19-4254(L)

20-31, 20-32, 20-41 (CON)

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 HAWAIʻI, 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 continues inside front cover)

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

BRIEF FOR GOVERNMENTAL PLAINTIFFS-APPELLEES

BARBARA D. UNDERWOOD
Solicitor General
STEVEN C. WU
Deputy Solicitor General
LINDA FANG
ESTER MURDUKHAYEVA
Assistant Solicitors General
of Counsel

(Counsel listing continues on signature pages.)

LETITIA JAMES
Attorney General
State of New York
Attorney for Governmental Plaintiffs-Appellees
28 Liberty Street
New York, New York 10005
(212) 416-8656

Dated: July 27, 2020

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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, UNITED STATES OF AMERICA,

Defendants-Appellants,

DR. REGINA FROST, CHRISTIAN MEDICAL AND DENTAL ASSOCIATION,

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.

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PRELIMINARY STATEMENT

For decades, several federal laws—in conjunction with state and local laws—have provided a well-understood framework for addressing some health care personnel's religious and moral concerns about certain procedures. In compliance with those laws, health care providers have developed and implemented policies that accommodate individuals' objections to particular procedures, while ensuring that patients can still continue to receive the care that they need, including in emergencies.

In May 2019, however, the United States Department of Health and Human Services (HHS) issued a final rule that vastly expanded the ability of individuals and entities involved in the provision of health care to deny patients access to lawful and medically necessary treatment, services, and even information based on the objector's personal views. Protecting Statutory Conscience Rights in Health Care: Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019) (codified at 45 C.F.R. pt. 88) (the "Rule"). In doing so, HHS disregarded the balance that Congress has struck, adopted novel definitions of key statutory terms, arrogated to itself extraordinary enforcement powers, and upended a longstanding

status quo that health care providers and patients around the country had relied on for decades.

The government plaintiffs—the State of New York and eighteen other States, the District of Columbia, the Cities of New York and Chicago, and Cook County, Illinois—brought this challenge to the Rule, asserting various claims under the Administrative Procedure Act (APA) and the federal Constitution. The United States District Court for the Southern District of New York (Engelmeyer, J.) entered summary judgment for the government plaintiffs, holding that HHS's Rule was contrary to law as well as arbitrary and capricious under the APA, and unconstitutional under the Spending Clause and the separation-of-powers doctrine. This Court should affirm.

As the district court correctly found, the Rule is contrary to law because, in several different ways, HHS trampled over the careful lines that Congress drew in the federal conscience statutes and consistently prioritized individuals' personal objections over patients' right to access essential care. In particular, the Rule's sweeping new interpretations of key terms in the federal conscience statutes disable providers from ensuring that patients receive uninterrupted care even while providers

accommodate the religious and moral objections of their employees—for example, by prohibiting providers from reassigning or rescheduling objectors, or from even asking employees and prospective job applicants whether they have objections to certain medical procedures that should be accommodated. The Rule also vastly expands the job functions that objectors may refuse to perform and impedes patients' ability not only to receive care but also to obtain basic information about their medical options. Federal law does not authorize HHS to impose such stark impediments to the provision of health care.

The Rule is also arbitrary and capricious for multiple, independent reasons. Most glaringly, HHS's factual predicates for the Rule were "demonstrably false," as the district court found: HHS outright misstated the number of complaints that it claimed to have received by a factor of nearly twenty, and cited no concrete evidence of confusion that the Rule would remedy. HHS also failed to acknowledge the decades of reliance on the status quo prior to the 2019 Rule; failed to address its own past guidance on the same federal conscience statutes; and failed to consider the extensive harms that the Rule will cause to patients and providers.

The district court properly vacated the Rule in its entirety in light of its glaring deficiencies. This Court should affirm.

QUESTIONS PRESENTED

1. Whether the Rule is contrary to law under the Administrative Procedure Act because it (a) adopts definitions that go beyond the authority provided by the federal conscience statutes and conflicts with other statutes, such as Title VII of the Civil Rights Act of 1964; (b) arrogates to HHS extraordinary enforcement powers not authorized by Congress; and (c) conflicts with federal laws mandating the provision of medical information irrespective of religious or moral objections.

2. Whether the Rule is arbitrary and capricious under the Administrative Procedure Act because (a) HHS's stated rationales for the Rule are contradicted by the administrative record; (b) the Rule does not reasonably explain HHS's change of position; (c) HHS did not address the substantial reliance interests engendered by its prior policies; and (d) HHS did not rationally assess the harms that the Rule will cause.

3. Whether the Rule violates the Spending Clause and the separation-of-powers doctrine by imposing funding conditions beyond those authorized by Congress.

4. Whether the district court properly vacated the Rule in its entirety, rather than limiting such relief to the plaintiffs, upon concluding that the Rule is unlawful and must be "set aside" under the Administrative Procedure Act, 5 U.S.C. § 706.

STATEMENT OF THE CASE

A. Statutory Background

1. Federal laws balancing patients' right to access health care and providers' objections to particular procedures

Over the span of nearly four decades, Congress has enacted several statutes protecting patients' access to care while recognizing that some health care providers may have religious or moral objections to participating in particular procedures. As the district court correctly noted here, Congress did not mandate broad-brushed accommodations for conscience objections in the provision of health care, but instead addressed such objections "in discrete contexts." (Special Appendix (S.A.) 4.) The particular language that Congress chose in this sensitive area and the specific contexts in which it legislated are thus critical to understanding the impact of, and defects in, the Rule under review.

Five federal statutes concerning conscience objections to certain medical procedures and services—including abortion, sterilization, and aid-in-dying—are at issue in this case.[1] As relevant here, the Rule purports to interpret several statutory terms contained in those statutes, namely: (1) "discriminate" or "discrimination" as used in the Church, Coats-Snowe, and Weldon Amendments, and the Patient Protection and Affordable Care Act (ACA); (2) "assist in the performance" in the Church Amendment; (3) "health care entity" in the Coats-Snowe and Weldon Amendments and in the ACA; and (4) "referral" or "refer for" as contained in the Coats-Snowe and Weldon Amendments, and in the Medicaid and Medicare statutes. *See* 45 C.F.R. § 88.2.

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[1] Although the Rule purports to implement a total of some thirty federal statutes (*see* S.A. 160-164, 253), HHS has not argued that these other statutes provide any distinct or additional authority or justification for the Rule. (*See* S.A. 5 n.1 (noting HHS "agreed at argument" that "the Rule's validity turns on the five provisions" identified in the district court's opinion).) Nor does HHS even identify any of these other statutes on appeal. *See* Br. for Defs.-Appellants & Consolidated Defs.-Appellants (Br.) at 3 n.1.

a. The Church Amendment

In 1973, Congress enacted the first federal health care conscience statute in 42 U.S.C. § 300a-7. That statute—known as the Church Amendment—prohibits courts and public officials from compelling individual and institutional recipients of federal funds under the Public Health Service Act[2] to "perform or assist in the performance of any sterilization procedure or abortion," or to make the institution's facilities or staff available for such procedures, if the participation "would be contrary to [the recipient's] religious beliefs or moral convictions." 42 U.S.C. § 300a-7(b)(1)-(2), (c)(1). The statute also provides that individuals shall not 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 [HHS-administered] program," if such performance or assistance "would be contrary to his religious beliefs or moral convictions." *Id.* § 300a-7(d). The sponsor of the Church Amendment confirmed, however,

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[2] The Church Amendment references two other funding statutes, but Congress subsequently repealed the statutes. Funding under the Public Health Service Act is thus the only federal funding currently implicated by the Church Amendment. (*See* S.A. 161 n.3.)

that conscience objections would not "deny such services" in "emergency situation[s]." 119 Cong. Rec. 9601 (Mar. 27, 1973).

The Church Amendment further protects individuals from "discrimination" in their employment on the basis of their "religious beliefs or moral convictions respecting sterilization procedures or abortions." 42 U.S.C. § 300a-7(c)(1). Although the Church Amendment did not define "discrimination," by the time of its enactment a robust body of case law had developed over employment discrimination under Title VII of the Civil Rights Act of 1964 (Title VII), 42 U.S.C. § 2000e et seq., including unlawful religious discrimination.

Specifically, the Church Amendment prohibits recipients of certain federal funds from "discriminat[ing] in the employment, promotion, or termination of employment of any physician or other health care personnel" if that individual either chooses to "perform[] or assist[] in the performance of a lawful sterilization procedure or abortion," or refuses to do so due to her "religious beliefs or moral convictions." *Id.* § 300a-7(c)(1). Entities receiving federal grants or contracts "for biomedical or behavioral research under any program administered by [HHS]" are subject to

similar proscriptions on employment discrimination with respect to "any physician or other health care personnel." *Id.* § 300a-7(c)(2).

b. The Emergency Medical Treatment and Labor Act

In 1986, Congress enacted the Emergency Medical Treatment and Labor Act (EMTALA) to ensure patient access to emergency medical care. EMTALA mandates that hospitals with emergency departments that participate in Medicare provide "necessary stabilizing treatment for emergency medical conditions" for all patients. *See* 42 U.S.C. § 1395dd(b). And EMTALA prohibits hospitals from transferring patients to other hospitals until the patient's condition has stabilized. *See id.* § 1395dd(c). Congress did not enact any exceptions to EMTALA's mandates based on an individual provider or hospital's conscience-related objections to providing treatment in emergency situations. *See Matter of Baby K.*, 16 F.3d 590, 596 (4th Cir. 1994).

c. The Coats-Snowe Amendment

In 1996, Congress enacted the Coats-Snowe Amendment, 42 U.S.C. § 238n. The statute prohibits government entities receiving federal funds from subjecting any "health care entity" to "discrimination" based on the entity's refusal "to undergo training in the performance of induced

abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions." *Id.* § 238n(a). The Coats-Snowe Amendment also prohibits government entities receiving federal assistance from discriminating against a "health care entity" on similar grounds in the accreditation context. *Id.* § 238n(b)(1).

The statute defines "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." *Id.* § 238n(c)(2). Like the Church Amendment, the Coats-Snowe Amendment does not contain its own definition of "discrimination."

d. Medicare and Medicaid statutes

In 1997, Congress amended certain statutes relating to Medicaid- and Medicare-managed care plans. As relevant here, Congress provided that organizations offering such plans "shall not prohibit or otherwise restrict" individual providers from advising a patient about the treatment options for the patient's health condition, regardless of whether the medically indicated treatment was offered or covered by the organization's plan. *See* 42 U.S.C. §§ 1395w-22(j)(3)(A), 1396u-2(b)(3)(A).

At the same time, Congress exempted the Medicaid- and Medicare-managed care plans from being required to "provide, reimburse for, or provide coverage of a counseling or referral service" if the "organization offering the [insurance] plan . . . objects to the provision of the service on moral or religious grounds." *Id.* §§ 1395w-22(j)(3)(B), 1396u-2(b)(3)(B). Congress made clear that this exemption "shall not be construed to affect" relevant state laws governing informed consent and patient disclosure. *See id.* §§ 1395w-22(j)(3)(C), 1396u-2(b)(3)(B). HHS's own regulation likewise requires hospitals participating in Medicaid and Medicare to ensure that patients are fully "informed of his or her health status," "involved in care planning and treatment," and "able to request or refuse treatment." 42 C.F.R. § 482.13(b)(2).

e. The Weldon Amendment

In 2004, Congress enacted the Weldon Amendment as a rider to an appropriations act for the Departments of Labor, Education, and HHS. Congress has since included the same rider in each appropriation act for these three federal agencies.

The Weldon Amendment prohibits federal funds "made available in this Act" from being provided to "a State or local government" if the

government "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." *See* Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 507(d)(1), 133 Stat. 2534, 2607 (2019). Statements of the statute's sponsor confirm that the law does not interfere with "access to life-saving care" in "emergency situations," or longstanding mandates under EMTALA. *See* 151 Cong. Rec. H177 (Jan. 25, 2005) (statement of Rep. Weldon).

The Weldon Amendment defines "health care entity" to include an individual physician "or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan," Pub. L. No. 116-94, § 507(d)(2). As with the Church and Coats-Snowe Amendments, Congress did not define "discrimination" in the Weldon Amendment.

f. The Patient Protection and Affordable Care Act of 2010

In 2010, Congress adopted a number of provisions in the ACA that are relevant here. Specifically, Congress prohibited government agencies receiving ACA funds from "subject[ing] an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service" for the purpose of causing or assisting in causing "the death of any individual, such as by assisted suicide, euthanasia, or mercy killing." 42 U.S.C. § 18113(a). For purposes of that section, 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." *Id.* § 18113(b).

The ACA also prohibits health care insurance plans offered through the ACA exchange from "discriminat[ing] against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions." *See id.* § 18023(b)(4). At the same time, in § 1554 of the ACA, Congress prohibited HHS from promulgating any regulation that, among other things,

"impedes [a patient's] timely access to health care services," or "violates the principles of informed consent and the ethical standards of health care professionals." *See id.* § 18114(2), (5).

2. State laws and institutional policies respecting conscience objections in health care

The government plaintiffs are both public providers and regulators of health care: they own and operate public hospital systems, employ individual health care personnel, and license and regulate the many other health care providers that operate within their jurisdictions. Like Congress, legislatures in the plaintiff jurisdictions recognize that health care providers may have objections to participating in medical procedures based on religious and conscience grounds,[3] and protect providers from

[3] *See, e.g.*, N.Y. Civil Rights Law § 79-i(1) (1971); Colo. Rev. Stat. § 15-18.7-105 (2010); Conn. Agencies Regs. § 19-13-D54(f) (1974); Del. Code Ann. tit. 16, § 2508(e)-(g) (1996); *id.* tit. 24, § 1791 (1969); 745 Ill. Comp. Stat. §§ 70/4, 70/5 (1998); Md. Code Ann., Health–Gen. § 20-214 (1982); Mich. Comp. Laws § 333.20182 (1978); N.J. Stat. Ann. §§ 2A:65A-1, 2A:65A-2 (1974); Or. Rev. Stat. § 435.485 (1969); 43 Pa. Cons. Stat. § 955.2 (1973); 23 R.I. Gen. Laws § 23-17-11 (1956); Va. Code Ann. § 18.2-75 (1975); Vt. Stat. Ann. tit. 18, §§ 5285, 5286 (2013); Wis. Stat. § 253.09(3) (1973).

discrimination on the basis of their beliefs.[4] Some of plaintiffs' conscience statutes predated Congress's first enactment of such laws in 1973. *See* N.Y. Civil Rights Law § 79-i(1) (1971); Del. Code Ann. tit. 24, § 1791 (1969); 23 R.I. Gen. Laws § 23-17-11 (1956).

At the same time, the government plaintiffs recognize the importance of patients' ability to access health care, and the need to ensure that such access not be disrupted even while accommodating the objections of individual providers to specific medical procedures. Accordingly, the government plaintiffs have also enacted informed consent laws to ensure that patients are able to meaningfully participate

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[4] *See, e.g.*, N.Y. Exec. Law § 296(10); Chicago Mun. Code § 2-160-050; D.C. Code §§ 2-1402.11, 2-1402.31; Haw. Rev. Stat. § 378-2; Mass. Gen. Laws ch. 151B, § 4(1A); Minn. Stat. § 363A.08, subd. 2; N.M. Stat. Ann. § 28-1-7(A)-(C); Administrative Code of City of N.Y. § 8-107(3)(a); Vt. Stat. Ann. tit. 21, § 495(a).

in decisions about their care and treatment,[5] as well as laws mandating that patients receive continuous and necessary care.[6]

Health care institutions—including those owned and operated by the plaintiffs' jurisdictions—have uniformly adopted policies balancing conscience objections to particular procedures with the institutions' obligations to ensure that the provision of medical care is not compromised.[7] Such policies typically provide that institutions will endeavor to accommodate an individual objector, as long as the institution is given sufficient advance notice of the objection, and the accommodation can reasonably be made in light of staffing constraints without compromising patient care or violating legal or ethical standards.

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[5] *See, e.g.*, N.Y. Pub. Health Law § 2805-d; Del. Code Ann. tit. 18, § 6852; D.C. Mun. Regs., tit. 22-B, § 2022; Haw. Rev. Stat. § 671-3(b)(4)-(6); 410 Ill. Comp. Stat. § 50/3; Md. Code Ann., Health–Gen. § 19-342; Mass. Gen. Laws ch. 111, § 70E; Minn. Stat. § 144.651, subd. 9; N.J. Stat. Ann. § 26:2H-12.8(d); Or. Rev. Stat. § 677.097; 40 Pa. Cons. Stat. § 1303.504; R.I. Gen. Laws § 23-4.7-2; Vt. Stat. Ann. tit. 12, § 1909; Wis. Stat. § 448.30.

[6] *See, e.g.*, N.Y. Educ. Law § 6530(30); 8 N.Y.C.R.R. § 29.2; Conn. Agencies Regs. § 19a-580d-9(a); 225 Ill. Comp. Stat. § 60/22(A)(16); N.M. Stat. Ann. § 61-6-15(D)(24); 49 Pa. Code § 16.61(a)(17); R.I. Gen. Laws § 5-37-5.1; 18 Va. Admin. Code § 85-20-28(B); Wis. Stat. § 448.02(3)(c).

[7] (*See, e.g.*, Joint Appendix (J.A.) 483-484, 491-493, 516-517, 527, 552-554, 596-597, 643-644, 691-692, 706-707, 744-745, 871-872, 908-909, 923, 1783, 1797-1798, 1898, 1903, 1211-1212, 1235-1238, 1986-1987.)

B. Department of Health and Human Services (HHS) Rulemaking

1. The 2008 and 2011 rules

In December 2008, thirty-five years after Congress enacted the first federal conscience statute, HHS decided, for the first time, to undertake rulemaking purporting to implement the Church, Coats-Snowe, and Weldon Amendments. *See* Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072 (Dec. 19, 2008). The 2008 rule provided its own definitions of certain terms used in these statutes, including "assist in the performance" and "health care entity"; required all recipients and subrecipients of HHS-administered funds to submit compliance certifications; provided for enforcement of violations; and designated HHS's Office of Civil Rights (OCR) to receive and coordinate the investigation and resolution of relevant complaints. *See id.* at 78,096-101.

The 2008 rule expressly declined, however, to define "discrimination" as that term is used in the Church, Coats-Snowe, and Weldon Amendments. As HHS explained, no definition of "discrimination" was needed because the term is "widely understood," and "significant federal

case law exists to aid entities in knowing what types of actions do or do not constitute unlawful discrimination." *See id.* at 78,077. While observing that the federal conscience statutes have a somewhat broader scope than existing antidiscrimination statutes, HHS declared that its enforcement would be "informed . . . by comparison to Title VII religious discrimination jurisprudence"; and, drawing from that jurisprudence, confirmed that the federal conscience statutes did not prohibit employers from determining whether conscience objections would preclude applicants from performing "the essential functions of a job," or from making "rational hiring decisions" based on such information. *See id.* at 78,085.

In January 2009, eight States and two reproductive care providers brought suit to enjoin the 2008 rule, on APA and other grounds. *See Connecticut v. United States*, No. 09-cv-054 (D. Conn.). Two months later, HHS issued a notice of proposed rulemaking soliciting comments on rescinding the 2008 rule. *See* 74 Fed. Reg. 10,207 (Mar. 10, 2009).

In 2011, after considering the comments it received, HHS promulgated a new rule superseding the 2008 rule in part. *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9971 (Feb. 23, 2011). The 2011 rule

continued to designate OCR as the receiver and investigator of complaints under the Church, Coats-Snowe, and Weldon Amendments, and announced initiatives "to develop a coordinated investigative and enforcement process" to address complaints and violations, and to further "increase the awareness of health care providers about the protections provided by" the federal conscience statutes.[8] *Id.* at 9969, 9972.

However, the 2011 rule rescinded other parts of the 2008 rule, including the definitional provisions. HHS found that the regulatory definitions contained in the 2008 rule had caused "confusion regarding the scope" of the federal conscience statutes by potentially going beyond what the statutes themselves said. *See id.* at 9969, 9974. HHS explained that it was also not necessary to provide regulatory definitions for the statutes' terms, as the 2008 rule did, because regulated parties had developed well-settled understandings of the statutes in the decades that they were in force before the 2008 rule's promulgation. *See id.* at 9974.

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[8] The sole statutory authority HHS invoked for the 2011 rule was 5 U.S.C. § 301, which generally authorizes rulemaking by federal agencies on internal matters. *See* 76 Fed. Reg. at 9975.

HHS also rescinded the 2008 rule's compliance provisions, explaining that the certification requirements were "unnecessary to ensure compliance with" the relevant statutes and instead "created unnecessary additional financial and administrative burdens." *See id.* HHS concluded that it could increase public awareness about the conscience protections through less burdensome means, such as by incorporating references to the statutes in grant administration documents and conducting broader public outreach. *See id.* at 9972.

2. The 2019 Rule

Nearly seven years later, in January 2018, HHS proposed a new rule for the federal conscience statutes. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3881, 3923 (Jan. 26, 2018). HHS received "over 242,000 comments in response to" the proposal. (S.A. 170.)

On May 21, 2019, HHS published the Rule under review here, codified at 45 C.F.R. part 88. (S.A. 160.) The Rule purports to implement and enforce some thirty federal statutes relating to providers' objections to certain medical care on religious and moral grounds—although only

five of the statutes are now at issue. (S.A. 253.) The Rule does so in three primary ways.

First, the Rule sets forth new definitions for a number of statutory terms appearing in the Church, Coats-Snowe, and Weldon Amendments; in sections 1303 and 1553 of the ACA; and in certain Medicaid and Medicare statutes. Specifically, the Rule broadly defines the terms "discriminate," "assist in the performance," and "referral" and "refer for" in a way that vastly expands individuals' ability to refuse to provide essential health care that they disagree with, while at the same time substantially limiting the actions that employers can take to ensure that patients can continue receiving access to the care that they need. *See* 45 C.F.R. § 88.2. The Rule also enlarges the universe of individuals and entities subject to the federal conscience statutes by expanding the definition of "health care entity." *Id.*

Second, the Rule imposes substantial new certification and assurance requirements on all regulated entities as a condition of the approval or "continued receipt" of any financial assistance administered by HHS. *Id.* § 88.4(a), (b)(5). Among other things, the direct recipients of federal funds are required to certify compliance with the Rule and the

federal conscience statutes, both as to themselves as well as to their subrecipients—that is, the entities receiving federal funds from recipients, rather than directly from HHS. *Id.* § 88.6(a).

Third, the Rule details HHS and OCR's enforcement of the federal conscience laws. *Id.* § 88.7. The Rule states that HHS is authorized to terminate or suspend all of an entity's federal funds based solely on OCR's finding of noncompliance—on the part of a direct funding recipient or a subrecipient—even during the pendency of voluntary remediation efforts. *Id.* § 88.7(i)(2)-(3).

HHS claimed that the Rule's new requirements and enforcement measures were necessary due to a "significant increase in complaints" since November 2016 "alleging violations of" the Church, Coats-Snowe, and Weldon Amendments. (S.A. 165.) Specifically, HHS claimed that it had "received 343 complaints alleging conscience violations" during fiscal year 2018. (S.A. 165, 219.) HHS suggested that these increased complaints showed that there was growing noncompliance with the federal conscience statutes, and stated that this "increase underscores the need for [HHS] to have the proper enforcement tools available to appropriately enforce all Federal conscience and anti-discrimination laws." (S.A. 165,

218-219.) HHS also claimed that the Rule was necessary to address the "lack of awareness" or "confusion" surrounding the obligations posed by the federal conscience statutes and to improve the agency's "[i]nadequate enforcement tools" for addressing such violations. (S.A. 218.)

C. Procedural Background

The government plaintiffs sued to invalidate and enjoin enforcement of the Rule under both the APA and the federal Constitution. (Joint Appendix (J.A.) 2, 21, 197-203.) In June 2019, Planned Parenthood Federation of America, Inc. and Planned Parenthood Northern New England, Inc. brought a similar lawsuit, as did the National Family Planning and Reproductive Health Association and Public Health Solutions, Inc. (J.A. 211-232.) A provider and an organization intervened as defendants. (J.A. 29.) The United States District Court for the Southern District of New York consolidated the three suits. (J.A. 29, 40.)

On November 6, 2019, the district court (Engelmayer, J.) issued a detailed opinion granting summary judgment to plaintiffs and vacating the Rule in its entirety. (S.A. 2-146.) As relevant here, the court rejected HHS's contention that the agency's interpretation of the statutory terms in the federal conscience statutes was entitled to deference under

Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984), and concluded that the Rule's definitional provisions were inconsistent with the statutory text. (S.A. 43, 60, 70 n.39.)

The district court concluded that the Rule's enforcement provisions exceeded HHS's authority insofar as HHS claimed the power to terminate *all* HHS-administered federal financial assistance received by a regulated entity based on any alleged violation of the Rule or the myriad statutes identified in the Rule. (S.A. 64-69.) The court also held that the Rule conflicted with Title VII and EMTALA. (S.A. 71-78.)

The court found that the Rule was also arbitrary and capricious. The court concluded that HHS's proffered justifications for the Rule were not supported by the administrative record. In particular, the court found that HHS's reliance on a "significant increase" in complaints and specific reference to 343 complaints in fiscal year 2018 (S.A. 165) was "demonstrably false." (*See* S.A. 80-82.) In fact, the overwhelming majority of those complaints had nothing to do with the federal conscience statutes, or any confusion about those statutes. The district court further found that HHS had failed to provide a reasoned explanation for its

radical change in course and failed to consider important problems caused by the Rule. (S.A. 79-109.)

Finally, the court concluded that HHS had violated the Spending Clause and the separation-of-powers doctrine by imposing funding conditions unauthorized by Congress. (S.A. 115-132.)

STANDARD OF REVIEW AND SUMMARY OF ARGUMENT

This Court reviews a grant of summary judgment de novo. *Mitchell v. City of New York*, 841 F.3d 72, 77 (2d Cir. 2016). On de novo review, this Court may affirm on "any ground appearing in the record." *Freedom Holdings, Inc. v. Cuomo*, 624 F.3d 38, 49 (2d Cir. 2010). Here, the district court properly granted summary judgment for plaintiffs and vacated the Rule in its entirety. This Court should affirm.

I. The Rule violates the APA because it is contrary to law and arbitrary and capricious.

A. HHS exceeded its statutory authority in promulgating the Rule. As the district court properly determined, the Rule's expansive definitions are inconsistent with the meanings of the statutory terms

enacted by Congress and create a conflict with other federal statutes, including Title VII.

First, HHS's unprecedented interpretation of "discriminate" breaks with the settled meaning of that term under other federal antidiscrimination laws, which Congress incorporated into the federal conscience statutes. When Congress enacted the first conscience statute, courts had already interpreted "discrimination" to encompass the established Title VII framework for accommodating religious beliefs, and Congress's use of the term without elaboration incorporated that common meaning. The Rule impermissibly discards essential features of the Title VII framework—including by prohibiting employers from being able to inquire whether an applicant is willing to perform the essential functions of a job prior to hiring, and severely restricting the range of actions employers can take to plan for and accommodate conscience objections without disrupting the provision of care to patients.

Second, the Rule improperly expands the reach of the Church Amendment by defining "assist in the performance" to include conduct by all manner of individuals—such as receptionists scheduling appointments and ambulance drivers transporting patients—that are

unconnected to the actual *performance* of abortions and sterilizations, as the statute requires. And the Rule's inclusion of "counseling" and "referral" in the definition of "assist in the performance" conflicts with another part of the Church Amendment, where Congress set forth "counseling" and "recommending" as conduct distinct from "assist[ing]."

Third, the Rule's definition of "health care entity" extends beyond the specific definition provided by Congress in the conscience statutes. In the Coats-Snowe Amendment—a statute focused on the accreditation of medical residency training programs—"health care entity" is limited to physicians or others who receive such training, and cannot reasonably be read to extend to pharmacists, who do not undergo medical residency training, or pharmacies and medical laboratories, which are not subject to the relevant accreditation standards. And in the Weldon Amendment, "health care entity" is likewise limited to a "health care facility, organization, or plan," and does not extend (as the Rule does) to any employer that offers group health insurance plans or administrators that process insurance claims.

Fourth, HHS's definition of "refer for" and "referral" conflicts with how Congress (and HHS itself) has defined those terms in analogous

statutes. As used by Congress, and in the medical context generally, "refer" and "referral" mean a doctor's ordering of a specific procedure or directing a patient to care by a specialist—not the mere provision of *any* information that may aid a person to obtain a particular procedure or insurance coverage for such a procedure, as the Rule provides.

Finally, the Rule's enforcement provisions are contrary to law because they purport to authorize HHS to terminate or suspend all of a recipient's HHS-administered federal funding based on a single violation of the Rule or any one of the numerous statutes cited in the Rule. Nothing in the federal conscience statutes or in longstanding regulations governing grant administration allows HHS to arrogate to itself such extraordinary enforcement powers.

B. The Rule is also arbitrary and capricious for multiple reasons.

First, HHS's factual predicates for engaging in this sweeping rulemaking were "demonstrably false," as the district court found (S.A. 81). HHS claimed that the Rule was necessary because of a "significant increase" in complaints—a claim that it supported by identifying 343 conscience-related complaints in a recent year. (S.A. 165, 219.) But, as the district court found, the overwhelming majority of these complaints had

nothing to do with the federal conscience statutes. Nor was there any other evidence of widespread noncompliance with the federal statutes as claimed by HHS, recent or otherwise. HHS does not meaningfully contest the district court's findings that the Rule's factual premises were simply false.

Second, HHS also acted arbitrarily and capriciously in failing to consider the decades of reliance that the Rule abruptly upends. The record in this case amply demonstrates that hospitals and other institutions have developed policies, made hiring and staffing decisions, and entered into contracts, all based on a decades-long understanding of their obligations under the conscience statutes that the Rule now disrupts. HHS utterly failed to even acknowledge this legitimate reliance, let alone provide a reasoned explanation for its radical departure from that interpretation.

Third, the Rule irrationally disregards the major disruptions to health care operations and the harms to patients that the Rule will cause, especially in emergency situations. And the Rule also ignores the uncontroverted evidence demonstrating the infeasibility of requiring resource-constrained emergency and rural care institutional providers to double- or triple-staff (as HHS suggests) in order to avoid the dilemma

posed by the Rule: potentially risk serious harms to patient health or the loss of critical federal funding.

II. HHS violated the Spending Clause and the separation-of-powers doctrine by imposing funding conditions unauthorized by Congress. As the district court properly concluded, the immediate and costly efforts required to ensure plaintiffs' compliance with the Rule's many new obligations establish the requisite present hardship warranting judicial review. Here, HHS violated constitutional proscriptions by imposing new funding conditions—none of which were contemplated by Congress. The Spending Clause was also violated because the Rule's threat to remove all of a recipient's HHS-administered funding—which collectively entail nearly *$200 billion* for plaintiffs in fiscal year 2018 alone—is unconstitutionally coercive. And by unlawfully attaching conditions to federal funds appropriated by Congress for the benefit of plaintiffs, HHS has usurped Congress's exclusive power of the purse in violation of the Constitution's separation of powers.

III. The district court properly vacated the Rule in its entirety. The APA expressly authorizes courts to "set aside" unlawful agency action, and courts have uniformly recognized that this statutory remedy

does not compel a court to limit vacatur to the particular parties before it. The court also properly declined to sever the invalid portions of the Rule since the errors that it identified pervaded the Rule. If HHS believes that portions of the Rule can be salvaged, it is free to try again.

ARGUMENT

POINT I

THE RULE VIOLATES THE ADMINISTRATIVE PROCEDURE ACT

Under the APA, courts must "hold unlawful and set aside agency action" when the challenged action is "arbitrary" or "capricious," "not in accordance with law," or was taken "in excess of statutory . . . authority." 5 U.S.C. § 706(2)(A), (C). The district court properly concluded that the Rule violated the APA in all of these ways.

A. The Rule is Contrary to Law.

As the district court noted, HHS conceded below that the Rule itself "does impose obligations on regulated entities." (S.A. 32 n.14.) HHS's insistence on appeal that the Rule "merely gives effect to the conscience statutes" without adding additional requirements (Br. for Defs.-Appellants & Consolidated Defs.-Appellants (Br.) at 1) should be rejected. Even

setting aside HHS's concession, the district court correctly found that the Rule was not merely interpretative because its terms "unavoidably would shape the primary conduct of participants throughout the health care industry," including by adopting definitions that would "impose heretofore unrecognized duties on funding recipients in connection with objections to medical procedures." (S.A. 32, 50.)

As further explained below, the Rule's definitions exceed the language carefully chosen by Congress in the various conscience statutes or conflict with other federal laws, such as Title VII—all in the service of extending HHS's power to deny federal funding on grounds that Congress never intended to authorize in the conscience statutes.[9] The Rule also confers on HHS extraordinary enforcement powers exceeding anything Congress authorized. And the Rule conflicts with statutory provisions mandating that patients be provided critical medical information regardless of a provider's religious or moral objections. For any or all of

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[9] On appeal, HHS does not challenge the district court's conclusion that *Chevron* deference was inapplicable to the Rule's definitional provisions, and has thus abandoned any such arguments. *See LoSacco v. City of Middletown*, 71 F.3d 88, 92-93 (2d Cir. 1995).

these reasons, this Court should affirm the district court's holding that "HHS acted contrary to law in promulgating the Rule" (S.A. 69).[10]

1. The Rule's definitional provisions impermissibly expand statutory terms beyond the meanings intended by Congress.

a. HHS's expansive definition of "discrimination" conflicts with the well-settled understanding of that term, including under Title VII.

Four of the five federal conscience statutes underlying the Rule prohibit "discrimination" against certain individuals or health care entities based on conscience objections to participating in certain medical procedures. *See, e.g.*, 42 U.S.C. §§ 238n(a)(1)-(2) (training for abortion procedures), 300a-7(c), (e) (abortion and sterilization), 18113(a) (aid-in-dying), 18023(b)(4) ("refer for" abortions); Pub. L. No. 115-245, § 507(d)(1), 132 Stat. 2981, 3118 (2018) ("provide, pay for, cover, or refer for" abortions). Although the statutes do not define "discrimination," at the time that Congress enacted the first such statute (the Church Amendment), an

[10] The government plaintiffs join, but do not separately brief, the provider plaintiffs' arguments that HHS also lacked substantive rulemaking authority to issue the Rule, and that the Rule conflicts with EMTALA.

extensive body of federal law had already developed under Title VII and similar antidiscrimination statutes that gave content to the meaning of the word "discriminate."

It was this body of law that led HHS to conclude in 2008 that there was no need to define "discrimination" under the conscience statutes because the statutory term had a "widely understood" meaning informed by "significant federal case law" under Title VII and similar statutes. *See* 73 Fed Reg. at 78,077, 78,085 (HHS's "enforcement of the provider conscience laws will be informed . . . by comparison to Title VII religious discrimination jurisprudence"). That conclusion properly reflected the well-established presumption that Congress intends statutory terms to have their "ordinarily accepted meaning" unless it defines the terms differently in a particular statute. *See NLRB v. Highland Park Mfg. Co.*, 341 U.S. 322, 325 (1951). The Supreme Court has applied this principle specifically to the meaning of the word "discrimination," holding that Congress's use of that term in Title IX of the Education Amendments Act of 1972 encompassed retaliation—despite the absence of any specific reference in Title IX—when the "general prohibition" on "discrimination" in other federal statutes, including Title VII, had previously been

interpreted to cover retaliation. *Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 176 (2005).[11]

Here too, Congress's use of the term "discriminate" (or "discrimination") without further elaboration or definition in the federal conscience statutes evinces its intent to adopt the well-settled understanding of that term under federal antidiscrimination law, including Title VII. As the district court correctly reasoned, in finding the Rule to be in conflict with Title VII, although Congress could have departed from "the Title VII framework and adopt[ed] a unique definition of 'discrimination'" in the conscience statutes, it did not do so—and "HHS has not pointed to any evidence of congressional intent to supersede the Title VII framework."[12] (S.A. 72.)

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[11] These principles rebut certain amici's reliance on the dictionary definition of "discriminate," since such dictionary definitions simply ignore the broader legal context against which Congress is presumed to legislate. *See* Br. of Members of Cong. as Amici Curiae in Supp. of Defs.-Appellants 18.

[12] Amici's contrary assertion is without merit. *See* Br. of Amicus Curiae Sen. Coats & Rep. Weldon in Supp. of Defs.-Appellants 11-13. Here, amici observe that the conscience statutes expressly expanded existing federal protections in several other ways not covered by Title VII—for example, by covering other grounds and not just religious objections; and by prohibiting discrimination in training and licensing,

The Rule nonetheless consciously breaks from the settled understanding of "discriminate" in a number of ways, adopting instead a lengthy definition that would label a broad range of conduct impermissible discrimination that could trigger the loss of federal funding. (S.A. 253.) As the district court properly concluded, there is no indication that Congress intended to authorize HHS to so thoroughly discard the key features of the well-established antidiscrimination framework from Title VII and other statutes. (S.A. 51-52 & n.21, 71-72.)

First, as HHS acknowledged below (S.A. 33), the Rule's definition of "discriminate" does not incorporate the familiar Title VII doctrine that an employer does not unlawfully discriminate on the basis of religion so long as it makes "reasonable accommodations" for the employee's religious practices and such accommodations will not impose an "undue hardship" on the employer. *See Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 72 (1977); 42 U.S.C. § 2000e(j). Under that doctrine, courts have

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not just in employment. But these provisions expanding upon Title VII show that, when Congress meant to depart from the well-established Title VII framework, it did so explicitly. Its decision not to provide a unique definition of "discrimination" thus supports, rather than undermines, its intent to incorporate existing understandings of that term.

recognized that employees do not suffer from unlawful discrimination when they are not given the specific accommodation that they request, so long as the employer offers them an accommodation that is reasonable under the circumstances.[13] Even HHS's (subsequently rescinded) 2008 rule, which suggested that the federal conscience statutes might provide broader protections than Title VII under certain circumstances, concluded that an employer need only provide a reasonable accommodation to satisfy those statutes; thus, "employers have no obligation under the health care conscience protection laws to employ persons who are unqualified to perform the functions required of the jobs that they seek to fill," even if the "unwillingness to perform those functions [is based] on conscience grounds." *See* 73 Fed. Reg. at 78,085. The Rule would abandon these principles and "decline[] to protect an employer who, on account of hardship," cannot grant an accommodation demanded by an objecting

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[13] *See, e.g.*, *Ansonia Bd. of Educ. v. Philbrook*, 479 U.S. 60, 69 (1986); *Rodriguez v. City of Chicago*, 156 F.3d 771, 776-77 (7th Cir. 1998) (employer not required to relieve police officer of duties guarding abortion clinics when officer was offered a transfer without those duties); *Shelton v. University of Med. & Dentistry of N.J.*, 223 F.3d 220, 226 (3d Cir. 2000) (nurse not entitled to remain in obstetrical unit despite unwillingness to assist with emergency abortions).

employee, no matter how unreasonable that accommodation may be. (S.A. 33.)

HHS objects (Br. 38) that the district court should not have faulted the Rule for disregarding Title VII's "reasonable accommodation" and "undue hardship" framework because Title VII explicitly incorporates such an affirmative defense in 42 U.S.C. § 2000e(j), while the conscience statutes do not. But courts had already adopted this framework as part of the inherent meaning of "discrimination" even before Congress enacted § 2000e(j). For example, in 1970, the Sixth Circuit held (and the Supreme Court affirmed by an equally divided vote) that an employer does not engage in unlawful discrimination under Title VII by terminating an employee who refused, for religious reasons, to work on Sundays and further refused to find coverage for his Sunday shift as the employer had requested. *See Dewey v. Reynolds Metals Co.*, 429 F.2d 324, 329-30 (6th Cir. 1970), *aff'd*, 402 U.S. 689 (1971).

More fundamentally, nothing in Congress's use of the bare term "discriminate" in the conscience statutes or in the legislative history of those statutes suggests that it intended to displace the common and well-established understanding of what constituted unlawful "discrimination"

at the time the statutes were enacted, or to create a unique framework for discrimination claims based on religious or moral beliefs made by health care providers. To the contrary, concerns about the consequences of accommodating objectors are particularly heightened in the health care context because any harms fall not just on the employer, but also on third-party patients who are themselves entitled to receive needed care. (*See also* J.A. 753 (denials of care may damage trust in public health system), 935 (same).) "[P]ublic trust and confidence requires that a public hospital's health care practitioners—with professional ethical obligations to care for the sick and injured—will provide treatment in time of emergency." *Shelton*, 223 F.3d at 228. There is no indication in the history of any of the federal conscience statutes that Congress intended its bare use of the word "discrimination" to be less attentive to the greater concerns about undue hardship in the health care context than in the ordinary employment context.

Second, the Rule's broad definition of "discrimination" includes any changes to "employment, title," "position, or status," or "*any* adverse treatment," 45 C.F.R. § 88.2 (discrimination (1), (3)) (emphasis added), regardless of how insignificant such a change may be. That sweeping

interpretation is contrary to settled legal principles that employment changes constitute impermissible disparate treatment only if they are "materially adverse," rather than "a mere inconvenience or an alteration of job responsibilities" that an employee may not like. *Galabya v. New York City Bd. of Educ.*, 202 F.3d 636, 640 (2d Cir. 2000) (quotation marks omitted). The D.C. Circuit has applied this principle specifically to the Weldon and Coats-Snowe Amendments, holding that a health care employer would not face liability under these statutes for merely reassigning to another unit an individual who is unwilling to perform an aspect of his job duties based on religious objections—such as by "refus[ing] to provide abortion counseling." *National Family Planning & Reprod. Health Ass'n, Inc. v. Gonzales*, 468 F.3d 826, 829-30 (D.C. Cir. 2006) (*NFPRHA*) (rejecting such theory as "anomalous"). As the D.C. Circuit recognized, these conscience statutes' "broadening of the grounds for resisting abortion activity" does not "suddenly transform an accommodating agency's reassignment into an act of discrimination" in the absence of an employment change that would be deemed materially adverse. *Id.* But the Rule would do away with this established antidiscrimination principle as well.

Third, the Rule's prohibition against employers even *inquiring* about an applicant's ability and willingness to perform certain medical procedures prior to hiring goes far beyond any existing antidiscrimination prohibitions. *See City & County of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1019-20 (N.D. Cal. 2019). As HHS has confirmed, it has never been regarded as unlawful under the conscience statutes (or any other federal antidiscrimination law, including Title VII) for employers "to make rational hiring decisions based on due consideration of an applicant's . . . ability, and desire to perform the essential functions of a job." *See* 73 Fed. Reg. at 78,085. And courts have long held under Title VII that an employee "has the duty to inform his employer of his religious needs so that the employer has notice of the conflict." *See, e.g.*, *Redmond v. GAF Corp.*, 574 F.2d 897, 902 (7th Cir. 1978). But the Rule simply disregards these settled principles: it both relieves employees of their longstanding obligation under federal antidiscrimination law to notify employers of a potential conflict, and impermissibly intrudes on the internal affairs of medical employers by arbitrarily limiting employers' ability to know in advance of employees' potential conflicts in order to inform staffing decisions and ensure seamless patient care. *See, e.g.*, *Delaney v. Bank of*

Am. Corp., 766 F.3d 163, 169 (2d Cir. 2014) (per curiam) (discrimination statutes are not license to second-guess employers' business decisions).

In sum, the Rule's multiple, stark departures from the well-established understandings of what constitutes unlawful "discrimination" under Title VII and other federal antidiscrimination laws stretch far beyond "the bounds of reasonable interpretation." *See Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 321 (2014) (quotation marks omitted). And it does so in ways that are particularly harmful in the health care context by interfering with providers' ability to ensure that patients receive the care that they need, notwithstanding particular individuals' objections to certain medical procedures. The district court thus correctly concluded that the Rule was contrary to law because it violated the conscience statutes and improperly discarded key elements of the antidiscrimination framework under Title VII and other laws that the conscience statutes incorporated.

b. HHS's definition of "assist in the performance" extends conscience protections to conduct that Congress never intended to cover in the Church Amendment.

The Church Amendment provides that individuals and health care organizations may not be subject to unlawful discrimination for refusing to "perform or assist in the performance of" "a lawful sterilization procedure or abortion." *See* 42 U.S.C. § 300a-7(c).

Congress did not define "assist in the performance," but the plain meaning of those words covers only the individuals who actually participate in the objected-to medical procedure. The dictionary definition of "assist" is "to give usually supplementary support or aid to," and "performance" is defined as the "execution of an action." *See Merriam-Webster Online Dictionary* (internet). The "assist[ance]" covered by the Church Amendment is thus limited to actions that support the actual execution of a particular medical procedure. This construction is confirmed by the statute's legislative history, which makes clear that the amendment was "meant to give protection to the physicians, to the nurses, to the hospitals themselves" from being compelled to perform abortions and sterilizations in spite of their conscience objections. *See* 119 Cong. Rec. 9597 (floor statement of Sen. Church); *San Francisco*, 411 F. Supp. 3d at

1013-15 (detailed recounting of legislative history); *see also In re Ionosphere Clubs, Inc.*, 922 F.2d 984, 990 (2d Cir. 1990) (citing sponsor's floor statements as evidence of legislative intent).

The Rule disregards this limiting language and instead defines "assist in the performance" broadly to include *any* "action that has a specific, reasonable, and articulable connection to *furthering* a procedure." 45 C.F.R. § 88.2 (emphasis added). As HHS acknowledged below, this sweeping definition "would authorize individuals at some remove from the operating theater or medical procedure at issue to withhold their services," including "a hospital or clinic receptionist responsible for scheduling appointments," or "an elevator operator or ambulance driver responsible for taking a patient to an appointment or procedure." (S.A. 35; *see also* S.A. 176-177.)

Such a broad definition contravenes the statutory text by effectively reading the word "performance" out of the statute and extending the Church Amendment to cover *any* conduct with an "articulable" connection to an objected-to procedure. Contrary to HHS's contention (Br. 30; S.A. 177-178), clerical staff who merely schedule appointments, hospital staff who clean an operating room that is later used for a procedure, or nurses

who monitor a patient's health after a procedure has already been conducted do not "assist" in the actual carrying out of the procedure in the way that physicians or assistants actually participating in the procedure would.

HHS's inclusion of "counseling" and "referral" in the definition of "assist in the performance" was also improper because Congress made clear elsewhere in the Church Amendment that these terms are distinct. The Church Amendment separately prohibits "discrimination" against medical training applicants for refusing, on religious or moral grounds, to "assist, or in any way participate in the performance of abortions or sterilizations," but also for the distinct conduct of refusing "to counsel, suggest, [or] recommend the performance of abortions or sterilizations." 42 U.S.C. § 300a-7(e). This separate, narrower prohibition in the Church Amendment plainly treats assistance as conduct distinct from counseling or referral—otherwise there would have been no need for Congress to enact the latter language. *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1659 (2017) (recognizing "presumption that each word Congress uses is there for a reason"). And because the general presumption is that "identical words used in different parts of the same

[statute] are intended to have the same meaning," *Utility Air Regulatory Grp.*, 573 U.S. at 319-20 (quotation marks omitted), there is no basis for HHS's insistence that Congress intended "assist in the performance" to cover counseling and referrals.

c. The Rule's definition of "health care entity" improperly includes individuals and entities that Congress did not intend to cover in either the Coats-Snowe or Weldon Amendments.

The Coats-Snowe Amendment prohibits discrimination, in the medical training and accreditation contexts, against a "health care entity" for declining to be trained or to provide training "in the performance of induced abortions," and for refusing "to perform such abortions, or to provide referrals for such training or such abortions," or "to make arrangements" for such activities. *See* 42 U.S.C. § 238n(a)(1)-(2). The statute defines "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." *Id.* § 238n(c)(2).

This statutory definition comports with the central purpose of the Coats-Snowe Amendment—that is, responding to the concern emerging (in 1996) that hospitals and medical training programs were being

required by the Accreditation Council for Graduate Medical Education (ACGME)[14] "to train residents to perform induced abortions." *See* Br. of Amicus Curiae Sen. Coats & Rep. Weldon in Supp. of Defs.-Appellants 5-6; *see also* 142 Cong. Rec. 4926, 5158 (1996). This statutory focus is confirmed by the title of the statute: "[a]bortion-related discrimination in governmental activities regarding training and licensing of *physicians*." 42 U.S.C. § 238n (emphasis added); *see Port Auth. Trans-Hudson Corp. v. Secretary, U.S. Dep't of Labor*, 776 F.3d 157, 166 n.14 (3d Cir. 2015) (title of statute supported narrow construction).

The Rule, however, improperly expands the statutory term of "health care entity" far beyond its intended scope by including "pharmacist[s]" and "pharmac[ies]," and "medical laborator[ies]." *See* 45 C.F.R. § 88.2. But these individuals and entities have no connection whatsoever to the subject of the Coats-Snowe Amendment. Pharmacists do not undergo medical residency training, and pharmacies and medical laboratories do not offer residency training programs and are not

[14] ACGME is a private non-profit organization "that sets standards for U.S. graduate medical education (residency and fellowship) programs and the institutions that sponsor them." *ACGME, What We Do* (internet).

accredited by ACGME. Nor do such entities provide medical training on abortions.

The Rule's definition of "health care entity" also exceeds the meaning of that term in the Weldon Amendment. The Weldon Amendment defines "health care entity" to include "an individual physician or other health care professional, a hospital," various types of health insurance plans, and "any other kind of health care facility, organization, or plan." Pub. L. No. 116-94, § 507(d)(2). The common feature of all of the individuals or entities covered by this definition is that they are direct participants in the health care industry. *See* 150 Cong. Rec. H10090 (Nov. 20, 2004) (statement of Rep. Weldon that statute was intended to cover individual providers, hospitals and clinics, and health insurance providers). But the Rule goes beyond these specified entities by counting as a health care entity any "plan sponsor"—a term that would include *any* employer that provides health insurance coverage to its employees, and any university that provides health insurance coverage to its students, even if the employer' or university's business has nothing to do with health care at all. *See* 45 C.F.R. § 88.2. An employer or university's decision to provide group health insurance, or a third-party administrator's mere

processing of insurance claims, does not transform it into the type of direct participant in the health care industry that is encompassed by the Weldon Amendment's definition of "health care entity." The statute thus does not authorize the Rule's far-reaching provisions.

d. HHS's definition of "referral or refer for" is inconsistent with Congress's definition.

Four of the five federal conscience statutes implicated in this case prohibit discrimination against individual providers and health care entities for refusing "to provide referrals for" abortions or for abortion training. *See* 42 U.S.C. §§ 238n(a)(1), 1395w-22(j)(3)(B), 1396u-2(b)(3)(B), 18023(b)(4); Pub. L. No. 115-245, § 507(d).

Although Congress did not define "referral" in these statutes, it does define the term elsewhere in the same title. In other Medicaid and Medicare provisions, Congress defined "referral" to mean "the request by a physician for a consultation with another physician" and "the request or establishment of a plan of care by a physician which includes the provision of [health services]." *See* 42 U.S.C. § 1395nn(h)(5)(A)-(B). In interpreting these provisions, HHS itself defined "referral" as "the request by a physician for, or ordering of, or the certifying . . . of the need

for, any designated health service" which may be covered by Medicare. *See* 42 C.F.R. § 411.351. And as the district court observed, "referral" and "refer," when used in the medical context, are terms of art generally understood to mean "sending a patient to another physician or provider." (S.A. 54-55.) *See United States v. Patel*, 778 F.3d 607, 613 (7th Cir. 2015); *San Francisco*, 411 F. Supp. 3d at 1022 & n.2.

The Rule here disregards this settled and ordinary meaning, and instead defines "refer for" and "referral" to encompass the mere provision of *any* information that might aid a person in obtaining certain procedures or insurance coverage for such procedures (S.A. 191),[15] as might be done by an insurance agent "performing administrative functions such as answering questions from covered individuals or processing claims" (J.A. 1044-1045 (comment from insurer expressing this concern)). But there is no reason to think that Congress intended

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[15] The Rule defines "referral or refer for" as "the provision of information in oral, written, or electronic form (including names, addresses, phone numbers, email or web addresses, directions, instructions, descriptions, or other information resources), where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, activity, or procedure." 45 C.F.R. § 88.2 (referral or refer for).

"referral" or "refer for" to mean something entirely different in the federal conscience statutes than in other statutes that also govern health care. Rather, the presumption is to the contrary. *See Utility Air Regulatory Grp.*, 573 U.S. at 319-20. Moreover, it is well settled that courts "assume that when a statute uses [a term of art], Congress intended it to have its established meaning." *McDermott Int'l, Inc. v. Wilander*, 498 U.S. 337, 342 (1991).

2. The enforcement remedies HHS arrogates to itself exceed its legal authority and are contrary to general grant administration regulations.

The Rule provides that "[i]f OCR determines that there is a failure to comply" with *any* of the federal conscience statutes listed in the Rule or *any* provision of the Rule, OCR may terminate or withhold *all* HHS-administered federal financial assistance received by the entity, "in whole or in part," including all contracts, grants, and reimbursement arrangements—like those used for Medicare and Medicaid. 45 C.F.R. § 88.7(i)(3). Although the Rule states that noncompliance "will be resolved by informal means whenever possible," it nonetheless authorizes OCR to "simultaneously" undertake actions to terminate or withhold all of an

entity's HHS-administered federal funding even during the pendency of efforts for informal resolution and good-faith compliance. *Id.* § 88.7(i)(2)-(3).

These enforcement provisions are contrary to law for several reasons. For one, no statute generally authorizes HHS to terminate *all* sources of a State's federal financial assistance based on a single violation of any of the more than thirty federal statutes referenced by HHS in the Rule, or a provision of the Rule itself. Certain of the statutes at issue are expressly tied only to specifically identified funding streams or programs. For example, a key provision in the Church Amendment applies only to recipients of Public Health Service Act funds. *See* 42 U.S.C. § 300a-7(c)(1). And the exemptions for providing or paying for "a counseling or referral service" on conscience-related grounds apply on their face only to certain Medicaid and Medicare managed care organizations. *See* 42 U.S.C. §§ 1395w-22(j)(3)(B), 1396u-2(b)(3)(B). But the Rule does not distinguish between the different statutes in its imposition of penalties. Rather, on its face, the Rule provides that a single violation of a discrete provision of the Church Amendment would permit HHS to terminate or withhold all of a State's federal health care funding—including funding not mentioned in the Church Amendment. (*See* S.A. 66.)

On appeal, HHS simultaneously argues that the Rule does not in fact authorize recipient-wide funding terminations *and* that it is not precluded from "recipient-wide termination of funds" under the Uniform Administrative Requirements (UAR)—the general regulations governing HHS grant administration. *See* Br. 21-23. Neither argument is sufficient to sustain the Rule. As the district court properly noted (S.A. 68), HHS's arguments about the limited nature of the termination contemplated by the Rule relies on language from the preamble stating that the only funds "threatened by a violation" of a federal conscience statute are those directly implicated by the relevant statute (S.A. 213). But the actual text in the Rule does not contain this limiting language. *See* 45 C.F.R. § 88.7(i)(3)(iv). If HHS means what it now says, its recourse is to amend the regulation to expressly limit the scope of its termination authority.

HHS's latter contention—that the UAR authorizes recipient-wide termination of funds—is flatly contradicted by its own express statement to the district court "that the UAR would not do that." (J.A. 2740.) It is also not supported by the UAR itself. No provision of the UAR authorizes the termination or suspension of an awarded grant for violations of statutes or conditions unrelated to the particular grant at issue. *Cf.*

45 C.F.R. § 75.372(a)(1) ("*The* Federal award may be terminated . . . if the non-federal entity fails to comply with the terms and conditions of *the* award" (emphasis added).)

Moreover, HHS cannot rely on the UAR to support recipient-wide fund termination when the Rule does not comply with the UAR's procedures. The UAR provides for graduated procedures in dealing with grantee noncompliance—procedures that are conspicuously absent from the Rule. Specifically, 45 C.F.R. § 75.371 provides that if a grantee "fails to comply with Federal statutes, regulations, or the terms and conditions of a Federal award," HHS may impose additional special conditions tailored to mitigate grantee-specific performance and financial risks. *See id.* §§ 75.371, 75.207. Only if HHS "determines that noncompliance cannot be remedied by imposing additional conditions" can it then consider terminating or suspending the grantee's federal awards. *See id.* § 75.371(c), (e). The Rule, however, wholly fails to provide for such procedures and protections. Instead, § 88.7(i)(2) provides that HHS may suspend or terminate all HHS funds without accounting for whether

compliance may be effected through the imposition of additional grant conditions instead.[16]

Finally, HHS identified no statutory authority for the Rule's provision that a direct funding recipient may lose all of its HHS funding based solely on a *subrecipient's* statutory or regulatory violation. *See id.* §§ 88.6(a), 88.7(i)(3)(iv). Nor is this provision consistent with the UAR, which provides that the only federal funds at risk by a subrecipient's noncompliance are those received by the subrecipient; the regulations do not authorize any upstream terminations or suspensions of the direct recipient's award. *See id.* § 75.371 (providing that HHS or "pass-through entity" may suspend or terminate "the Federal Award" based on an entity's failure to comply); *id.* § 75.2 (defining "Federal Award" as the financial assistance the entity "receives directly from a Federal awarding agency or indirectly from a pass-through entity").

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[16] Additionally, many HHS-administered funds are block grants governed by 45 C.F.R. part 96—a separate set of regulations from the UAR. *See* 45 C.F.R. § 75.101(d)-(e). Under those regulations, HHS is permitted to withhold funds to States and localities only after a hearing. *See id.* § 96.51(c). The Rule does not provide for such procedures and is thus inconsistent with these block grant regulations as well.

3. The Rule's mandates are contrary to federal laws mandating the provision of medical information irrespective of religious or moral objections.

The Rule also conflicts with the Medicaid and Medicare counseling and referral statutes that it purports to implement.[17] In those statutes, Congress provided that certain Medicaid and Medicare organizations may not be required to provide "a counseling or referral service" if the organization objects to it on religious or moral grounds, but made clear that these provisions shall not "be construed to affect disclosure requirements under State law." *See* 42 U.S.C. §§ 1395w-22(j)(3)(B), (C), 1396u-2(b)(3)(B).

The Rule unlawfully omits these provisions' express carveout for state informed consent laws, which Congress enacted to cabin the scope of the federal statutes. *See* 45 C.F.R. § 88.3(h)(1)(ii), (2)(i)-(ii). Instead, the Rule imposes a blanket prohibition on any requirement that an objecting Medicaid or Medicare organization provide counseling and

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[17] The district court did not reach this ground below. Because the government plaintiffs pleaded such a claim (J.A. 199) and moved for summary judgment on this ground (S.A. 71 n.40), this Court may address this issue as an alternative basis for affirmance. *See Freedom Holdings*, 624 F.3d at 49.

referral services, even if a state law mandates disclosures. The Rule's failure to incorporate an express statutory exemption is contrary to law.

B. The Rule Is Arbitrary and Capricious.

The APA requires agencies to "engage in reasoned decisionmaking." *Department of Homeland Sec. v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020). An agency must "articulate a satisfactory explanation for its action" that demonstrates that it has considered the "relevant factors" and has not missed any "important aspect of the problem" or made any "clear error of judgment." *Motor Vehicles Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983). Where, as here, an agency reverses course, it must "supply a reasoned analysis for the change." *Id.* at 42. At minimum, the agency must "display awareness that it is changing position" and provide "good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (emphasis omitted). And if the prior policy had "engendered serious reliance interests," the agency must take those reliance interests into account. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

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

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

As the administrative record demonstrated, before this Rule's promulgation, hospitals and other health care institutions had already adopted policies that reflected a careful balancing of the interests of individual health care professionals and those of the patients they served, in accordance with longstanding federal and state conscience laws. See *supra* n.7. The Rule dramatically upended this decades-long status quo in 2019. To justify this sweeping change, HHS claimed that there had been "a significant increase" in complaints since November 2016 "alleging violations of the laws that were the subject of the 2011 Rule," and specifically emphasized that it had received 343 such complaints in fiscal year 2018. (S.A. 165, 219.) HHS also claimed that the 2011 rule had "created confusion over what is and is not required under" the federal conscience statutes and that HHS's enforcement powers under that rule were inadequate. (S.A. 165.)

The record, however, flatly contradicts all of these justifications. Where, as here, the record demonstrates that the "crucial factual premise" underlying HHS's decisionmaking was "indisputably incorrect," the district court properly concluded that the Rule was arbitrary and

capricious. *See Mizerak v. Adams*, 682 F.2d 374, 376 (2d Cir. 1982); *see also Bowen v. American Hosp. Ass'n*, 476 U.S. 610, 643 (1986) (vacating antidiscrimination rule when "the Secretary has pointed to no evidence that such discrimination occurs"); *Kansas City v. Department of Hous. & Urban Dev.*, 923 F.2d 188, 194 (D.C. Cir. 1991) ("Agency action based on a factual premise that is flatly contradicted by the agency's own record does not constitute reasoned administrative decisionmaking.").

First, as the district court found, HHS's specific factual claim that it had received 343 conscience-related complaints in fiscal year 2018—which it claimed reflected a "significant increase" (S.A. 165)—was "demonstrably false." (*See* S.A. 80-82.) As the district court detailed (S.A. 80-82), the vast majority of the complaints that HHS had included as part of this figure did not, as HHS asserted, implicate "violations of the laws that were the subject of the 2011 Rule" (S.A. 165). Rather, the record showed that 94% of the complaints HHS relied on concerned vaccination objections, grievances that had nothing to do with the procedures covered

by the conscience statutes, or complaints about HHS's practices on other grounds altogether. (J.A. 2284-2285.)[18]

On appeal, HHS does not dispute the court's finding that the actual number of complaints that were even "*potentially* related" to the federal conscience statutes was no more than around twenty (S.A. 81-82)—nowhere close to the 343 that HHS emphasized during rulemaking (S.A. 219, 235).[19] *See* Br. 44-45. Nor could it, since HHS had conceded below that the actual number of relevant complaints was "something probably relatively similar to the number that the plaintiffs provided." (J.A. 2743.) Instead, HHS now complains that the district court improperly faulted the agency for not compiling any "particular number of violations" before promulgating the Rule. *See* Br. 44-45 (emphasis omitted). But the court

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[18] (*See, e.g.,* J.A. 2113 (complaint about HHS's "appalling, unethical" actions), 2125-2135 (complaint about being directed to remove online ads), 2137-2145 (parent complaint about newborn screening test), 2148 (complaint about identity fraud and privacy violation), 2152 (complaint about mandatory insurance coverage for prescriptions), 2336-2342 (summary chart compiling anti-vaccination complaints).)

[19] HHS argues that the district court "erroneously" concluded that HHS had "miscounted" the complaints (Br. 18), but does not explain what was erroneous about the district court's analysis, what the correct number of conscience-related complaints was, or why it conceded below that its own numbers were wrong.

did not require any particular number of complaints—it merely found that the specific number that HHS itself relied on was unsupported in the record. (S.A. 81.) The responsibility for that factual error belonged to HHS, not the district court.

HHS nonetheless insists that the Rule's factual misrepresentation is immaterial because even just twenty complaints in fiscal year 2018 would still "reflect a troubling number of alleged violations" sufficient to justify the Rule. *See* Br. 46. But "[a]n agency must defend its actions based on the reasons it gave when it acted," *Regents*, 140 S. Ct. at 1909, and the Court's review is "limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record," *Department of Commerce v. New York*, 139 S. Ct. 2551, 2573 (2019).

Here, HHS premised its justification for the Rule on having received 343 complaints in fiscal year 2018—not twenty. And the specific number was critical because HHS justified the Rule's significant change to the status quo in large part based on an alleged "significant increase" in conscience-related complaints in fiscal year 2018 (S.A. 219)—an increase that, according to HHS, showed growing noncompliance with the federal conscience statutes. Once corrected, however, the record does

not support HHS's inference that a major change in the status quo was needed to address any purportedly vast new noncompliance.[20] HHS's contention that the increase in complaints was merely "one of the many metrics used to demonstrate the importance of the rule" (Br. 45-46 (quotation and alteration marks omitted)) thus ignores the fact that its empirical claim of an increase in noncompliance was necessary to support its decision to fundamentally alter the regulatory regime enforcing the federal conscience statutes. Absent support for such a claim, "[t]he Rule represents a classic solution in search of a problem." (S.A. 88.)

Second, notwithstanding HHS's constant refrain that the 2011 rule "created confusion over what is and is not required under Federal conscience" statutes (S.A. 165), HHS has never identified any concrete evidence in the record demonstrating any confusion on the part of regulated entities arising from the 2011 rule. HHS again points to the claimed increase in complaints to show confusion, but, as discussed, the

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[20] The amicus brief filed by Ohio and other States in support of HHS also undercuts HHS's assertion that there has been widespread violations of conscience protections. As amici note, "State conscience protections have long been in place without any widespread problems" and have generally "led to little litigation." Br. of States of Ohio et al. as Amici Curiae in Supp. of Defs.-Appellants 15-16.

vast majority of the complaints HHS cited had nothing to do with the conscience statutes at all, let alone the 2011 rule; and the few that did were not premised on confusion about the scope of existing protections. (S.A. 80-82.) And *patient* lawsuits alleging malpractice, discrimination, or EMTALA violations from being denied care based on conscience objections (S.A. 168) similarly do not demonstrate confusion *on the part of providers* about their obligations. Nor does the Rule even purport to clarify "how its provisions may or may not interact with other statutes," such as EMTALA and other antidiscrimination laws, so as to resolve any claimed confusion with these other protections. (*See* S.A. 173.)

Upon closer examination, what HHS refers to as "confusion" here is simply the view that the federal conscience statutes should be interpreted more broadly than they had been.[21] But a policy preference for expanding federal conscience protections does not demonstrate any "confusion" warranting the Rule. And if HHS's objective were simply to effect a naked policy change, then it should have said so, rather than

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[21] For instance, HHS cites, as evidence of "confusion," OCR's 2016 determination to close complaints against California based on the agency's prior interpretations of the Weldon Amendment—interpretations that HHS criticized in 2019 as "unduly narrow." (S.A. 168-169.)

providing the "contrived reason[]" that it was addressing confusion that did not actually exist. *Department of Commerce*, 139 S. Ct. at 2576; *see also id.* at 2575 (vacating agency action due to "significant mismatch between the decision the Secretary made and the rationale he provided"). The absence of "data or evidence" supporting the stated reason that HHS proffered here renders the Rule arbitrary and capricious. *See Islander E. Pipeline Co., LLC v. Connecticut Dep't of Envtl. Prot.*, 482 F.3d 79, 103 (2d Cir. 2006); *State Farm*, 463 U.S. at 43.

Third, the record does not support HHS's related claim that the Rule's new enforcement powers were needed because the agency's preexisting tools were "[i]nadequate." (S.A. 218.) Indeed, nothing in the record suggests that there existed any gaps in HHS's enforcement authority, or that the agency was constrained in its ability to resolve the few problems that did arise.

HHS also fails to explain how the Rule addresses any such claimed inadequacies. To the contrary, HHS consistently disclaims on appeal that the Rule's enforcement provisions confer *any* new powers on the agency that it did not have before. *See* Br. 21-22 (arguing the Rule's enforcement powers are "consistent with preexisting regulations"). And the record

confirms that HHS has long had the authority to conduct investigations and to resolve complaints, as the Rule permits it to do. (*See* S.A. 167-168 (detailing complaints against California and Hawaii resolved by OCR prior to the Rule's adoption, and complaint against private hospital resolved in 2011).)

It is fundamentally inconsistent to both insist that the inadequacy of enforcement tools justified the Rule, yet contend that the Rule did not set forth any additional powers not already authorized. Such an "unexplained inconsistency" further renders the Rule invalid under the APA. *See Encino Motorcars*, 136 S. Ct. at 2126.

2. The Rule fails to provide a reasoned explanation for HHS's change in position.

The record demonstrates that regulated entities have had "decades of experience" in effectively discharging their legal obligations under various state and federal conscience statutes while fulfilling their responsibility to ensure patient access to care. (*See, e.g.*, J.A. 1168, 1211-1213, 1782-1783, 1898.) HHS unquestionably and radically upended the longstanding status quo when it promulgated the Rule in 2019. HHS was required under the APA to provide a "detailed

justification" for its departures from these prior positions, and a "reasoned explanation . . . for disregarding facts and circumstances that underlay . . . the prior policy." *See Fox Television Stations*, 556 U.S. at 515-16. It failed to do so.

For example, in concluding that the Rule will not reduce access to care (S.A. 170-172), HHS relied heavily on findings made during the 2008 rulemaking. But in 2011, HHS expressly concluded that the 2008 rule "may negatively affect the ability of patients to access care" and potentially conflict with Medicaid's mandate that "States provide contraceptive services to Medicaid beneficiaries." 76 Fed. Reg. at 9974. The current Rule does not address—or even mention—these findings from the 2011 rule. But an agency "cannot simply disregard contrary or inconvenient factual determinations that it made in the past." *See Fox Television Stations*, 556 U.S. at 537 (Kennedy, J., concurring in part and concurring in the judgment).

Moreover, in adopting the Rule's unprecedented definition of "discrimination," HHS failed to even "display awareness that it [was] changing position." *See Encino Motorcars*, 136 S. Ct. at 2126 (quotation marks omitted). HHS did not acknowledge its own past statements from

2008 that the federal conscience statutes' prohibition on "discrimination" should be understood by reference to the "significant federal case law" governing discrimination in other contexts, including Title VII. 73 Fed. Reg. at 78,077. Nor did HHS acknowledge its prior position, borrowing from that case law, that the federal conscience statutes' prohibition on "discrimination" does not obligate health care employers to hire applicants who are "fundamentally opposed on religious or moral grounds" to performing core job functions in a way that would prevent such employers from ensuring that patients can reliably receive the care that they need. *Id.* at 78,085.

Far from "display[ing] awareness" of these prior positions, *Encino Motorcars*, 136 S. Ct. at 2126 (quotation marks omitted), HHS instead suggested that the current Rule changed nothing about compliance obligations. (*See* S.A. 231 (estimating "there would likely not be any costs" for compliance for entities who were already fully compliant with the federal conscience laws prior to the Rule).) HHS's failure even to acknowledge the significance of the Rule's changes, and its concomitant failure to provide any explanation—let alone a reasoned one—for its dramatic departure from the status quo, supports the district court's

conclusion that the Rule is arbitrary and capricious. *See Fox Television Stations*, 556 U.S. at 515.

3. HHS entirely failed to address the substantial reliance interests engendered by the agency's prior policy.

The reliance interests implicated in this case are substantial. The numerous comments contained in the administrative record show that HHS-funded entities have long "shaped their conduct" based on HHS's pre-2019 guidance on the federal conscience statutes in "making hiring decisions, entering into employee contracts and collective bargaining agreements, implementing staffing arrangements, developing . . . practices and policies to accommodate conscience objections, and conducting their general business operations." (S.A. 99.) These comments amply established that the Rule would upend the entities' long-established policies and practices, and disrupt the effective functioning of the delivery of care. (*See, e.g.*, 1798 (Rule "impact[s] the business operations of physicians, hospitals, . . . including the rules governing relationships with employees, contracts with other entities"), 1900 (Rule would "make more difficult the process of predicting and planning for

scenarios in which conscience rights might need to be exercised" thereby "running the risk of creating unintended consequences for patient care").)

The record here, however, contains no evidence that HHS gave *any* consideration to the "decades of industry reliance" by plaintiffs and medical employers on the common understandings of the scope of the federal conscience laws that predated HHS's rulemaking, as the APA requires. *See Encino Motorcars*, 136 S. Ct. at 2126. (*See also* S.A. 99-101.) Nor does HHS argue to the contrary. *See* Br. 48.

Instead, HHS contends that a party can have "no legitimate reliance interest . . . in an erroneous statutory interpretation." *See id.* But the Rule did not contend that any of HHS's prior guidance was "erroneous." Indeed, even in this appeal, HHS does not contend that its new reading of the federal conscience statutes is dictated by those statutes' unambiguous meaning; instead, it merely claims that its interpretations "represent[] the best reading of the statutes" (*id.* 28). There is thus no basis for HHS to claim that regulated entities relied on "an erroneous statutory interpretation" (*id.* 48); instead, entities quite reasonably relied on a decades-long understanding of the federal

conscience statutes that HHS, to this day, has not disputed was within the agency's interpretive authority.

In any event, the Supreme Court has now made clear that even a credible claim that past agency action was unlawful does not excuse the agency from considering the existence of reliance interests when undertaking a regulatory change. In *Regents*, the Court rejected the claim that the purported illegality of the Deferred Action for Childhood Arrivals program "automatically preclude[s] reliance interests," and held that the agency was still "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." 140 S. Ct. at 1913-15. HHS's failure to do so here renders the Rule invalid.

4. The Rule failed to rationally assess the serious problems that it will cause.

HHS also acted arbitrarily and capriciously in failing to adequately consider or justify the substantial—and wholly unnecessary—harms that the Rule will cause to hospitals and patients. By refusing to grapple with the magnitude of the Rule's harms, HHS irrationally "failed to consider an important aspect of the problem." *See State Farm*, 463 U.S. at 43;

Public Citizen, Inc. v. Mineta, 340 F.3d 39, 55-58 (2d Cir. 2003) (vacating rule given agency's failure to consider costs); *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732-33 (D.C. Cir. 2016) (Kavanaugh, J., dissenting) ("[C]osts of an agency's action are a relevant factor that the agency must consider.").

The administrative record is replete with evidence that the Rule will severely disrupt the operations of hospitals and health care facilities, and unnecessarily endanger the health and safety of patients—especially in emergency settings and in rural facilities. In such contexts, where there is frequently a shortage of time or nearby alternative providers—or both—even a single provider's refusal to provide care may practically be tantamount to a per se barrier to the patient obtaining care at all. (J.A. 708, 1649, 1675, 1723, 1740, 1921.) These harms resulting from refusals to provide care in such settings are not "hypothetical," as amici suggest. *See* Br. of Amicus Curiae Am. Ass'n of Pro-Life Obstetricians & Gynecologists 24-25; Br. of States of Ohio et al. as Amici Curiae in Supp. of Defs.-Appellants 13. To the contrary, the administrative record contains concrete examples of such harms. (*See, e.g.*, J.A. 1187, 1649, 1690 (rape victims denied emergency contraception), 1721 (denied emergency care

for ectopic pregnancy), 2025-2026, 2275-2276 (denied abortions of nonviable pregnancies even though women were septic and hemorrhaging).)

Yet the Rule is entirely silent on the risk to patients' health and safety in emergency contexts. Nor, as the district court observed (S.A. 76 n.43), did HHS meaningfully address the consistently stated concerns that granting individual providers an absolute right to refuse to provide care and information about treatment options—even in emergency situations and without any advance notice—potentially impairs a facility's ability to comply with its obligation under EMTALA to provide necessary and stabilizing emergency care to *all* patients, irrespective of any religious or conscience objections on the part of facility staff. (*See* J.A. 1000-1001, 1674, 1716, 1801, 1909, 1920, 2056-2057.) HHS's failure to address this consequence of its Rule is particularly striking given that the legislative history of the Weldon and Church Amendments confirms that those statutes were not intended to override potential patient needs for urgent care. *See* 151 Cong. Rec. H177 (Jan. 25, 2005) (Rep. Weldon clarifying Weldon Amendment applies to forced participation in procedures in "nonlife-threatening" situations); 119 Cong. Rec. 9601

("[I]n an emergency situation—life or death type—no hospital, religious or not, would deny such services").

Nor did HHS grapple with the demonstrated "budget and staffing constraints" (J.A. 1921) faced by emergency departments and rural facilities that make it practically infeasible, if not "impossible" (J.A. 1213), to accommodate unexpected conscience objections from staff without also disrupting patient care. (*See* J.A. 909-911, 1213-1215, 1870, 1921.) And by conferring upon individual providers an unconditional right to decline to provide necessary medical services (or even information about all medically-indicated treatment options), HHS placed the conscience rights of providers above the rights of patients to receive the medical care they need—in derogation of HHS's own stated mission "to enhance the health and well-being of all Americans." *See* U.S. Dep't of Health & Human Services, *Introduction: About HHS* (internet).

HHS's only response to these weighty concerns is to assume that there will be no disruptions to care in emergency settings because it has purportedly never happened in the past. (*See* S.A. 173 (citing 73 Fed. Reg. at 78,087-88).) But the past was not governed by this Rule. It is irrational for HHS to dispute any harmful effects from the Rule's substantial

changes to the status quo by claiming that the status quo did not involve such harms.

HHS also unreasonably failed to give serious consideration to comments (*e.g.*, J.A. 982-983, 1005-1006, 1013-1016, 1680-1684, 1790, 1812-1813, 1897-1899, 1920-1921) that the Rule poses conflicts with standards governing medical ethics and professional licensing, which prohibit abandoning patients without making suitable arrangements for the transfer of care. See *supra* at n.6. Moreover, by prohibiting employers from taking disciplinary or other adverse action against employees who refuse care or treatment information at will, without first transferring a patient to another provider's care, the Rule exposes plaintiffs and other medical institutions to substantial legal liability. Since HHS acknowledged that increased "lawsuits by patients" are a likely consequence of the Rule, it was irrational for the agency not to give meaningful consideration to this harm merely because HHS was "unaware of any reliable basis for estimating the frequency or costs of such lawsuits." (*See* S.A. 229.)

POINT II

THE RULE VIOLATES THE SPENDING CLAUSE AND SEPARATION OF POWERS

A. The District Court Properly Granted Summary Judgment on Plaintiffs' Spending Clause Claim.

1. The Spending Clause claim is ripe.

As the district court correctly found, the Rule requires "major and immediate changes" to plaintiffs' preexisting policies and practices—entailing immediate and substantial expenditures of time and costs on the part of plaintiffs, even before the Rule takes effect. (S.A. 120-121; s*ee, e.g.*, J.A. 464-466, 586-587, 882-883, 924, 935, 953, 976-978.) HHS does not dispute these "direct and immediate" impacts of the Rule. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 148, 152 (1967). Nor could it: by HHS's own estimates, compliance efforts are likely to exceed $150 million in the aggregate for regulated entities in the first year—even assuming that only a fraction of regulated entities proactively undertake such compliance efforts. (*See* S.A. 231.)

The district court thus properly rejected HHS's argument (Br. 54-55) that plaintiffs' challenge is not ripe until *after* HHS has brought an enforcement action pursuant to the Rule. (S.A. 120-22.) This argument

ignores that the burdens of compliance alone are sufficient to establish "a present hardship" warranting judicial review where, as here, plaintiffs "must either incur great expense to comply with the requirements, or (if they choose to challenge the regulation through noncompliance) run the risk of incurring potentially even greater burdens"—here, the potential loss of hundreds of billions of dollars of federal funding. *Thomas v. City of New York*, 143 F.3d 31, 36 (2d Cir. 1998).

In arguing to the contrary, HHS misplaces its reliance on prior cases that dismissed facial challenges to the Weldon Amendment. *See* Br. 54. Neither of those cases presented the substantial and immediate compliance burdens imposed here by the Rule. Rather, the claims of harm at issue in those cases concerned only HHS's potential enforcement of violations of the Weldon Amendment. *Cf. California v. United States*, No. 05-328, 2008 WL 744840, *5-6 (N.D. Cal. Mar. 18, 2008) (no indication that HHS will enforce Weldon Amendment as plaintiffs claim so as to implicate risk of defunding); *NFPRHA*, 468 F.3d at 829-30 (same).

Nor can HHS rely on the purported availability of administrative review of any termination of funds as a basis for evading judicial review. *See* Br. 55. The Rule conspicuously omits mention of any notice and

opportunity for challenging HHS's funding determinations akin to those that have long existed under the UAR. See *supra* at 54-55. *Cf.* 45 C.F.R. § 88.7(i)(2), (3)(i), (iv).

2. The Rule's imposition of new conditions on federal funds and threat to terminate all HHS-administered funding violate the Spending Clause.

On the merits, the district court correctly held that the Rule violates the Spending Clause in two ways. (S.A. 124-132.) First, by conditioning federal grants created by Congress on a host of regulatory terms that go beyond the statutory text, HHS violated settled clear notice principles set forth in *Pennhurst State School & Hospital v. Halderman*, 451 U.S. 1 (1981). *Pennhurst* held that notice of a funding condition must be made "unambiguously" to the States *by Congress*—not by the Executive Branch in a regulation promulgated decades later. *See id.* at 17; *see also Bennett v. Kentucky Dep't of Educ.*, 470 U.S. 656, 670 (1985) (rejecting argument that States had agreed to "satisfy whatever interpretation of the terms might later be adopted" by an agency).

The Rule violates this clear-notice requirement by imposing new conditions and obligations beyond those authorized by Congress. See

supra at 33-51, 56. As was the case in *National Federation of Independent Businesses v. Sebelius* (*NFIB*), the government plaintiffs could hardly have anticipated that the federal conscience statutes they have long complied with would be "transform[ed]" and expanded "so dramatically" years later. *See* 567 U.S. 519, 584 (2012); *LaShonda D. v. Monroe County Bd. of Educ.* 526 U.S. 629, 647 (1999).

Second, the Rule violates the Spending Clause because it threatens such vast consequences from even a single regulatory or statutory violation—namely, the potential loss of all federal funds administered by HHS, including Medicaid—that it leaves the government plaintiffs with no "legitimate choice" as to whether to comply. *See NFIB*, 567 U.S. at 578. In *NFIB*, the Supreme Court held that an even narrower funding threat—to Medicaid funding alone—was impermissibly coercive. *Id.* at 581-82, 585. The same is true here, as the district court properly recognized. (S.A. 131-132.)

B. HHS's Imposition of *Ultra Vires* Conditions Violates the Separation of Powers.

Under basic separation-of-powers principles, an executive "agency literally has no power to act . . . unless and until Congress confers power upon it." *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 375 (1986). Here, the Rule exceeds HHS's authority in many ways, as explained above. See *supra* at 33-56. HHS's threat to cut off federal funding under the unlawful Rule thus impermissibly intrudes on Congress's exclusive "power of the purse" and violates the Constitution's structural limitations. *See City of Chicago v. Sessions*, 888 F.3d 272, 277 (7th Cir. 2018) (agency violates separation of powers by conditioning federal funds on terms unauthorized by Congress).

POINT III

THE DISTRICT COURT PROPERLY VACATED THE RULE IN ITS ENTIRETY, WITHOUT LIMITING RELIEF TO PLAINTIFFS

The district court properly set aside the Rule in its entirety. HHS's assertion that the court was required to limit such relief to the plaintiffs here (Br. 61) disregards both the plain language of the APA and directly applicable case law.

The APA instructs courts to "set aside agency action" that is found to be unlawful. *See* 5 U.S.C. § 706(2)(A). In this case, the relevant "agency action" is the Rule, and it is well-settled "that '[w]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.'" *National Mining Ass'n v. United States Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998).

HHS's contrary contention that the Rule here must be "set aside" only as applied to plaintiffs here (Br. 63) ignores the nature of the illegality found by the district court. The court here did not find fault with the application of the Rule to these particular plaintiffs. *Cf. American Hosp. Ass'n v. NLRB*, 499 U.S. 606, 619 (1991) (declining to vacate rule in its entirety where only one particular application "might lead to [an]

arbitrary result"). Rather, the court concluded that HHS had exceeded its statutory authority and engaged in arbitrary-and-capricious rulemaking—defects that are inherent to the Rule. Vacatur of the Rule thus is necessary not only to fully redress plaintiffs' injuries (as HHS does not contest), but also to respond to HHS's failure to abide by the governing statutes and the APA. *See Regents*, 140 S. Ct. at 1916 (affirming judgment vacating challenged agency action).

HHS's reliance on principles of equity and Article III standing to contest straightforward vacatur of the Rule here (Br. 61-64) invokes arguments it has made in other cases against the issuance of program-wide injunctions by individual district courts. *Cf.* Office of the Att'y Gen., *Litigation Guidelines for Cases Presenting the Possibility of Nationwide Injunctions* (Sept. 13, 2018) (internet). But those arguments are inapposite here because the district court did not grant injunctive relief (S.A. 146), and because the "less drastic remedy" of vacatur is expressly authorized by the APA, 5 U.S.C. § 706(2)(A). *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165-66 (2010); *see also American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001) (distinguishing vacatur from injunctive relief).

Finally, the district court appropriately declined to sever the portions of the Rule that it found invalid and allow the rest to be implemented. In arguing to the contrary (Br. 65-66), HHS ignores that its APA violations were not limited to discrete provisions of the Rule, but rather were "numerous, fundamental" and rendered the entire challenged rulemaking process arbitrary and capricious—such as the defects in its definitions, which pervade the Rule. (S.A. 142.) And in any event, where, as here, excising all offending provisions would "severely distort" the regulatory scheme and produce a "strikingly different" rule than was originally promulgated, the question of severability should be determined by the agency in the first instance. *See MD/DC/DE Broads. Ass'n v. F.C.C.*, 236 F.3d 13, 23 (D.C. Cir. 2001). Here, the district court properly invalidated the Rule in its entirety.

CONCLUSION

This Court should affirm the district court's judgment.

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Respectfully submitted,

LETITIA JAMES
Attorney General
State of New York
Attorney for Governmental
Plaintiffs-Appellees

By: */s/ Linda Fang*
LINDA FANG
Assistant Solicitor General

28 Liberty Street
New York, NY 10005
(212) 416-8656

BARBARA D. UNDERWOOD
Solicitor General
STEVEN C. WU
Deputy Solicitor General
LINDA FANG
ESTER MURDUKHAYEVA
Assistant Solicitors General
of Counsel

(Counsel listing continues on the next three pages.)

PHILIP J. WEISER
Attorney General
State of Colorado
1300 Broadway
Denver, CO 80203

KWAME RAOUL
Attorney General
State of Illinois
100 West Randolph Street
Chicago, Illinois 60601

WILLIAM TONG
Attorney General
State of Connecticut
165 Capitol Avenue
Hartford, CT 06106

BRIAN E. FROSH
Attorney General
State of Maryland
200 St. Paul Pl.
Baltimore, MD 21202

KATHLEEN JENNINGS
Attorney General
State of Delaware
VANESSA L. KASSAB
Deputy Attorney General

MAURA HEALEY
Attorney General
Commonwealth of Massachusetts
One Ashburton Place
Boston, MA 02108

By: */s/ Christian Douglas Wright*
CHRISTIAN DOUGLAS WRIGHT
Director of Impact Litigation

Delaware Department of Justice
820 N. French Street, 5th Floor
Wilmington, DE 19801
(302) 577-8600

CLARE E. CONNORS
Attorney General
State of Hawai'i
425 Queen Street
Honolulu, HI 96813

DANA NESSEL
Attorney General
State of Michigan
P.O. Box 30212
Lansing, MI 48909

KEITH ELLISON
Attorney General
State of Minnesota

By: */s/ Scott H. Ikeda*
SCOTT H. IKEDA
Assistant Attorney General

445 Minnesota Street, Suite 1400
St. Paul, MN 55101
(651) 757-1385

HECTOR BALDERAS
Attorney General
State of New Mexico

By: */s/ Tania Maestas*
TANIA MAESTAS
Chief Deputy Attorney General

P.O. Drawer 1508
Santa Fe, NM 87504
(505) 490-4060

AARON D. FORD
Attorney General
State of Nevada
100 North Carson Street
Carson City, NV 89701

ELLEN F. ROSENBLUM
Attorney General
State of Oregon
1162 Court Street N.E.
Salem, OR 97301

GURBIR S. GREWAL
Attorney General
State of New Jersey
Hughes Justice Complex
25 Market Street
Trenton, NJ 08625

JOSH SHAPIRO
Attorney General
Commonwealth of Pennsylvania
AMBER SIZEMORE
Deputy Attorney General
Health Care Section

By: */s/ Aimee D. Thomson*
AIMEE D. THOMSON
Deputy Attorney General
Impact Litigation Section

1600 Arch Street, Suite 300
Philadelphia, PA 19103
(267) 940-6696

PETER F. NERONHA
Attorney General
State of Rhode Island
150 South Main Street
Providence, RI 02903

KARL A. RACINE
Attorney General
District of Columbia
441 4th Street, NW
Washington, D.C. 20001

THOMAS J. DONOVAN, JR.
Attorney General
State of Vermont
109 State Street
Montpelier, VT 05609

MARK A. FLESSNER
Corporation Counsel
City of Chicago
BENNA RUTH SOLOMON
Deputy Corporation Counsel
30 N. LaSalle Street, Suite 800
Chicago, IL 60602

MARK R. HERRING
Attorney General
Commonwealth of Virginia
202 North Ninth Street
Richmond, VA 23219

JAMES E. JOHNSON
Corporation Counsel
City of New York
100 Church Street
New York, NY 10007

JOSH KAUL
Attorney General
State of Wisconsin
17 West Main Street
Madison, WI 53703

KIMBERLY M. FOXX
State's Attorney
Cook County, Illinois
500 Richard J. Daley Center
Chicago, IL 60602

CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a) of the Federal Rules of Appellate Procedure, William P. Ford, an employee in the Office of the Attorney General of the State of New York, hereby certifies that according to the word count feature of the word processing program used to prepare this brief, the brief contains 15,617 words and complies with the typeface requirements and length limits of Rule 32(a)(5)-(7), Local Rule 32.1, and the Court's order dated July 13, 2020, authorizing that the brief not exceed 16,000 words.

/s/ *William P. Ford*