network of laws that balance providers’ conscience rights with patients’ rights to healthcare, and the Rule would destroy that balance. In November 2019, the district court below, along with two other district courts, entered summary judgment and vacated the Rule.

The district court correctly found the Rule violated the Administrative Procedure Act (APA) and the U.S. Constitution in multiple ways. The Rule's expansion of the federal conscience statutes exceeds HHS's statutory authority, disregards Congress's intent, and impermissibly conflicts with other federal statutes, including Title VII of the Civil Rights Act (Title VII) and the Emergency Medical Treatment and Labor Act (EMTALA).

The Rule also is arbitrary and capricious. HHS manufactured evidence to create the appearance of support for the Rule. While the agency claimed to have received hundreds of administrative complaints alleging discrimination covered by the conscience statutes, a review of the record revealed that over 90 percent of these complaints did not implicate those statutes. Moreover, HHS failed to adequately respond to evidence of the potentially devastating harms to vulnerable populations the Rule would cause or provide a reasoned explanation for its reversal of prior agency policy. The district court further correctly found that the Rule violates the Constitution's Spending Clause and separation of powers principles.

In lights of the Rule's fundamental and pervasive defects, the district court properly set it aside. This Court should affirm the district court's order.

II. STATEMENT OF JURISDICTION

Washington agrees with defendants-appellants' statement of jurisdiction.

III. STATEMENT OF THE ISSUES

1. Whether the Rule exceeds HHS's statutory authority and is contrary to law.
2. Whether the Rule is arbitrary and capricious.
3. Whether the Rule violates the Spending Clause and the separation-of-powers doctrine.
4. Whether the district court properly vacated the Rule under the APA.

IV. STATEMENT OF THE CASE

A. Statutory Background

1. Federal Statutes Addressing Patients' Timely Access to Care and Providers' Conscience Rights

Congress has enacted several statutes protecting patients' access to care while recognizing that some health care providers may have religious or moral objections to participating in particular procedures. Congress did not mandate imprecise or all-encompassing accommodations for conscience objections, but instead addressed such objections "in discrete contexts." *New York v. United States Dep't of Health & Human Servs.*, 414 F. Supp. 3d 475, 497 (S.D.N.Y. 2019). The particular language Congress chose in this sensitive area

and in the specific contexts in which it legislated are critical to understanding the impact of, and defects in, the Rule under review.

Principally at issue here are three federal statutes concerning conscience objections to certain medical procedures and services, including abortion and sterilization: the Church, Coats-Snowe, and Weldon Amendments (the conscience statutes). The Rule also addresses provisions of the Patient Protection and Affordable Care Act (ACA), including 42 U.S.C. § 18113(a), which bars discrimination against healthcare providers that do not provide services related to “assisted suicide,” as well as various Medicare and Medicaid provisions.¹ The Rule, in turn, purports to interpret several statutory terms contained in those statutes, namely: (1) “discriminate” or “discrimination” as used in the Church, Coats-Snowe, and Weldon Amendments; (2) “assist in the performance” in the Church Amendment; (3) “health care entity” in the Coats-Snowe and Weldon Amendments; and (4) “referral” or “refer for” as contained in the Coats-Snowe and Weldon Amendments. *See* 45 C.F.R. § 88.2.

¹ Although the Rule purports to implement a total of some thirty federal statutes, HHS has not argued that these other statutes provide any distinct or additional authority or justification for the Rule. *See New York*, 414 F. Supp. 3d at 498, n.1. Nor does HHS even identify any of these other statutes on appeal. *See* Br. for Defs.-Appellants & Consolidated Defs.-Appellants (Br.) at 3 n.1.

Church. Congress passed the Church Amendment in 1973. 42 U.S.C. § 300a-7. It was the first federal conscience statute and was enacted in response to the Supreme Court’s decision in *Roe v. Wade*, 410 U.S. 113 (1973), and a district court’s decision ordering a religiously-affiliated hospital to allow a physician to perform a sterilization procedure. *See, e.g., Taylor v. St. Vincent’s Hosp.*, 523 F.2d 75, 76 (9th Cir. 1975); *Watkins v. Mercy Med. Ctr.*, 364 F. Supp. 799, 801 n.6 (D. Idaho 1973), *aff’d*, 520 F.2d 894 (9th Cir. 1975); 119 Cong. Rec. 9,595 (Mar. 27, 1973). The statute prohibits courts and public officials from compelling Public Health Service Act (PHSA) funding recipients to “perform or assist in the performance of any sterilization procedure or abortion” if it would “be contrary to his religious beliefs or moral convictions,” or to require an entity to make its facility or staff available for such a procedure if the procedure is “prohibited by the entity on the basis of religious beliefs or moral convictions.” 42 U.S.C. § 300a-7(b).² The Amendment further prohibits entities receiving PHSA funds from discrimination in the “employment, promotion, or termination of employment of any physician or other health care personnel” or the extension of “privileges” based on an employee’s “religious beliefs or moral convictions

² The Church Amendment references two other funding statutes, but they were subsequently repealed.

respecting sterilization procedures or abortions” and their willingness or refusal to perform or assist in the performance of such procedures. *Id.* § 300a-7(c)(1).

Coats-Snowe. In 1996, Congress enacted the Coats-Snowe Amendment following a decision by a national accrediting body to require OB-GYN residency programs to offer abortion training; it focuses specifically on “[a]bortion-related discrimination in governmental activities regarding training and licensing of physicians.” 42 U.S.C. § 238n; *see* 142 Cong. Rec. S2264 (daily ed. Mar. 19, 1996) (statement of Sen. Coats). The Amendment prohibits governments receiving federal funding from discriminating against a health care entity for refusing “to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions” or refusing “to make arrangements for any of th[os]e activities.” 42 U.S.C. § 238n(a). The statute contains a similar prohibition in the accreditation context. *Id.* § 238n(b)(1). The statute applies only to health care entities, which includes “an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions.” *Id.* § 238n(c)(2).

Weldon. In every appropriations act since 2004, Congress included the Weldon Amendment, which is a rider to appropriations for the Departments of

Labor, Education, and HHS. It provides that none of the appropriated funds “may be made available to a Federal agency or program, or to a State or local government,” if the recipient “subjects any institutional or individual healthcare entity to discrimination on the basis that the healthcare entity does not provide, pay for, provide coverage of, or refer for abortions.” Pub. L. No. 115-245, § 507(d)(1), 132 Stat. 2981, 3118 (Sept. 28, 2018). The Weldon Amendment applies only to health care entities, which include “an individual physician or 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.” *Id.* § 507(d)(2).

Alongside these statutes are complementary federal laws aimed at, among other things, ensuring patients’ access to emergency health care, *e.g.*, EMTALA, 42 U.S.C. § 1395dd (requiring hospitals receiving certain funds to stabilize or transfer patients experiencing “emergency medical conditions”), and preventing religious discrimination in the workplace, Title VII, 42 U.S.C. §§ 2000e(j), 2000e-2(a)(1) (making it unlawful for an employer to take an adverse employment action against a job applicant or employee because of any aspect of that individual’s religious observance or practice “unless an employer demonstrates that he is unable to reasonably accommodate [that] religious

observance or practice without undue hardship”). Taken together, these federal statutes carefully balance the religious beliefs of health care employees with the needs of patients and the obligations of health care employers to provide emergency care to all patients, including pregnant patients.

2. Washington’s Laws Balancing Conscience Rights and Patient Access to Timely Care

Washington’s Legislature crafted a careful balance between individuals’ religious and moral beliefs and patients’ rights to health care. Its general conscience statute provides:

No individual health care provider, religiously sponsored health carrier, or health care facility may be required by law or contract in any circumstances to participate in the provision of or payment for a specific service if they object to so doing for reason of conscience or religion.

Wash. Rev. Code § 48.43.065(2)(a); *see also* Wash. Rev. Code § 48.43.065(2)(b); Wash. Rev. Code § 70.47.160(2)(b). The statute protects persons from discrimination “in employment or professional privileges” because they assert a conscience objection. Wash. Rev. Code § 48.43.065(2)(a); *see also* Wash. Rev. Code § 70.47.160(2)(a).

At the same time, the Washington Legislature has enacted laws guaranteeing the rights of Washingtonians to receive appropriate and fully informed medical care consistent with medical standards and ethical rules. These

laws include Washington's Informed Consent statute, Wash. Rev. Code § 7.7.050; its statute mandating emergency contraception for sexual assault victims, Wash. Rev. Code § 70.41.350; the statute prohibiting health care-related discrimination based on gender identity, Wash. Rev. Code § 74.09.875(1); and Washington's charity care law prohibiting patient abandonment, among other laws. *See* ER91-98 (¶¶ 16-32).

B. Regulatory Background

In December 2008, 35 years after the first federal conscience statute was enacted, HHS issued a rule implementing the Church, Coats-Snowe and Weldon Amendments. *See* 73 Fed. Reg. 78,072 (Dec. 19, 2008) (the 2008 Rule). The 2008 Rule provided its own definitions of certain terms, including “assist in the performance” and “health care entity.” While opining that the scope of the conscience statutes was broader than Title VII, HHS nevertheless declined to define discrimination because the term was “widely understood” and “significant federal case law exist[ed] to aid entities in knowing what types of actions do or do not constitute unlawful discrimination.” *Id.* at 78, 085, 78,077. The 2008 Rule also required compliance certifications, provided for enforcement of violations, and designated HHS's Office of Civil Rights (OCR) to receive and coordinate the investigation and resolution of complaints. *See id.* at 78,096-101.

Shortly after a multistate action challenging the rule was filed, *see Connecticut v. United States*, No. 09-cv-054 (D. Conn.), HHS issued a notice of proposed rulemaking soliciting comments on rescinding the 2008 Rule. *See* 74 Fed. Reg. 10,207 (Mar. 10, 2009).

In February 2011, HHS issued a superseding rule. 76 Fed. Reg. 9968, 9969 (Feb. 23, 2011) (the 2011 Rule). The 2011 Rule maintained OCR's role to receive discrimination complaints, but rescinded the definitions contained in the 2008 Rule because they may have "caused confusion regarding the scope of the federal health care provider conscience protection statutes." *Id.* at 9972-74. HHS also "agree[d] with comments that the 2008 Final Rule may negatively affect the ability of patients to access care if interpreted broadly." *Id.* The agency further found that "the Federal health care provider conscience statutes have provided protections for decades, and will continue to protect health care providers," specifically rejecting the contention that "providers would either leave the health care industry or choose not to enter it" if the 2008 rule were rescinded. *Id.* at 9974.

Nearly seven years later, in January 2018, HHS proposed a new rule, 83 Fed. Reg. 3880 (Jan. 26, 2018), which received over 242,000 comments, 84 Fed. Reg. 23,180. On May 21, 2019, HHS published the Rule challenged in

this litigation. Its purpose is to “provide for the implementation and enforcement of the Federal conscience and anti-discrimination laws.” 45 C.F.R. § 88.1.

To accomplish its purported purpose, the Rule first sets forth broad definitions for several terms in the conscience statutes, including “discriminate or discrimination,” “assist in the performance,” and “referral or refer for.” 45 C.F.R. § 88.2. The Rule’s definitions of these terms vastly expand individuals’ ability to refuse to provide a variety of health care services, while simultaneously limiting the actions health care employers can take to ensure continuous patient care. *Id.* The Rule’s definition of “health care entity” similarly expands the universe of individuals and entities subject to the conscience statutes. *Id.* In addition, the Rule requires funding recipients to certify compliance with both federal law and the Rule. *Id.* §§ 88.4-88.6. The Rule also expands the agency’s enforcement authority, authorizing sweeping remedies, including allowing HHS to withhold, deny, suspend, or terminate funding “in whole or in part” for any “failure to comply” with a provision of the Rule or the conscience statutes. *Id.* § 88.7.

C. Procedural Background

The State of Washington challenged the Rule under both the APA and the federal Constitution, alleging the Rule placed over \$10.5 billion in federal

funding to Washington at risk. ER82-144; *see* ER 132. Following Washington's preliminary injunction motion, which led to the postponement of the Rule's effective date, the parties filed cross-motions for summary judgment.

On November 6, 2019, the day before oral argument on those motions, United States District Court Judge Paul A. Engelmayer granted summary judgment in a related action brought in the Southern District of New York and vacated the Rule in its entirety. *New York*, 414 F. Supp. 3d 475.

After spending much of the oral argument discussing the ruling from the Southern District of New York, the Washington district court granted Washington's motion for summary judgment and denied the federal government's cross-motion. SER2294. In so ruling, the district court explained that it was "rul[ing] that Judge Engelmayer ha[d] approached the issue in the way . . . [the court] was approaching it . . . but he did it in a very thorough and comprehensive way," and made clear that the court did not "intend to plow the same ground that he plowed" and that it was "accept[ing] his ruling." *Id.*

Shortly thereafter, on November 21, 2019, the district court issued a written opinion, which repeated that "[i]t adopted the conclusions of Judge Engelmayer, finding that first, it is appropriate for this Court to decide this issue on summary judgment; second, HHS exceeded its statutory authority in

adopting this Rule; third, it acted arbitrarily and capriciously because HHS’s justifications for the Rule were contrary to the evidence in the record and because HHS failed to supply a reasoned explanation for its policy change from the previous Rule and finally, the Rule violated the U.S. Constitution—specifically, the separation of powers and Spending Clause.” ER30. The Court further clarified it was “adopt[ing] the reasoning set forth in Judge Engelmayer’s Order in making these findings.” *Id.* The district court then went to address “additional arguments” and ruled in Washington’s favor on those issues as well. ER30-33. This appeal followed. ER72-74.

V. SUMMARY OF THE ARGUMENT

The Washington district court correctly ruled that the Rule violates the APA and the U.S. Constitution and properly vacated the Rule in its entirety. This Court should affirm.

1. The Rule violates the APA because it exceeds HHS’s authority and is contrary to law. 5 U.S.C. §§ 706(2)(A), (C). In particular, the Rule’s expansive definitions are inconsistent with the meanings of the statutory terms enacted by Congress in the federal conscience statutes and create a conflict with other federal statutes, including Title VII. They also are impermissibly substantive, as they grant new rights and impose new obligations on regulated parties.

Discrimination. The Rule abandons the common Title VII framework for assessing claims of religious discrimination and dramatically expands what constitutes “discrimination” in the health care sector by, among other things, preventing health care employers from inquiring whether job candidates are willing to perform all essential functions of their jobs, giving an employee absolute veto power over a proposed accommodation, and eliminating the “undue burden” defense for health care employers. 45 C.F.R. § 88.2.

Assist in Performance. The Rule improperly expands the Church Amendment’s reach by defining “assist in the performance” to include the conduct by individuals unconnected to the actual performance of abortions and sterilizations, including receptionists scheduling appointments and ambulance drivers transporting patients.

Health Care Entity. The Rule’s definition of “health care entity” extends beyond the specific and particularized definitions Congress gave that term in the Coats-Snowe and Weldon Amendments, and impermissibly includes new individuals and entities not covered by those statutes.

Refer for or Referral. The Rule’s definition of “refer for” and “referral” disregards the common medical definition of that term—*i.e.*, a doctor’s order referring a patient to receive a specific procedure or other healthcare provider.

Instead, the Rule redefines that term to cover the provision of any information that might aid an individual in obtaining a particular procedure, drastically expanding the conduct to which the Coats-Snowe and Weldon Amendments apply.

The Rule also exceeds HHS's authority and is contrary to law because HHS lacks authority to promulgate substantive regulations implementing the Church, Coats-Snowe, and Weldon Amendments; the Rule's enforcement provisions vastly exceed HHS's enforcement powers; and the Rule conflicts with EMTALA.

2. The Rule also violates the APA because it is arbitrary and capricious. 5 U.S.C. § 706(2)(B). First, HHS acted arbitrarily and capriciously because its "justifications for the Rule were contrary to the evidence in the record." ER 30. While HHS claimed that there had been "a significant increase in complaints with OCR alleging violations of the laws that were the subject of the 2011 Rule," 84 Fed. Reg. 23,175, the overwhelming majority of those complaints had nothing to do with the conscience statutes. Nor was there evidence of widespread noncompliance with the conscience statutes necessitating increased enforcement authority.

Second, HHS failed to consider or meaningfully address evidence of the severe harms the Rule will inflict, including patient harm, interference with EMTALA, harms to vulnerable populations, and departure from the long relied upon Title VII framework.

3. The Rule also violates the Spending Clause of the U.S. Constitution and the separation of powers doctrine, by imposing new federal funding conditions not anticipated by Congress and by threatening to terminate all HHS-administered funding.

4. Finally, the district court properly vacated the Rule in its entirety because the APA expressly authorizes courts to “set aside” unlawful action. 5 U.S.C. § 706(2).

VI. STANDARD OF REVIEW

This Court reviews a grant of summary judgment de novo and “may affirm on any ground supported by the record.” *Gill v. United States Dep’t of Justice*, 913 F.3d 1179, 1184 (9th Cir. 2019).

VII. ARGUMENT

A. The Rule Exceeds HHS’s Statutory Authority and Is Contrary to Law

Under the APA, courts must “hold unlawful and set aside agency action” when the challenged action was taken “in excess of statutory . . . authority” or

was “not in accordance with law.” 5 U.S.C. §§ 706(2)(A), (C). Here, the *New York* and *Washington* district courts properly held that the Rule violated the APA on numerous grounds, including that the Rule’s definitions “do not inexorably follow from the spare terms used in the Conscience Provisions” but instead “give rise to previously unannounced rights and obligations”; “the extreme termination power that the Rule claims for HHS”—the right to terminate all of a recipient’s federal health care funds—“exceeds the bounds of the agency’s authority, including under the Conscience Provisions”; and the Rule conflicts with Title VII and EMTALA. *New York*, 414 F. Supp. 3d at 523, 526, 532, 535-39; *see* ER 29-30. Each of these rulings should be affirmed.³

³ HHS contends that the Washington district court did not adopt Judge Engelmayer’s holding on the conflict-of-law issue. Br. at 15. But at both oral argument and in the district court’s written decision, the court explained that Judge Engelmayer’s decision was “well-reasoned and thorough,” ER28, and stated that it “adopted the conclusions of Judge Engelmayer,” ER29. It is, therefore, Washington’s position that the district court adopted the *New York* decision in its entirety. In any event, HHS does not dispute that Washington argued below that the Rule conflicted with EMTALA and Title VII. Accordingly, even if the Washington district court’s decision does not encompass the conflict-of-law issue, it is appropriately before this Court on appeal. *See, e.g., United States v. Lemus*, 582 F.3d 958, 961 (9th Cir. 2009) (legal theories not reached by the district court provide alternative grounds for affirmance).

1. The Rule’s definitions exceed HHS’s authority and are contrary to law

The Rule’s new definitions exceed HHS’s authority because they go far beyond the language used by Congress in the underlying conscience statutes at issue and, in some instances, conflict with other federal laws.

Notably, on appeal, HHS has abandoned its request for *Chevron* deference. Instead, it now contends that the challenged definitions are permissible because the definitional provisions are interpretative and represent the agency’s “best reading of the statutes.” Br. at 27-29. HHS further contends that “[t]he definitional provisions have no independent effect, and the duties reflected in the Rule flow from the conscience statutes, not the Rule.” App. 28-29. But this “litigation posture” does not pass muster. *See, e.g., Guedes v. Bureau of Alcohol, Tobacco, Firearms, & Explosives*, 920 F.3d 1, 19 (D.C. Cir. 2019) (rejecting government’s position that sought to “reimagine the Rule as merely interpretive” and “not an act of legislative rulemaking”; finding no merit in the government’s argument that the Rule only “sets forth the agency’s interpretation of the best reading of the statutory definition”).

As a threshold matter, notwithstanding the agency’s attempts to recast its definitions as merely interpretative, HHS already conceded in related litigation that “with regard to the definitions, there are some substantive elements there,”

and “[t]he agency does take the position that the rule is substantive, that it does impose obligations on regulated entities.” SER1818. Having made this concession regarding the nationwide Rule, HHS should not be permitted to switch positions now. *See New York*, 414 F. Supp. 3d at 513 and n.14.⁴

Further, far from merely “expressing ‘what [the] statute has always meant,’” the Rule’s definitions for “discriminate or discrimination,” “assist in the performance,” “health care entity,” and “referral or refer for,” “impose heretofore unrecognized duties on funding recipients in connection with objections to medical procedures.” *Id.* at 523 (quoting *Guedes*, 920 F.3d at 19). By expanding statutory terms to impose new rights and obligations on regulated parties, the Rule’s definitions are impermissibly substantive. HHS’s attempts to otherwise characterize the Rule “cannot be taken seriously.” *Id.* at 513.

⁴ The Rule also is unlawful because HHS lacked authority to promulgate regulations implementing the Church, Coats-Snowe, and Weldon Amendments. *See* ER 28 (“[W]ith respect to the Church, Coats-Snowe, and Weldon Amendments, HHS was never delegated and did not have substantive rule-making authority.”). To avoid duplicative briefing on this issue, Washington joins the argument of Plaintiff San Francisco explaining why the definitional provisions are substantive rules that HHS lacked authority to promulgate. *See* City and County of San Francisco’s Answering Brief (San Francisco Br.) at I.A.1.; Fed. R. App. P. 28(i).

a. “Discriminate or discrimination”

The terms discriminate or discrimination are used, but not defined, in the Church Amendment, the Coats-Snowe Amendment, and the Weldon Amendment. But when the first conscience statute was adopted, a comprehensive body of federal case law involving employment discrimination had been developed under Title VII, including unlawful religious discrimination. As HHS previously explained in declining to adopt a statutory definition of discrimination in the 2008 Rule, “[t]he term ‘discrimination’ is widely understood, and significant federal case law exists to aid entities in knowing what types of actions do or do not constitute unlawful discrimination.” 73 Fed. Reg. at 78,077.

Notwithstanding this “widely understood” definition of discrimination, the Rule nevertheless adopted a new definition that breaks from the “significant federal case law” interpreting discrimination under Title VII. *Id.* The Rule now defines “[d]iscriminate or discrimination,” as any negative change to an individual’s “title,” “position,” or “status,” the denial of “any benefit or privilege,” or the imposition of “any penalty” in employment, 45 C.F.R. § 88.2, and abandons Title VII’s reasonable accommodation/undue burden framework. HHS posits that its new definition “reflects the best reading of the relevant

statutes” (Br. at 32), but in fact, it both breaks with the common legal definition of discrimination and impermissibly expands what conduct is actionable under the conscience statutes.

(1) The Rule’s definition breaks with the common legal definition

“To ascertain the plain meaning of [] statutory text, [courts] look to the ‘ordinary meaning at the time Congress enacted the statute.’” *Rittmann v. Amazon.com, Inc.*, 971 F.3d 904, 910 (9th Cir. 2020) (quoting *New Prime Inc. v. Oliveira*, 139 S. Ct. 532, 539 (2019)); *see also, e.g., Sandifer v. U.S. Steel Corp.*, 571 U.S. 220, 227 (2014). This inquiry may include looking “to statutes contemporaneous” with the statute at issue. *Id.*

Here, the Church Amendment, the first of the conscience statutes, was passed by Congress in 1973. It focused on discrimination that physicians or health care personnel might face in employment due to, among other things, “his religious beliefs or moral convictions respecting sterilization procedures or abortions.” 42 U.S.C. § 300a-7(c)(1)(B).

While this statute does not define either “discrimination” or “religious beliefs or moral convictions,” at the time of its enactment there was employment discrimination case law on the issue, and unlawful religious discrimination was an issue that Congress had addressed just the year prior. Specifically, in 1972,

Congress amended Title VII to codify a 1967 EEOC guideline regarding the steps an employer must take to accommodate an employee's religious beliefs under Title VII. *See Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 71-76 (1977). Federal courts had been divided as to what constituted religious discrimination in the employment context, *id.* and n.10, but Congress settled this debate by defining "religion" to include "all aspects of religious observance and practice, as well as belief, unless an employer demonstrates that he is unable to reasonably accommodate to an employee's or prospective employee's religious observance or practice without undue hardship on the conduct of the employer's business." *Id.* at 73-74 (quoting 42 U.S.C. § 2000e(j)). Through this amendment, Congress imposed a statutory obligation on employers to make a reasonable accommodation for the religious beliefs and observances of its employees, short of incurring an undue hardship. *Id.* at 74. It was against this backdrop, then, that Congress adopted the Church Amendment in 1973 "without any indication that it perceived a conflict with Title VII claims of religious discrimination in employment." *New York*, 414 F. Supp. 3d at 524.

For the last 45-plus years, the "significant federal case law" interpreting Title VII has provided the basis for entities subject to the conscience statutes to evaluate "what types of actions do or do not constitute unlawful discrimination."

73 Fed. Reg. at 78,077; *see also id.* at 78,085 (stating, in 2008 Rule, the Department’s enforcement of the conscience statutes “will be informed” by “comparison to Title VII religious discrimination jurisprudence”). That changed with the 2019 Rule.

In the 2019 Rule, HHS contends that its “non-exhaustive list of actions that may constitute discrimination”—without inclusion of the reasonable accommodation/undue hardship framework—represents “the best reading of the relevant statutes.” Br. at 32-33. The agency’s main argument is that the Title VII framework is not applicable because the terms “undue hardship” and “reasonable accommodation” were “nowhere mention[ed]” in the various conscience statutes. Br. at 34, 41-44. Relying on *Dep’t of Homeland Sec. v. MacLean*, 574 U.S. 383 (2015), HHS asserts that Congress’s decision not to include those specific terms in the conscience statutes “confirms that Congress deliberately chose not to include the Title VII defenses.” Br. at 43. But *MacLean* does not support this contention.

MacLean involved whether the term “law” referred to regulations, when Congress had repeatedly used the phrase “law, rule, or regulation” in the statute at issue but only used the phrase “law” in the operative statutory section. 574 U.S. at 391-92. The Supreme Court held that the term “law” did not

encompass regulations based on “[t]he interpretive canon that Congress acts intentionally when it omits language included elsewhere” in a statute, and focused on the fact that “Congress used ‘law’ and ‘law, rule, or regulation’ in close proximity—indeed, in the same sentence”—which required those phrases to be read separately in order to give them each meaning. *Id.* at 392. But that principle has no application here.

Unlike *MacLean*, there are no competing statutory phrases “in close proximity” with the discrimination clauses in the conscience statutes. Instead, the critical issue is whether Congress intended the “ordinary meaning” of discrimination to apply to the various conscience statutes. “While Congress was at liberty to displace” the Title VII framework “and adopt a unique definition of ‘discrimination’ for purposes of the Conscience Provisions, the Conscience Provisions that contain that term do so without elaboration,” and “HHS has not pointed to any evidence of congressional intent to supersede the Title VII framework.” *New York*, 414 F. Supp. 3d at 536. Congress’s choice not to redefine religious discrimination in a manner distinct from the Title VII framework demonstrates its intent that “discrimination” be given its “‘ordinary meaning’” under federal antidiscrimination case law.

HHS contends that Title VII’s comprehensive framework has no application in the context of the ““more targeted conscience statutes,”” which are ““health care specific.”” Br. at 43 (quoting 84 Fed. Reg. at 23,191). But Congress gave no indication in the statutory language or history that it intended to displace the common meaning of discrimination in the context of religious discrimination against health care providers. Nor would such displacement make sense. The important balance that Title VII’s reasonable accommodation/undue burden framework strikes is particularly significant in the context of public health care providers, where an accommodation impacts not only the employee and employer, but also patients. As another circuit explained in examining a claim of religious discrimination in the medical context, “public trust and confidence requires that a public hospital’s health care practitioners—with professional ethical obligations to care for the sick and injured—will provide treatment in time of emergency.” *Shelton v. University of Medicine & Dentistry*, 223 F.3d 200, 228 (3d Cir. 2000). Obliterating the undue burden defense impacts not only employees and employers but also third-party patients—an outcome never contemplated by Congress. *See id.*

Finally, while insisting that the Title VII framework is inapplicable because Congress “nowhere mention[ed]” reasonable accommodation and

undue burden in the conscience statutes, HHS undercuts itself by acknowledging that “components of th[e] [reasonable accommodation] approach are appropriate in this context,” 84 Fed. Reg. 23,191 (discussing its addition of paragraph (4) to the definition of “discriminate or discrimination”), and then integrating an “effective accommodation” defense into the Rule, 45 C.F.R. § 88.2(4). The federal conscience statutes are just as silent as to “effective accommodation” as to “reasonable accommodation” and “undue burden.” HHS’s decision to cherry-pick and modify Title VII’s carefully-balanced reasonable accommodation/undue hardship framework completely undercuts its textualist argument. It is absurd for the agency to insist that its new definition of discrimination is superior to the one Congress itself adopted in Title VII and that courts and regulated entities have relied upon for the last 45-plus years in evaluating what constitutes unlawful discrimination under the conscience statutes.

(2) The Rule’s definition impermissibly expands what conduct is actionable under the conscience statutes

By abandoning the Title VII framework for evaluating religious discrimination claims, the Rule expands the conduct deemed illegal in several ways.

First, by replacing Title VII’s “reasonable accommodation” standard with a newly-minted “effective accommodation” standard, which gives employees authority to decide whether to “voluntarily accept[]” a proffered accommodation, the Rule massively expands employees’ rights—at institutions’ and patients’ expense. *See* 45 C.F.R. § 88.2(4). Under employment discrimination law, employers must attempt to reasonably accommodate the religious beliefs of an employee, unless any accommodation would impose undue hardship. 42 U.S.C. § 2000e(j); *see, e.g., E.E.O.C. v. Abercrombie & Fitch Stores, Inc.*, 575 U.S. 768 (2015) (Alito, J., concurring) (“[a]n employer may not take an adverse employment action against an applicant or employee because of any aspect of that individual’s religious observance or practice unless the employer demonstrates that it is unable to reasonably accommodate that observance or practice without undue hardship”). In proposing an accommodation, an employer must “negotiate with the employee in an effort reasonably to accommodate the employee’s religious beliefs.” *Heller v. EBB Auto Co.*, 8 F.3d 1433, 1440 (9th Cir. 1993). But an employee has a “concomitant duty’ to cooperate” because “[i]t is clear ‘that ‘bilateral cooperation is appropriate in the search for an acceptable reconciliation of the needs of the employee’s religion and the exigencies of the employer’s

business.’” *Id.* at 1440-41 (citations omitted); *see also Am. Postal Workers Union, San Francisco Local v. Postmaster Gen.*, 781 F.2d 772, 777 (9th Cir. 1986) (“a reasonable accommodation need not be on the employee’s terms only”); *Yott v. N. Am. Rockwell Corp.*, 602 F.2d 904, 908 (9th Cir. 1979) (employee “cannot shirk his duties to try to accommodate himself or to cooperate with his employer in reaching an accommodation” (citation omitted)). The Rule abandons this standard. Under the Rule, whether or not discrimination has occurred depends on an employee’s willingness to “voluntarily accept[]” an accommodation, regardless of the reasonableness of the accommodation offered. 45 C.F.R. § 88.2(4).

The difference between Title VII’s “reasonable accommodation” and the Rule’s “effective accommodation” standard is demonstrated by *Shelton*, a seminal Title VII involving a nurse’s claims of religious discrimination on conscience grounds. 223 F.3d 200. In *Shelton*, a nurse repeatedly refused to assist in emergency procedures involving pregnant patients, including refusing to assist a pregnant patient “who was ‘standing in a pool of blood,’” delaying the patient’s emergency medical procedure by thirty minutes. After the hospital determined that the nurse’s “refusals to assist risked patient safety,” it offered the nurse a lateral transfer or gave her the option of working with the hospital to

identify another position. *Id.* After the nurse refused to accept a different position, the hospital terminated her employment. The district court rejected her discrimination claim, and the Third Circuit affirmed. *Id.* at 223-24, 226-28. The Rule would produce the opposite outcome due to the nurse’s refusal to “voluntarily accept[]” the hospital’s reasonable accommodations.⁵ The fact that HHS’s “decision not to adopt a ‘reasonable accommodation’ standard could yield an opposite result under the Rule than under Title VII in scenarios like that addressed by *Shelton*” demonstrates the definition impermissibly broadens existing law. *New York*, 414 F. Supp. 3d at 421.

Second, the Rule’s definition of “discrimination” expands liability by making “any” employment change actionable, including reassignment to ensure essential job functions are covered. 45 C.F.R. § 88.2 (any negative change to an individual’s “title,” “position,” or “status,” or the denial of “any benefit[s] or privilege[s]” or the imposition of “any penalty” in employment constitutes “discrimination”). Thus, if a women’s reproductive care clinic learned after hiring an employee that she objected to performing essential functions of her job on conscience grounds and offered reassignment to a different position, which

⁵ In the *New York* case, counsel for HHS eventually conceded that it could not represent that the case would “come out the same way” under the Rule. SER1817-18.

the employee refused, that would constitute discrimination under the Rule. *See id.* § 88.2(4). But such an outcome runs counter to the common understanding of unlawful discrimination, which recognizes the appropriateness of reassignment in such a situation. *See Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Gonzales*, 468 F.3d 826 (D.C. Cir. 2006) (rejecting the “anomalous equation of reassignment with discrimination,” and dismissing assertion that the Weldon Amendment “would suddenly transform an accommodating agency’s reassignment into an act of discrimination”).

Third, the Rule’s prohibitions against employers inquiring during the job interview process as to whether a job applicant has objections to participating in core functions of the job runs astray of the undue hardship exception in existing antidiscrimination law. *See* 45 C.F.R. § 88.2(5). It is well-established that in order to prove discrimination, job applicants must show, among other things, that they were qualified for a job the employer was trying to fill and though qualified, they were rejected. *McDonnell Douglas Corp. v. Green*, 411 U.S. 792, 802 (1973). Even HHS previously recognized as much. 73 Fed. Reg. at 78,085 (recognizing in 2008 rule that, under Title VII, “employers have no obligation under the health care conscience protection laws to employ persons who are unqualified to perform the functions required of the jobs that they seek to fill,”

even if the “unwillingness to perform those functions [is based] on conscience grounds”). By no longer permitting such an inquiry, the Rule further breaks with the common definition of discrimination.

The Rule’s unprecedented prohibitions on re-employment inquiries traps employers because they not only are barred from asking if a job applicant is willing to assist with potentially objectionable procedures that are core job functions, but once the individual is hired “the Rule declines to protect an employer who, on account of hardship, refuses to accommodate the employee.” *New York*, 414 F. Supp. 3d at 513; *see also* 84 Fed. Reg. at 23,919 (the Rule’s “approach will differ from Title VII . . . by not incorporating the additional concept of an ‘undue hardship’ exception for reasonable accommodations”). For instance, if a woman’s health clinic “unwittingly hired” a receptionist who “refuses to schedule abortions and refuses to switch jobs” and “[b]usiness slows to a halt,” it would be unlawful discrimination under the Rule for the employer to terminate the receptionist. SER1819.

This is true even in a rural hospital setting where emergency health care providers must be available to treat all medical conditions, including those involving pregnant women. *See* SER1823-1824 (Rule “applies the same [in rural settings] as it applies in other settings”). By imposing new hiring restrictions on

employers and requiring them to retain employees unwilling to perform essential functions even in rural settings where “it is not realistic to have a substitute in the wings,” *id.*, the Rule’s definition of discrimination expands the scope of the conscience statutes beyond their language and common understanding.

In sum, the Rule’s definition of discrimination is “game-changing.” *New York*, 414 F. Supp. 3d at 524. Far from providing “the best reading of the statutes,” the Rule’s definition breaks with judicial precedent, conflicts with the agency’s prior statements, and radically changes the healthcare environment by replacing Congress’s reasonable accommodation/undue burden framework with an “effective accommodation” standard of the agency’s own making. Accordingly, the Rule’s definition of discrimination exceeds the agency’s authority and conflicts with Title VII in violation of the APA.

b. “Assist in the performance”

HHS’s attempt to broadly redefine “assist in the performance,” which is found only in the Church Amendments, fares no better. *See* 42 U.S.C. § 300a-7. The Church Amendments state that recipients of certain federal funds may not discriminate against “any physician or other health care personnel” “because he performed or *assisted in the performance* of a lawful sterilization procedure or abortion, [or] because he refused to perform or *assist in the performance* of such

a procedure or abortion,” 42 U.S.C. § 300a-7(b), and further provides that receipt of certain federal funds does not allow a court or public official to require “individual[s] to perform or *assist in the performance* of any sterilization procedure or abortion.” *Id.* § 300a-7(a).

The Rule defines the term “assist in the performance” to mean “to take an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity,” which “may include counseling, referral, training, . . . or otherwise make arrangements for the procedure . . . , depending on whether aid is provided by such actions.” 45 C.F.R. § 88.2. As the *New York* Court explained, this definition claims to implement the Church Amendments, but it “expands the coverage of the Church Amendments beyond any previously articulated definition, so as, among other things, to confer refusal rights on persons engaged in activities ancillary to a covered procedure (e.g., scheduling and receptionist services, transportation of a patient, and provision of information related to a procedure) and activities carried out on days before and after these procedures.” 414 F. Supp. 3d at 525. “Neither the text nor history of the Church Amendments made Congress’s intent to reach such activities clear.” *Id.*

The Rule’s expansive definition conflicts with statutory text in at least two ways. First, the Rule’s broad definition effectively reads the word “performance” out of the statute. It extends the Church Amendment to any conduct with an “articulable connection” to a sterilization procedure or abortion, not just conduct that furthers its performance. 84 Fed. Reg. at 23,186-87. Second, the Rule’s broad definition is contradicted by Congress’s use of precise language elsewhere in the Church Amendments and in the other conscience statutes. For instance, while Congress used the term “counseling” in other Church Amendment provisions, “training” in Coats-Snowe, and “referrals” in Weldon, it did not include any of these terms in §§ 300a-7(b), or (c), or (d). Yet HHS’s definition of “assist in the performance” subsumes these activities. Because Congress used language to cover these specific additional activities in other sections of the Church Amendment, HHS may not overrule Congress’s choice not to do so in §§ 300a-7(b), or (c), or (d).

The Amendment’s statutory history further confirms the Rule’s overbreadth. As Senator Church explained: “The Amendment is meant to give protections to the physicians, to the nurses, to the hospitals themselves if they are religious affiliated institutions.” 119 Cong. Rec. S9597 (daily ed. Mar. 27, 1973) (statement of Sen. Church). “There is no intention [] 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.” *Id.* While HHS attempts to minimize the context in which Congress drafted the Church Amendments (Br. at 32), it is “a fundamental canon that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” *The Wilderness Soc’y v. U.S. Fish & Wildlife Serv.*, 353 F.3d 1051, 1060 (9th Cir. 2003) (citation omitted). Both “the structure and purpose of a statute may [] provide guidance in determining the plain meaning of its provisions,” *id.* at 1060-61 (citing cases).

Downplaying the Church Amendment’s legislative history, the agency speculates that “Congress sought to reach all forms of assistance, for religious or moral objections to complicity in acts believed to be immoral often do not distinguish between ancillary and direct support.” Br. at 31-32 (citing *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 724 (2014); *Thomas v. Review Bd. of Indiana Employment Sec. Div.*, 450 U.S. 707, 715 (1981)). But the cases cited by the agency were decided long after the enactment of the Church Amendments and provide no assistance in interpreting the plain meaning of the statutory language.

Because the Rule’s definition of “assist in the performance” “extends refusal rights to a range of personnel not previously identified by the Church Amendment” and “correspondingly imposes heretofore unrecognized obligations on employers and other providers,” it is “unavoidably substantive” and exceeds HHS’s authority. *New York*, 414 F. Supp. 3d at 525.

c. “Health care entity”

HHS exceeded its authority by defining “health care entity” to include entirely different individuals and entities not identified by Congress in the Coats-Snowe and Weldon Amendments. *See New York*, 414 F. Supp. 3d at 525-26.

Coats-Snowe. The Coats-Snowe Amendment, which is titled “Abortion-related discrimination in governmental activities regarding training and licensing of physicians,” prohibits discrimination against “any health care entity . . . on the basis that” the entity “refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions,” or “refuses to make arrangements” for such activities.” 42 U.S.C. §§ 238n(a)(1)-(2). The Amendment then defines “health care entity” as “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). Congress focused on

the narrow class of individuals to whom abortion training was relevant in defining “health care entity”: physicians, residents, and those participating in training programs in the health profession. As Senator Coats, one of the Amendment’s sponsors, made clear: the purpose of the legislation “was simply [to] address the question of training for induced abortion.” 142 Cong. Rec. 5165 (daily ed. Mar. 19, 1996).

Ignoring the narrow class of individuals chosen by Congress to address a specific issue, the Rule’s expansive definition broadens Coats-Snowe’s application far beyond the abortion-training context to include “other health care professionals, including a pharmacist,” “pharmac[ies],” and “medical laboratories.” 84 Fed. Reg. at 23264. But those individuals and entities have no connection to the Coats-Snowe Amendment.

Weldon. The Weldon Amendment provides that federal funds may not accrue “to a Federal agency or program, or to a State or local government,” if the recipient “subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.” *Act of September 28, 2018*, Pub. L. No. 115-245, 132 Stat. 2981 § 507(d)(1). The Amendment defines the term “health care entity” to include “an individual physician or 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.” *Id.* § 507(d)(2). The common feature of the individuals and entities chosen by Congress is that they are all direct participants in the health care industry.

Despite the Amendment’s limited definition, the Rule expands the term to include entities that are entirely outside of the health profession—like health plan sponsors (typically employers who provide employees health benefits) and third-party administrators (firms that perform claims processing and other administrative tasks). *See* 84 Fed. Reg. at 23,264.

The Rule. HHS argues that because Congress used the term “include” in its definition in Coats-Snowe and Weldon, what follows must be nonexhaustive. *Br.* at 36-37 (citing *Samantar v. Yousuf*, 560 U.S. 305, 317 (2010)). While the term “‘include’ can signal that the list that follows is meant to be illustrative rather than exhaustive,” courts examine what Congress included in the list to determine whether including the proposed definition would strain the meaning of the statute. *See Samantar*, 560 U.S. at 317 (using the statute’s “textual clues” and “[o]ther provisions of the statute” to conclude that the term “foreign state” does not encompass officials because the listed illustrative examples “are all

entities” not people); *see also, e.g., Washington State Dep’t of Soc. & Health Servs. v. Guardianship Estate of Keffeler*, 537 U.S. 371, 384 (2003) (a term must be “construed to embrace only objects similar in nature to those objects enumerated by the preceding” words); *Gutierrez v. Ada*, 528 U.S. 250, 255 (2000) (“words and people are known by their companions”). As set forth above, the Coats-Snowe and Weldon Amendments use the term “health care entity” to refer to discrete—and different—categories of individuals and entities based on their differing statutory objectives, yet the Rule entirely ignores the statutes’ precision and limits. By using the word “include” to dramatically expand the definition of health care entity under the Coats-Snowe and Weldon Amendments, HHS exceeded its statutory authority.

d. “Referral or refer for”

The terms “referral” and “refer for” are used in both the Coats-Snowe and Weldon Amendments. *See, e.g.,* 42 U.S.C. §§ 238n(a)(1), (a)(3) (Coats-Snowe) (protecting physicians, medical residents, and trainees in the health profession from being discriminated against for refusing to provide “referrals for such training or such abortions” or attending a training program that does not “provide or refer for training in the performance of induced abortions”); *Consolidated Appropriations Act of 2010*, Pub. L. No. 111-117, § 508(d)(1), 123 Stat. 3034

(Weldon) (funds appropriated in the appropriations act not may be made available to governmental entities that discriminate against any “institutional or individual health care entity” because the entity “does not provide, pay for, provide coverage of, or refer for abortions”).

Although neither statute contains a definition of “referral” or “refer for,” these terms have an accepted meaning in the medical field: a provider directing a patient to another provider for care. *See, e.g.*, Merriam-Webster’s Medical Dictionary, <https://www.merriam-webster.com/dictionary/refer#medicalDictionary> (last visited Oct. 12, 2020) (defining “refer” as “to send or direct for diagnosis or treatment”); Merriam-Webster Dictionary, <https://www.merriam-webster.com/dictionary/referral> (last visited Oct. 12, 2020) (“[m]edical [d]efinition of referral”: “the process of directing or redirecting (as a medical case or a patient) to an appropriate specialist or agency for definitive treatment”). Applying the medical definition to statutes directed at physicians and health care entities is consistent with “the rule of construction that technical terms of art should be interpreted by reference to the trade or industry to which they apply.” *Louisiana Pub. Serv. Comm’n v. F.C.C.*, 476 U.S. 355, 372 (1986); *e.g.*, *Sullivan v. Strop*, 496 U.S. 478, 483

(1990) (using Black’s Law Dictionary to define child support because it was a “term of art”).

Notwithstanding this common medical definition, the Rule defines “referral or refer for” as including “the provision of information in oral, written, or electronic form . . . where the purpose or reasonably foreseeable outcome of provision of the information 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.” 45 C.F.R. § 88.2. Once again, “the Rule’s definition is broader than what is inherent in the statutory text.” *New York*, 414 F. Supp. 3d at 526. The language of the Coats-Snowe and Weldon Amendments do not provide, as the Rule does, “that ‘referral’ also covers providing any information that could help the patient obtain the service or procedure at issue.” *New York*, 414 F. Supp. 3d at 526.

In an attempt to evade this conclusion, HHS argues for the first time on appeal that the Rule’s definition means “actually sending or directing a person for the particular activity.” Br. at 40. But that is not what the Rule’s definition says. The Rule makes no mention of “actually sending or directing a person.” As HHS explained in the Rule’s preamble, the Rule’s definition is not limited to “protect[ing] the action of declining to refer to an abortion provider,” but instead

“more broadly protects a decision not to provide contact information or guidance likely to assist a patient in obtaining an abortion elsewhere.” 84 Fed. Reg. at 23,200. Because HHS’s new litigation posture is inconsistent with the overly broad language of its own definition, and because its definition extends the conduct to which the Coats-Snowe and Weldon Amendments apply, HHS has once again exceeded its authority.

2. The Rule’s new enforcement powers exceed HHS’s statutory authority and the Rule conflicts with EMTALA

The Rule also exceeds HHS’s statutory authority by creating draconian enforcement powers not authorized by Congress. 45 C.F.R. §§ 88.4-88.7. In addition, the Rule violates the APA by creating an irreconcilable conflict with EMTALA, which prohibits hospitals from denying emergency medical care to patients with emergency medical conditions. To avoid duplicative briefing, Washington adopts the arguments of, respectively, Plaintiff-Appellees San Francisco and California on these issues. San Francisco Br. at I.B.; Answering Brief of Plaintiffs-Appellees State of California (California Br.) at I.B.

B. The Rule is Arbitrary and Capricious

The APA requires agencies to “engage in reasoned decisionmaking.” *Dep’t of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891,

1905 (2020). To survive judicial review, the agency must engage in a “reasoned analysis” that indicates it “examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983) (citation and internal quotation marks omitted). A rule is arbitrary and capricious where the agency “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Id.* at 43. The agency must consider “the advantages and the disadvantages” of the proposal before taking action. *Id.*, 463 U.S. at 43.

When an agency reverses position, it must “supply a reasoned analysis for the change.” *State Farm*, 463 U.S. at 42. If it departs from a well-established prior policy that “engendered serious reliance interests”—as HHS has done here—the agency must provide a more “detailed justification” for its actions. *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Regents*, 140 S. Ct. at 1913; *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

HHS failed to discharge these obligations. The district court thus properly found the Rule arbitrary and capricious. *See* 5 U.S.C. § 706(2)(A).

1. HHS’s stated rationales for the Rule are contradicted by the administrative record

In enumerating the reasons for the new Rule, HHS claimed it was necessary because of a “significant increase in complaints alleging violations of the laws that were the subject of the 2011 Rule,” emphasizing that it had received 343 such complaints in fiscal year 2018. 84 Fed. Reg. at 23,175, 23,183, 23,229; *see also* 83 Fed. Reg. at 3887. HHS further claimed the 2011 rule had “created confusion over what is and is not required under” the conscience statutes and that HHS’s enforcement powers under that rule were inadequate. 84 Fed. Reg. at 23,175. But the administrative record contradicts these justifications.

Because “[a]gency action based on a factual premise that is flatly contradicted by the agency’s own record does not constitute reasoned administrative decisionmaking,” the district court properly concluded that the Rule was arbitrary and capricious. *City of Kansas City, Mo. v. Dep’t of Hous. & Urban Dev.*, 923 F.2d 188, 194 (D.C. Cir. 1991); *see, e.g., Dioxin/Organochlorine Ctr. v. Clarke*, 57 F.3d 1517, 1521 (9th Cir. 1995) (reversal under APA required where agency “offered an explanation for its decision that runs counter to the evidence before the agency”); *Bowen v.*

Am. Hosp. Ass'n, 476 U.S. 610, 643 (1986) (vacating antidiscrimination rule when “the Secretary has pointed to no evidence that such discrimination occurs”).

a. The administrative record does not support HHS’s sweeping expansion of conscience rights in health care

(1) Conscience-Related Complaints

As the *New York* district court found, HHS’s specific factual assertion that it had received 343 conscience-related complaints in fiscal year 2018—which it claimed reflected a “significant increase”—was “demonstrably false.” *New York*, 414 F. Supp. 3d at 541; 84 Fed. Reg. at 23,175. Instead, the vast majority of the complaints HHS included did not, as HHS asserted, implicate “violations of the laws that were the subject of the 2011 Rule,” 84 Fed. Reg. at 23,175. Rather, the record showed that *a full 94%* of the complaints HHS relied on had nothing to do with procedures covered by the conscience statutes. *New York*, 414 F. Supp. 3d at 541-43; SER2126-2127, ¶¶ 14-17, SER2130-2146. Of the 336 unique OCR complaints in the administrative record (not 343, as HHS claimed), 79% (266 complaints) addressed vaccinations, which are not a subject of the conscience statutes (SER2126, ¶ 15). Except for 21 complaints that could potentially be covered by the conscience statutes, the remainder did not implicate

them or addressed HHS's practices on other grounds altogether (SER2126-2127, ¶¶ 16-17).

HHS does not dispute that its stated rationale for the Rule massively overstated the number of relevant complaints. *See* Br. 50-51. Nor could it, since HHS conceded below that the actual number of complaints that implicated the conscience provisions was “in [the] ballpark” of 20 rather than 343. *New York*, 514 F. Supp. 3d at 542. Instead, HHS now complains the district court improperly required the agency to compile a “particular number of violations” before promulgating the Rule. *See* Br. 49 (emphasis omitted). But the *New York* court merely found the specific number HHS itself relied on to justify the Rule was not supported by the record. 514 F. Supp. 3d at 544.

And while HHS seeks to minimize the importance of the supposed large number of complaints it received, this misrepresents the Rule. Br. 50. HHS's first rationale for the Rule is the “significant increase in complaints filed with OCR alleging violations of the laws that were the subject of the 2011 rule,” 84 Fed. Reg. 23,175—an increase that turned out to be almost entirely false. Further, HHS's insistence that the Rule's factual misrepresentation is immaterial because just 20 complaints in fiscal year 2018 would still “reflect a troubling number of alleged violations” misses the mark. Br. 51. “An agency must defend

its actions based on the reasons it gave when it acted,” *Regents*, 140 S. Ct. at 1909, and the Court’s review is “limited to evaluating the agency’s contemporaneous explanation in light of the existing administrative record,” *Dep’t of Commerce v. New York*, 139 S. Ct. 2551, 2573 (2019). HHS’s *post hoc* rationalization violates this requirement.

Moreover, the true number of complaints that even allege conduct potentially covered by the conscience statutes—twenty-one—does not support HHS’s inference that a major change in the status quo was necessary to address purportedly vast new noncompliance. SER2127, ¶ 17. Indeed, the opposite is true. This small number of complaints demonstrate the religious discrimination the Rule purports to address is actually *not* prevalent, given how miniscule it is compared with complaints of other forms of discrimination OCR receives. *See* Department of Health and Human Services Office of Civil Rights, *Fiscal Year 2019 Justification of Estimates for Appropriations Committee* at 30, <https://www.hhs.gov/sites/default/files/fy2019-ocr-congressional-justification-accessible.pdf> (last visited Oct. 12, 2020) (OCR received a total of 24,523 complaints in FY 2016).

(2) Evidence of Discrimination and Coercion

Setting aside HHS's inflated account of relevant OCR complaints, its other purported evidence that "discrimination and coercion" has "increased over time" also evaporates under scrutiny. 84 Fed. Reg. 23,175.

HHS first cites a sentence plucked from a "perspective" column by a single physician in the *New England Journal of Medicine*—essentially a private opinion expressed in a guest editorial. *Id.* This editorial piece is not a typical medical journal "article," as HHS misleadingly describes it.

Next, it relies on a 2009 survey in which "91% of the respondents reported that 'they would rather stop practicing medicine altogether than be forced to violate [their] conscience.'" *Id.* But this survey actually is a dated poll conducted on behalf of the Christian Medical and Dental Association, including an online survey of "self-select[ed]" members of faith-based medical organizations. SER876, SER882. Even if a decade-old survey had any relevance to the health care field today, the pollster herself stated the poll was "intended to demonstrate the views and opinions [solely] of members surveyed" and "is not intended to be representative of the entire medical profession nor [even] the entire membership rosters of these organizations." SER885.

For its third justification, HHS claimed “[t]ens of thousands of comments to the 2009 proposed rule” warned that, without robust enforcement of conscience statutes, individuals would flee the health care field “and hospitals would shut down.” 84 Fed. Reg. at 23,175-76. But these comments were merely identical form letters. *See, e.g.*, 84 Fed. Reg. at 23,176 n.20 (citing form letters with, respectively, 1,916 copies, 9,532 copies, 3,272 copies, 3,516 copies, and 4,842 copies); n.21 (same; with 3,196 copies, 1,685 copies, and 2,002 copies); n.22 (same; with 8,472 copies); n.25.

In short, beyond HHS’s reliance on OCR complaints that had nothing to do with the conscience statutes, its evidence of “discrimination and coercion . . . increas[ing] over time” (84 Fed. Reg. at 23,175) is strained at best. The paucity of HHS’s evidence confirms that “[t]he Rule represents a classic solution in search of a problem.” *New York*, 414 F. Supp. at 546; *see also Nat’l Fuel Gas Supply Corp. v. F.E.R.C.*, 468 F.3d 831, 837, 841-43 (D.C. Cir. 2006) (agency rule arbitrary and capricious where explanation for its decision runs counter to the evidence).

(3) Evidence of Confusion

HHS also lacked support for its claim that the 2011 Rule “created confusion over what is and is not required under Federal conscience” statutes.

84 Fed. Reg. 23,175. Although HHS pointed to the claimed increase in complaints to show confusion, as discussed above, the overwhelming majority of complaints HHS cited had nothing to do with the conscience statutes, let alone the 2011 rule; and the few that did were not premised on confusion about existing protections. *See supra* 46-47; *see also New York*, 414 F. Supp. 3d at 542 n.48. And patient lawsuits alleging malpractice, discrimination, or EMTALA violations from being denied care based on conscience objections do not demonstrate confusion on the part of providers about their obligations. 84 Fed. Reg. 23,178.

* * *

In sum, HHS fabricated a “significant increase” in administrative complaints and relied on a biased, outdated survey and other insubstantial evidence in order to overturn prior agency policy. But a change in policy because of a change in administration does not authorize or excuse HHS’s unreasoned and unsupported rulemaking. *See, e.g., State v. United States Bureau of Land Mgmt.*, 277 F. Supp. 3d 1106, 1123 (N.D. Cal. 2017). An agency cannot fabricate the administrative record to support its preferred policy position. Instead, it must identify accurate, honestly presented facts to support the “detailed justification” necessary to support the reversal of prior policy. *Fox Television*, 556 U.S. at 515;

Dep't of Commerce, 139 S. Ct. at 2575. Because HHS “based its decision on a factual premise that the record plainly showed to be wrong,” the Rule is arbitrary and capricious. *Nat. Res. Def. Council, Inc. v. Rauch*, 244 F. Supp. 3d 66, 96 (D.D.C. 2017).

b. The record does not support HHS’s claimed need for new enforcement tools

HHS’s related claim that the Rule’s new enforcement powers were needed because the agency’s preexisting tools were “[i]nadequate” also lacks evidentiary support. 84 Fed. Reg. at 23,228. The record shows that HHS actually investigated and resolved less than five percent of the 336 complaints it compiled. SER2128, SER2147-2148. And in the few instances where it did investigate complaints, it was able to resolve them with its current enforcement tools. *See, e.g.*, SER2154-2156 (complaint closed for failure to state a claim of discrimination); SER2157-2159 (complaint withdrawn after grantee took actions to come into compliance). In short, nothing in the record supports any alleged gaps in HHS’s enforcement authority, or that the agency lacked the tools to resolve the few problems that did arise.

HHS also fails to explain how the Rule addresses any such claimed inadequacies. To the contrary, HHS disclaims on appeal that the Rule’s enforcement provisions confer any powers it did not have before. *See Br. 22*

(arguing the Rule’s enforcement powers are “consistent with preexisting regulations”). Instead, HHS argues that the record confirms it has long had the authority to conduct investigations and to resolve complaints. *See* 84 Fed. Reg. 23,177-78 (detailing complaints against California and Hawaii resolved by OCR prior to the Rule’s adoption, and complaint against private hospital resolved in 2011). It is fundamentally inconsistent for HHS to both insist that the inadequacy of enforcement tools justified the Rule, yet contend that the Rule did not set forth any new powers. Such an “unexplained inconsistency” further renders the Rule invalid under the APA. *See Encino Motorcars*, 136 S. Ct. at 2126.

2. HHS failed to consider or meaningfully address evidence of severe harms the Rule will inflict

Under the APA, a regulation is arbitrary and capricious if the agency “entirely failed to consider an important aspect of the problem.” *State Farm*, 463 U.S. at 43. HHS failed to adequately consider or meaningfully address many devastating effects associated with the Rule, including: (i) patient harm caused by a significant disruption in the provision of medical services; (ii) interference with EMTALA; (iii) harms to vulnerable populations; and (iv) abandonment of the Title VII framework.

a. Patient harm

HHS failed to adequately consider evidence showing the Rule will harm patients. It received comments from a wide range of healthcare provider systems and national organizations discussing the catastrophic effects the Rule will have on the provision of medical services. These impacts stem from the Rule’s new definitions, which, as discussed above, dramatically expand the number of prospective objectors while at the same time drastically curtailing health care employers’ ability to learn about and accommodate religious objections. *See supra* 21-33. These consequences limit providers’ ability to provide uninterrupted medical services to patients—particularly in emergency situations and rural areas. SER108; SER153; SER431-432; SER637; SER132-133; SER521-529. In such contexts, where there frequently is a shortage of time or nearby alternative providers—or both—even a single provider’s refusal to provide care may be tantamount to a per se barrier to a patient receiving care at all.

As the American Medical Association warned, under the Rule “any entity in a patient’s care—from a hospital board of directors to the receptionist that schedules procedures—[may] use their personal beliefs to determine a patient’s access to care.” SER131. Commenters warned of this harm in the context of health insurance employees’ refusals to disclose coverage for benefits and

services (SER2181); clinic or hospital receptionist refusals to schedule appointments for pregnancy termination or contraception consultation (SER139); disruptions to hospital operations, undermining patient care (SER387); and ambulance driver refusals to transport women experiencing pregnancy complications that could result in termination (SER2188).

HHS failed to address these comments. It now points to two lines of reasoning in the Rule purporting to address patient care. Br. 54-55.

First, HHS stated it is “reasonable to assume” more religious providers would enter and remain in the health field in light of the Rule. 84 Fed. Reg. 23,180-181, 23,246-47. This, however, fails to confront the very real harm to patients that commenters identified when a provider, ambulance driver, or insurance representative refuses to supply care or information based on religious beliefs. And even if it did, HHS was required to do more than speculate as to patient harm. “In light of the agency’s prior factual assessment that its 2008 rule could impede access to care, HHS’s bare contrary *assumption* in 2019 was not the ‘detailed justification’ required by *Fox Television Stations*.” *New York*, 514 F. Supp. 3d at 551-52 (emphasis in original).

Second, HHS falsely argued that the Rule did not expand on the conscience statutes, so it could not possibly alter patient access to care. 84 Fed.

Reg. 23,181. Its failure to acknowledge the significance of the Rule's changes and the concomitant failure to provide any explanation—let alone a reasoned one—for its reversal of course, only confirms the conclusion that the Rule is arbitrary and capricious. *See Encino Motorcars*, 136 S. Ct. at 2126; *Fox Television*, 556 U.S. at 515-16.

b. Impact on emergency medical services

HHS also ignored evidence of the devastating consequences the Rule will have on emergency medical services. Because HHS failed to reconcile the Rule with EMTALA—notwithstanding the numerous comments discussing the life-or-death impact the Rule could have in emergency medical situations—the district court properly found the Rule arbitrary and capricious. ER29-30; *New York*, 414 F. Supp. 3d at 555.

EMTALA requires providers to treat patients, including pregnant women, in certain emergency situations. 42 U.S.C. § 1395dd; *see id.* § 1395dd(e)(1). But the Rule is completely silent as to what responsibilities, if any, objectors might have in such circumstances. Numerous commenters highlighted this troubling omission as fundamentally inconsistent with the practice of emergency medicine, which often depends on small crews working together to save lives quickly, in unison, and with little margin for error. *See, e.g.*, SER112 (American

College of Emergency Physicians) (“emergency departments operate on tight budgets and do not have the staffing capacity to be able to have additional personnel on hand 24 hours a day, 7 days a week to respond to different types of emergency situations that might arise involving patients with different backgrounds, sexual orientations, gender identities, or religious or cultural beliefs”); SER133.

In adopting the Rule, HHS brushed aside these concerns despite acknowledging that it received “many comments” on the issue. *See* 84 Fed. Reg. at 23,182-23. HHS’s response was that “[w]ith respect to EMTALA, the Department generally agrees with the explanation in the preamble to the 2008 Rule that the requirement under EMTALA that certain hospitals treat and stabilize patients who present in an emergency does not conflict with Federal conscience antidiscrimination statutes laws.” *Id.* at 23,183; *see also id.* at 23,188, 23,263. But the 2008 Rule was equally summary and dismissive of commenters’ concerns. *See* 73 Fed. Reg. 78,087-88. Further, HHS’s response was contradicted by its own later statement that whether a hospital-based ambulance driver may refuse to transport a patient with a life-threatening ectopic pregnancy “would depend on the facts and circumstances.” 84 Fed. Reg. at 23,188. And HHS gave no practical input as to how a small, rural emergency department, for

example, could balance its obligation to provide emergency care with its employees' absolute right to refuse to provide care under the Rule.

HHS attempts to downplay any potential harm to emergency services by stating that a conscience-based refusal by emergency personnel "is unlikely to occur" (Br. 54), but this contention is directly contradicted by evidence submitted during the public comment period. *See, e.g.*, SER2209; SER650; SER463.

As the *New York* district court correctly found, 414 F. Supp. 3d at 555, HHS's generalized conclusions failed to respond to the significant concerns raised by commenters and thus was arbitrary and capricious. *See AEP Texas N. Co. v. Surface Transp. Bd.*, 609 F.3d 432, 441 (D.C. Cir. 2010) ("By relying only on generalized conclusions . . . the [agency] 'entirely failed to consider an important aspect of the problem,' making its [conclusion] arbitrary and capricious" (citing *State Farm*, 463 U.S. at 43)); *PPL Wallingford Energy LLC v. F.E.R.C.*, 419 F.3d 1194, 1198 (D.C. Cir. 2005).

c. Harm to vulnerable populations

Likewise, HHS disregarded evidence that the Rule would significantly harm vulnerable populations, including women, lesbian, gay, bisexual, and transgender (LGBT) people, individuals with disabilities, and people living in

rural areas. The Washington district court properly found the Rule was arbitrary and capricious on this ground. ER31-32.

Many commenters noted the Rule would worsen health outcomes and increase discrimination against women seeking treatment for a host of conditions, including pregnancy and family planning. SER2231-2232; SER521-522. Commenters highlighted the serious obstacles to care the Rule would create for LGBT patients (SER524), disabled individuals (SER2204); and persons living in rural communities (SER522-524; SER724).

HHS defends the Rule by arguing that it does not protect providers who deny care on religious grounds to individuals because they are gay or transgender. Br. at 55. But this is simply false. In response to comments that the Rule harms LGBT patients, HHS read 42 U.S.C. § 300a-7(d) and § 300a-7(c)(2) as “direct[ing] the protection of conscientious objections in contexts not tied to specific treatments,” 84 Fed. Reg. at 23,189, and it refused to foreclose “objections to serving particular populations” (Br. 55).

HHS now dismisses these comments as providing only anecdotal evidence of discrimination and lacking sufficient proof of causation. Br. 55-56. This argument mirrors the Rule itself, in which HHS disregarded many “anecdotal accounts of discrimination from LGBT” people as “offer[ing] no suitable data

for estimating the impact of this rule,” *id.* at 23,252. But HHS’s dismissal of this pertinent evidence is fatally inconsistent, as the agency relied extensively on anecdotal evidence to support the Rule. *See, e.g.*, 84 Fed. Reg. 23,228, 23,247; *see also id.* at 23,175 (repeatedly citing as support for the Rule a survey analyzing exclusively anecdotal responses from self-selecting participants). This “internally inconsistent” treatment of anecdotal evidence—relying upon it when it supports the Rule, but dismissing it when it does not—renders the rulemaking process arbitrary and capricious. *See* ER32; *Nat. Res. Def. Council v. U.S. Nuclear Regulatory Comm’n*, 879 F.3d 1202, 1214 (D.C. Cir. 2018) (“Of course, it would be arbitrary and capricious for the agency’s decision making to be ‘internally inconsistent.’”). And, in any event, HHS’s assertion that commenters had failed to establish causation is belied by the record. *See, e.g.*, SER389-396 (statistics and qualitative evidence of discrimination against LGBT patients).

HHS’s unwillingness to consider the serious harms resulting from an expansion of refusal rights amid currently widespread discrimination against vulnerable populations—an important aspect of the problem—further underscores the arbitrariness of the Rule.

d. Abandonment of Title VII framework

Finally, the Rule is arbitrary and capricious because HHS failed to address evidence of significant harm resulting from its repudiation of Title VII's regulatory framework, which "has governed religious accommodation in the health care sector since 1972." *New York*, 414 F.3d at 555. Although Title VII carefully balances the interests of employers, employees, and patients, HHS without justification abandoned it for an unbalanced system where employers have no meaningful ability to protect their patients by anticipating or responding to their employees' religious objections.

Concerned about the agency's repudiation of Title VII's framework, many commenters warned the Rule will lead to harmful and absurd results, including that "individual[s] could be hired into and remain in" jobs they refuse to perform, without any guardrails in place to "enable employers to take advance steps to ensure patients get the care they need." SER2165; *see also* SER132; SER515-516. HHS largely ignored commenters' concerns that overturning years of employment law and practice would disrupt their businesses and impose unanticipated costs. It provided little explanation of its decision to abandon the Title VII framework, except to view Congress's silence in the conscience

statutes as tacitly reflecting its intent that Title VII’s framework not apply to them. 84 Fed. Reg. at 23,191.

HHS’s superficial explanation falls far short of what is necessary to justify a complete overhaul of the Title VII standard that has effectively governed health care workplaces for decades. As the Supreme Court recently reiterated, agencies must “be cognizant that longstanding policies may have ‘engendered serious reliance interests that must be taken into account.’” *Regents*, 140 S. Ct. at 1913 (quotation omitted). By failing to meaningfully consider and address commenters’ concerns on this issue, HHS failed to provide the “reasonable explanation” necessary to justify a departure from decades of settled law. *Encino Motorcars*, 136 S. Ct. at 2126.

C. The Rule is Unconstitutional

1. The Rule violates the Spending Clause

a. Washington’s Spending Clause argument is ripe

The Rule requires major and immediate changes to Washington’s and its subrecipients’ preexisting policies and practices—entailing immediate and substantial expenditures of time and costs, even before the Rule takes effect. *See, e.g.*, SER1999, ¶ 5; SER2002, ¶ 12; SER2020-2021, ¶¶ 22-23; SER2092-2093, ¶ 6; SER2031-2034, ¶¶ 17-18, 21, 24; SER2053, ¶ 6; SER2067, ¶ 11; SER2071,

¶ 21; SER2099-2101, ¶¶ 13-14; SER2106-2107, ¶ 8]. HHS does not and cannot dispute these “direct and immediate” impacts of the Rule. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 148, 152 (1967). Even HHS estimates that compliance costs exceed \$150 million for regulated entities in the first year—and that assumes only a fraction of regulated entities proactively undertake such compliance efforts. 84 Fed. Reg. at 23,256.

When an agency issues “a substantive rule which as a practical matter requires the plaintiff to adjust his conduct immediately . . . [s]uch agency action is ‘ripe’ for review at once.” *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 891 (1990) (citing *Abbott Labs.*, 387 U.S. at 152-54). This Rule does just that. It assigns significant new substantive meaning to the conscience provisions, requiring major and immediate changes in the policies and actions of Washington and its subrecipients, including with respect to hiring, staffing, and other employment decisions. The Rule itself asserts its intent that States and others comply. *See, e.g.*, 84 Fed. Reg. at 23,227-28 (the Rule “incentivizes the desired behavior” and will cause recipients to “institute proactive measures,” including by enhancing HHS’s previously “[i]nadequate enforcement tools”); *id.* at 23,269-70 (requiring recipients to sign enforceable assurances and certifications of compliance). HHS’s own mandates refute any argument that

enforcement might be hypothetical, as it now incorrectly argues. *See* Br. 57-59; *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1126 (9th Cir. 2009) (even if record is sparse and the nature of the record preliminary, a party has standing to challenge the definitive statement of the agency’s position).

The district court properly rejected HHS’s argument that Washington’s challenge is not ripe until after HHS has brought an enforcement action pursuant to the Rule. The argument ignores that the burdens of compliance alone are sufficient to establish “a present hardship” warranting judicial review and that Washington must either incur great expense to comply with the requirements, or (if they choose to challenge the regulation through noncompliance) run the risk of incurring potentially even greater burdens—here, the potential loss of billions of dollars of federal funding. *See Lujan*, 497 U.S. at 891; *Stormans, Inc.*, 586 F.3d at 1126; *Ass’n of Am. Med. Colleges v. United States*, 217 F.3d 770, 783 (9th Cir. 2000) (even if record is sparse and the nature of the record preliminary, a party has standing to challenge the definitive statement of the agency’s position).⁶

⁶ HHS misplaces reliance on prior cases that dismissed facial challenges to the Weldon Amendment. *See* Br. 58-60. Neither case presented the substantial and immediate compliance burdens imposed here by the Rule, as the claims of harm at issue concerned only HHS’s potential enforcement of violations of the Weldon Amendment. *Cf. California v. United States*, No. C 05-328, 2008 WL

The purported availability of administrative review of any termination of funds is not sufficient to avoid judicial review. The Rule includes no mechanism to challenge HHS's funding determinations akin to those that existed under the Uniform Administrative Requirements (UAR). *See* Br. 59-60; 45 C.F.R. §§ 88.7(i)(2), (3)(i), (4).

b. The Rule violates the Spending Clause by imposing new conditions on federal funds and threatening to terminate all HHS-administered funding

The Rule violates the Spending Clause in at least two ways. First, by conditioning federal grants created by Congress on a host of regulatory terms that are beyond the statutory text, HHS violated clear notice principles. *See Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1 (1981). *Pennhurst* requires that notice of a funding condition must be made “unambiguously” to the States by Congress, not through a regulation the Executive Branch promulgates decades later. *See id.* at 17; *Bennett v. Kentucky Dep’t of Educ.*, 470 U.S. 656, 670 (1985) (rejecting argument that States had agreed to “satisfy whatever interpretation of the terms might later be adopted” by an agency).

744840, at *5-6 (N.D. Cal. Mar. 18, 2008) (no evidence HHS will enforce Weldon Amendment as those plaintiffs claimed so as to implicate risk of defunding); *NFPRHA v. Gonzalez*, 468 F.3d 826, 829-30 (D.C. Cir. 2006) (same).

Washington and its subrecipients could not have anticipated that the conscience statutes they have long complied with would be significantly altered and expanded so dramatically. *See Nat'l Fed'n of Indep. Bus. v. Sebelius (NFIB)*, 567 U.S. 519, 584 (2012); *Davis Next Friend LaShonda D. v. Monroe Cty. Bd. of Educ.*, 526 U.S. 629, 647 (1999).

Second, the Rule threatens such harsh consequences from even a single violation—*i.e.*, potentially losing all federal funds administered by HHS, including Medicaid—that Washington and its subrecipients have no “legitimate choice” as to whether to comply. *See NFIB*, 567 U.S. at 578. The *NFIB* Court held a narrower threat to Medicaid funding was impermissibly coercive. *Id.* at 581-82, 585. For these reasons, as well as the additional arguments made by Plaintiff-Appellee California, which Washington adopts, the Rule violates the Spending Clause. California Br. at II.B.

2. The Rule Violates Separation of Powers Principles

To avoid duplicative briefing on this issue, the State of Washington adopts the arguments of Plaintiff-Appellee San Francisco on this issue. San Francisco Br. at II.C.1.

D. The District Court Properly Vacated the Rule Against All Persons and in Its Entirety

This Court has “observed that ‘when a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.’” *Empire Health Found. for Valley Hosp. Med. Ctr. v. Azar*, 958 F.3d 873, 886 (9th Cir. 2020). That vacatur is proper follows from the plain text of the APA itself. *See* 5 U.S.C. § 706(2) (reviewing court shall “set aside agency action” found to violate the APA). Here, the district court found that “the APA violations are numerous, fundamental, and far-reaching,” and the violations “would affect any person living in the United States and would result in a miscarriage of justice” if not vacated on a nationwide basis. ER32-33. For this and the additional reasons set forth in the brief of Plaintiff-Appellee Santa Clara, which Washington adopts, the district court properly vacated the Rule in its entirety pursuant to 5 U.S.C. § 706(2). *See* Answering Brief of Plaintiffs-Appellees County of Santa Clara, *et al.*, at IV.

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VIII. CONCLUSION

The Order of the Washington district court should be affirmed.

RESPECTFULLY SUBMITTED this 13th day of October, 2020.

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**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court's CM/ECF System, which will send notification to all counsel of record.

DATED this 13th day of October 2020, at Seattle, Washington.

*/s/ Jeffrey T. Sprung*_____

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