Nos. 19-4254 (L), 20-31, 20-32, 20-41

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF OREGON, COMMONWEALTH OF PENNSYLVANIA, STATE OF RHODE ISLAND, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WISCONSIN, CITY OF CHICAGO, COOK COUNTY, ILLINOIS,

Plaintiffs-Appellees,

(Caption continued on and counsel listed on inside cover)

On Appeal from the United States District Court
for the Southern District of New York

BRIEF FOR CONSOLIDATED-PLAINTIFFS-APPELLEES PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND, INC., NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION, AND PUBLIC HEALTH SOLUTIONS, INC.

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND, INC., NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION, PUBLIC HEALTH SOLUTIONS, INC.,

Consolidated-Plaintiffs-Appellees,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ALEX M. AZAR, II, in his official capacity as Secretary of the United States Department of Health and Human Services, AND UNITED STATES OF AMERICA,

Defendants-Appellants,

DR. REGINA FROST AND CHRISTIAN MEDICAL AND DENTAL ASSOCIATIONS,

Intervenors-Defendants-Appellants,

ROGER T. SEVERINO, in his official capacity as Director, Office for Civil Rights, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND OFFICE FOR CIVIL RIGHTS, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Consolidated-Defendants-Appellants.

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.
Diana O. Salgado
1110 Vermont Ave., NW, Ste. 300
Washington, D.C. 20005
202-973-4800
diana.salgado@ppfa.org

Hana Bajramovic
123 William Street, 9th Floor
New York, NY 10038
212-261-4593
hana.bajramovic@ppfa.org

NATIONAL WOMEN'S LAW CENTER
Michelle Banker
Sunu Chandy
11 Dupont Circle, NW, Suite 800
Washington, DC 20036
202-588-5180
mbanker@nwlc.org
schandy@nwlc.org

COVINGTON & BURLING, LLP
Kurt G. Calia
3000 El Camino Real
Palo Alto, CA 94306
650-632-4717
kcalia@cov.com

David M. Zionts
One CityCenter
850 10th Street, NW
Washington, DC 20001
202-662-5987
dzionts@cov.com

Sarah Mac Dougall
The New York Times Building
620 Eighth Ave
New York, NY 10027
212-841-1215
smacdougall@cov.com

Counsel for Plaintiffs-Appellees Planned Parenthood Federation of America, Inc. & Planned Parenthood of Northern New England, Inc.

(Counsel information continued on following page)

AMERICAN CIVIL LIBERTIES UNION FOUNDATION
Alexa Kolbi-Molinas
Lindsey Kaley
125 Broad Street, 18th Floor
New York, NY 10004
212-519-7845
212-519-7823
akolbi-molinas@aclu.org
lkaley@aclu.org

Daniel Mach
915 15th Street NW
Washington, DC 20005
202-548-6604
dmach@aclu.org

NEW YORK CIVIL LIBERTIES UNION
Christopher Thomas Dunn
125 Broad Street
New York, NY 10004
212-607-3300
cdunn@nyclu.org

Counsel for Plaintiffs-Appellees National Family Planning and Reproductive Health Association and Public Health Solutions, Inc.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Consolidated-Plaintiffs-Appellees Planned Parenthood Federation of America, Inc. ("PPFA"), Planned Parenthood of Northern New England ("PPNNE"), National Family Planning and Reproductive Health Association ("NFPRHA"), and Public Health Solutions, Inc. ("PHS") each certifies that it is a corporation that has no parent and that no publicly-traded corporation owns 10 percent or more of its stock.

TABLE OF CONTENTS

INTRODUCTION 1

STATEMENT OF ISSUES 3

STATEMENT OF THE CASE.....4

A. Provider Plaintiffs.....4

B. Statutory Background.....6

C. Regulatory Background.....8

D. Procedural Background 11

SUMMARY OF ARGUMENT 13

STANDARD OF REVIEW 15

ARGUMENT 16

I. The Rule Exceeds Statutory Authority in Violation of the APA. 16

A. HHS Lacked the Substantive Rulemaking Authority to Implement the Refusal Statutes.....16

1. The Rule Is a Legislative Rule Intended to Have the Force of Law. 17

2. Congress Did Not Delegate HHS Authority to Issue Substantive Rules Implementing the Refusal Statutes. 26

B. Congress Did Not Delegate the Sweeping Enforcement Authority that HHS Claims.....27

II. The Rule Is Contrary to Law in Violation of the APA. 32

A. The Rule Impermissibly Expands the Underlying Statutes. 33

B. The Rule Is Contrary to EMTALA. 46

III. The Rule Is Arbitrary and Capricious. 52

A. HHS Admits that Its Primary Justification for the Rule Was False....52

B. HHS Failed to Consider the Rule's Departure from Title VII and Upending of Reliance Interests. 57

C. HHS Failed to Consider the Radical Disruption of Healthcare Delivery and Harm to Disadvantaged Patient Populations. 60

IV. The Final Rule's Definition of "Discrimination" Is Not a Logical Outgrowth of the Proposed Rule. 62

V. The APA and Precedent Dictate Vacatur of the Rule in Its Entirety. 65

A. Vacatur Cannot Be Limited to the Parties. 65

B. No Part of the Rule Is Valid. 67

CONCLUSION 69

CERTIFICATE OF COMPLIANCE 72

CERTIFICATE OF SERVICE 73

TABLE OF AUTHORITIES

Page(s)

Cases

Animal Legal Def. Fund, Inc. v. Perdue,
872 F.3d 602 (D.C. Cir. 2017) 56

Arrington v. Wong,
237 F.3d 1066 (9th Cir. 2001) 50

Atl. City Elec. Co. v. FERC,
295 F.3d 1 (D.C. Cir. 2002) 32

Matter of Baby K,
16 F.3d 590 (4th Cir. 1994) 50

Batterton v. Marshall,
648 F.2d 694 (D.C. Cir. 1980) 17

Burwell v. Hobby Lobby Stores, Inc.,
573 U.S. 682 (2014) 41, 42

California v. Azar,
911 F.3d 558 (9th Cir. 2018) 66

California v. United States,
No. 05-cv-328, 2008 WL 744840 (N.D. Cal. March 18, 2008) 48, 49

Catholic Health Initiatives v. Sebelius,
617 F.3d 490 (D.C. Cir. 2010) 23

Central Tex. Telephone Co-op., Inc. v. FCC,
402 F.3d 205 (D.C. Cir. 2005) 23

Chrysler Corp. v. Brown,
441 U.S. 281 (1979) 30, 65

Circuit City Stores v. Adams,
532 U.S. 105 (2001) 44

City of San Francisco v. Azar,
411 F.Supp.3d 1001 (N.D. Cal. 2019) 43, 44, 45, 66

CSX Transp., Inc. v. Ala. Dep't of Revenue,
562 U.S. 277 (2011).....36

Desert Survivors v. U.S. Dep't of the Interior,
336 F.Supp.3d 1131 (N.D. Cal. 2018).....66

DHS v. New York,
140 S.Ct. 599 (2020).....66

DHS v. Regents of Univ. of Cal.,
140 S.Ct. 1891 (2020).....55, 57, 59, 66

District of Columbia v. U.S. Dep't of Agric.,
No. 20-cv-119, 2020 WL 1236657 (D.D.C. Mar. 13, 2020).....66

Encino Motorcars, LLC v. Navarro,
136 S.Ct. 2117 (2016).....17, 59

Envtl. Integrity Project v. EPA,
425 F.3d 992 (D.C. Cir. 2005).....63

EPA v. EME Homer City Generation, L.P.,
572 U.S. 489 (2014).....51

FCC v. NextWave Pers. Commc'ns, Inc.,
537 U.S. 293 (2003).....32

Fertilizer Inst. v. EPA,
935 F.2d 1303 (D.C. Cir. 1991).....64

Gonzales v. Oregon,
546 U.S. 243 (2009).....26, 28

Greater Yellowstone Coal., Inc. v. Servheen,
665 F.3d 1015 (9th Cir. 2011).....61

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

Guertin v. United States,
743 F.3d 382 (2d Cir. 2014).....15

Hardy v. NYC Health & Hosp. Corp.,
164 F.3d 789 (2d. Cir. 1999) 46

Humane Soc'y of U.S. v. Zinke,
865 F.3d 585 (D.C. Cir. 2017).....60

Jackson v. Birmingham Board of Education,
544 U.S. 167 (2005).....38, 39

Jett v. Dallas Indep. Sch. Dist.,
491 U.S. 701 (1989).....48

Kisor v. Wilkie,
139 S.Ct. 2400 (2019).....20

Liberty Mut. Ins. Co. v. Hurlbut,
585 F.3d 639 (2d Cir. 2009) 15

Long Island Care at Home, Ltd. v. Coke,
551 U.S. 158 (2007).....19, 21

McCarthy v. SEC,
406 F.3d 179 (2d Cir. 2005) 26

MD/DC/DE Broad. Ass'n v. FCC,
236 F.3d 13 (D.C. Cir. 2001).....68

Mejia-Ruiz v. INS,
51 F.3d 358 (2d Cir. 1995) 17

Mizerak v. Adams,
682 F.2d 374 (2d Cir. 1982) 54, 57

Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.,
463 U.S. 29 (1983).....52, 57, 59, 66

N.M. Health Connections v. HHS,
340 F.Supp.3d 1112 (D.N.M. 2018).....66

Nat'l Black Media Coal. v. FCC,
791 F.2d 1016 (2d Cir. 1986) 62, 63

Nat'l Min. Ass'n v. U.S. Army Corps of Eng'rs,
145 F.3d 1399 (D.C. Cir. 1998).....65

Nat. Res. Def. Council, Inc. v. Rauch,
244 F.Supp.3d 66 (D.D.C. 2017).....56

Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.,
894 F.3d 95 (2d Cir. 2018) 16

NFPRHA v. Gonzales,
468 F.3d 826 (D.C. Cir. 2006).....36

NFPRHA v. Leavitt,
No. 09-cv-00055, Dkt. 1 (D. Conn. Jan. 15, 2009) 49

NRDC v. U.S. Nuclear Regulatory Comm'n,
879 F.3d 1202 (D.C. Cir. 2018).....62

NYC Emps.' Ret. Sys. v. SEC
45 F.3d 7 (2d Cir. 1995) 21

NYC Envtl. Justice All. v. Giuliani,
214 F.3d 65 (2d Cir. 2000) 64

O.A. v. Trump,
404 F.Supp.3d 109 (D.D.C. 2019).....66

United States ex rel. O'Keefe v. McDonnell Douglas Corp.,
132 F.3d 1252 (8th Cir. 1998) 27

Office of Commc'n of United Church of Christ v. FCC,
707 F.2d 1413 (D.C. Cir. 1983).....59

PPFA v. Leavitt,
No. 09-cv-00057, Dkt. 1 (D. Conn. Jan. 15, 2009) 49

Perales v. Sullivan,
948 F.2d 1348 (2d Cir. 1991) 17, 25

Perez v. Mortgage Bankers Ass'n,
575 U.S. 92 (2015).....52

Shell Oil Co. v. EPA,
950 F.2d 741 (D.C. Cir. 1991).....63

Shelton v. University of Medicine & Dentistry of New Jersey,
223 F.3d 220 (3d Cir. 2000) 35, 47, 51

State v. Dep't of Justice,
951 F.3d 84 (2d Cir. 2020) 60

Sweet v. Sheahan,
235 F.3d 80 (2d Cir. 2000) 21

Thomas v. Review Bd. of Ind. Emp't Sec. Div.,
450 U.S. 707 (1981).....41, 42

Trans World Airlines, Inc. v. Hardison,
432 U.S. 63 (1977).....38

Trump v. Hawaii,
138 S.Ct. 2392 (2018).....66

United States v. Lott,
750 F.3d 214 (2d Cir. 2014) 18, 19, 24

United States v. Marion Cty. Sch. Dist.,
625 F.2d 607 (5th Cir. 1980) 29

United States v. Mead Corp.,
533 U.S. 218 (2001).....18, 24

W.C. v. Bowen,
807 F.2d 1502 (9th Cir. 1987) 65

Washington v. Azar,
No. 19-cv-35394, Dkt. 16 (9th Cir. May 31, 2019).....43

Water Quality Ins. Syndicate v. United States,
225 F.Supp.3d 41 (D.D.C. 2016).....62

Watkins v. Mercy Med. Ctr.,
364 F.Supp. 799 (D. Idaho 1973) 6, 40

West Ala. Women's Ctr. v. Williamson,
900 F.3d 1310 (11th Cir. 2018) 30

Whole Woman's Health v. Hellerstedt,
136 S.Ct. 2292 (2016).....68

Wojchowski v. Daines,
498 F.3d 99 (2d Cir. 2007) 44, 46

Wyo. Outdoor Council v. U.S. Forest Serv.,
165 F.3d 43 (D.C. Cir. 1999).....31

Statutes

Administrative Procedure Act.....*passim*
5 U.S.C. §702.....4
5 U.S.C. §706(2) 65
5 U.S.C. §706(2)(A) 16, 32, 52
5 U.S.C. §706(2)(C).....16
5 U.S.C. §706(2)(D) 16

Church Amendments.....*passim*
42 U.S.C. §300a-7.....6, 39
42 U.S.C. §300a-7(b).....6

Civil Rights Act of 1964, tit. VII .....*passim*
42 U.S.C. §2000e(j) 33, 36
42 U.S.C. §2000e-2(a) 36

Coats-Snowe Amendment .....*passim*
42 U.S.C. §238n.....7
42 U.S.C. §238n(a)(1).....6, 7
42 U.S.C. §238n(a)(2).....7
42 U.S.C. §238n(c)(2).....44

Dep'ts of Labor, HHS, and Education, and Related Agencies
Appropriations Act, 2019 Div. B, §507(d), Pub. L. No. 115-
245132 Stat. 2981, 3118 (2018). .....*passim*

Emergency Medical Treatment and Active Labor Act ("EMTALA")..... *passim*
42 U.S.C. §1395dd.....14
42 U.S.C. §1395dd(b)(1)(A).....46, 49

Patient Protection and Affordable Care Act ("ACA") 8, 27, 29, 49
42 U.S.C. §18023(c)(2)(A) 49
42 U.S.C. §18113(a) 8
42 U.S.C. §18116(a) 29

5 U.S.C. §301 .....27, 29

5 U.S.C. §553(b)(3) 62

20 U.S.C. §1682 29

29 U.S.C. §794 29

42 U.S.C. §216 26

42 U.S.C. §2000d-1 .....28, 29

42 U.S.C. §6104 29

Regulations

29 C.F.R. §1605.2 .....36, 58

42 C.F.R. §489.24(b)(3) 47

42 C.F.R. §489.24(d)(1) 50

45 C.F.R. §75 28

45 C.F.R. §75.352 32

45 C.F.R. §75.371 31

45 C.F.R. §75.371(b) 31

45 C.F.R. §88.1 .....9, 19, 22

45 C.F.R. §88.2 .....*passim*

45 C.F.R. §88.3(a)(2)(iv) 47

45 C.F.R. §88.4 11

45 C.F.R. §88.4(a) 25

45 C.F.R. §88.4(b) 25
45 C.F.R. §88.4(b)(1) 20
45 C.F.R. §88.4(b)(4) 20
45 C.F.R. §88.5(b) 20
45 C.F.R. §88.6 11
45 C.F.R. §88.6(a) 20, 32
45 C.F.R. §88.6(b) 20
45 C.F.R. §88.7 .....20, 22, 27
45 C.F.R. §88.7(c) 20
45 C.F.R. §88.7(i)(3)(iv) 27, 30, 31
48 C.F.R. §1.301 32
48 C.F.R. §49.402-1 32
48 C.F.R. §52.249–8 32

Rule

Fed. R. App. P. 28(i) 39, 52

Legislative Material

119 Cong. Rec. 9,597 (1973) 41
119 Cong. Rec. S9601 (daily ed. Mar. 27, 1973) 48
142 Cong. Rec. 4,926 (1996) 45
142 Cong. Rec. 5166 (daily ed. Mar. 19, 1996) 48
142 Cong. Rec. 5,171 (2006) 45
142 Cong. Rec. S2264 (daily ed. March 19, 1996) 7
142 Cong. Rec. S2269 (Mar. 19, 1996) 50

150 Cong. Rec. 25,044 (2004) 43

150 Cong. Rec. H10,090 (Nov. 20, 2004) 46

151 Cong. Rec. H177 (daily ed. Jan. 25, 2005) 48

Other Authorities

73 Fed. Reg. 78,072 (Dec. 19, 2008) 8

74 Fed. Reg. 10,207 (Mar. 10, 2009) 8

76 Fed. Reg. 9,968-02 (Feb. 23, 2011) 8

83 Fed. Reg. 3,880 (Jan. 26, 2018) 9, 49, 63, 64

Advanced Technology Vehicles Manufacturer Assistance Program, 82 Fed. Reg. 41157–58 (Aug. 30, 2017) 24

Black's Law Dictionary 534 (9th ed. 2009) 36

Emergency Cases, State Operations Manual 100-07, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf (last visited July 24, 2020) 50

Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019) ..... *passim*

INTRODUCTION

For nearly half a century, federal law has balanced the beliefs of healthcare workers with the ability of healthcare facilities to provide—and patients to receive—healthcare services and information. The Department of Health and Human Services ("HHS") seeks to upend this balance in a Rule with sweeping consequences HHS does not deny. Under the Rule, objectors may refuse care without prior notice and without providing a referral. Health care employers may not reassign workers who refuse to perform core job responsibilities, or even ask job applicants about their willingness to perform essential aspects of their job. Nurses may refuse to answer patients' questions about their options, receptionists may refuse to schedule appointments, and paramedics may refuse to transport a patient needing emergency care. In fact, drawing from a real-world example, HHS admits that the Rule would prohibit a hospital from transferring a nurse who repeatedly refused to assist in emergency abortions—once leaving a patient standing in a pool of blood—from labor-and-delivery to the neonatal intensive care unit.

Congress enacted no new law mandating such radical change to the delivery of healthcare. Instead, an agency issued a Rule purporting to "implement" existing laws, but in fact unilaterally legislating new requirements. The problems with this Rule are legion. To begin, Congress never delegated rulemaking authority concerning the principal laws HHS seeks to implement. HHS no longer contends it

has substantive rulemaking power and instead defends the Rule as interpretive—in direct contradiction of its previous position, the plain text of the Rule, and binding precedent. The Rule's effort to "define"—really, reimagine—key statutory terms is also contrary to law. From spare language like "may [not] discriminate," HHS constructs an absolute requirement to accommodate employee objections, even in emergencies, disregarding the hardships on patients and to healthcare employers' obligations to provide care. And the rulemaking process that produced this untenable regime was shot-through with deficiencies, including that the agency's central justification for the Rule was factually untrue—a falsehood HHS has conceded.

The district court properly set aside the Rule.

STATEMENT OF ISSUES

1. Is the Rule a legislative rule that HHS lacked the authority to promulgate?

2. Does HHS lack authority for the sweeping enforcement power it claims under the Rule?

3. Is the Rule contrary to law because it impermissibly expands and/or conflicts with federal statutes, including the Church, Coats-Snowe, and Weldon Amendments?

4. Did HHS act arbitrarily and capriciously in promulgating the Rule?

5. Did HHS violate the APA by issuing a final Rule that was not a logical outgrowth of the proposed version?

6. Did the district court properly set aside the Rule under the APA?

STATEMENT OF THE CASE

HHS issued a Rule purporting to implement a number of federal statutory provisions governing refusals to participate in certain medical procedures. *See Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23,170 (May 21, 2019) (codified at 45 C.F.R. Part 88) (the "Rule").[1] Consolidated-Plaintiffs-Appellees Planned Parenthood Federation of America ("PPFA"), Planned Parenthood of Northern New England ("PPNNE"), National Family Planning & Reproductive Health Association ("NFPRHA"), and Public Health Solutions ("PHS") (together "Provider Plaintiffs") challenged the Rule under the Administrative Procedure Act ("APA"), 5 U.S.C. §702.

A. Provider Plaintiffs

PPFA is a non-profit corporation dedicated to ensuring access to comprehensive reproductive healthcare services, advocating for policies that support access to healthcare—especially for individuals who have low incomes or are from underserved communities—and providing educational programs relating to reproductive and sexual health. JA337 ¶11, JA338 ¶13. Medical services are provided by approximately 50 PPFA affiliates, including PPNNE, which together

[1] Unless otherwise indicated, all internal citations and quotation marks are omitted and emphases are added.

operate more than 600 health centers in 48 states and the District of Columbia. JA338 ¶12, JA358 ¶6.

NFPRHA is a non-profit membership association that advances and elevates the importance of family planning in the nation's healthcare system and promotes and supports the work of family planning providers and administrators, especially those providing publicly-funded care. JA380 ¶9. Medical services are provided by NFPRHA's members, including PHS, which together comprise more than 850 healthcare organizations—including state, county, and local health departments; private non-profit family planning organizations; hospital-based practices; and federally qualified health centers—in all 50 states, the District of Columbia, and the U.S. territories. JA381 ¶11, JA411–13 ¶¶1–6.

Provider Plaintiffs and their members deliver—and their patients expect—high-quality, evidence-based healthcare in accordance with ethical standards. JA368 ¶43, JA391–94 ¶¶38–46. In providing care to millions of patients annually, Provider Plaintiffs rely on, *inter alia*, HHS funds that make them subject to the Rule. JA342–43 ¶¶28–32, JA361–63 ¶¶18–26, JA381–84 ¶¶12, 15–17, JA413–15 ¶¶7–14, JA2373 ¶¶9–10, JA2376–77 ¶¶7–8, JA2382–84 ¶¶12, 14, JA2387–88 ¶6. To comply with the Rule's new requirements, including its demand of absolute accommodation irrespective of hardship on a healthcare employer or its patients, the Provider Plaintiffs would need to alter their operations—*i.e.*, staffing, security, referral

practices, and possibly services—in ways that, even if feasible, would require significant expenditures. JA345–54 ¶¶39–49, 54–67, JA364–74 ¶¶30–59, JA407–08 ¶¶80–82, JA419–29 ¶¶27–49. Provider Plaintiffs could lose critical funding if HHS believes they have violated the Rule, which would devastate their ability to deliver care. JA2373 ¶11, JA2377 ¶¶9–10, JA2384 ¶15.

B. Statutory Background

The Rule purports to implement three principal statutes: the Church, Coats-Snowe, and Weldon Amendments (hereinafter the "Refusal Statutes" or "Statutes").[2]

The Church Amendments, 42 U.S.C. §300a-7, were first enacted in 1973 in response to a district court decision ordering a religiously-affiliated hospital to allow a physician to perform a sterilization procedure. *See Watkins v. Mercy Med. Ctr.*, 364 F.Supp. 799, 802 n.6 (D. Idaho 1973). Subsection (b) specifies that receipt of federal funds under, *inter alia*, the Public Health Service Act ("PHSA") does not obligate individuals or entities to provide abortion or sterilization services. 42 U.S.C. §300a-7(b).[3] Subsection (c)(1) provides that entities receiving PHSA funds may not "discriminate" in employment or extension of staff privileges against "any physician

[2] Provider Plaintiffs use the term "Refusal Statutes" because it accurately reflects the statutory text. *See, e.g.*, 42 U.S.C. §238n(a)(1) (prohibiting discrimination "on the basis that" a health care entity "refuses" to "undergo training for abortions").

[3] Congress subsequently repealed the other implicated funding streams. 84 Fed. Reg. at 23,171.

or other health care personnel[] because" the provider "performed or assisted in the performance of" a lawful abortion or sterilization procedure, or "refused to perform or assist in the performance of" such procedures based on "religious beliefs or moral convictions." *Id*. §300a-7(c)(1). In 1974, Congress enacted subsection (c)(2), which extends the employment non-discrimination requirement to recipients of biomedical and behavioral research funding, *id.* §300a-7(c)(2), and subsection (d), which provides that "[n]o individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by [HHS] if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions," *id*. §300a-7(d).

The Coats-Snowe Amendment, 42 U.S.C. §238n, was enacted in 1996 in response to a decision by a national accrediting body to require OB-GYN residency programs to offer abortion training. *See* 142 Cong. Rec. S2264 (daily ed. March 19, 1996) (statement of Sen. Coats). It prohibits the federal government, as well as state and local governments that receive federal funds, from discriminating against "any health care entity … on the basis that" the entity "refuses" to: "undergo [abortion] training"; "require or provide such training"; "provide referrals for such training or such abortions"; or "make arrangements" for any such activities. 42 U.S.C. §238n(a)(1)–(2).

The Weldon Amendment is an appropriations rider that has been attached to the bill funding the departments of Labor, Health and Human Services, and Education since 2004.[4] 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 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." 132 Stat. at 3118.

The Rule also addresses, *inter alia*, provisions of the Patient Protection and Affordable Care Act ("ACA"), including 42 U.S.C. §18113(a), which bars discrimination against healthcare entities that do not provide services related to "assisted suicide," as well as various Medicare and Medicaid provisions. *See* SA10–11.

C. Regulatory Background

For 35 years after the first Church Amendment became law, the Refusal Statutes were never the subject of rulemaking. In 2008, HHS promulgated the first such rule, 73 Fed. Reg. 78,072 (Dec. 19, 2008), but it was immediately challenged. Shortly thereafter, HHS proposed to withdraw it, 74 Fed. Reg. 10,207 (Mar. 10, 2009), and, in 2011, HHS finalized a new rule rescinding it, 76 Fed. Reg. 9,968-02,

[4] *E.g.*, Dep'ts of Labor, HHS, and Education, and Related Agencies Appropriations Act, 2019, Div. B, §507(d), Pub. L. No. 115-245, 132 Stat. 2981, 3118 (2018).

9,973–74 (Feb. 23, 2011). HHS explained that the 2008 Rule had caused "confusion" and could "negatively affect the ability of patients to access care if interpreted broadly." *Id.* at 9,969, 9,974. Pursuant to its housekeeping authority, HHS retained a provision designating HHS's Office for Civil Rights ("OCR") to receive and handle complaints alleging violations of the Refusal Statutes. *Id.* at 9,976–77.

In January 2018, HHS published a Notice of Proposed Rulemaking ("NPRM") outlining its intent "to revise regulations previously promulgated" concerning the Refusal Statutes. 83 Fed. Reg. 3,880 (Jan. 26, 2018). HHS received thousands of comments opposed to the proposed Rule, *see* 84 Fed. Reg. at 23,180, including from Provider Plaintiffs, *see* JA1768, JA2001; state and local governments, *see, e.g.*, JA1523, JA1561, JA1666, JA1725, JA1808, JA1840, JA1867; and a broad coalition of the nation's trusted medical organizations, *see, e.g.*, JA1539, JA1565, JA1612, JA1788, JA1811, JA1848, JA1919.

HHS published the final Rule on May 21, 2019. 84 Fed. Reg. 23,170. The Rule's stated purpose "is to provide for the implementation and enforcement of the Federal conscience and anti-discrimination laws listed in §88.3." 45 C.F.R. §88.1. Section 88.3 imposes "requirements" and "prohibitions" on regulated entities, *id.* §§88.3, 88.6(e), to which the Rule gives content by expansively defining several terms "for the purposes of this part" of the Code of Federal Regulations ("C.F.R."), *id.* §88.2.

For example, the Rule defines **"*discriminate* or *discrimination*"** to include a non-exhaustive list of prohibited conduct, including "[t]o withhold, reduce, exclude from, terminate, restrict, or make unavailable or deny any … employment, title, … position, or status[,] … benefit or privilege or impose any penalty." 45 C.F.R. §88.2(1)–(3). The definition also provides regulated parties with specific instructions to avoid committing discrimination. For example, subsection (4) states that a healthcare employer "shall not be regarded as having engaged in discrimination" where it "offers and the protected entity *voluntarily accepts* an effective accommodation for the exercise of such protected entity's protected conduct, religious beliefs, or moral convictions." *Id.* §88.2(4). Subsection (5) states that a healthcare employer "may require a protected entity to inform it of [covered] objections," but this "inquiry may only occur after the hiring of … a protected entity, and one per calendar year thereafter, unless supported by a persuasive justification." *Id*. §88.2(5). And subsection (6) states that a healthcare employer may only "use alternate staff or methods to provide or further any objected-to conduct" *if* the employer does "not require any additional action by, or does not take any adverse action against, the objecting protected entity" and *if* "such methods do not exclude protected entities from fields of practice on the basis of their protected objections." *Id*. §88.2(6).

The Rule broadly defines **"*assist in the performance*"** to mean "tak[ing] an action that has a specific, reasonable, and articulable connection to furthering a procedure," which "may include counseling, referral, … or otherwise making arrangements for the procedure … depending on whether aid is provided by such actions." 45 C.F.R. §88.2. It defines **"*referral or refer for*"** to include the provision of any "information in oral, written, or electric form" if "the purpose or reasonably foreseeable outcome" of providing that information is "to assist a person in receiving funding or financing for, training in, obtaining, or performing" a healthcare service or procedure. *Id*. And it defines **"*health care entity*"** to extend to any and all "health care personnel," including "pharmacist[s]," "pharmac[ies]," "medical laborator[ies]," and research facilities, "health insurance issuers," "health insurance plan[s]," and "plan sponsor[s] or third-party administrator[s]." *Id*.

The Rule requires funding recipients to certify compliance with both federal law *and* the Rule. 45 C.F.R. §§88.4–88.6. It also authorizes 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 Refusal Statutes. *Id.* §88.7(i)(3).

D. Procedural Background

In June 2019, before the Rule took effect, Provider Plaintiffs filed suit in the Southern District of New York, which was consolidated with parallel litigation

brought by state and local governments. On November 6, 2019, the district court granted summary judgment for Provider Plaintiffs and "vacate[d] the Rule in its entirety." SA143. The court held:

1. "With respect to the Church, Coats-Snowe, and Weldon Amendments, HHS was never delegated and did not have substantive rulemaking authority" and so, "[i]n undertaking substantive rulemaking, HHS therefore acted in violation of §706(2)(C) of the APA." SA137.

2. HHS "was never delegated and did not have authority to promulgate a Rule authorizing, as a penalty available for the agency for a recipient's non-compliance, the termination of all of the recipient's HHS funds." *Id.*

3. The Rule was contrary to law because it conflicted with Title VII and EMTALA. *Id.*

4. "HHS acted arbitrarily and capriciously in promulgating the Rule" because (a) its "stated reasons for undertaking rulemaking are not substantiated by the record before the agency," (b) "HHS did not adequately explain its change in policy," and (c) "HHS failed to consider important aspects of the problem before it." SA138.

5. The Rule was enacted without "observ[ing] proper rulemaking procedure" because the final Rule's definition of discrimination was not a logical outgrowth of the proposed version. *Id.*

6. The Rule "violated Separation of Powers and the Spending Clause of the United States Constitution." *Id.*

SUMMARY OF ARGUMENT

I.A. HHS lacks substantive rulemaking authority to implement the Refusal Statutes. In a reversal of its prior position, HHS admits on appeal that it has not been delegated substantive rulemaking authority and claims that the Rule is merely interpretive. Whatever its litigation position, the agency's action makes clear the Rule is substantive: HHS expressly stated it was "implementing" the Refusal Statutes, which is a hallmark of a legislative rule; the Rule expressly imposes "requirements" and "obligations" and contemplates enforcement of violations not just of the Statutes but the Rule itself; and HHS published the Rule in the C.F.R. following notice and comment. Contrary to HHS's attempt to isolate the definitional provisions as an interpretive rule, those provisions are prescriptive and intertwined with the Rule's substantive obligations.

I.B. HHS also lacks statutory authority to terminate all of a recipient's HHS funding—across funding streams—for a single violation of a Refusal Statute or of the Rule itself. Such draconian punishment is nowhere contemplated in the Statutes.

II.A. The Rule is contrary to law because it adopts definitions of the terms "*discriminate/discrimination*," "*assist in the performance*," "*referral/refer for*," and "*health care entity*" that go far beyond what the Refusal Statutes permit and imposes

new legal obligations on regulated entities. In particular, the absolute duty to accommodate with no consideration of hardship defies the established understanding of the statutory term "discrimination."

II.B. By allowing hospitals and individual healthcare workers to withhold emergency and even life-saving care, the Rule also directly conflicts with the Emergency Medical Treatment and Active Labor Act ("EMTALA"), 42 U.S.C. §1395dd, which requires hospitals to treat anyone who presents at an emergency room with an emergency medical condition. In arguing otherwise, HHS ignores the text and statutory purpose of both EMTALA and the Refusal Statutes, and the longstanding application of those statutes by Congress, courts, and HHS itself.

III.A. The Rule is also arbitrary and capricious for numerous reasons. Chief among them, HHS's primary justification for the Rule—a purported increase in complaints submitted to the agency regarding violations of the Refusal Statutes—is directly contradicted by the evidence in the record, which HHS has conceded. When an agency's stated reason for regulating is factually false, the Rule cannot stand.

III.B. HHS failed to consider that the Rule upends nearly five decades of reliance on the Title VII reasonable accommodation/undue hardship framework and the consequent reliance interests it engendered. HHS's justification for rejecting this well-settled understanding of "discrimination" in the employment context—that the

Refusal Statutes do not expressly incorporate it—is inconsistent with its decision to borrow certain aspects of the Title VII framework.

III.C. HHS also ignored copious evidence in the record that the Rule would block patient access to healthcare, undermine public health, and disproportionately burden marginalized and underserved populations who already experience discrimination accessing care.

IV. The Rule is not a logical outgrowth of the proposed rule because the unprecedented obligations imposed by subsections (4) through (6) of the Rule's definition of "discrimination" effect a sea-change in the law that was not included in the proposed Rule.

V.A. Finally, the district court properly vacated the Rule as provided for by the APA. HHS's unfounded request to limit vacatur to the parties has no basis in the APA or precedent.

V.B. The district court properly invalidated the entire Rule, which is arbitrary and capricious and thus invalid as a whole. Further, in light of the Rule's many flaws and the co-dependent nature of its provisions, no provision of the Rule is severable.

STANDARD OF REVIEW

A district court's grant of summary judgment is reviewed *de novo*. *Guertin v. United States*, 743 F.3d 382, 385 (2d Cir. 2014). This Court has discretion to "affirm the district court's judgment on any ground appearing in the record." *Liberty Mut.*

Ins. Co. v. Hurlbut, 585 F.3d 639, 648 (2d Cir. 2009). Under the APA, the reviewing court "shall … hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law." 5 U.S.C. §706(2)(A), (C), (D).

ARGUMENT

I. The Rule Exceeds Statutory Authority in Violation of the APA.

A. HHS Lacked the Substantive Rulemaking Authority to Implement the Refusal Statutes.

"[A]n agency literally has no power to act unless and until Congress confers power upon it." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 112 (2d Cir. 2018). In the district court, HHS correctly acknowledged that the Rule is a substantive rule purporting to implement the Refusal Statutes, but incorrectly argued that Congress delegated it authority to issue such a rule. On appeal, the agency does not contest the district court's conclusion that it lacks substantive rulemaking authority under the Statutes but makes a new error, now contending that the Rule is merely a non-binding interpretive rule. Remarkably, in accusing the district court of misunderstanding the Rule's nature, HHS ignores that it *told* the district court "the rule is substantive" because it "does impose obligations on regulated entities." JA2748. HHS was right the first time. The Rule bears every

hallmark of a substantive rule—one that HHS now recognizes it lacks authority to issue.

1. The Rule Is a Legislative Rule Intended to Have the Force of Law.

"A 'substantive regulation' is one which 'grant[s] rights, impose[s] obligations, or produce[s] other significant effects on private interests.'" *Perales v. Sullivan*, 948 F.2d 1348, 1354 (2d Cir. 1991) (quoting *Batterton v. Marshall*, 648 F.2d 694, 701–02 (D.C. Cir. 1980)).[5] By contrast, an interpretive rule "is simply an agency's 'intended course of action, its tentative view of the meaning of a particular statutory term, or internal house-keeping measures organizing agency activities.'" *Perales*, 948 F.2d at 1354 (quoting *Batterton*, 648 F.2d at 702). "To determine whether a rule is legislative or interpretive, [courts] ask whether the agency 'intended' to speak with the force of law," examining the "language actually used by the agency." *Guedes v. Bureau of Alcohol, Tobacco, Firearms & Explosives*, 920 F.3d 1, 18 (D.C. Cir. 2019), *cert. denied*, 140 S.Ct. 789 (2020) (quoting *Encino Motorcars, LLC v. Navarro*, 136 S.Ct. 2117, 2122 (2016)); *see Mejia-Ruiz v. INS*, 51 F.3d 358, 365 (2d Cir. 1995) ("An agency's characterization of a rule is the starting point for an analysis of its status as legislative or interpretive."). Applying this framework, the Rule does not present a close question: It is substantive.

[5] Courts use the terms "legislative rule" and "substantive rule" interchangeably. *See, e.g.*, *id.* at 702.

a. HHS Expressly Characterized the Rule as Substantive.

As noted above, HHS's argument on appeal directly contradicts the agency's position in the district court—that "the agency does take the position that the rule is substantive," because it "does impose obligations on regulated entities." JA2748; *see also* JA1428 (describing the Rule as an "exercise of [HHS's] authority to impose requirements"). HHS claimed that the Rule was "promulgated in the exercise" of authority to "make rules carrying the force of law" on the basis of an "implicit delegation from the Federal Conscience Statutes themselves." JA2409. And though HHS surely knows that "interpretive rules … enjoy no *Chevron* status as a class," *United States v. Mead Corp.*, 533 U.S. 218, 232 (2001), HHS claimed *Chevron* deference for the interpretations in the Rule, *see* JA1428–29, JA2403, JA2408–12. That "further evinced its intent to exercise legislative authority." *Guedes*, 920 F.3d at 18. HHS's robust initial defense of the Rule as substantive is a far more reliable indication of the agency's intent than an argument crafted on appeal after its original argument was resoundingly rejected.

b. The Rule Expressly Purports to "Implement" the Refusal Statutes.

As this Court has held, substantive rules "*implement* the statute." *United States v. Lott*, 750 F.3d 214, 217 (2d Cir. 2014) (emphasis in original). Thus, a regulation's "reference" to the agency's "authority to 'interpret and implement'" a statute supports the conclusion that it is "an act of substantive rulemaking." *Id.* Here,

as the district court noted, SA49, the Rule expressly states that its "purpose" is "to provide for the *implementation* and enforcement of the Federal conscience and anti-discrimination laws." 45 C.F.R. §88.1; *see also id.* §88.7(c) (addressing "non-compliance" with "this part [of the C.F.R.] or the laws *implemented* by this part").

c. The Rule Expressly Imposes "Requirements," "Obligations," and "Prohibitions," and Creates "Rights" and "Privileges."

When "statements" in a regulation "embody an effort to directly govern[] the conduct of members of the public, affecting individual rights and obligations," that is "powerful evidence that the [agency] intended the [Rule] as a binding application of its rulemaking authority." *Guedes*, 920 F.3d at 18 (quoting *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 172 (2007)). Thus, this Court has held that only substantive rules "create new law, right[s], or duties." *Lott*, 750 F.3d at 217. That is precisely what the Rule says it does—repeatedly.

Section 88.3 of the Rule directly imposes "requirements and prohibitions." 45 C.F.R. §88.3. At every turn, the Rule then refers back to the requirements imposed by "this part" of the C.F.R. For example, Section 88.4 creates "[a]ssurance and certification of compliance requirements," under which a regulated entity must certify to compliance with "applicable Federal conscience and anti-discrimination laws *and this part*." *Id.* §88.4(a). The Rule includes a section entitled "Compliance requirements," which among other things "prohibit[s]" regulated entities from interfering with "any *right* or *privilege* under the Federal conscience and anti-

discrimination laws *or this part*." *Id.* §88.6(e). And Section 88.7 prescribes consequences for "failure to comply with Federal conscience and anti-discrimination laws *or this part*." *Id.* §88.7(i)(3).[6] This was a conscious drafting choice. The proposed version of section 88.7(i)(3)(vi) referred only to obligations "created by Federal law," but "for greater accuracy," HHS replaced that phrase in the final Rule with "under Federal law or this part." 84 Fed. Reg. at 23,223. Moreover, throughout the Rule's text and preamble, HHS refers to regulated entities as "subject to" the Rule, *see, e.g.*, 45 C.F.R. §88.2 (*Discriminate/discrimination*) (4)–(6), and "covered by" the Rule, *see, e.g.*, 84 Fed. Reg. at 23,234 (estimating as many as 600,000 "persons and entities covered by this Final Rule"); *id.* at 23,240 (estimating the Rule will impose $394 million in total costs on covered entities the first year).

As the Supreme Court recently reiterated, "[a]n interpretive rule itself never forms the basis for an enforcement action [ ] because … such a rule does not impose any legally binding requirements on private parties." *Kisor v. Wilkie*, 139 S.Ct. 2400, 2420 (2019). It makes no sense for HHS to claim that an interpretive rule can mandate compliance with provisions of the C.F.R., authorize enforcement actions for regulatory violations, and create a class of regulated entities "subject to" the Rule.

[6] *See also* 45 C.F.R. §§88.4(b)(1), 88.4(b)(4), 88.5(b), 88.6(a), 88.6(b), 88.6(d), 88.7(c) (all referring to obligations under, or compliance with, "this part" of C.F.R.).

d. HHS Published the Rule in the C.F.R. After Notice and Comment.

HHS's decision to publish the Rule in the C.F.R., after notice-and-comment procedures, further proves that the Rule is substantive. *See, e.g.*, 84 Fed. Reg. 23,170. As this Circuit has held, the fact that "the agency has published the rule in the [C.F.R.]" is sufficient to establish that a rule is substantive. *NYC Emps.' Ret. Sys. v. SEC*, 45 F.3d 7, 13 (2d Cir. 1995). Further, since interpretive rules are exempt from the APA's notice-and-comment requirements, an agency's use of "full notice-and-comment procedures" "strongly suggest[s]" that the resulting rule is substantive. *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 161, 172–73 (2007); *see also Sweet v. Sheahan*, 235 F.3d 80, 92–93 (2d Cir. 2000) (notice-and-comment procedures "lend[] force to the conclusion that the regulations were an exercise in legislative rulemaking").

e. The Rule's Definitions Are Interwoven with the Rule's Substantive Requirements.

In an attempt to bracket the obvious substantive language throughout the Rule, HHS's brief seems to stop short of claiming that the entire Rule is interpretive, implying some unusual hybrid in which only "[t]he Rule's definitional provisions are interpretive." HHS Br. 27. This attempt to slice-and-dice the Rule fails many times over.

First, HHS's attempt to isolate the definitional provisions as non-substantive is flatly at odds with how the Rule describes its definitions. Section 88.2 introduces

the definitions as provided "for the purposes of this part," which includes the regulatory directives. 45 C.F.R. §88.2. The Rule's definitional provisions can hardly be separated from substantive provisions that are expressly governed by those definitions.

Second, the Rule's structure confirms that the Rule's definitional and substantive provisions are integrally linked. For instance, Section 88.2 defines "discriminate" for purposes of the Rule; this definition gives content to the "requirement" in Section 88.3 not to discriminate; Section 88.4 then imposes a duty to certify compliance with *the Rule*'s requirement not to discriminate, and Section 88.7 establishes consequences for violating *the Rule's* requirement not to discriminate.

Third, though styled as "definitions," Section 88.2 uses undeniably prescriptive terms, such as "shall not" and "may only." 45 C.F.R. §88.2; *see Guedes*, 920 F.3d at 18 (language such as "will be prohibited" is a "pertinent indicia of agency intent" that a rule is substantive). For example, in defining discrimination, the Rule limits a regulated entity's ability to ask about an employee's objections: "Such inquiry may only occur after the hiring … and once per calendar year thereafter, unless supported by a persuasive justification." 45 C.F.R. §88.2(5). This looks nothing like an advisory definition and everything like a legislative direction. Unsurprisingly, the preamble describes this definition in inherently legislative terms,

saying HHS made "modifications to the scope of prohibited discrimination under this final rule" in order to "strike the right balance" among various interests. 84 Fed. Reg. at 23,192.

HHS relies on *Health Insurance Association of America Inc. v. Shalala* to argue that the Rule's definitional provisions simply "suppl[y] crisper and more detailed lines than the authority being interpreted," HHS Br. 28 (quoting 23 F.3d 412, 423 (D.C. Cir. 1994)), but that case is not comparable. There, the Court found to be interpretive a regulatory provision in which the agency "equate[d] the statutory phrase 'responsible … to pay' with the phrase 'responsible for making … payment.'" *Id*. at 415. That is hardly analogous to "interpreting" the word "discriminate" to *inter alia* impose fine-grained instructions concerning precisely when an employee may be asked about objections. *See Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 496 (D.C. Cir. 2010) ("The short of the matter is that there is no way an interpretation of reasonable costs can produce the sort of detailed—and rigid—investment code set forth in §2162.2.A.4.").[7]

The definitions are also far afield from what anyone reading the plain terms of the Statutes would expect. As explained below, *infra* Part II.A, the Rule's

[7] *Central Tex. Telephone Co-op., Inc. v. FCC*, 402 F.3d 205, 214 (D.C. Cir. 2005), *see* HHS Br. 28, is also inapposite. There, the court held that the outcome of an agency adjudication was an interpretive rule because it did not "repudiate[]," nor was it "irreconcilable with," a prior legislative rule. *Id.* at 211.

definitions are contrary to law. But, at a minimum, they "do not inexorably follow from the spare terms used in the" Refusal Statutes and "impose heretofore unrecognized duties on funding recipients in connection with objections to medical procedures." SA50–55.

Ultimately, in addition to the many ways the Rule's interpretive provisions are integrated into binding directives, HHS's theory proves far too much. Under HHS's theory, any aspect of a rule that purports to identify the "best reading" of a statute, HHS Br. 26, would be considered interpretive—even if, as here, that reading is expressly incorporated into regulatory directives.[8] It cannot be correct that any time an agency interprets a statute, that means it is not exercising substantive rulemaking authority. Indeed, this Circuit has held that a rule is substantive precisely when its purpose is to "interpret and implement" a statute. *Lott*, 750 F.3d at 217. HHS's argument also flouts the very premise of *Chevron* deference, *i.e.*, that agencies often interpret statutes in the course of promulgating substantive regulations with the "force of law." *See*, *e.g.*, *Mead*, 533 U.S. at 229. That is exactly what HHS told the district court it did here. JA2409.

[8] Codifying definitions in the C.F.R. and tying them to binding directives would be an odd way for an agency to signal intent to issue an interpretive rule. Indeed, agencies know how to state clearly that they are "adopting an interpretive rule to clarify [their] interpretation of" a statute. *See*, *e.g.*, *Advanced Technology Vehicles Manufacturer Assistance Program*, 82 Fed. Reg. 41157–58 (Aug. 30, 2017) (DOE).

f. The Rule's Assurance-and-Certification Provision Imposes New Substantive Requirements.

HHS fares no better on the Rule's substantive assurance-and-certification requirements. Section 88.4 obliges regulated entities to submit to HHS an assurance and certification in the specific "form and manner" required by OCR "as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department." 45 C.F.R. §88.4(a)–(b). HHS now argues that there is no daylight between the Statutes and the Rule—that compliance with the Rule means nothing more than compliance with the applicable Statutes. HHS Br. 25–26 (attempting to distinguish *Perales* on this ground). This is demonstrably untrue.

Under the Rule, regulated entities must provide an assurance and certification that they are complying with both federal law *and the Rule itself*. *See* 45 C.F.R. §88.4(a)–(b). This distinction has practical meaning. For example, if a provider adhered to the Statutes' plain terms but asked its employees to disclose objections to any health service every six months rather than every year, it would be able to certify compliance with the Statutes but not the Rule. The assurance-and-certification provision is yet another demonstration that the Rule is substantive. *See Perales*, 948 F.2d at 1354 (finding "[t]here can be no question that the assurance requirement" at issue in that case "was a substantive regulation" because "[i]t precluded what would otherwise have been a valid claim for federal reimbursement").

In short, the agency's strategy on appeal is to craft an "account of the Rule in its brief" that "is incompatible with the Rule's terms." *Guedes*, 920 F.3d at 20. Every factor courts consider to assess agency intent confirms the Rule is substantive, purporting to implement the Refusal Statutes with the force and effect of law.

2. Congress Did Not Delegate HHS Authority to Issue Substantive Rules Implementing the Refusal Statutes.

HHS has waived any challenge to the district court's holding that it lacks substantive rulemaking authority. *See McCarthy v. SEC*, 406 F.3d 179, 186 (2d Cir. 2005) ("[A]rguments not raised in an appellant's opening brief … are not properly before an appellate court even when the same arguments were raised in the trial court."). Though HHS argued in the district court that Congress delegated it authority to issue force-of-law regulations implementing the Refusal Statutes, *see, e.g.*, JA2409, the district court disagreed, SA47–48, and on appeal, HHS does not contest that conclusion.

The district court was correct. *See* SA42–48. The Church, Coats-Snowe, and Weldon Amendments delegate no substantive rulemaking authority, and the motley string of other provisions cited in the Rule provide none either. *See, e.g.*, 42 U.S.C. §216 (cited at 84 Fed. Reg. at 23,263) (delegation to "the Surgeon General" to promulgate regulations "necessary to the administration of the [Public Health] Service," including on matters such as "uniforms for employees."). Neither is any claim of implicit authority sustainable. *See Gonzales v. Oregon*, 546 U.S. 243, 264,

267 (2009) (rejecting argument that Congress would grant "broad and unusual authority through an implicit delegation"). And the housekeeping statute, 5 U.S.C. §301, is not "an authorization for the promulgation of substantive rules." *United States ex rel. O'Keefe v. McDonnell Douglas Corp.*, 132 F.3d 1252, 1255 (8th Cir. 1998); *see generally* 19-cv-4676-PAE, Dkt. 184 at 19–24; Dkt. 233 at 8–13 (explaining in more detail HHS's lack of rulemaking authority). As the district court held, HHS "exceeded its statutory authority in promulgating the Rule insofar as it substantively defines and implements the Church, Coats-Snowe, and Weldon Amendments." SA64.[9]

B. Congress Did Not Delegate the Sweeping Enforcement Authority that HHS Claims.

HHS continues to assert expansive enforcement powers that Congress has not authorized. *See* 45 C.F.R. §88.7. The Rule would for the first time empower HHS to "[t]erminat[e] Federal financial assistance or other Federal funds from the Department, *in whole* or in part" for a single violation. *Id.* §88.7(i)(3)(iv).

As the district court recognized and Provider Plaintiffs never disputed, *see* SA69, HHS can take certain steps to enforce the Statutes on a case-by-case basis as

[9] Congress granted HHS limited substantive rulemaking authority under provisions of the ACA and Social Security Act. SA56–60. As the district court found, "[t]hese delegations of rulemaking authority authorize a subset—but far from all—of the Rule." SA58–60.

provided for in the 2011 Rule. *See* 76 Fed. Reg. 9,976–77 (Feb. 23, 2011) (codified at 45 C.F.R. §88.2); *see also Gonzales,* 546 U.S. at 264. For example, under the HHS Uniform Administrative Requirements ("UAR"), 45 C.F.R. Pt. 75, it may be appropriate to terminate "the Federal Award" tied to the specific statute violated. But the Rule goes much further, authorizing the "ultimate penalty"—even though "no law authorizes HHS to terminate all of a recipient's HHS funding for a violation." SA69.

HHS insists it does have power to "terminate all HHS funds," HHS Br. 23–24, but it cannot identify a single statutory provision delegating such sweeping authority. The Refusal Statutes are silent on enforcement and remedy, *see id*. at 23 (conceding that the Church and Coats-Snowe Amendments do not "specify[] a consequence for noncompliance"), which HHS mistakenly interprets as implicit authority, *id.* at 23–24. The Church Amendments are triggered by just one funding stream, making wholesale termination of HHS funds particularly incongruous.

Comparing the silence of the Refusal Statutes to the *express* remedial provisions of civil rights laws underscores HHS's error. For example, Title VI explicitly authorizes agencies to terminate funding, but limits that drastic remedy to the "particular program, or part thereof, in which such noncompliance has been so found." 42 U.S.C. §2000d-1. Title VI further states that no funds may be terminated until the agency "has advised the appropriate person or persons of the failure to

comply with the requirement and has determined that compliance cannot be secured by voluntary means." *Id*. It further guarantees an opportunity for a hearing, express findings on the record, and written advance notice by the agency to relevant congressional committees. *Id.*[10] To put it mildly, Congress understands the gravity of terminating federal funding based on an agency's finding of a civil rights violation. It cannot be that by saying *nothing* about enforcement in the Refusal Statutes, Congress implicitly delegated HHS *broader* termination power.

Unable to muster such statutory text, HHS offers a truly tenuous analogy to Title VI, citing a case holding that the government "may sue to enforce contractual assurances of nondiscrimination." HHS Br. 23 (citing *United States v. Marion Cty. Sch. Dist.*, 625 F.2d 607, 611 (5th Cir. 1980)). Whether HHS could seek "specific performance" of the Refusal Statutes through enforcing the terms of a grant or contract, *Marion Cty.*, 625 F.2d at 609, has no bearing on its authority to strip an entity of all its federal funds.

HHS tries unsuccessfully to minimize how extreme these new powers are. First, it claims that the Rule's remedies are mere "housekeeping" and thus authorized by 5 U.S.C. §301. HHS Br. 20–21. But Section 301 is "simply a grant of authority

[10] Other civil rights statutes contain comparable protections for funding recipients. *See, e.g.*, 20 U.S.C. §1682 (Title IX); 42 U.S.C. §6104 (Age Discrimination Act); 29 U.S.C. §794 (Rehabilitation Act of 1973); 42 U.S.C. §18116(a) (Section 1557 of the ACA).

to the agency to regulate its own affairs" and cannot authorize HHS "to make rules regarding the substantive legal obligations of regulated entities." *See* SA44–45 (citing *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979)). The Rule's enforcement provision exposes recipients to termination of all HHS funding for a violation not only of the Statutes but also any provision of the Rule itself. *See supra* Part I.A. That is not housekeeping.

Second, HHS proffers limits on the Rule's funding-termination provision that appear nowhere in the Rule. By its plain terms, the Rule empowers HHS to "[t]erminat[e] Federal financial assistance or other Federal funds from the Department, *in whole* or in part." 45 C.F.R. §88.7(i)(3)(iv). HHS now suggests that a violation would threaten only the "relevant funding." HHS Br. 23. Exactly how much HHS is conceding is unclear—the agency does not define "relevant" and suggests that in some cases every funding stream could be "relevant." *Id.* Regardless, the Rule speaks of terminating funding "in whole," not "relevant funding."[11] Nor can HHS invoke the preamble in an effort to limit the Rule's breadth. HHS Br. 21–23. Where, as here, the plain language of the operative regulatory text is unambiguous, the "language in the preamble of a regulation is not controlling over

[11] HHS asserts that the "enforcement provision is framed in permissive terms" and that funding termination will be "rarely impose[d]." HHS Br. 21–22. But an agency cannot "permit" itself to do what Congress has not authorized, and such "[m]id-litigation assurances are all too easy to make and all too hard to enforce." *West Ala. Women's Ctr. v. Williamson*, 900 F.3d 1310, 1328 (11th Cir. 2018).

the regulation itself." *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999).

Finally, the agency claims the Rule "merely outlines steps HHS may take" under preexisting regulations, such as the UAR. *See* HHS Br. 21–22, 24. That is a surprising interpretation of a Rule whose *purpose*, according to HHS, was to remedy "inadequate to non-existent regulatory frameworks to enforce" the Refusal Statutes. 84 Fed. Reg. at 23,228. Comparing the UAR to the Rule only highlights the Rule's bite. UAR remedies do not threaten termination of funding "in whole," but instead focus on, *e.g.*, "the cost of the activity or action not in compliance." 45 C.F.R. §75.371(b). HHS thus admitted below that the UAR's remedies are "tied to the specific funds that are at issue with regard to the specific statute" violated. JA2740. The Rule, by contrast, authorizes termination of "Federal financial assistance" from HHS "in whole." 45 C.F.R. §88.7(i)(3)(iv). The Rule's preamble even warns of "funding claw backs," 84 Fed. Reg. at 23,180, an extreme remedy not included among the UAR's list of remedies for noncompliance, *see* 45 C.F.R. §75.371. Moreover, under the Rule, a recipient and all of its subrecipients risk losing HHS funding because OCR has found a single subrecipient in violation—which the UAR

does not permit. *Compare* 45 C.F.R. §88.6(a) *with* UAR, 45 C.F.R. §75.352; *see also* JA304–05 ¶117, JA1748.[12]

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In short, HHS cannot point to any grant of authority for the sweeping powers claimed in the text of the Rule. The Rule creates new rights and imposes new obligations intended to alter the conduct of regulated entities, and allows HHS to impose draconian penalties for noncompliance. 84 Fed. Reg. at 23,228. Where an agency assumes such unprecedented new powers, it must invoke some delegation of authority from Congress, and such "authority may not be lightly presumed." *Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 9 (D.C. Cir. 2002). None exists here.

II. The Rule Is Contrary to Law in Violation of the APA.

Even assuming HHS had authority to issue the Rule, courts must "hold unlawful and set aside agency action" that is "not in accordance with law." 5 U.S.C. §706(2)(A). That includes "any law," including but not limited to "those laws that the agency itself is charged with administering." *FCC v. NextWave Pers. Commc'ns, Inc.*, 537 U.S. 293, 300 (2003). Here, the Rule conflicts with the Refusal Statutes themselves, EMTALA, and Title VII.

[12] HHS also claims that the Federal Acquisition Regulation ("FAR") supports its authority to enforce the Refusal Statutes. *See* HHS Br. 24 n.3 (citing 48 C.F.R. §1.301). But under the FAR the remedy for a violation would be "to terminate the contract completely or partially," 48 C.F.R. §§49.402-1, 52.249–8, not all of a contractor's HHS funding.

A. The Rule Impermissibly Expands the Underlying Statutes.

HHS has abandoned on appeal its request for *Chevron* deference, and now wrongly contends that the Rule's definitional provisions are "the best reading of the statutes." HHS Br. 28. To the contrary, the Rule impermissibly expands the underlying Statutes by defining key terms far beyond what Congress permitted, improperly creating new and independent rights and obligations.

1. ***Discriminate/Discrimination.*** As the district court properly held, the Rule's definition of the terms "discriminate" and "discrimination" is "game-changing" and "would materially expand the rights of employees articulating objections to covered procedures, and correspondingly enhance the duties of health care employers in this area." SA52. In particular, subsections (4) to (6) of that definition obligate healthcare employers, such as Provider Plaintiffs, to hire and provide *absolute* accommodation to individuals who refuse to perform essential job functions, including refusing to provide care or information to patients—a drastic departure from the reasonable accommodation/undue hardship framework under Title VII. The familiar Title VII doctrine makes clear that employers do not unlawfully discriminate on the basis of religion if they "reasonably accommodate" the employee's religious beliefs, and do not have to grant accommodations causing "undue hardship" on the employer. 42 U.S.C. §2000e(j). Under the Rule, however, Provider Plaintiffs may not reassign an employee to a position with responsibilities

they are willing to perform unless the employee voluntarily accepts the reassignment. *See* 45 C.F.R. §88.2(4). The Rule also dictates whether and when employers may even ask employees if they are willing to perform essential job functions, and could obligate an employer to hire someone for a job with primary responsibilities the applicant is unwilling to do. *See* 84 Fed. Reg. at 23,192.

In the district court, HHS argued that subsections (4) to (6) of the discrimination provision merely described a "safe harbor" from which no "prohibition[s]" could be "infer[rred]." JA2414. HHS wisely abandons this argument and now admits that these sections do prohibit conduct. *See, e.g.*, HHS Br. 11 (stating employers "may" "only" inquire about prospective employees' unwillingness to perform job responsibilities after being hired). At times, though, HHS's brief hints at its prior position, noting that the Rule "clarifies its application to certain actions … that might be considered discrimination" and "describes conduct that will *not* be understood to constitute discrimination." *Id.* at 31, 32.

Whatever HHS means to argue, the Rule's text and structure are clear: If a proposed accommodation or other action taken is *not* permitted by subsections (4) through (6) (for example, because the employee does not "voluntarily accept[]" it), then it *is* discrimination under the sweeping terms of subsections (1) through (3). 45 C.F.R. §88.2. The Rule thus provides no limit to what an employer must do to accommodate employees unwilling to perform functions central to their job—even

where such refusal would pose a threat to patient safety. *See* SA33; JA2746–48. Take, for example, the facts of *Shelton v. University of Medicine & Dentistry of New Jersey*, 223 F.3d 220, 222–28 (3d Cir. 2000), in which the Third Circuit dismissed a Title VII lawsuit by a nurse who was fired after refusing to assist in emergency procedures involving pregnant patients multiple times and after refusing to accept all reasonable offers of accommodation, such as a lateral transfer to the neonatal intensive care unit. On one occasion, the nurse refused to scrub into the operating room to treat a patient with a "life-threatening" condition "who was standing in a pool of blood" because she considered the premature delivery to be an abortion. *Id.* at 223. HHS conceded that under the Rule's definition of discrimination, the hospital would have been forced to acquiesce both to the nurse's refusal to provide care and rejection of alternative solutions—regardless of the harm to patients or potential liability. SA33–35; JA2746–48.

Similarly, HHS admitted that even in the case of a rural hospital with limited staff, the hospital would be limited in whether and when it can inquire about an employee's objections. JA2748–50. And even then, the hospital would be forbidden from taking steps not "voluntarily accept[ed]" by the objecting employee—such as finding alternate staff coverage—to mitigate the effects of the refusal and ensure patient safety. *Id.*

This cannot be what Congress meant by saying generally, without further elaboration, that an employer may not "discriminate" against an employee who refuses to participate in certain healthcare services. Indeed, whereas HHS asserts that a healthcare employer engages in discrimination when an employee who refuses to perform central functions of their job is reassigned unwillingly, the D.C. Circuit has held, in discussing the Weldon and Coats-Snowe Amendments, it would be "anomalous" to "equat[e] . . . reassignment with discrimination." *NFPRHA v. Gonzales*, 468 F.3d 826, 829–30 (D.C. Cir. 2006) (noting the reassignment of caregiver who refuses to provide abortion counseling had never been considered discrimination under the Coats-Snowe Amendment, and the Weldon Amendment was no different).

More generally, and as HHS apparently agrees, *see* HHS Br. 31–32, the word "discrimination" is sensitive to context. All laws classify, but "[d]iscrimination" means the "failure to treat all persons equally when no *reasonable* distinction can be found between those favored and those not favored." *CSX Transp., Inc. v. Ala. Dep't of Revenue*, 562 U.S. 277, 286 (2011) (quoting Black's Law Dictionary 534 (9th ed. 2009)). In the employment context, it has been understood for nearly 50 years that an employer does not discriminate when the employee's religious or moral beliefs cannot reasonably be accommodated. *See* 42 U.S.C. §§2000e(j), 2000e-2(a); 29 C.F.R. §1605.2; *see also* SA15–16.

HHS's principal defense to the Rule's "game-changing" definition of discrimination, SA52, is that Title VII's reasonable accommodation/undue hardship defenses are "nowhere mentioned in the conscience statutes," and thus Congress did not intend to incorporate them into the Refusal Statutes. HHS Br. 32; *see also id*. at 38–39. This argument is belied by the agency's own statement that "components of [Title VII's] approach *are* appropriate in this context"—specifically, the requirement of "effective accommodation" of objections. 84 Fed. Reg. at 23,191. But the Refusal Statutes are just as silent on the subject of "accommodations" as they are on the subject of "undue hardship." HHS is simply picking and choosing to incorporate some aspects of the Title VII framework but not others, so its textual argument rings hollow.

Given that the concepts of accommodation and undue hardship have always gone hand-in-hand, interpreting "discrimination" to require one without the other would have been shocking to the Congress that enacted the first Church Amendment in 1973. When the Church Amendments were passed, Congress had just settled a debate over whether employers *ever* had to provide accommodations to employees with religious objections. Title VII, as originally passed, banned "discrimination" generally without mentioning any accommodation. Over the next several years, two views emerged: that the duty not to discriminate required employers to accommodate employees' religious or moral objections so long as those

accommodations did not impose "undue hardship" on the employer, and that a failure to accommodate was never discrimination. *See Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 71–76 (1977). Congress resolved this debate in 1972, codifying the reasonable accommodation/undue hardship framework that the EEOC had already read into the obligation not to discriminate. *See id.* at 73–74. What was never suggested, however, was that the duty not to discriminate meant an *unlimited* obligation to accommodate, regardless of hardship. The fact that Congress passed the Church Amendments a year after codifying the reasonable accommodation/ undue hardship framework, "without any indication that it perceived a conflict with Title VII, makes it all the more improbable that Congress silently intended effectively to override that framework in the context of the health care industry." SA51.

Further, the Supreme Court has squarely rejected the type of inference HHS seeks to draw from the absence of the words "undue hardship" in the Refusal Statutes. In *Jackson v. Birmingham Board of Education*, 544 U.S. 167, 174–75 (2005), a lower court reasoned that since Title VII expressly prohibits retaliation and Title IX does not mention it, Title IX must not bar retaliation. The Supreme Court disagreed. It explained that while "Congress certainly could have mentioned retaliation in Title IX expressly, as it did in [Title VII]," Title IX is "a broadly written general prohibition on discrimination." *Id.* at 175. Thus, Congress's "failure to

mention one such practice says nothing about whether it intended that practice to be covered." *Id.* at 168; *see also* SA51 n.21. Similarly, here, the generic non-discrimination language of the Refusal Statutes can hardly be construed as a *sub silentio* abandonment of the principle—recognized by Congress just a year before the first Church Amendment—that an employer's duty to accommodate employees' objections is not limitless. Had Congress meant to upend the law of religious accommodation in the way HHS believes, surely it would have done more than simply adopt the term "discriminate."[13]

2. ***Assist in the performance.*** The Rule's definition of the phrase "assist in the performance," which is found in the Church Amendments, 42 U.S.C. 300a-7, contradicts the plain meaning of these provisions and their statutory purpose. The Rule defines "assist in the performance" to mean "an action that has a specific, reasonable, and articulable connection to furthering a procedure," including "counseling, referral, training, or otherwise making arrangements for the procedure." 84 Fed. Reg. at 23,263.

While the parties agree that to "assist" is "to give support or aid," and "performance" is "the execution of an action," HHS Br. 29 (quoting Webster's

[13] The Rule conflicts with Title VII for substantially the same reasons, as explained by the State Plaintiffs and adopted here pursuant to Rule 28(i). As the district court explained, in enacting the Refusal Statutes, Congress manifested no "intent to supersede the Title VII framework," SA72, so the Rule's conflict with the Refusal Statutes and with Title VII are two sides of the same coin.

Dictionary), the statute is clear that what an individual must be "assist[ing] in" is the actual "*performance* of an abortion or sterilization procedure." Yet the Rule is much broader and covers actions that might have some connection to "*furthering*" such a procedure, regardless of whether and when it is actually performed. For example, HHS admitted that the Rule's definition of "assist in the performance" extends to a receptionist responsible for scheduling appointments, an ambulance driver responsible for transporting an individual to a hospital for the purpose of having a procedure, JA2749, and other ancillary activities, including those that occur "on a day other than the date of the procedure," JA2750; *see also* 84 Fed. Reg. at 23,187–88. Nor did HHS deny that simply telling a patient that abortion is an option—even if the patient never has an abortion—would fall under HHS's definition of "assist in the performance" of an abortion. 84 Fed. Reg. at 23,189. Congress could not have meant that any of these tangential activities should constitute "giv[ing] support or aid" in "the execution of" the performance of an abortion or sterilization procedure. *See* SA52 ("Neither the text nor history of the Church Amendments made Congress's intent to reach such [ancillary] activities clear.").

The context in which the Church Amendments were enacted underscores HHS's error. The Amendments were enacted in direct response to a decision requiring a religiously-affiliated hospital to permit the *performance* of a sterilization procedure, solely because the hospital received certain federal funds. *See Watkins*,

364 F.Supp. at 801 n.6 (explaining "background" of Church Amendments). The purpose was to prevent the receipt of specific federal funds from being used as the justification for coercing the performance of one of the objected-to procedures.

Indeed, just prior to passage, the Amendments' sponsor, Senator Church, was asked whether a patient could be denied care because someone "in the hospital objected who had no responsibility" for the procedure, or whether it "would only be that one who was involved in *performing the operation or in assisting to perform the operation* could not be required to participate when he or she held convictions against that type of procedure." 119 Cong. Rec. 9,597 (1973). Senator Church explained it was the latter, and that the amendment was not meant to protect "someone unconnected with the procedure." *Id*. The Rule, however, impermissibly expands the statutory text to allow objectors to refuse to perform ancillary activities (*i.e.*, scheduling appointments) unconnected to the actual performance of a procedure.

HHS asserts that "Congress sought to reach all forms of assistance in this context, for religious or moral objections to complicity in acts believed to be immoral often do not distinguish between ancillary and direct support." HHS Br. 30 (citing *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 724 (2014); *Thomas v. Review Bd. of Ind. Emp't Sec. Div.*, 450 U.S. 707, 715 (1981)). But the cases cited by HHS were decided long after the Church Amendments were enacted and cannot

have any bearing on the plain meaning of "assist in the performance" in the Church Amendments. Indeed, neither *Burwell* nor *Thomas* deal with questions of statutory construction generally, much less the Church Amendments.

3. ***Referral/refer for*****.** The terms "referral" and "refer for" are used in the Coats-Snowe and Weldon Amendments. In the Rule, HHS distorts the plain meaning of "referral" and "refer for" and broadly extends them to include the provision of any information if a "reasonably foreseeable outcome" is that the information would assist a person in, *inter alia*, obtaining or performing a procedure. 45 C.F.R. §88.2. This extremely broad definition does not comport with the common understanding of these terms and, as such, "the Rule's definition is broader than what is inherent in the statutory text." SA54.

As the district court properly held, while "a common understanding of the term 'referral' … would include sending a patient to another physician or provider," the statute "do[es] not … make clear, as the Rule does, that 'referral' also covers providing any information that could help the patient obtain the service or procedure at issue." SA55. Indeed, the Rule's definition of referral is so broad that it "means, for example, that an entity could lose all of its HHS funding if it fired a hospital front-desk employee for refusing to tell a woman seeking an emergency abortion for

an ectopic pregnancy which floor she needed to go to for her procedure." *City of San Francisco v. Azar*, 411 F.Supp.3d 1001, 1021 (N.D. Cal. 2019).[14]

On appeal, "[r]ecognizing the terms' potential breadth," HHS argues for the first time that the Rule's definition means "actually sending or directing a person for the particular activity." HHS Br. 36. But the definition of "referral" or "refer for" in the Rule makes no mention of "actually sending or directing"; it says "reasonably foreseeable outcome," and many things are reasonably foreseeable. As HHS clarified in the preamble, the definition of "referral" or "refer for" "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. Simply put, HHS's litigation-developed position to make the Rule seem more limited than it is conflicts with the plain text of the Rule.

The Rule's broad definition of referral also defies legislative statements made at the time the Weldon Amendment first passed. In explaining its purpose, Representative Weldon stated that the Amendment "will not affect access to abortion, the *provision of abortion-related information* or services by willing providers or the ability of States to fulfill Federal Medicaid legislation." 150 Cong.

[14] Notably, HHS conceded in other litigation that the term "referral" does not broadly encompass merely providing a patient information (in essentially any form) regardless of how limited the information. *See Washington v. Azar*, No. 19-cv-35394, Dkt. 16 at 26 (9th Cir. May 31, 2019) (Appellants' Opening Brief).

Rec. 25,044–45 (2004). This confirms that the Weldon Amendment "used the term 'refer for' as separate from the provision of information," and therefore "was not meant to apply to the provision of abortion-related information." *City of San Francisco*, 411 F.Supp.3d at 1021.

4. ***Health care entity.*** In the Coats-Snowe Amendment, Congress defined "health care entity" to include "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). In the Weldon Amendment, Congress defined "health care entity" to "include[] an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan." 132 Stat. at 3118(b). The Rule substantively amends these statutes by altering—and expanding—their definitions of "health care entity."

HHS argues that the Coats-Snowe and Weldon Amendments contemplate a broader group of individuals because their definitions of "health care entity" use the word "include," and have, according to HHS, "catch-all phrases." HHS Br. 33–34. But "[w]here general words follow specific words in a statutory enumeration, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words." *Circuit City Stores v. Adams*, 532 U.S. 105, 114–15 (2001); *see also Wojchowski v. Daines*, 498 F.3d 99, 108 (2d

Cir. 2007). Thus, "even when the listed terms in an inclusive definition are illustrative, a list still cannot be inflated with terms lacking the defining essence of those in the list, as has occurred here." *City of San Francisco*, 411 F.Supp.3d at 1016.

Whereas the essence of the list in the Coats-Snowe Amendment is individuals and entities involved in residency abortion training, the Rule seeks to add, *inter alia*: "a pharmacist"; "a medical laboratory"; "an entity engaging in biomedical or behavioral research; a pharmacy"; and "any other health care provider or health care facility," regardless of whether they are involved in abortion training. 45 C.F.R. §88.2. Congress selectively focused on "participant[s] in a program of training in the health professions" because it was responding to a newly adopted standard requiring all OB-GYN residency training programs to offer training in induced abortions. *See* 142 Cong. Rec. 4,926 (1996). "Congress's intent was to protect any health care entity that chooses not to be trained in or provide training for participation in abortions." Coats-Weldon Amicus Br. 5; 142 Cong. Rec. 4,926, 5,158 (1996) (statements of Sen. Coats); *see also* 142 Cong. Rec. 5,171, 5,172 (2006) (statement of Sen. Snowe).

Likewise, the Weldon Amendment's definition of "health care entity" is limited to individuals and entities involved in the provision of healthcare. But the Rule impermissibly expands the statute to add entities that are not, such as a "plan sponsor" or "third-party administrator." 45 C.F.R. §88.2. A "plan sponsor" is an

employer with no connection to healthcare other than the provision of employee benefits, and a "third-party administrator" simply processes benefit claims. Such entities—which would include an organization like the New York Knicks, for example, because it offers its employees health insurance—are not "similar in nature" to the entities enumerated in Weldon. *Wojchowski*, 498 F.3d at 108. The Weldon Amendment "is intended to protect the decisions of physicians, nurses, clinics, hospitals, medical centers, and even health insurance providers … ." 150 Cong. Rec. H10,090 (Nov. 20, 2004) (statement of Rep. Weldon).

Because the agency has strayed from the ordinary meaning of these terms in the underlying Statutes in order to advance a wholly different agenda than the one Congress enacted, the Rule is contrary to law.

B. The Rule Is Contrary to EMTALA.

The Rule also conflicts with EMTALA, which "impos[es] on hospitals [participating in Medicare] a legal duty … to provide emergency care to all." *Hardy v. NYC Health & Hosp. Corp.*, 164 F.3d 789, 792–93 (2d. Cir. 1999). If "any individual" with an "emergency medical condition" presents "for treatment at a hospital's emergency room," EMTALA requires the hospital to provide appropriate screening, and then treatment to "'stabilize the medical condition.'" *Id.* at 792 (quoting 42 U.S.C. §1395dd(b)(1)(A)). It is undisputed that such treatment may include an emergency abortion necessary to stabilize a person experiencing a

miscarriage or pregnancy complications. *See, e.g.*, JA1009 (American Medical Association Comment), JA1187; *see also* JA436–442.

The Rule prevents hospitals from delivering the care that EMTALA mandates in myriad ways. For example, under the Rule, a paramedic transporting a patient with a life-threatening complication that may require an emergency abortion would be "assisting in the performance" of the procedure. *See* 45 C.F.R. §88.2; *see also* 84 Fed. Reg. at 23,188.[15] And, as HHS admits, the Rule authorizes a paramedic to refuse to transport that patient. JA2748–49. The Rule also permits a physician or nurse to withhold emergency stabilizing treatment, *see, e.g.*, 45 C.F.R. §88.3(a)(2)(iv), or another staff member to refuse to summon the on-call OB-GYN or arrange a patient's transfer to another hospital, *see* 45 C.F.R. §88.2 (*Assist in the performance*; *Referral/refer for*). And, as discussed above, the Rule makes it "discrimination" to reassign those employees, unless they "voluntarily accept," 45 C.F.R. §88.2 (*Discriminate*/*discrimination*), which they might refuse to do, *see Shelton*, 220 F.3d 223–24. A hospital would effectively have to double-staff to ensure it could provide emergency care, which is untenable. Moreover, a person experiencing a life-threatening emergency often cannot wait to be treated by another provider. *See* AR

[15] *See* 42 C.F.R. §489.24(b)(3) (hospital-owned ambulance covered by EMTALA).

000147981–82. As such, the Rule directly blocks hospitals from delivering the life-saving care EMTALA requires.

In the Rule's preamble and before the district court, HHS conceded that the Rule and EMTALA conflict, vaguely promising to "harmoni[ze] to the extent possible," depending on the "facts and circumstances." 84 Fed. Reg. at 23,188; *see also* JA2748–49. Now, HHS changes tune, maintaining that "EMTALA is properly read not to permit or require a hospital to override conscience objections." HHS Br. 40. This argument defies the "rudimentary principle[]" of statutory interpretation that "the specific governs the general." *Jett v. Dallas Indep. Sch. Dist.*, 491 U.S. 701, 704, 738–39 (1989) (Scalia, J., concurring in part and concurring in the judgment). EMTALA speaks directly to the context of emergencies; the Refusal Statutes do not address them at all. *See, e.g.*, *California v. United States*, No. 05-cv-328, 2008 WL 744840, at *4 (N.D. Cal. March 18, 2008) (finding "no clear indication" that "enforcing … EMTALA to require medical treatment for emergency medical conditions would be considered 'discrimination'"). Legislative history confirms this: The sponsors of the Refusal Statutes all expressly stated that these amendments would not interrupt care "in an emergency situation." 119 Cong. Rec. S9601 (daily ed. Mar. 27, 1973) (statement of Sen. Church); *see* 142 Cong. Rec. 5166 (daily ed. Mar. 19, 1996) (statement of Sen. Coats); 151 Cong. Rec. H177 (daily ed. Jan. 25, 2005) (statement of Rep. Weldon).

HHS argues that because the ACA expressly states that its conscience protections do not relieve healthcare providers of their obligations under EMTALA, the lack of such language in the Refusal Statutes suggests Congress intended a different result. *See* HHS Br. 41. But the ACA does not include just any conscience protections—it directly incorporates the Refusal Statutes. *See* 42 U.S.C. §18023(c)(2)(A). Thus, the ACA underscores that to "harmonize" these statutes, the Refusal Statutes must be read in light of EMTALA, not the other way around.[16]

HHS's new position also requires it to reinterpret the text of EMTALA. HHS Br. 40–41. Whereas EMTALA mandates stabilization "within the staff and facilities available at the hospital," 42 U.S.C. §1395dd(b)(1)(A), HHS now asserts that if any hospital staff members object to providing emergency treatment, the staff is not "available," HHS Br. 41. The Fourth Circuit has rejected this very argument—that "because [the hospital's] physicians object" to a treatment, "it has no physicians available to provide" it—holding "EMTALA does not provide an exception for

[16] It was not until litigation over the Weldon Amendment in 2006, and subsequently the 2008 Rule, that a question even emerged over the interaction between the Refusal Statutes and EMTALA. *See California*, 2008 WL 744840; *NFPRHA v. Leavitt*, No. 09-cv-00055, Dkt. 1 ¶¶70–74 (D. Conn. Jan. 15, 2009); *PPFA v. Leavitt*, No. 09-cv-00057, Dkt. 1 ¶¶51–53 (D. Conn. Jan. 15, 2009). In 2010, when the ACA was enacted, Congress had reason to speak on the issue and resolve any lingering doubt. The ACA confirmed that EMTALA's specific requirements govern in emergency situations. *See also* 76 Fed. Reg. 9968-02 (rescinding 2008 Rule "in part" because of "the potential to negatively impact patient access to [emergency services] without a basis in federal conscience protection statutes").

stabilizing treatment physicians may deem medically or ethically inappropriate." *Matter of Baby K*, 16 F.3d 590, 597 (4th Cir. 1994).[17]

This argument also defies HHS's longstanding interpretation of "availab[ility]." EMTALA's implementing regulations explain that the stabilization requirement applies "within the capabilities of the staff and facilities available." *See* 42 C.F.R. §489.24(d)(1). "Capabilities" is defined to mean "the level of care that the personnel of the hospital can provide within the training and scope of their professional licenses," and the "physical space, equipment, supplies, and specialized services that the hospital provides."[18] Thus, as long as hospital staff are trained and licensed to perform a procedure, and there is space and equipment to perform it, it is within the "capabilities" of the hospital and is "available" under EMTALA—regardless of any staff objections. *See also* 142 Cong. Rec. S2269 (Mar. 19, 1996)

[17] HHS incorrectly argues that *Matter of Baby K* does not "address[] the conscience statutes or any similar situation involving a statutory right." HHS Br. 41. The hospital in that case asserted its physicians were unavailable *because* a Virginia statute allowed physicians to refuse to provide care they find medically or ethically inappropriate. *See* 16 F.3d at 596–97. HHS's reliance on *Arrington v. Wong*, 237 F.3d 1066, 1073 (9th Cir. 2001), fares no better, as that case does not define "insufficient emergency staff available." HHS Br. 41.

[18] Ctrs. for Medicare & Medicaid Servs., *Appendix V—Interpretive Guidelines—Responsibilities of Medicare Participating Hospitals in Emergency Cases*, State Operations Manual 100-07, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_v_emerg.pdf (last visited July 24, 2020).

(statement of Sen. Coats that all OB-GYNs have "sufficient training" to perform abortions "if necessary").

Finally, HHS suggests that, if there is a conflict, "as-applied" challenges could address such issues as they arise. HHS Br. 40. However, as the administrative record illustrates, these are anything but "hypothetical scenario[s]." *See, e.g.*, AR 000055623, AR 000066546, AR 000067668, AR 000068429, AR 000135569.[19] By severely restricting a hospital's ability to inquire about conscience objections during the hiring process and subsequently reassign an employee if it later becomes aware of an objection, the Rule makes it impossible to avoid such situations through staffing and scheduling. *See* 45 C.F.R. §88.2 (*Discriminate/discrimination*). Because the Rule *creates* situations in which hospitals will be unable to deliver time-sensitive emergency care—even preventing hospitals from learning that they will be unable to do so—an as-applied challenge would come too late to redress the conflict with EMTALA. *See* JA484–85.[20]

[19] *Shelton*, 223 F.3d at 222–23, discussed *supra* Part II.B, likewise belies Intervenors-Defendants' claim that no evidence of denials of emergency care exists. *See* Intervenors' Br. 31.

[20] This is far from a situation where a rule is consistent with law "on its face" "despite possible arbitrary applications." *EPA v. EME Homer City Generation, L.P.*, 572 U.S. 489, 524 (2014) (cited at HHS Br. 40).

III. The Rule Is Arbitrary and Capricious.

The district court correctly held that the Rule is arbitrary and capricious.[21] The Rule violates the APA's requirement of reasoned decision making in numerous respects, each of which is sufficient to invalidate it. 5 U.S.C. §706(2)(a). HHS incorrectly attempts to avoid these deficiencies by arguing that arbitrary and capricious review does not apply because the Rule is interpretive. The Rule is not interpretive. *See supra* Part I.A. Regardless, in appropriate circumstances, an agency's "decision to issue an interpretive rule," including its lack of "substantial justification," may require the rule to be vacated as "arbitrary and capricious." *Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 105–06 (2015); *cf. Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (setting forth requirements of reasoned decision making).

A. HHS Admits that Its Primary Justification for the Rule Was False.

The agency's stated rationale for issuing the Rule is flatly contradicted by the record evidence—a fact HHS has conceded. This alone renders the Rule arbitrary and capricious. *State Farm*, 463 U.S. at 43, 52–53.

[21] As set forth in the State Plaintiffs' brief and adopted here, Fed. R. App. P. 28(i), the district court correctly concluded that HHS did not adequately explain its departure from the prior contradictory factual findings in the 2011 Rule, SA90–98, and HHS did not consider the Rule's application to medical emergencies, SA103–06.

In its "Overview of Reasons for the Final Rule," HHS claimed the Rule was issued to address widespread "confusion" over the scope of the Refusal Statutes and HHS's supposedly inadequate enforcement tools. 84 Fed. Reg. at 23,175; *see* HHS Br. 44. As principal evidence of both alleged problems, HHS claimed that after November 2016, there was a "significant increase in complaints filed with OCR alleging violations of the laws that were the subject of the 2011 Rule [*i.e.*, the Church, Coats-Snowe, and Weldon Amendments]," 84 Fed. Reg. at 23,175—including 343 complaints[22] submitted during fiscal year 2018, *id.* at 23,229—and that "[t]he increase [in complaints] underscores the need for the Department to have the proper enforcement tools available," *id.* at 23,175.

As the district court concluded, HHS's supposed evidence of 343 complaints in one year was "demonstrably false." SA81–83. Indeed, contrary to what the Rule states, 94% of the complaints in the administrative record involved conduct clearly outside the scope of the Refusal Statutes—a fact HHS conceded to the district court. SA81, 82 & n.47 (noting HHS's admission that at most about 20 complaints even arguably implicate the Refusal Statutes); *see also*, *e.g.*, JA2428 (HHS explaining that it "already acknowledged that many of the complaints that OCR received related

[22] As the district court noted, the record contains only 336 unique complaints received between November 2016 and the end of fiscal year 2018. SA81; JA2284 ¶13.

to matters that are outside the scope of the Federal Conscience Statutes"). "This conceded fact is fatal to HHS's stated justification for the Rule." SA82.

On appeal, HHS now argues "the district court erroneously thought HHS miscounted conscience-related complaints." HHS Br. 18. But—faced with damning evidence that 79% of the 343 complaints are actually about vaccinations, and another 15% relate to topics that are similarly not covered by the Rule (including complaints that *opposed* the Rule)—the agency rightly admitted its error to the district court, on numerous occasions. SA81–83 & n.47 (district court identifying HHS concessions); JA2284 ¶¶15–16, JA2104–23, JA2336–49. HHS's revisionist history continues on appeal, claiming the district court erred by requiring it to "compile evidence" of past statutory violations and enforcement problems. HHS Br. 44–45. Not so—it is the agency that falsely asserted it had evidence of complaints that justified its decision to regulate. "[A]n agency decision is arbitrary and must be set aside when it rests on a crucial factual premise shown by the agency's records to be indisputably incorrect." *Mizerak v. Adams*, 682 F.2d 374, 376 (2d Cir. 1982).

HHS resorts to offering a post-hoc justification that the Rule is still supported by the remaining *potentially* relevant complaints. HHS Br. 45–46. But these remaining complaints amount to, at most, 21 complaints[23]—"a far cry from the 343

[23] As the district court noted, it is unclear that even these 21 complaints are all relevant. Indeed, HHS identified only seven complaints in its briefing below that were "fairly characterized as implicating the Conscience provisions." SA83.

that the Rule declared represented a '*significant* increase' in complaints." SA82 (emphasis in original). HHS's *appellate brief* may view 21 complaints as "troubling" enough to justify rulemaking, *see* HHS Br. 46, but the *agency's* reason was an incorrect claim of a much higher number, and "[a]n agency must defend its actions based on the reasons it gave when it acted." *DHS v. Regents of Univ. of Cal.*, 140 S.Ct. 1891, 1909 (2020). Moreover, HHS admits that any increase in complaints occurred *after* the NPRM was issued, *see* JA2752; these complaints are therefore "more likely attributed to the 2018 NPRM, rather than an increase, independent of the NPRM, in Conscience Provision violations or, as HHS claimed, in public confusion about these laws," SA85.

HHS next contends that the supposed increase in complaints was just one of "many metrics" it considered. HHS Br. 45–46 (stating HHS also relied on public comments and an increase in state laws and policies that allegedly violated federal conscience statutes). However many "metrics" HHS considered, the agency "rel[ied] on the purported increase in complaints as a principal basis for the Rule," both in the Rule itself and in its briefing below. SA89; *see* 84 Fed. Reg. at 23,175. (listing supposed "significant increase in complaints filed" as the very first point under "Reasons for the Final Rule"). Indeed, when HHS noted in the preamble that it considered "many metrics," it did so to address commenters' concern about the small number of complaints (thirty-four, by HHS's count) alleging coercion or

discrimination from November 2016 to January 2018—and the only example HHS gave of other "metrics" it considered was *the false claim* of "343 complaints alleging conscience violations" in FY 2018. *Id.* at 23,229. *Any* "[r]eliance on facts that an agency knows are false," even "*in part,*" "is the essence of arbitrary and capricious decisionmaking." *Animal Legal Def. Fund, Inc. v. Perdue*, 872 F.3d 602, 619 (D.C. Cir. 2017); *see also Nat. Res. Def. Council, Inc. v. Rauch*, 244 F.Supp.3d 66, 95–96 (D.D.C. 2017) (invalidating rule where record "show[s] its critical … assumption to be false"); SA88 (listing similar cases).

HHS's professed need for "clarifying the enforcement procedures," HHS Br. 46, is likewise infected by the agency's factual error, since it was supposedly the "increase" in complaints that "underscore[d]" the need for "proper enforcement tools," 84 Fed. Reg. at 23,175. That argument is also entirely inconsistent with HHS's claim that the Rule does not give the agency any new enforcement power. *See supra* Part I.B. Nor does it make sense for HHS's brief to suggest that the agency's failure to "investigate[] many complaints in the record" "counsels in favor of clarifying the enforcement procedures, as it did." HHS Br. 46. Surely the agency did not need to promulgate a rule to clarify *for itself* how to investigate complaints. It is also indisputable that 94% of the complaints it cited did not warrant investigation as even potential violations of the Refusal Statutes. And of the small number of complaints that were identified in the record as being investigated by

HHS, all but two were satisfactorily resolved by the time the Rule was issued. SA86.[24] In short, the Rule "represents a classic solution in search of a problem." SA88.

Ultimately, though, HHS's brief misses the point in debating the handful of potentially relevant complaints. What matters are the reasons the agency gave when it promulgated the Rule. *Regents*, 140 S.Ct. at 1909. Since the "factual premise" actually articulated by the agency was "incorrect," the Rule is arbitrary and capricious. *Mizerak*, 682 F.2d at 376; *see State Farm*, 463 U.S. at 52–53.

B. HHS Failed to Consider the Rule's Departure from Title VII and Upending of Reliance Interests.

The district court correctly concluded that the Rule is arbitrary and capricious because it displaces the Title VII reasonable accommodation/undue hardship framework without considering the reliance interests it has upended or otherwise grappling with the consequences of this decision. SA98–103, SA106–09.

As the Supreme Court recently reaffirmed, when an agency is "not writing on a blank slate … it [i]s required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents*, 140 S.Ct. at 1915. For nearly 50 years, Title

[24] Additionally, the majority of the investigated complaints were filed before November 2016, belying HHS's assertion that the agency's "prior approach to enforcement" "devoted no meaningful attention" to enforcing some laws. HHS Br. 46 (citing 84 Fed. Reg. at 23,178–79, 23,183).

VII's established framework has permitted employers, like Plaintiffs and others throughout the nation's healthcare industry, to balance an employee's objection to providing certain services with an employer's interest in providing care to patients, while considering the costs and operational difficulty of accommodating an employee's objection. *Cf.* 29 C.F.R. §1605.2 (discussing reasonableness and undue hardship). The Rule expressly rejects this balancing, imposing an absolute requirement to accommodate employee objections, regardless of hardship. 84 Fed. Reg. at 23,191; *see supra* Part II.A.1. Yet the agency did not discuss the burden on employers to adapt to an entirely new framework imposed by the Rule (in contrast to their longstanding familiarity with Title VII), nor the difficulty and confusion resulting from two divergent standards on accommodating workplace objections.

As the district court concluded and HHS does not contest, "plaintiffs and other funding recipients have relied on—they have shaped their conduct around—HHS's historical application" of the Refusal Statutes, in particular as to various hiring and employment policies. SA99. Intervenors-Defendants argue that there could be no reliance interest absent a prior HHS interpretation of the Refusal Statutes. *See* Intervenors' Br. 43–44. But HHS's historical view of the Statutes allowed employers to conform to a uniform and established legal framework. *See* JA2680. The disruption of these "serious reliance interests," and the failure to "provide a reasoned explanation … for disregarding facts and circumstances that … were engendered by

the prior policy," make the Rule arbitrary and capricious. *Regents*, 140 S.Ct. at 1913 (quoting *Encino Motorcars,* 136 S.Ct. at 2126 (2016).

Despite being required to consider reasonable alternatives, *id.* (citing *State Farm*, 463 U.S. at 51), HHS did not explain why the existing Title VII framework was insufficient to protect healthcare workers, *see*, *e.g.*, *Office of Commc'n of United Church of Christ v. FCC*, 707 F.2d 1413, 1439 (D.C. Cir. 1983) (holding that agency "failed to give sufficient consideration" to alternative that had applied "for almost 50 years"). HHS cannot justify its failure to address these issues on the ground that the Rule's inconsistency with Title VII is statutorily compelled. Aside from this argument being legally incorrect, *see supra* Part II.A.1, HHS's reasoning is internally inconsistent. HHS expressly determined that "components of [Title VII's] approach *are* appropriate in this context"—specifically, the "effective accommodation" of religious objections. 84 Fed. Reg. at 23,191. Yet the word "accommodation" appears nowhere in the Refusal Statutes, just like the phrase "undue hardship" is absent. A decision to pick and choose from Title VII's longstanding balancing framework—leaving it deeply unbalanced—cannot have been an inexorable statutory command, but a policy decision requiring an

explanation. *See id.* at 23,192 (stating that HHS's revised definition of discrimination "strike[s] the right balance").[25]

C. HHS Failed to Consider the Radical Disruption of Healthcare Delivery and Harm to Disadvantaged Patient Populations.

HHS also failed to consider the Rule's significant disruption of healthcare delivery and its harm to public health and specific patient populations, rendering the Rule arbitrary. *See Humane Soc'y of U.S. v. Zinke*, 865 F.3d 585, 606 (D.C. Cir. 2017).

As discussed above, the Rule significantly disrupts the operations of healthcare providers, thereby threatening access to essential healthcare services. As many commenters explained, the Rule would lead to negative health outcomes by reducing access to care, impairing patients' informed consent, and violating medical standards of care.[26] Commenters repeatedly highlighted that women, people of color, LGBTQ people, immigrants and refugees, and people living with HIV/AIDS or disabilities—communities that already face barriers to healthcare—would be

[25] Intervenors-Defendants incorrectly cite *State v. Dep't of Justice*, 951 F.3d 84, 122 (2d Cir. 2020), to suggest that HHS's passing discussion of Title VII was sufficient. Intervenors' Br. 44–45. In that case, the Court determined that the agency's failure to discuss certain detrimental effects did not make the agency action arbitrary and capricious because such effects were unlikely, not because the agency's disregard for them met the standard for reasoned decision making.

[26] *See, e.g.*, JA215 ¶9, JA229–30 ¶60, JA248–51 ¶¶108–16 (citing comments), JA291–93 ¶¶84–85, JA311–16 ¶¶131–40 (same).

disproportionately harmed, financially, physically, and mentally.[27] Commenters also highlighted that the Rule would deprive patients—especially those who rely on federally-funded healthcare—even basic information about care to which they are legally entitled.[28]

While HHS acknowledged that "people in such demographic categories face health care disparities of various forms" and that denial of care could result in harm to patient health, it nonetheless claimed the Rule's impact on healthcare delivery was a "difficult question" and faulted commenters for not providing quantifiable data. 84 Fed. Reg. at 23,250–51. Putting aside that some comments *did* suggest how to estimate reduction in access to care, *see* JA1084 n.22, HHS should have "rationally explain[ed] why the uncertainty" on the issue "counsels in favor of" taking agency action "now, rather than, for example, more study," *Greater Yellowstone Coal., Inc. v. Servheen*, 665 F.3d 1015, 1028 (9th Cir. 2011).

The agency's decision to ignore the harmful impact on patients for lack of quantifiable data is blatantly inconsistent with its decision to rely on anecdotal, nonquantifiable data to justify the Rule. For example, while HHS "assume[d]" based on "anecdotal[]" evidence from "[s]everal commenters" that the Rule would benefit

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[27] *See, e.g.*, JA1642, JA1697, JA1933, JA1939, JA1965, JA1992, JA2001, JA2070.

[28] *See, e.g.*, *id.*

patient care by increasing the number and quality of available providers, the agency acknowledged it "is not … aware of data that provides a basis for quantifying these effects." 84 Fed. Reg. at 23,247, 23,250. HHS cannot "cherry-pick[] … evidence" in this way. *Water Quality Ins. Syndicate v. United States*, 225 F.Supp.3d 41, 69 (D.D.C. 2016). Such "internally inconsistent" decision making is arbitrary. *NRDC v. U.S. Nuclear Regulatory Comm'n*, 879 F.3d 1202, 1214 (D.C. Cir. 2018).

IV. The Final Rule's Definition of "Discrimination" Is Not a Logical Outgrowth of the Proposed Rule.

Because the Rule is substantive, *see supra* Part I.A, HHS was required to follow notice-and-comment requirements, 5 U.S.C. §553(b)(3). This Court has long construed those requirements to mean that "[w]hile a final rule need not be an exact replica of the [proposed] rule," it "must be a 'logical outgrowth' of the rule proposed" such that "affected parties … [have] notice and an opportunity to respond." *Nat'l Black Media Coal. v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986).

The final Rule fails that test, making radical changes to the proposed Rule's definition of discrimination. *See* SA109–15. Although the final Rule substantially retained the first three subsections of the definition from the proposed Rule, it added three new subsections that dramatically expand the definition's sweep and replace the familiar reasonable accommodation/undue hardship framework with a completely different standard. Among other things, the new additions prevent employers from ensuring they hire applicants willing to perform the job's core

functions. *Compare* 83 Fed. Reg. at 3,892 *with* 84 Fed. Reg. at 23,263, 23,190–92; *see also supra* Part II.A1. The proposed Rule did not propose to override the longstanding framework for assessing claims of discrimination, which has governed the healthcare sector for nearly 50 years, and replace it with a novel system of requirements governing hiring and dictating when and (how often) an employer can speak to their employees. SA112 (citing *Nat'l Mining Ass'n*, 116 F.3d at 532).[29]

Though HHS notes that the proposed Rule omitted mention of "employer defenses," *see* HHS Br. 50, silence is not fair notice that the agency means to revolutionize half a century of law and practice. "[S]omething is not a logical outgrowth of nothing." *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005). Neither can HHS save the Rule by noting it "received and responded to" comments relating to the absence of defenses and *potential* conflicts with Title VII. HHS Br. 50. Courts have repeatedly rejected similar attempts to "bootstrap notice from a comment." *Nat'l Black Media Coal.*, 791 F.2d at 1023; SA114 (collecting cases). The most Provider Plaintiffs could glean from the proposed Rule was that it was unclear if HHS meant to adhere to the reasonable accommodation/undue hardship standard. JA1201 (PPFA comment); *see* JA1778 (NFPRHA comment)

[29] Intervenors-Defendants argue that "there was no need to address Title VII in the notice of proposed rulemaking" because it "does not govern the Rule." Intervenors' Br. 46. This is wrong on the merits, *see supra* Part II.A.1, and disregards that a logical outgrowth challenge attacks the agency's procedure, not the rule's substance, *see Shell Oil Co. v. EPA*, 950 F.2d 741, 759 (D.C. Cir. 1991).

("HHS should clarify that any final rule does not conflict with Title VII … "). In fact, the proposed Rule suggested that Title VI's disparate impact analysis, which looks to Title VII's burden-shifting framework for guidance, *NYC Envtl. Justice All. v. Giuliani*, 214 F.3d 65, 72 (2d Cir. 2000), might be incorporated into the final Rule, *see* 83 Fed. Reg. at 3,893, 3,917. The agency's rejection of the reasonable accommodation/undue hardship framework appeared for the first time in the final Rule, as did its provisions forbidding employers from even asking applicants if they object to performing essential functions of the job for which they are being hired, and preventing employers from telling patients about alternate staff or methods if an employee objects to providing a particular service. 84 Fed. Reg. 23,191.

HHS claims this failure of notice did not prejudice Plaintiffs because the new subsections supposedly provide employers with "more protections than the proposed rule did." HHS Br. at 50–51. That is doubly wrong. Where the proposed Rule was silent, the new subsections codify strict and unprecedented accommodation requirements. *See supra* Part II.A.1. And even if these additions provided some manner of safe harbor, Plaintiffs were still denied the opportunity to comment on their draconian parameters. *See Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1311 (D.C. Cir. 1991) (explaining that a final rule is not a logical outgrowth of a proposed rule "if a new round of notice and comment would … provide commenters with 'their first occasion to offer new and different criticisms which the agency might find

convincing'" (quoting *United Steelworkers of America v. Marshall*, 647 F.2d 1189, 1225 (D.C. Cir. 1980))). In sum, the final Rule makes radical changes to the definition of discrimination that were not subject to notice and comment and therefore are not a "logical outgrowth" of the proposed Rule.

V. The APA and Precedent Dictate Vacatur of the Rule in Its Entirety.

A. Vacatur Cannot Be Limited to the Parties.

The APA instructs that "[t]he reviewing court *shall* … hold unlawful and set aside" unlawful agency action, 5 U.S.C. §706(2), which is precisely what the district court did, SA139. HHS does not dispute that vacatur is the appropriate remedy. Nor could it: "An agency rule which violates the APA is void," and, as such, "[a]gency action taken under a void rule has no legal effect." *W.C. v. Bowen*, 807 F.2d 1502, 1505 (9th Cir.), *opinion amended on denial of reh'g*, 819 F.2d 237 (9th Cir. 1987); *see also Chrysler Corp.*, 441 U.S. at 313.

Instead, HHS argues that vacatur should be limited to the parties, but this argument was properly rejected by the district court as it finds no support in the law. SA144–46. Under the APA, "if the plaintiff prevails, the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual." *Nat'l Min. Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998).

That is why the Supreme Court consistently directs its holding and remedy in APA cases to the illegal rule—not to the parties that brought the suit. *See, e.g.*, *Regents*, 140 S.Ct. at 1925 n.7 (vacatur of agency action, not limited to parties); *State Farm*, 463 U.S. at 34, 57. Unsurprisingly, when the government has argued that vacatur should be limited to the parties, courts have soundly rejected the argument as contrary to the APA. *See, e.g.*, *District of Columbia v. U.S. Dep't of Agric.*, No. 20-cv-119, 2020 WL 1236657, at *34 (D.D.C. Mar. 13, 2020), *appeal docketed,* 20-5136 (D.C. Cir. May 14, 2020); *O.A. v. Trump*, 404 F.Supp.3d 109, 152–53 (D.D.C. 2019); *City of San Francisco*, 411 F.Supp.3d at 1025; *N.M. Health Connections v. HHS*, 340 F.Supp.3d 1112, 1183 (D.N.M. 2018); *Desert Survivors v. U.S. Dep't of the Interior*, 336 F.Supp.3d 1131, 1134 (N.D. Cal. 2018).

HHS ignores the dearth of precedent for its proposed remedy, and instead misleadingly cites cases that address the proper scope of *injunctions* as "cases that have grappled with whether or not the APA requires nationwide *vacatur*." HHS Br. 64. Vacatur is not the equivalent of an injunction, and the district court properly distinguished the cases cited by HHS. SA140–41.[30]

[30] HHS's argument that challenges to government policies must be permitted to "percolate" among the lower courts is unfounded. HHS Br. 62. The challenged relief in *California v. Azar*, 911 F.3d 558 (9th Cir. 2018), *Trump v. Hawaii*, 138 S.Ct. 2392 (2018), and *DHS v. New York*, 140 S.Ct. 599 (2020), were preliminary injunctions. Here, the district court "resolved the competing motions for summary judgment based on a full administrative record," SA140, and thus cannot be characterized as a "rushed" or "low-information" decision, *DHS*, 140 S.Ct. at 600.

Even assuming vacatur could be limited to parties, such a remedy could not be viable because it does not fully redress the Plaintiffs' injury. Although HHS cherry-picks language invoking standing and equitable principles, *see* HHS Br. 61, these cases stand for the "the familiar general proposition" that remedy must be tailored to redress the plaintiff's particular injury. SA145. Those principles dictate vacatur here. Given the complex and interdependent network of HHS funding, if HHS is permitted to enforce the Rule to terminate or claw back funds from non-parties, Provider Plaintiffs' members—*i.e.*, healthcare organizations that are often sub-recipients of HHS funds, SA144; JA217, JA269, JA305—could lose critical funding, just the same as if the Rule had been enforced against them directly. *See* JA380–84, JA386, JA407–08. Accordingly, even applying "traditional equitable principles" instead of the plain text of the APA, HHS Br. 63–64, vacatur is still necessary to provide Plaintiffs full redress.

B. No Part of the Rule Is Valid.

The premise of HHS's severability argument—that "[t]here is no dispute that numerous provisions of the Rule are valid," HHS Br. 65—is wrong. Among other flaws, HHS's rationale for *issuing the Rule in the first place* was arbitrary and capricious. *See supra* Part III.A. Because the promulgation of the Rule violated the APA, the Rule as a whole is invalid, which means there is nothing to sever.

Even overlooking these all-encompassing defects, the agency's APA

violations are "numerous, fundamental, and far-reaching." SA142. In such a situation, "a severability clause is an aid merely; not an inexorable command." *Whole Woman's Health v. Hellerstedt*, 136 S.Ct. 2292, 2319 (2016). Courts have thus refused to sever parts of a Rule notwithstanding such a clause, where, as here, doing so would "severely distort" the agency's intentions and "produce a rule strikingly different from any the [agency] … considered or promulgated." *MD/DC/DE Broad. Ass'n v. FCC*, 236 F.3d 13, 23 (D.C. Cir. 2001) (holding unlawful "provisions of the rule cannot be severed and the entire rule must be vacated" despite severability clause). As explained above, *supra* Part I.A, numerous provisions of the Rule are co-dependent, as several sections cross-reference and rely on one another, and indeed compliance with certain provisions of the Rule was intended to inform HHS's enforcement of other sections, *see* 84 Fed. Reg. at 23,216 ("OCR will consider the posting of notices [described in §88.5] as non-dispositive evidence of compliance … ."). Similarly, HHS's flawed interpretations of the Refusal Statutes—for example, construing the word "discrimination" to mandate absolute accommodation—permeate the Rule.[31] Even more fundamentally, as the district court held, "HHS lacked substantive rule-making authority as to three of the

[31] Since this absolute accommodation requirement is central to the Rule's definition of discrimination requirement, it is unclear what HHS means when it suggests the definition might have "applications plaintiffs do not contend are unlawful." HHS Br. 65.

five principal [Amendments,] nullif[ying] the heart of the Rule." SA142. To the extent HHS believes there are portions of the Rule that could be promulgated consistent with the APA, nothing prevents it from commencing a new rulemaking process and considering whether to include such provisions in a valid rule.

CONCLUSION

The judgment of the district court should be affirmed.

Dated: July 27, 2020

Respectfully submitted,

/s/ Diana O. Salgado
Diana O. Salgado

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC.
Diana O. Salgado
1110 Vermont Ave., NW, Ste. 300
Washington, D.C. 20005
202-973-4800
diana.salgado@ppfa.org

Hana Bajramovic
123 William Street, 9th Floor
New York, NY 10038
212-261-4593
hana.bajramovic@ppfa.org

NATIONAL WOMEN'S LAW CENTER
Michelle Banker
Sunu Chandy
11 Dupont Circle, NW, Suite 800
Washington, DC 20036
202-588-5180
mbanker@nwlc.org
schandy@nwlc.org

COVINGTON & BURLING, LLP
Kurt G. Calia
3000 El Camino Real
Palo Alto, CA 94306
650-632-4717
kcalia@cov.com

David M. Zionts
One City Center
850 10th Street, NW
Washington, DC 20001
202-662-5987
dzionts@cov.com

Sarah Mac Dougall
The New York Times Building
620 8th Ave
New York, NY 10027
212-841-1215
smacdougall@cov.com

Counsel for Plaintiffs-Appellees Planned Parenthood Federation of America, Inc. & Planned Parenthood of Northern New England, Inc.

/s/ Alexa Kolbi-Molinas
Alexa Kolbi-Molinas*

AMERICAN CIVIL LIBERTIES UNION FOUNDATION
Alexa Kolbi-Molinas
Lindsey Kaley
125 Broad Street, 18th Floor
New York, NY 10004
212-519-7845
212-519-7823
akolbi-molinas@aclu.org
lkaley@aclu.org

Daniel Mach
915 15th Street NW
Washington, DC 20005
202-548-6604
dmach@aclu.org

NEW YORK CIVIL LIBERTIES UNION
Christopher Thomas Dunn
125 Broad Street
New York, NY 10004
212-607-3300
cdunn@nyclu.org

Counsel for Plaintiffs-Appellees National Family Planning and Reproductive Health Association and Public Health Solutions, Inc.

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CERTIFICATE OF COMPLIANCE

1. This brief complies with this Court's order of July 13, 2020 because this brief contains 15,948 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman. As permitted by Fed. R. App. P. 32(g), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

Dated: July 27, 2020
Washington, DC

/s/ Diana O. Salgado
Diana O. Salgado

CERTIFICATE OF SERVICE

I hereby certify that on July 27, 2020, I electronically filed the foregoing motion with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

Dated: July 27, 2020
Washington, DC

/s/ Diana O. Salgado
Diana O. Salgado