November 6, 2019

ATTORNEY GENERAL RAOUL: COURT VACATES HEALTH CARE DISCRIMINATION RULE

Federal 'Refusal-of-Care' Rule Would Have Allowed Businesses and Individuals to Refuse to Provide Health Care Based on Their Own Religious, Moral, Ethical Beliefs

Chicago — Attorney General Kwame Raoul today lauded a federal court decision to vacate a Department of Health and Human Services (HHS) rule that would have allowed health care providers to arbitrarily deny patients access to important health care services.

The opinion was issued today in the Southern District of New York in a lawsuit joined in May by Raoul as part of a coalition of states and local governments. In its opinion, the court found that HHS did not have the authority to implement significant portions of the rule. Additionally, the court found that the agency's stated justification for imposing the rule was factually untrue and not supported by the evidentiary record. The court also determined that the rule's provision allowing termination of federal funding as punishment for noncompliance was unconstitutional and violated the separation of powers.

"Access to critical health care services should not depend upon the prejudices of another person," Raoul said. "I will always fight to protect the right of patients to make health care decisions in consultation with medical professionals, and without government interference."

HHS initially proposed the rule in January 2018 to expand the ability of businesses and individuals to refuse to provide necessary health care on the basis of their "religious beliefs or moral convictions." Raoul and the coalition challenged the rule, arguing that it would fundamentally increase the number of reasons and ways Americans across the country could be denied essential health services. The lawsuit alleged that the final rule, if implemented, would drastically expand the number of providers eligible to refuse care, ranging from ambulance drivers to emergency room doctors to receptionists to customer service representatives at insurance companies. Additionally, the rule would make that right absolute and categorical, and no matter what reasonable steps a health provider or employer makes to accommodate the views of an objecting individual, the provider or employer would be left with no recourse if that individual rejects a proposed accommodation.

Under the rule, a hospital could not inquire, prior to hiring a nurse, if that individual objected to administering a measles vaccination — even if this was a core duty of the job in the middle of an outbreak of the disease. A doctor could also refuse to assist a woman who arrived with a ruptured ectopic pregnancy. Businesses, including employers, would be able to object to providing insurance coverage for procedures they consider objectionable, and allow individual health care personnel to object to informing patients about their medical options or referring them to providers of those options. The devastating consequences of the rule would fall particularly hard on marginalized patients, including LGBTQ+ patients, who already confront discrimination in obtaining health care.

In a motion for summary judgment filed in September, Raoul and the coalition asked the court to block the rule because its drastic expansion of refusal rights and its draconian threat to terminate federal funds violate the federal Administrative Procedure Act, as well as the Spending and Establishment Clauses and the separation of powers principles in the U.S. Constitution.

Joining Attorney General Raoul in filing the lawsuit were the attorneys general of Colorado, Connecticut, Delaware, Hawaii, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New

York, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin, and the District of Columbia; as well as the cities of New York and Chicago; and Cook County, Ill. Additionally, Planned Parenthood Federation of America and one of its affiliates, as well as the National Family Planning and Reproductive Health Association and Public Health Solutions, brought two separate lawsuits against the administration for implementation of this rule which were consolidated into this lawsuit.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, CITY OF NEW YORK, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF HAWAI'I, 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, and COOK COUNTY, ILLINOIS,

Plaintiffs,

-v-

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

Defendants,

DR. REGINA FROST and CHRISTIAN MEDICAL AND DENTAL ASSOCIATION,

Defendant-Intervenors.

19 Civ. 4676 (PAE)
(lead)

OPINION AND ORDER

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., and PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND, INC., Plaintiffs, -v- ALEX M. AZAR II, *in his official capacity as Secretary, United States Department of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER 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*, Defendants.	19 Civ. 5433 (PAE) (consolidated)
NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION, and PUBLIC HEALTH SOLUTIONS, INC., Plaintiffs, -v- ALEX M. AZAR, II, *in his official capacity as Secretary of the U.S. Department of Health and Human Services*; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; ROGER SEVERINO, *in his official capacity as Director of the Office for Civil Rights of the U.S. Department of Health and Human Services*; and OFFICE FOR CIVIL RIGHTS OF THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	19 Civ. 5435 (PAE) (consolidated)

PAUL A. ENGELMAYER, District Judge:

These consolidated cases involve challenges to a rule recently promulgated by the United States Department of Health and Human Services ("HHS") entitled "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" or "2019 Rule"). The Rule purports to interpret and provide for the implementation of more than 30 statutory provisions that recognize the right of an individual or entity to abstain from participation in medical procedures, programs, services, or research activities on account of a religious or moral objection. The Rule was originally set to take effect on July 22, 2019. HHS, during this litigation, agreed to delay the effective date until November 22, 2019.

There are three sets of plaintiffs. One consists of 19 states, the District of Columbia, and three local governments, led by the State of New York (collectively, the "State Plaintiffs"). Another consists of Planned Parenthood Federation of America, Inc., and Planned Parenthood of Northern New England, Inc. (together, "Planned Parenthood"). A third consists of National Family Planning and Reproductive Health Association and Public Health Solutions, Inc. (together, "NFPRHA" and, with Planned Parenthood, the "Provider Plaintiffs"). Plaintiffs argue that the Rule was issued in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, and is unconstitutional. They ask the Court to enter summary judgment invalidating the Rule based on the administrative record, or alternatively, to enter a preliminary injunction staying the Rule's implementation pending further review. As to the APA, plaintiffs argue that the Rule exceeds HHS's statutory authority, was not adopted in accordance with law, is arbitrary and capricious, and was adopted in breach of APA procedural requirements. *See* 5 U.S.C. § 706(2)(A), (C)–(D). As to the Constitution, plaintiffs principally argue that the Rule conflicts with the Spending, U.S. Const. art. I, § 8, cl. 1, and Establishment Clauses, *id.* amend. I, and violates the Separation of Powers.

Defendants are HHS, HHS's Secretary Alex M. Azar II, the HHS Office for Civil Rights ("OCR"), OCR Director Roger Severino, and the United States (collectively, "HHS"). They

defend the Rule as lawful; oppose plaintiffs' motions for summary judgment and a preliminary injunction; and cross-move for dismissal of plaintiffs' complaints, or alternatively, for summary judgment sustaining the Rule. The Court has also permitted the intervention of the Christian Medical and Dental Associations ("CMDA") and Dr. Regina Frost (collectively, "Defendant-Intervenors"). They seek the same relief as HHS.

On the pending motions, the Court benefited from extensive and thoughtful briefing from all parties, and from 10 helpful amicus briefs submitted by a combined 40 amici. The Court reviewed substantial factual submissions, including the relevant aspects of the administrative record before HHS. This record formed the factual backdrop for all claims, particularly those under the APA. The Court also benefited from extended oral argument, held on October 18, 2019.

For the following reasons, the Court vacates the Rule in full.

I. Background

This section reviews the statutory provisions pursuant to which HHS promulgated the 2019 Rule, which HHS presents as systematically interpreting and implementing more than 30 statutory provisions that recognize the rights of conscience-based objectors in the health care arena. It then reviews the history of conscience regulations proposed by HHS. It then reviews the 2019 Rule. Finally, it recaps this litigation.

A. Statutory and Regulatory Background

1. The Conscience Provisions

HHS promulgated the Rule against the backdrop of numerous federal statutory provisions (the "Conscience Provisions") that aim, in discrete contexts, to accommodate religious and moral objections to health care services provided by recipients of federal funds. These provisions principally, although not exclusively, address objections to abortion, sterilization, and assisted

suicide, in addition to counseling and referrals related to these services. *See* 84 Fed. Reg. at 23,170.

Of the more than 30 such provisions that the Rule purports to interpret, it and the parties identify five as the most central. These are (1) the Church Amendments, 42 U.S.C. § 300a–7; (2) the Coats-Snowe Amendment, *id.* § 238n(a); (3) the Weldon Amendment, *i.e.*, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Pub. L. No. 115-245, Div. B., § 507(d), 132 Stat. 2981, 3118 (2018); (4) the Conscience Provisions in the Patient Protection and Affordable Care Act ("ACA") of 2010, 42 U.S.C. §§ 14406(1), 18023(b)(1)(A) and (b)(4), 18113; and (5) the Medicaid and Medicare Advantage Conscience Provisions, 42 U.S.C. §§ 1395w–22(j)(3)(B), 1396(u)–2(b)(3)(B).[1]

a. The Church Amendments

The Church Amendments were the first federal Conscience Provisions to be enacted. They are also the broadest in scope.

[1] The Conscience Provisions not highlighted here include conscience protections related to: (1) advance directives, which document a patient's wishes for medical treatment if he or she is unable to speak or make such decisions, 42 U.S.C. §§ 1395cc(f), 1396a(w)(3), 14406(2); (2) organizations receiving funds for HIV/AIDS prevention, treatment, or care globally, 22 U.S.C. § 7631(d); (3) abortion and involuntary sterilization where HHS administers international development funds, *id.* § 2151b(f), *e.g.*, the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2019, Pub. L. No. 116-6, Div. F, § 7018, 133 Stat. 13, 307 (2019); (4) federal or state governments that might require individuals (or parents and guardians on behalf of their children) to acquire general medical treatment that is against their religious beliefs, 42 U.S.C. §§ 1396f and 5106i(a), including related specifically to hearing screening, *id.* § 280g–1(d); (5) employer-administered testing for dangerous substances and illnesses, 29 U.S.C. § 669(a)(5); (6) pediatric vaccinations, 42 U.S.C. § 1396s(c)(2)(B)(ii); (7) mental health treatment for youth, 42 U.S.C. § 290bb–36(f); and (8) protections for religious, nonmedical health care providers and their patients with respect to certain Medicare and Medicaid requirements, *e.g.*, 42 U.S.C. §§ 1320a–1(h), 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j–1(b). HHS agreed at argument that, given the narrow subject-area focus of the other provisions, the Rule's validity turns on the five provisions described in the text. *See* Oral Argument Transcript ("OA Tr.") at 76.

In 1973, Congress passed the Health Programs Extension Act of 1973. It extended appropriations for various programs under the Public Health Services Act, the Community Mental Health Centers Act, the Developmental Disabilities and Facilities Construction Act, and the Medical Facilities Construction and Modernization Amendment. *See* Pub. L. No. 93-45, 87 Stat. 91 (1973). The Church Amendments are contained at the end of the "Miscellaneous" section, Title IV, of the Health Programs Extension Act. *See id.* § 401(b)–(c), 87 Stat. at 95–96 (codified at 42 U.S.C. § 300a–7). As explained by their sponsor, Senator Frank Church of Idaho, the Amendments were a response to the decision in *Roe v. Wade*, 410 U.S. 113, 164–65 (1973), which had invalidated prohibitions on abortion in the first trimester, and to a federal district court decision that had preliminarily enjoined a Catholic hospital from prohibiting sterilizations, *see Taylor v. St. Vincent's Hosp.*, 369 F. Supp. 948, 951 (D. Mont. 1973) (withdrawing preliminary injunction in response to Church Amendments). *See* 119 Cong. Rec. 9,595 (Mar. 27, 1973) (statement of Sen. Church); *see also* Douglas NeJaime & Reva B. Siegel, *Conscience Wars: Complicity-Based Conscience Claims in Religion and Politics*, 124 Yale L.J. 2516, 2535–36 & n.80 (2015).

The Church Amendments contain five major provisions.

Three recognize conscience objections to abortions and sterilizations in the context of entities that receive federal funding from specified sources.

First, under 42 U.S.C. § 300a–7(b), no court, public official, or public authority may require that an individual or entity receiving specified federal funds—grants, contracts, loans, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act—perform or "*assist*

in the performance"[2] of a sterilization or abortion, or make facilities or personnel available for such a procedure, if the procedure violates the individual's or the entity personnel's religious or moral beliefs. 42 U.S.C. § 300a–7(b) (emphasis added).

Second, under § 300a–7(c)(1), no entity receiving grants, contracts, loans, or loan guarantees under the same statutes denoted in § 300a–7(b) may "*discriminate*" in employment, promotion, termination of employment, or privileges given to health care personnel because an individual performed or "*assisted in the performance*" of, or refused to perform or assist in, an abortion or sterilization; further, the entity may not discriminate more generally based on an individual's religious or moral beliefs regarding the procedure. *Id.* § 300a–7(c)(1) (emphasis added).

Third, under § 300a–7(e), no entity receiving grants, contracts, loans, loan guarantees, or interest subsidies from these sources may "*discriminate* against any applicant . . . for training or study" because of the applicant's willingness or reluctance to participate in or assist with abortions or sterilizations. *Id.* § 300a–7(e) (emphasis added).

The fourth and fifth provisions of the Church Amendments are not limited by the same specific funding sources or by the subject matter of abortions and sterilizations.

The fourth, § 300a–7(c)(2), states that no entity receiving a grant or contract for biomedical or behavioral research under any program administered by the HHS Secretary may "*discriminate*" against any health care personnel because they performed or "*assisted in the performance*" of, or refused to perform or assist, in any lawful health service or research activity, or more generally because of their religious or moral beliefs related to the service.

[2] As guidance to the reader, when a term used in a Conscience Provision is defined by the 2019 Rule, the Court has denoted that term using quotations and italics.

Id. § 300a–7(c)(2) (emphasis added).

Similarly, the fifth, § 300a–7(d), although not including an anti-discrimination clause, states that no individual may be required to perform or "*assist in the performance*" of any HHS-funded health service program or research activity contrary to his religious or moral belief. *Id.* § 300a–7(d) (emphasis added).

Although the Church Amendments repeatedly use the terms "*assist in the performance*" and "*discriminate*," the Amendments do not define these terms. The Church Amendments do not expressly grant rulemaking authority to the HHS Secretary.

b. The Coats-Snowe Amendment

For two decades, the sole federal Conscience Provisions were the Church Amendments. In 1996, Congress passed the Omnibus Consolidated Rescissions and Appropriations Act of 1996. Pub. L. No. 104-134, 110 Stat. 1321 (1996). This bill spanned 382 pages and addressed a variety of matters, including funding for the Departments of Commerce, Justice, State, the Judiciary, Interior, Labor, HHS, Education, Veterans Affairs, Housing and Urban Development, and other agencies, *see, e.g.*, *id.* 110 Stat. at 1321, 1321-23, 1321-32, 1321-36, 1321-156, 1321-211, 1321-257; prison litigation reform, *see id.* § 801, 110 Stat. at 1321-66; funding for the District of Columbia and reform of its schools, *see id.* 110 Stat. at 1321-77, 1321-107; and amendments to the Goals 2000: Educate America Act, *see id.* § 701, 110 Stat. at 1321-251.

The Coats-Snowe Amendment is contained in a portion of the bill entitled the "Departments of Labor, Health and Human Services, Education, and Related Agencies Appropriations Act, 1996"; it appears in Title V, "General Provisions." *See id.* § 515, 110 Stat. at 1321-245 (codified as amended at 42 U.S.C. § 238n(a)). The Coats-Snowe Amendment provides conscience protections for health care entities and individuals in connection with abortion training. As explained by a sponsor, Senator Dan Coats of Indiana, the Amendment

was enacted in response to a new standard from the Accreditation Council for Graduate Medical Education ("ACGME"), an organization governing medical residencies, that required that "access to experience with induced abortion must be part of a residency education," unless a program or resident has a moral or religious objection to such abortions.[3] Previously, training for abortions had been voluntary and was not required for residency accreditation. 142 Cong. Rec. S2264 (Mar. 19, 1996) (statement of Sen. Coats).

Section 238n(a) of the Coats-Snowe Amendment prevents the federal government and any state or local government that receives any federal financial assistance from subjecting any "*health care entity*" to "*discrimination*" for refusing to train or make arrangements for training for induced abortions. 42 U.S.C. § 238n(a)(1)–(2) (emphasis added). Such government units also may not discriminate against persons who attend a post-graduate training program that lacks abortion training. *Id.* § 238n(a)(3). The Amendment defines "*health care entity*" to "includ[e] an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions." *Id.* § 238n(c)(2). It does not define "*discrimination*."

The Coats-Snowe Amendment also addresses the accreditation of medical training programs. Under § 238n(b)(1), the federal government and any state or local government that receives federal funds must accredit a "*health care entity*" that, but for its refusal to provide abortion training, would be accredited. *Id.* § 238n(b)(1) (emphasis added). As to this provision only, the Amendment expressly confers rulemaking authority. It provides that "[t]he government

[3] Accreditation Council for Graduate Medical Education, 1996–1997 Graduate Medical Education Directory 135 (1996), http://acgme.org/Portals/0/PDFs/1996-97.pdf; *see also, e.g.*, 142 Cong. Rec. S2264 (Mar. 19, 1996) (statement of Sen. Coats).

involved shall formulate such regulations . . . as are necessary to comply with this subsection." *Id.*

c. Medicaid and Medicare Advantage

One year later, Congress passed the Balanced Budget Act of 1997. Pub. L. No. 105-33, 111 Stat. 251 (1997). Like the 1996 omnibus bill, the Balanced Budget Act covered a range of subjects: food stamps, *see id.* Title I, 111 Stat. at 251; housing, *see id.* Title II, 111 Stat. at 257; communications, *see id.* Title III, 111 Stat. at 258; Medicare, Medicaid, and children's health, *see id.* Title IV, 111 Stat. at 270; welfare, *see id.* Title V, 111 Stat. at 575; education, *see id.* Title VI, 111 Stat. at 648; civil service retirement, *see id.* Title VII, 111 Stat. at 653; veterans' affairs, *see id.* Title VIII, 111 Stat. at 663; asset sales and user fees, *see id.* Title IX, 111 Stat. at 670; budget enforcement and processes, *see id.* Title X, 111 Stat. at 677; and the revitalization of the District of Columbia, *see id.* Title XI, 111 Stat. at 712.

In various sections addressing Medicaid and Medicare, Congress included Conscience Provisions. The statute prohibited Medicaid-managed organizations and Medicare Advantage plans from prohibiting or restricting a physician from informing a patient about his or her health and full range of treatment options. *See id.* § 1852(j)(3)(A), 111 Stat. at 295 (codified at 42 U.S.C. § 1395w–22(j)(3)(A)) (Medicare Advantage); *id.* § 4704(b)(3)(A), 111 Stat. at 496 (codified at 42 U.S.C. § 1396u–2(b)(3)(A)) (Medicaid). But it also provided that Medicaid-managed organizations and Medicare Advantage plans are not required to provide, reimburse for, or cover a counseling or "*referral*" service if the organization or plan objects to the service on moral or religious grounds. *See id.* § 1852(j)(3)(B), 111 Stat. at 295 (codified at 42 U.S.C. § 1395w–22(j)(3)(B)) (Medicare Advantage); *id.* § 4704(b)(3)(B), 111 Stat. at 496–97 (codified at 42 U.S.C. § 1396u–2(b)(3)(B)) (Medicaid). The organization or plan must, however, provide

sufficient notice of their moral objections to prospective enrollees. 42 U.S.C. §§ 1395w–22(j)(3)(B)(ii) (Medicare Advantage), 1396u–2(b)(3)(B)(ii) (Medicaid).

Neither the Medicaid nor Medicare Advantage provisions define "*referral*." The HHS Secretary does, however, have explicit rulemaking authority under the Social Security Act to implement these provisions. *See id.* § 1302(a); *see also id.* § 1395w–26(b)(1) (Medicare Advantage).

d. The Weldon Amendment

In 2004, Congress adopted, for the first time, a conscience-related appropriations rider in the appropriations act for the Departments of Labor, HHS, and Education. The rider, which affords protection for objectors to abortion, was sponsored by Representative Joseph Weldon of Florida. *See* 84 Fed. Reg. at 23,172. Representative Weldon explained that his concern derived from decisions construing "health care entity" to cover only individuals and not institutions. 150 Cong. Rec. H10,090 (Nov. 20, 2004) (statement of Rep. Weldon). He sought to clarify that the term "health care entity" also included institutions, such as hospitals and health insurance plans, while noting the rider's limited scope. *See id.* ("This provision only applies to health care entities that refuse to provide abortion services. Furthermore, the provision only affects instances when a government requires that a health care entity provide abortion services. Therefore, . . . this provision will not affect access to abortion, the provision of abortion-related information or services by willing providers or the ability of States to fulfill Federal Medicaid legislation."). Since 2004, Congress has included the same rider in each appropriation act for these three Departments. 84 Fed. Reg. at 23,172. This annual rider has become known as the Weldon Amendment.

The Weldon Amendment prevents federal agencies, federal programs, and state and local governments from receiving federal funding under the appropriations act if the agency, program,

or government subjects any "*health care entity*" to "*discrimination*" because the entity does not provide, pay for, cover, or "*refer for*" abortions. *See, e.g.*, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Pub. L. No. 115-245, Div. B., § 507(d)(1), 132 Stat. 2981, 3118 (2018). It 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." *Id.* § 507(d)(2).

The Amendment does not define "*discrimination*" or "*refer for*." It does not expressly provide the Secretary of any of these agencies with rulemaking authority.

e. The ACA

In 2010, Congress passed the ACA. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified at 42 U.S.C. § 18001, *et seq.*). The ACA's "10 titles stretch over 900 pages and contain hundreds of provisions" regulating health insurance in the United States. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 538–39 (2012) ("*NFIB*"). Enacted after "a long history of failed health insurance reform," *King v. Burwell*, 135 S. Ct. 2480, 2485 (2015), the ACA made "major reforms to the American health-insurance market," *id.* at 2496 (Scalia, J., dissenting). The ACA's central provisions included guaranteed issue and community rating requirements, requiring health insurers to accept individuals with pre-existing conditions, *see* 42 U.S.C. § 300gg–1(a); the individual mandate, requiring individuals to purchase health insurance or pay a penalty to the IRS, 26 U.S.C. § 5000A; and tax credits to help those near the poverty line purchase health insurance, *id.* § 36B. *King*, 135 S. Ct. at 2486–87. The ACA also expanded Medicaid coverage, requiring states to cover more individuals or risk losing all of their federal funds. *See NFIB*, 567 U.S. at 542, 581–85 (holding that ACA's Medicaid expansion violated Spending Clause).

The ACA also contained Conscience Provisions. These are included in sections 1553 (assisted suicide), 1303 (abortion), and 1411 (moral objections to individual mandate).

Section 1553: This section provides that the federal government, any state or local government, and any health care provider that receives federal funding under the ACA, or any health plan created under the ACA, may not subject a "*health care entity*" to "*discrimination*" on the ground that the entity does not provide services for the purpose of causing or assisting in the death of any individual, including through assisted suicide, euthanasia, and mercy killing. *See* 42 U.S.C. § 18113(a) (emphasis added). Like the Weldon Amendment, section 1553 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." *Id.* § 18113(b) (emphasis added). It does not define "*discrimination*." Unlike the earlier Conscience Provisions, section 1553 provides that HHS's Office for Civil Rights ("OCR") will receive complaints of discrimination related to that section. *Id.* § 18113(d).

Section 1303: This section provides that a State may choose to prohibit abortion coverage in its qualified health plans, 42 U.S.C. § 18023(a)(1), and that such a plan is not required to provide abortion coverage as part of its "essential health benefits," *id.* § 18023(b)(1)(A)(i). However, a qualified health plan that declines to provide abortion coverage must provide notice of this exclusion to potential enrollees. *Id.* § 18023(b)(3)(A). And no qualified health plan may "*discriminate*" against any health care provider or facility because it refuses to provide, pay for, cover, or "*refer for*" abortions. *Id.* § 18023(b)(4) (emphasis added). Section 1303 does not define "*discriminate*" or "*refer for*."

Congress recognized the potential conflict between section 1303 and other federal and state statutes. As a result, section 1303 states that nothing in the ACA shall be construed to preempt or effect state laws on abortion, federal laws on abortion (specifically, those related to conscience protection, willingness or refusal to provide abortion, and discrimination based on that willingness or refusal), *id.* § 18023(c)(2)(A), or to relieve health care providers of their obligations to provide emergency services under federal or state laws, including the Emergency Medical Treatment and Labor Act ("EMTALA"), *id.* § 18023(d). Section 1303 also states that it does not "alter the rights and obligations of employees and employers" under Title VII. *See id.* § 18023(c)(3).

Section 1411: This section addresses exemptions to the ACA's "individual responsibility requirement" (the "individual mandate"). 42 U.S.C. § 18081(b)(5)(A). Under this section, HHS may grant exemptions based on hardship (which HHS has stated includes an individual's inability to secure affordable coverage that does not provide for abortions, 84 Fed. Reg. at 23,172), membership in a particular religious organization, or membership in a "health care sharing ministry."[4]

Finally, as to the ACA in full, section 1321(a) provides the HHS Secretary with rulemaking authority to carry out the statute. *See* 42 U.S.C. 18041(a)(1).

2. Title VII and the Reasonable Accommodation / Undue Hardship Framework

Separate from the Conscience Provisions, Title VII of the Civil Rights Act of 1964 has long provided qualified protection to employees, including in the health care field, who have conscience-based objections to employment activities.

[4] The Internal Revenue Code defines "health care sharing ministry" as an organization with members who share common ethical or religious beliefs and share medical expenses among those members in accord with those beliefs. 26 U.S.C. § 5000A(d)(2)(B)(ii).

When Title VII was first enacted in 1964, it included a provision making it unlawful for an employer to discriminate against an employee because of the employee's religion. *See* Civil Rights Act of 1964, Pub. L. No. 88-352, § 703(a), 78 Stat. 241, 255 (1964) (codified at 42 U.S.C. § 2000e–2(a)). The statute, however, lacked a framework for evaluating whether an employer's conduct with respect to an employee with a religious objection constituted discrimination.

In 1966, prompted by instances in which employees had refused on religious grounds to work during normal working hours, the Equal Employment Opportunity Commission ("EEOC") promulgated guidance as to how Title VII applied to religious objections in the workplace. It stated that employers were to accommodate an employee's religious practices if the accommodation could be made "without serious inconvenience" to the employer. *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 72 (1977) (quoting 29 C.F.R. § 1605.1 (1967)). The next year, the EEOC revised its guidance. *Id.* It now stated that employers must make "reasonable accommodations" for an employee's religious practice where such accommodations could be made "without undue hardship" to the employer. *Id.* (quoting 29 C.F.R. § 1605.1 (1968)).

In 1972—after an equally divided Supreme Court had affirmed a Sixth Circuit decision upholding the termination of an employee for refusing to work on Sundays after the employer had tasked the employee with finding a replacement worker—Congress acted. *See id.* at 73 (citing *Dewey v. Reynolds Metals Co.*, 402 U.S. 689, 689 (1971)). Seeking "to resolve by legislation" the uncertainties that had developed regarding an employer's duties with respect to religious accommodation, Congress amended Title VII. *Id.* (quoting 118 Cong. Rec. 706 (1972) (statement of Sen. Randolph)). Its 1972 amendments codified the EEOC concepts of "reasonable accommodation" and "undue hardship." They did so by defining the statutory term "religion" to include "all aspects of religious observance and practice, as well as belief, unless an

employer demonstrates that he is unable to *reasonably accommodate* to an employee's or prospective employee's religious observance or practice without *undue hardship* on the conduct of the employer's business." 42 U.S.C. § 2000e(j) (emphases added).

In the area of employment, Title VII's reasonable accommodation / undue hardship framework governs religious objections by employees. The Supreme Court has since clarified that, under Title VII, a workplace accommodation that would present "more than a de minimis cost" to an employer constitutes an "undue hardship." *See Trans World Airlines*, 432 U.S. at 84. The EEOC's regulations addressing Title VII have long construed "religion" in Title VII broadly, to include "religious beliefs, practices, and observances."[5] This concept in turn has been applied to encompass both traditional beliefs and "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views." EEOC Guidelines on Discrimination Because of Religion, 29 C.F.R. § 1605.1 (1980); *see also* EEOC 2008 Comment.

B. HHS Conscience Regulations

Although the first statutory Conscience Provision dates to 1973, HHS did not promulgate any implementing or interpretive regulation until 2008.

1. The 2008 Rule and the 2011 Withdrawal

In 2008, HHS first promulgated a rule interpreting the Conscience Provisions. *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"). The 2008 Rule identified, as the statutes being interpreted, the Church,

[5] *See* U.S. Equal Emp't Opportunity Comm'n, Comment Letter on Proposed HHS Provider Conscience Regulation (Sept. 24, 2008), https://www.eeoc.gov/eeoc/foia/letters/2008/titlevii_religious_hhsprovider_reg.html ("EEOC 2008 Comment").

Coats-Snowe, and Weldon Amendments. *See id.* at 78,072. The 2008 Rule had three major components relevant here: (1) it defined several terms used in one or more Conscience Provisions, including "assist in the performance" and "health care entity," *id.* at 78,097; (2) it required entities that received HHS funds, both as recipients and subrecipients,[6] to provide a written certificate of compliance with the 2008 Rule, *id.* at 78,098; and (3) it designated HHS's OCR to receive and coordinate the handling of complaints based on the Conscience Provisions, *id.* at 78,101.

On January 15, 2009, before the 2008 Rule's effective date, a challenge to the 2008 Rule was filed in the District of Connecticut. *Connecticut v. United States*, No. 09 Civ. 0054 (VLB), Dkt. 1 (D. Conn. Jan. 15, 2009). Much of the 2008 Rule took effect on January 20, 2009, the day of President's Obama's inauguration. *See* Rescission of the Regulation Entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law"; Proposal, 74 Fed. Reg. 10,207, 10,209 (Mar. 10, 2009). The Rule's certification requirements, however, were never operative because HHS did not complete the required Paperwork Reduction Act processes. *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9,968, 9,971 (Feb. 23, 2011). In March 2009, the new HHS introduced a Notice of Proposed Rulemaking that proposed to rescind the 2008 Rule. 74 Fed. Reg. at 10,207. As a result, the District of Connecticut litigation was stayed pending promulgation of a final rule. *Connecticut v. United States*, No. 09 Civ. 0054 (VLB), Dkt. 103 (D. Conn. Apr. 30, 2009). Although the 2008

[6] A subrecipient receives federal funds not directly from HHS, but from a recipient or another subrecipient.

Rule appears technically to have been in effect for some period, it appears not to have been enforced. *See* OA Tr. at 40.[7]

In February 2011, after receiving more than 300,000 comments, HHS promulgated a final rule that rescinded much of the 2008 Rule. *See* 76 Fed. Reg. at 9,971 (the "2011 Rule"). Among the rescinded portions of the 2008 Rule were the definitions of statutory terms and the certification requirements. The 2011 Rule, however, left in place OCR's authority to handle and coordinate complaints of violations of the Conscience Provisions. *Id.* at 9,976–77. Explaining the rescission, HHS stated that the 2008 Rule had "caused confusion regarding the scope of the federal health care provider conscience protection statutes"; HHS expressed concern, too, that the 2008 Rule might "negatively affect the ability of patients to access care if interpreted broadly." *Id.* at 9,974. HHS further stated that "none of these statutory provisions require promulgation of regulations for their interpretation or implementation." *Id.* at 9,975.

2. The 2018 Notice of Proposed Rulemaking

On May 4, 2017, President Trump issued an executive order entitled "Promoting Free Speech and Religious Liberty." Exec. Order 13,798, 82 Fed. Reg. 21,675 (May 9, 2017). The order instructed the Attorney General to "issue guidance interpreting religious liberty protections in Federal law." *Id.* at 21,675.

On October 6, 2017, Attorney General Jeff Sessions, as directed, issued a memorandum to guide agencies and executive departments with respect to federal religious liberty laws. Dkt. 43 ("Colangelo Decl. 1"), Ex. 60 ("Attorney Gen. Mem.").[8] Attorney General Sessions

[7] *See also* Robert Pear, *A Bush Rule on Providers of Abortions Is Revised*, N.Y. Times (Feb. 18, 2011), https://www.nytimes.com/2011/02/19/health/policy/19health.html.

[8] Unless otherwise indicated, a docket citation refers to the docket of No. 19 Civ. 4676, the lead case in this litigation.

noted that the Free Exercise Clause protects not only the right to believe and worship, but also "the right to perform or abstain from performing certain physical acts in accordance with one's beliefs." *Id.* at 2. The memorandum identified several Conscience Provisions as "key . . . federal statutory protections for religious liberty," *id.* at 10, including the Church, Coats-Snowe, and Weldon Amendments, and the ACA's Conscience Provisions, *see id.* at 25–26.

On January 26, 2018, pursuant to the executive order and the Attorney General's memorandum, HHS issued a notice of proposed rulemaking ("NPRM") to "enhance the awareness and enforcement of Federal health care conscience and associated anti-discrimination laws, to further conscience and religious freedom, and to protect the rights of individuals and entities to abstain from certain activities related to health care services without discrimination or retaliation." Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3,880, 3,881 (Jan. 26, 2018). In response to the NPRM, HHS received more than 242,000 comments. 84 Fed. Reg. at 23,180.

3. The 2019 Rule

On May 21, 2019, HHS published the final Rule. *See* 84 Fed. Reg. at 23,170. Explaining why a new Rule was needed, HHS stated that the withdrawal of the 2008 Rule had created confusion about the Conscience Provisions. *Id.* at 23,175. HHS also stated that, beginning in November 2016, there had been a "significant increase" in the number of complaints that OCR received relating to the Conscience Provisions. *Id.* HHS expressed hope that the new Rule would give it "the proper enforcement tools" to "enforce all Federal conscience and anti-discrimination laws." *Id.*

In content, the 2019 Rule reinstates the major rescinded provisions of the proposed 2008 Rule but also substantially expands upon the 2008 Rule. It applies to more than 30 Conscience Provisions, not merely the three addressed by the 2008 Rule.

The 2019 Rule's substantive provisions fall into five categories. It (1) defines statutory terms; (2) imposes assurance and certification requirements, similar to those in the 2008 Rule; (3) reaffirms OCR's enforcement authority, much as in the 2008 Rule; (4) imposes records and cooperation requirements; and (5) adopts a voluntary notice provision.

First, the Rule defines terms used in one or more Conscience Provisions. *See* 45 C.F.R. § 88.2. Like the 2008 Rule, the Rule defines "assist in the performance" and "health care entity." *See id.* It also adds definitions of the statutory phrases "discriminate or discrimination" and "referral or refer for." *Id.* The Rule defines the following four terms or sets of terms as follows. Of these, only "health care entity"—defined in the Coats-Snowe Amendment, the Weldon Amendment, and the ACA—is defined in any Conscience Provision itself.

- *"Assist in the performance"*: The Rule defines the Church Amendment term "assist in the performance" as "tak[ing] an action" with a "specific, reasonable, and articulable connection" to furthering a particular procedure, program, service, or research activity. *Id.* Assisting may include "counseling, referral, training, or otherwise making arrangements" for the procedure, program, service, or research activity at issue. *Id.*
- *"Health care entity"*: For the purposes of the Coats-Snowe Amendment, the Weldon Amendment, and the ACA, the Rule defines "health care entity" to include physicians, pharmacists, health care personnel, medical trainees, and applicants for medical training programs. *Id.* It also includes post-graduate medical training programs, hospitals, pharmacies, medical laboratories, entities that engage in medical research, and "any other health care provider or health care facility." *Id.* For the purposes of the Weldon Amendment and the ACA only, the definition also includes provider-sponsored organizations, health maintenance organizations, health insurance issuers, health

insurance plans, plan sponsors, third-party administrators, and "any other kind of . . . plan." *Id.*

- *"Discriminate or discrimination"*: The Rule defines "discriminate" and "discrimination" by setting a non-exclusive list of examples of adverse treatment or actions taken against an individual on account of a refusal to perform, assist in the performance of, or undergo health care or research activities on account of "religious, moral, ethical or other reasons." *Id.* §§ 88.1, 88.2(1)–(3). These adverse actions include the termination of employment and the denial of benefits or privileges. *Id.* § 88.2(1)–(3). If there is a "reasonable likelihood" that an employee's job will involve objectionable conduct, the Rule allows a recipient of federal funds to ask the employee to inform it of any objections only after an employee is hired "and once per calendar year thereafter," unless the recipient has a "persuasive justification" for further inquiry. *Id.* § 88.2(5). A recipient's attempts to accommodate an employee's religious or moral objections will not constitute discrimination if the recipient offers an "effective accommodation" and the employee "voluntarily accepts" that accommodation. *Id.* § 88.2(4). If the employee does not consent to the recipient's accommodation, that accommodation constitutes discrimination unless the accommodation uses "alternate staff or methods" that do not require additional action by the employee, does not constitute an "adverse action" against the employee, and does not exclude the employee from her "fields of practice." *Id.* § 88.2(6).
- *"Referral or refer for"*: The Rule defines "referral" and "refer for" to include "the provision of information in oral, written, or electronic form . . . where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in

receiving funding or financing for, training in, obtaining, or performing" a particular procedure, program, service, or activity. *Id.* § 88.2.

Second, the Rule imposes assurance and certification requirements. *See id.* § 88.4. These require an applicant for federal funds to provide an assurance and certification that the applicant will comply with the Conscience Provisions and the Rule. *Id.* § 88.4(a)(1)–(2). If an entity is already receiving federal funds, it need not provide the assurance and certification until it reapplies for funds. *Id.* § 88.4(b)(1). HHS can require more frequent assurance and certifications from an applicant for federal funds if the applicant violates the Rule or OCR suspects such a violation. *Id.* § 88.4(b)(1)(i)–(ii).

Third, the Rule grants OCR broad authority to enforce the Rule. *Id.* § 88.7. OCR may receive and handle complaints, initiate compliance reviews, conduct investigations, coordinate compliance within HHS, attempt to reach voluntary resolutions of complaints, refer cases to the Department of Justice, withdraw federal funding, and take whatever "remedial action . . . [HHS] deems necessary and [is] allowed by law and applicable regulation." *Id.* § 88.7(a)(1)–(8). OCR may also begin an investigation whenever it receives information that "indicates a threatened, potential, or actual failure to comply" with the Conscience Provisions or the Rule. *Id.* § 88.7(d). If OCR finds that a recipient or subrecipient has violated a Conscience Provision or the Rule, it may attempt to use informal means to resolve the non-compliance, but that does not prevent OCR from pursuing its other means of effecting compliance. *Id.* § 88.7(i)(2). OCR has authority, after finding a violation, to, *inter alia*, "terminat[e] Federal financial assistance or other Federal funds from the Department, in whole or in part." *Id.* § 88.7(i)(3)(iv).

Fourth, the Rule provides that each recipient of federal funds must maintain records of compliance efforts and cooperate with any OCR review or investigation. *See id.* § 88.6(b)–(c).

To determine whether a recipient is complying, all recipients must supply OCR with "reasonable access" to their records. *Id.* § 88.6(b). Every recipient must also ensure that its subrecipients—those who receive funds from the recipient, as opposed to HHS directly—are complying with the Conscience Provisions and the Rule, or the recipient risks losing its funds. *See id.* § 88.6(a).

Fifth, the Rule recommends that each recipient post a voluntary notice of conscience protections. 45 C.F.R. § 88.5 (notice requirement); *see also* 84 Fed. Reg. at 23,217 (changing requirement from mandatory to voluntary in response to comments); *id.* § 88 Appendix A (model notice). Because the purpose of such a notice is to inform employees and entities of their rights to conscientiously object, the Rule recommends it be posted on the recipient's website, in a personnel manual, or in another prominent area where notices are "read[ily] observ[ed]." *Id.* § 88.5(b). HHS states, however, that a notice that identifies objecting staff by name—for example, in the course of alerting patients to alternate staff or methods to obtain an objected-to procedure—could constitute discrimination on account of that disclosure. 84 Fed. Reg. at 23,192. When a recipient posts a notice that complies with the Rule, OCR will consider the notice as non-dispositive evidence of compliance with the Rule. 45 C.F.R. § 88.5(a).

The Rule also contains provisions guiding its construction. It provides that "[n]othing in this part shall be construed to preempt any Federal, State, or local law that is equally or more protective of religious freedom or moral convictions," and that "[n]othing in this part shall be construed to narrow the meaning or application of any State or Federal law protecting the free exercise of religious beliefs or moral convictions." *Id.* § 88.8. It further provides that it "shall be construed in favor of broad protection" of religious and moral convictions, "to the maximum extent permitted by the Constitution and the terms of the Federal conscience and anti-discrimination laws." *Id.* § 88.9. Lastly, the Rule contains a severability provision, which

instructs courts, if they find part of the Rule invalid, to give effect to the remainder of the Rule. *See id.* § 88.10.

C. This Litigation

1. The Parties

This litigation consolidates three lawsuits challenging the Rule that were filed soon after its promulgation. On May 21, 2019, the day the Rule was announced, the first lawsuit, No. 19 Civ. 4676, was filed by the State of New York and 18 other States, the District of Columbia, the City of New York, the City of Chicago, and Cook County, Illinois. Dkt. 3 ("State Compl."). On June 11, 2019, a second lawsuit, by Planned Parenthood Federation of America, Inc., and Planned Parenthood of Northern New England, Inc., was filed. No. 19 Civ. 5433, Dkt. 1 ("PP Compl."). The same day, a third lawsuit, by the National Family Planning and Reproductive Health Association and Public Health Solutions, Inc. was filed. No. 19 Civ. 5435, Dkt. 1 ("NFPRHA Compl."). On June 26, 2019, the Court consolidated the cases. Dkt. 70.

On June 26, 2019, Christian Medical and Dental Associations and Dr. Regina Frost moved to intervene as defendants under Federal Rule of Civil Procedure 24(a) for intervention as of right or 24(b) for permissive intervention. Dkt. 64. On August 2, 2019, the Court granted the Defendant-Intervenors' motion to intervene on the basis of permissive intervention. Dkt. 142.

2. Overview of Plaintiffs' Claims

Plaintiffs' claims are in two categories: (1) APA claims and (2) constitutional claims.

a. APA Claims

Plaintiffs make four broad arguments under the APA.

First, plaintiffs argue that HHS exceeded its statutory authority by enacting the Rule, in violation of APA § 706(2)(C). *See* 5 U.S.C. § 706(2)(C). They argue that, with limited exceptions, the Conscience Provisions do not delegate authority to HHS to promulgate

regulations with the force of law, or to withhold all federal funds for violating such laws. *See* State Compl. ¶¶ 163–64; PP Compl. ¶¶ 130–31; NFPRHA Compl. ¶¶ 144–45. Plaintiffs further argue that the Rule's definitions, namely, of "assist in the performance," "health care entity," "discriminate or discrimination," and "referral or refer for," exceed the scope authorized by the statutory text. *See* State Compl. ¶ 162; *see also* PP Compl. ¶ 133 (analyzing this claim under APA § 706(2)(A)); NFPRHA Compl. ¶ 148 (same).

Second, plaintiffs argue that the Rule is contrary to law, in violation of APA § 706(2)(A). *See* 5 U.S.C. § 706(2)(A). Plaintiffs argue that the Rule violates or conflicts with the ACA, the Medicaid statute, the Emergency Medical Treatment and Labor Act ("EMTALA"), Title VII,[9] and Title X. *See* State Compl. ¶¶ 169–72; PP Compl. ¶¶ 134–36; NFPRHA Compl. ¶¶ 149–52.

Third, plaintiffs argue that the Rule is arbitrary and capricious in violation of APA § 706(2)(A). *See* 5 U.S.C. § 706(2)(A). Plaintiffs argue, *inter alia*, that in enacting the Rule, HHS provided justifications for the Rule that ran counter to the evidence before it, did not provide a reasoned explanation for its change in policy, failed to consider important aspects of the problem, and failed to appropriately assess the costs and benefits of the Rule. *See* State Compl. ¶¶ 177–80; PP Compl. ¶¶ 138–39; NFPRHA Compl. ¶¶ 160–67.

Fourth, the Provider Plaintiffs argue that HHS enacted the Rule without observing proper rulemaking procedure, in violation of APA § 706(2)(D). *See* 5 U.S.C. § 706(2)(D). They argue that portions of the final Rule that define "discriminate or discrimination"—particularly insofar

[9] Although the State Plaintiffs alleged that the 2019 Rule conflicts with Title VII and hence is contrary to law, State Compl. ¶ 172, in their briefs, plaintiffs primarily frame their argument based on Title VII as relating to the claim that the Rule was arbitrarily and capriciously adopted. HHS, in their view, failed to adequately explain the Rule's departure from Title VII. *See* Dkt. 182 ("State SJ") at 34–36. Plaintiffs do, however, argue that the Rule is contrary to law insofar as its "discrimination" definition creates a conflict between the Conscience Provisions and the Title VII framework. *See* Dkt. 184 ("Provider SJ") at 20–21.

as they address workplace accommodations and limit a recipient's ability to ask an employee or applicant about his or her religious objections—were not a "logical outgrowth" of the NPRM, and that the NPRM did not give plaintiffs sufficient notice that these aspects of this definition would be adopted. *See* PP Compl. ¶¶ 141–43; NFPRHA Compl. ¶¶ 169–70.

b. Constitutional Claims

Collectively, plaintiffs make five constitutional claims. The claims vary by party.

First, all plaintiffs claim that the Rule violates the Establishment Clause. U.S. Const. amend. I. Plaintiffs' main argument to this effect is that the Rule forces recipients to conform their business practices to the religious practices of their employees, imposing an absolute duty to accommodate such practices. *See* State Compl. ¶¶ 199–200; PP Compl. ¶ 147; NFPRHA Compl. ¶ 155.

Second, the State Plaintiffs claim that the Rule violates the Spending Clause. U.S. Const. art. I, § 8, cl. 1. They argue that the Rule's threat, in the event of a breach, to withhold all of a recipient's HHS funding is unconstitutionally coercive. State Compl. ¶ 185. They also contend that the conditions of funding imposed by the Rule are ambiguous, retroactive, not reasonably related to the purpose of HHS's program, and (insofar as they induce the State Plaintiffs to breach the Establishment Clause) unconstitutional. *See id.* ¶¶ 186–89, 199.

Third, the State Plaintiffs claim that the Rule violates the Separation of Powers because the Constitution vests the legislative branch, not the executive branch, with the spending power, State Compl. ¶ 192, whereas the Rule empowers the executive branch to unconstitutionally impound funds that Congress has appropriated, *see id*. ¶¶ 194–96.

Fourth, the Provider Plaintiffs claim that the Rule violates the Fifth Amendment because it is unconstitutionally vague. U.S. Const. amend V. They argue that the Rule's ambiguities and alleged inconsistencies with other federal laws deny them fair notice of what conduct would

violate the law. *See* PP Compl. ¶¶ 149–50; NFPRHA Compl. ¶ 156. This lack of guidance, they argue, invites arbitrary enforcement of the Rule. NFPRHA Compl. ¶ 156.

Fifth, the Provider Plaintiffs claim that the Rule violates the Fifth Amendment because it deprives their patients of privacy and liberty rights without due process of law. U.S. Const. amend. V. In particular, they claim, the Rule interferes with patients' ability to obtain abortions necessary to preserve their health and life. PP Compl. ¶ 152; NFPRHA Compl. ¶ 157.[10]

3. Procedural History

Complaints and consolidation: On May 21, 2019, the State Plaintiffs filed their complaint. Dkt. 3 ("State Compl."). On June 11, 2019, the Provider Plaintiffs filed their complaints. *See* No. 19 Civ. 5433, Dkt. 1 ("PP Compl."); No. 19 Civ. 5435, Dkt. 1 ("NFPRHA Compl."). On June 12, 2019, the Provider Plaintiffs moved to consolidate their cases with the State Plaintiffs' case. No. 19 Civ. 5433, Dkt. 12; No. 19 Civ. 5435, Dkt. 20. On June 26, 2019, the Court granted that motion, designating No. 19 Civ. 4676 as the lead case. Dkt. 70.

Intervention: On June 26, 2019, the Defendant-Intervenors filed a motion to intervene, a memorandum of law, and declarations. Dkts. 64–67. On June 26, 2019, the Court set a briefing schedule for that motion. Dkt. 73. On July 9, 2019, plaintiffs filed a memorandum of law in opposition. Dkt. 109. On July 16, 2019, the Defendant-Intervenors filed a reply memorandum of law in support of their motion. Dkt. 127. On August 2, 2019, the Court granted the motion on the basis of permissive intervention, but not on the basis of intervention as of right. Dkt. 142.

Initial motion for a preliminary injunction: On June 7 and 13, 2019, the Court set schedules for anticipated motions for a preliminary injunction to enjoin the Rule from taking effect on July 22, 2019. Dkts. 27, 38. On June 14, 2019, the State Plaintiffs filed such a motion,

[10] In their summary judgment brief, Provider Plaintiffs indicated that they were no longer seeking relief on their Fifth Amendment claims. Provider SJ at 53 n.39.

Dkt. 41, along with a memorandum of law, Dkt. 45 ("State PI"), and supporting declarations, *see, e.g.*, Dkt. 43 ("Colangelo Decl. 1"). On June 17, 2019, the Provider Plaintiffs filed such a motion, No. 19 Civ. 5433, Dkt. 19, along with a memorandum of law, No. 19 Civ. 5433, Dkt. 20 ("Provider PI"), and declarations in support, No. 19 Civ. 5433, Dkt. 21; *see also* No. 19 Civ. 5435, Dkts. 25–27. On June 21 and 26, 2019, various entities filed amicus briefs in support of plaintiffs.[11]

Deferral of effective date and the summary judgment schedule: On July 1, 2019, with briefing underway as to the preliminary injunction motions, the Court entered a stipulation between the parties that postponed the Rule's effective date to November 22, 2019 and vacated the briefing schedule as to a preliminary injunction. Dkt. 90. The Court scheduled a conference to discuss a new schedule for the preliminary injunction and/or summary judgment motions and solicited views as to such a schedule. Dkt. 91. On July 12, 2019, the Court held a conference to discuss a revised schedule. *See* Dkt. 133. On July 16, 2019, guided by that discussion, the Court issued a new schedule, which called for the prompt production by HHS of the administrative record, briefing during August and September 2019 for motions for a preliminary injunction or alternatively for summary judgment, and oral argument on October 18, 2019. Dkt. 121. On July 22, 2019, HHS produced much of the administrative record. *See* Dkt. 132. On August 15, 2019,

[11] These were (1) the Institute for Policy Integrity, Dkts. 52, 54; and (2) various leading medical organizations, including the American College of Obstetricians and Gynecologists, the American Medical Association, the American Academy of Pediatrics, the American College of Emergency Physicians, the American College of Osteopathic Obstetricians and Gynecologists, the American Society for Reproductive Medicine, the National Association of Nurse Practitioners in Women's Health, the Society for Maternal-Fetal Medicine, the American College of Nurse-Midwives, the North American Society for Pediatric and Adolescent Gynecology, the American Muslim Health Professionals, and the World Professional Association for Transgender Health ("Leading Medical Organizations"), Dkt. 77.

plaintiffs filed a motion to compel HHS to produce the remainder of the administrative record. Dkt. 157. On August 16, 2019, the Court ordered HHS to do so by August 19, 2019. Dkt. 158. On August 19, 2019, HHS produced the balance of the administrative record. *See* Dkt. 161.

Briefing on the instant motions: On August 14, 2019, HHS filed a motion to dismiss, or in the alternative, for summary judgment, Dkt. 147, and a memorandum of law in support, Dkt. 148 ("HHS SJ"). The same day, Defendant-Intervenors filed a motion for summary judgment, Dkt. 149, a memorandum of law in support, Dkt. 150 ("DI SJ"), supporting declarations, Dkts. 151–53, and a Rule 56.1 statement, Dkt. 154. On August 21, 2019, various amici filed briefs in support of HHS.[12]

On September 3, 2019, the Court approved plaintiffs' request to file summary judgment motions without accompanying Rule 56.1 statements. Dkts. 176–77. On September 5, 2019, the State Plaintiffs filed their motion for summary judgment, Dkt. 179, along with supporting declarations, Dkt. 180 ("Colangelo Decl. 2"), and a memorandum of law, Dkt. 182 ("State SJ"). They also filed a response to Defendant-Intervenors' Rule 56.1 statement. Dkt. 181. The same day, the Provider Plaintiffs filed their summary judgment motion, Dkt. 183, a memorandum of law, Dkt. 184 ("Provider SJ"), and supporting declarations, Dkts. 185–88. On September 12, 2019, various additional amici filed briefs in support of plaintiffs.[13]

[12] These were: (1) the American Center for Law and Justice, Dkt. 168; and (2) Alliance Defending Freedom and the American Association of Pro-Life Obstetricians & Gynecologists, American College of Pediatricians, Catholic Medical Association, and National Catholic Bioethics Center, Dkt. 171.

[13] These were: (1) the National Center for Lesbian Rights, Dkt. 194; (2) Scholars of the LGBT Population, Dkt. 195; (3) the Callen Lorde Community Health Center, Care Resource Community Health Centers, Inc., the National LGBTQ Task Force, and the National LGBT Cancer Network, Dkt. 197; (4) the Institute of Policy Integrity, Dkt. 202; (5) the Leading Medical Organizations, Dkt. 203; and (6) 15 local governments, Dkt. 206.

On September 19, 2019, HHS filed its reply, Dkt. 224 ("HHS Reply"), accompanied by various exhibits, as did the Defendant-Intervenors, Dkt. 223 ("DI Reply"). On September 20, 2019, HHS filed an additional exhibit. Dkt. 226.

On October 3, 2019, the State Plaintiffs filed their reply, Dkt. 232 ("State Reply"), accompanied by a reply affidavit, Dkt. 231 ("Colangelo Decl. 3"). The same day, the Provider Plaintiffs filed their reply. Dkt. 233 ("Provider Reply").

Argument: On October 18, 2019, the Court heard argument.

II. Nature of the 2019 Rule: Substantive or Exclusively Housekeeping?

At the threshold, the Court assesses the nature and impact of the 2019 Rule: in particular, whether the Rule would alter the substantive obligations, and potential exposure to enforcement action, of recipients of HHS funding, including hospitals, clinics, and other providers, and State and local governments. The parties disagree on this fundamental point. This disagreement informs the parties' opposing views on various challenges to the Rule. The Court accordingly addresses it at the outset.

Plaintiffs cast the 2019 Rule as substantive and as a watershed. Emphasizing that they are not challenging the statutory Conscience Provisions themselves, plaintiffs portray HHS as using the Rule to add, by regulatory fiat, major new substantive content to these laws. Plaintiffs argue that the Rule expands the meaning of core statutory terms and enhances HHS's enforcement powers. As a result, plaintiffs argue, federally funded hospitals, clinics, and other health care providers, and units of State and local government that receive Medicare, Medicaid, and other HHS funding, will be at risk of losing all such funding in the event that HHS finds a breach of these statutes as the Rule construes them. *See* Provider Reply at 2 (Rule recognizes "new legal rights and obligations"); Provider SJ at 8 (Rule "impos[es] massive new burdens on

private entities and State and local governments."); State SJ at 39 (describing Rule as "a new regime that HHS create[d] out of whole cloth").

HHS, in contrast, depicts the 2019 Rule as solely a "housekeeping matter[ ]." HHS SJ at 23–24. It states that the Rule, "far from constituting a sea change," merely "implements and clarifies th[e] . . . preexisting conscience protections enacted by Congress." HHS Reply at 1. The Rule, HHS states, "does not alter the Statute's substantive requirements," *id.* at 39; "does not alter or amend the obligations of the respective statutes," HHS SJ at 25; "simply implements the Federal Conscience Statutes," *id.* at 50; and "does not change the substantive law of the Federal Conscience Statutes, as established by Congress," *id.* at 61. In HHS's account, the Rule is "truly a housekeeping measure," *id.* at 27, "concerning how HHS is governed and how it administers federal statutes," *id.* at 23. HHS describes the Rule's definitions of statutory terms as a "housekeeping matter concerning how HHS interprets the Federal Statutes when it complies and ensures compliance with them," *id.* at 24, and the Rule's enforcement provisions as "merely set[ting] forth existing internal processes," *id.* at 23. *See* HHS Reply at 6–7 ("The housekeeping statutes are a grant of authority to the agency to regulate its own affairs. This is precisely what the Rule does; it provides guidance on how HHS defines key terms and the procedures it will use to enforce the condition imposed on its federal awards under the Federal Conscience Statutes." (internal quotation marks and citation omitted)). In short, HHS asserts, the Rule is but a "modest exercise of [HHS's] authority to impose requirements associated with the receipt of federal funds." HHS SJ at 28.

On this threshold dispute, there is a definite answer. Although the 2019 Rule has housekeeping features, plaintiffs' description of it as largely substantive—and, indeed, in key respects transformative—is correct. And HHS's characterization of the Rule as solely

ministerial cannot be taken seriously. (Indeed, at argument, HHS abandoned this position.).[14] Whether or not the Rule was properly adopted—including whether there was statutory authorization for HHS to undertake substantive rule-making, and whether HHS otherwise complied with the APA—the Rule unavoidably would shape the primary conduct of participants throughout the health care industry. It would upend the legal status quo with respect to the circumstances and manner in which conscience objections must be accommodated. And the maximum penalty the Rule authorizes for a violation of the Conscience Provisions—the termination of all of a recipient's HHS funding, from whatever program derived—is new, too. It does not appear in any of the Conscience Provisions, in any statute governing HHS, or in existing regulations prescribing the remedies available to HHS in the event of a breach by a funding recipient.

The following are among the Rule's more consequential dimensions:

Departure from the Title VII framework: As reviewed above, since 1967 by EEOC rule, and since 1972 by statute, Title VII has defined the duties of employers with respect to religious objections in the employment context. The 2019 Rule would effectively supersede Title VII in the health care field, to the extent that an employee claimed discrimination because an HHS funding recipient had failed to accommodate, or improperly or inadequately accommodated, a religious objection. The Rule would do so in at least two broad ways.

First, the Rule defines "discrimination" so as not to contain the defense that the accommodation sought by the employee would present an "undue hardship" to the employer. Although shielding an employer from loss of federal funds where the employee "voluntar[il]y

[14] *See* OA Tr. at 115 ("The agency does take the position that the rule is substantive, that it does impose obligations on regulated entities.").

accept[s] an effective accommodation," the Rule declines to protect an employer who, on account of hardship, refuses to accommodate the employee. *See* 84 Fed. Reg. at 23,191 (Rule's "approach will differ from Title VII . . . by not incorporating the additional concept of an 'undue hardship' exception for reasonable accommodations."). The EEOC, charged with the administration of Title VII, had opposed a similar component of the conscience rule that HHS had proposed in 2008. *See* EEOC 2008 Comment.[15]

HHS's decision not to recognize an undue hardship defense would shift, relative to the present framework set by Title VII, leverage from health care employers to employees who object to covered procedures (*e.g.*, abortion or sterilization). Colloquy at argument illustrated the point. The Court inquired about scenarios in which a nurse or other employee refused to accept a transfer from a unit that performed procedures to which the employee objected (*e.g.*, obstetrics) to a unit that did not (*e.g.*, neo-natal care). HHS counsel acknowledged that a funding recipient that insisted on such a transfer could face liability to HHS—including a loss of funding—under the Rule. That would be so even where the employer's insistence on a transfer complied with Title VII—for example, where keeping the employee in a unit to whose work the employee objected imposed budgetary hardship by forcing the employer to hire additional staff. *See* OA Tr. at 108–15. HHS counsel similarly acknowledged that, to avoid jeopardizing federal funds under the Rule, a remote clinic might be required to add duplicate staff if an employee objected to the clinic's abortion work but refused to take on a different assignment within the small clinic. *See id.* at 120–22.

Second, the 2019 Rule departs from the Title VII framework insofar as the Rule does not protect an employer who offers the objecting employee a "reasonable accommodation." Instead,

[15] The record does not appear to reflect any comments by the EEOC on the 2019 Rule.

the Rule, in its definition of "discrimination" as used in the Conscience Provisions, would shield a recipient from liability to HHS only in two narrower circumstances: where the recipient makes "an effective accommodation" (*i.e.*, one that the objecting employee accepts), 45 C.F.R. § 88.2(4), or an accommodation that does not require "additional action" from the employee, does not exclude the employee from her "field[ ] of practice," and does not constitute an "adverse action," *id*. § 88.2(6).

At argument, HHS counsel acknowledged that the decision not to adopt a "reasonable accommodation" standard could yield an opposite result under the Rule than under Title VII in scenarios like that addressed by *Shelton v. Univ of Med. & Dentistry of N.J.*, 223 F.3d 220, 222–23, 224–28 (3d Cir. 2000), a leading Title VII case involving a religious objection in a hospital setting. OA Tr. at 114–15. The plaintiff in *Shelton*, a nurse, had twice refused to assist in emergency treatment of pregnant women. One incident involved the inducement of labor in a woman with a life-threatening ruptured membrane; the other, an emergency cesarean-section for a woman, "standing in a pool of blood," who had been diagnosed with placenta previa. *See Shelton*, 223 F.3d at 222–23. The nurse had refused to assist because the procedures, she believed, could terminate a pregnancy; in the second instance, the nurse's refusal caused a half-hour delay of the procedure. *Id*. Rather than terminate the nurse, the hospital in *Shelton* offered her a transfer to the Newborn Intensive Care Unit, but the nurse declined to transfer or to apply to another nursing unit. *Id*. After she was terminated, she sued under Title VII. The Third Circuit upheld the grant of summary judgment to the hospital, finding reasonable the accommodation it had proposed. *Id*. at 228. HHS counsel acknowledged that, under the Rule, the hospital's termination of the nurse for refusing to transfer to a unit not implicating her

objections could be viewed as an act of discrimination in violation of the Conscience Provisions. *See* OA Tr. at 113–15.

Broadened definition of protected activities: The 2019 Rule broadly defines the activities in which health care personnel may refuse to participate on account of conscience objections. The Rule does so by defining the Church Amendment term "assist in the performance" to permit abstention by any person tasked with "tak[ing] an action" with a "specific, reasonable, and articulable connection" to a covered medical procedure or service.[16] 45 C.F.R. § 88.2. Such a connection, the Rule states, includes "counseling, referral, training, or otherwise making arrangements" for a procedure. *Id.* The Rule, in turn, defines "referral" to encompass personnel who "provi[de] information" to a patient regarding a procedure or service, where a "reasonably foreseeable outcome" includes assisting that person in obtaining the procedure or service, regardless of when or where that information was provided. *Id*.

At argument, HHS counsel acknowledged that these definitions would authorize individuals at some remove from the operating theater or medical procedure at issue to withhold their services. Under the Rule, the Church Amendment would apply, for example, to a hospital or clinic receptionist responsible for scheduling appointments, and to an elevator operator or ambulance driver responsible for taking a patient to an appointment or procedure. *See* OA Tr. at 116–17; 84 Fed. Reg. at 23,186 ("assist in the performance" includes "scheduling . . . or preparing a room and the instruments for an abortion"). The Rule would also, for the first time, construe the Church Amendment to permit abstention from activities ancillary to a medical

[16] Although several provisions of the Church Amendments protect objectors only as to abortion or sterilization, others apply more broadly, including protecting objectors as to "any lawful health service or research activity" that is contrary to the individual's religious or moral beliefs. *See* 42 U.S.C. § 300a–7(c)(2), (d).

procedure, including ones that occur on days other than that of the procedure. *See* OA Tr. at 123–24. HHS counsel acknowledged that the agency had never previously articulated this view, enforced a Conscience Provision to reach activities ancillary to or on days other than that of the medical procedure, or, to counsel's knowledge, received a complaint regarding participation in activities at this level of remove from the procedure itself. *See id.* at 123–25.

New restrictions on employers' authority to inquire into conscience objections: The 2019 Rule newly restricts the ability of employers to inquire about employees' conscience objections. Under the Rule's definition of "discrimination," a covered entity may not inquire of an applicant about potential conscience objections until *after* the employee has been hired; and thereafter, may ask only once per year about this subject, unless the provider has a "persuasive justification" for additional inquiry. *See* 45 C.F.R. § 88.2(5); *see also* OA Tr. at 120.

Broadened definition of "health care entity": The 2019 Rule newly defines the term "health care entity" used in several Conscience Provisions. It construes the Coats-Snowe Amendment, for the first time, to apply to pharmacists and medical laboratories. *See* 45 C.F.R. § 88.2. And it construes the Weldon Amendment and the ACA, for the first time, to apply to health care plan sponsors and third-party administrators. *See id.*

Expanded enforcement tools and penalty: The parties agree that, before the Rule, a 2014 regulation entitled "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards," 79 Fed. Reg. 75,889 (Dec. 19, 2014) (the "UAR"), governed HHS's enforcement of the conditions imposed on funding recipients. *See* OA Tr. at 9, 13; HHS SJ at 24–25. The UAR tasks HHS with ensuring that recipients are "in full accordance with U.S. statutory and public policy requirements." 45 C.F.R. § 75.300. Under the UAR, where a recipient is found not in compliance, HHS is, first, to attempt to impose additional conditions on

the recipient. *Id.* § 75.371. If that proves unsuccessful, HHS may then, *inter alia*, "[w]holly or partly suspend (suspension of award activities) or terminate the Federal award," *id.* § 75.371(c), or "[w]ithhold further Federal awards for the project or program," *id.* § 75.371(e).

The 2019 Rule goes beyond the UAR in two respects. First, instead of prescribing graduated responses in which added conditions are imposed before a decision to terminate funds is reached, the Rule states that any informal processes "shall not preclude OCR from simultaneously pursuing" other actions, including investigations and "involuntary enforcement," which may include termination of funding. *Id.* § 88.7(i)(2); *see also id.* §§ 88.7(a)(5)–(7), (i)(3). Second, and more important, the Rule, for the first time, empowers HHS to terminate not merely the line of funding at issue, but *all* federal funds that a recipient receives from HHS if OCR finds that the recipient or its subrecipient has violated a Conscience Provision or the Rule. *See* 45 C.F.R. § 88.7(i)(3)(iv) (OCR may "[t]erminat[e] Federal financial assistance or other Federal funds from the Department, in whole or in part"). HHS concedes that the UAR does not authorize wholesale termination of funding. OA Tr. at 81.

In sum, contrary to HHS's depiction of it as mere housekeeping, the Rule relocates the metes and bounds—the who, what, when, where, and how—of conscience protection under federal law.

III. Summary Judgment Standards Applicable to Claims Challenging Agency Action

Under Federal Rule of Civil Procedure 56, a movant is entitled to summary judgment if he or she "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. Pro. 56(a); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). However, when "'a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal,' and '[t]he entire case on review is a question of law.'" *Koopmann v. U.S. Dep't of Transp.*, 335 F. Supp. 3d 556, 560 (S.D.N.Y.

2018) (alteration in original) (quoting *Am. Biosci., Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001)); *see also Flores Zabaleta v. Nielsen*, 367 F. Supp. 3d 208, 210 (S.D.N.Y. 2019). As a result, the usual Rule 56 summary judgment standard "does not apply in such cases," because the court is resolving "legal questions" when it determines if the agency acted in excess of statutory authorization, not in accordance with law, arbitrarily and capriciously, or "in some other way that violates 5 U.S.C. § 706." *Ass'n of Proprietary Colls. v. Duncan*, 107 F. Supp. 3d 332, 344 (S.D.N.Y. 2015) (footnotes omitted) (addressing APA and constitutional claims); *see also Sec. Indus. & Fin. Markets Ass'n v. U.S. Commodity Futures Trading Comm'n*, 67 F. Supp. 3d 373, 399 (D.D.C. 2014) ("[T]he general standard for summary judgment set forth in Rule 56 of the Federal Rules of Civil Procedure does not apply to a review of agency actions."). Summary judgment is "generally appropriate" in such cases, as these legal issues are "amenable to summary disposition." *Ass'n of Proprietary Colls.*, 107 F. Supp. 3d at 344 (quoting *Noroozi v. Napolitano*, 905 F. Supp. 2d 535, 541 (S.D.N.Y. 2012)); *see also Estes v. U.S. Dep't of the Treasury*, 219 F. Supp. 3d 17, 27 (D.D.C. 2016) ("When an agency action is challenged under the APA, summary judgment serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the relevant APA standard of review." (internal quotation marks and alterations omitted)) (addressing APA and constitutional claims).

Generally, a court "reviewing an agency decision is confined to the administrative record compiled by the agency when it made the decision." *Nat'l Audubon Soc'y v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997) (citing *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985)). After the agency resolves factual issues and develops the administrative record, the district court "determine[s] whether or not as a matter of law the evidence in the administrative record

permitted the agency to make the decision it did." *Roberts v. United States*, 883 F. Supp. 2d, 56, 62 (D.D.C. 2012), *aff'd*, 741 F.3d 152 (D.C. Cir. 2014).

IV. Did HHS Exceed Its Statutory Authority in Promulgating the Rule?

The Court first considers plaintiffs' APA claim that HHS exceeded its statutory authority in promulgating the Rule.

A. Applicable Legal Principles Under the APA

"It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *see also Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 108 (2d Cir. 2018) ("*NRDC*") ("It is well settled that an agency may only act within the authority granted to it by statute."). A federal administrative agency is a "creature of statute, having no constitutional or common law existence or authority, but *only* those authorities conferred upon it by Congress." *NRDC*, 894 F.3d at 108 (emphasis in original) (quoting *Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002)); *see also Nat. Res. Def. Council v. Abraham*, 355 F.3d 179, 202 (2d Cir. 2004) (noting "well-established principle" that "an agency literally has no power to act . . . unless and until Congress confers power upon it" (quoting *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986))). An agency's statutory authority will "not be lightly presumed." *Michigan v. EPA*, 268 F.3d 1075, 1082 (D.C. Cir. 2001).

The APA instructs courts to "hold unlawful and set aside agency action" that is "in excess of statutory . . . authority." 5 U.S.C. § 706(2)(C). In reviewing an agency's statutory authority, or lack thereof, "the question . . . is always whether the agency has gone beyond what Congress has permitted it to do." *NRDC*, 894 F.3d at 108 (quoting *City of Arlington v. FCC*, 569 U.S. 290, 297–98 (2013)).

This analysis differs depending on whether the agency is charged with administering the statute under which it claims authority.

If the agency administers the statute that it is interpreting to determine if it has authority, then the familiar two-step *Chevron* analysis controls. *See City of Arlington*, 569 U.S. at 296–301 (when "confronted with an agency's interpretation of a statute it administers," courts should apply *Chevron* to "ambiguit[ies] that concern[ ] the scope of the agency's statutory authority," *id.* at 296–97); *see also New York v. FERC*, 783 F.3d 946, 953 (2d Cir. 2015). Under the *Chevron* analysis, at step one, the court considers "whether 'Congress has directly spoken to the precise question at issue' because, if 'the intent of Congress is clear, that is the end of the matter.'" *New York*, 783 F.3d at 954 (quoting *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984)). To determine if Congress spoke clearly, the court employs "the ordinary tools of statutory construction." *City of Arlington*, 569 U.S. at 296. These tools include the "statutory text, structure, and purpose as reflected in [the statute's] legislative history," and, if the text is ambiguous, "canons of statutory construction." *Catskill Mountains Chapter of Trout Unltd., Inc. v. EPA*, 846 F.3d 492, 512 (2d Cir. 2017).

If Congress was not clear—meaning the statute was "silent or ambiguous with respect to the specific issue"—then the court continues to step two. *Chevron*, 467 U.S. at 843. At step two, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* This "inquiry is deferential, asking only whether the agency's interpretation is 'reasonable,' while 'respect[ing] legitimate policy choices' made by the agency." *New York*, 783 F.3d at 954 (alteration in original) (quoting *Chevron*, 467 U.S. at 843–44, 866). But, under either *Chevron* step, "[a]n agency construction of a statute cannot survive

judicial review if a contested regulation reflects an action that exceeds the agency's authority." *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1174 (D.C. Cir. 2003).

In the alternative, if the agency does not administer the statute it purports to interpret, then *Chevron* does not apply. *See Karaj v. Gonzales*, 462 F.3d 113, 120 (2d Cir. 2006) (collecting cases); *see also Sherley v. Sebelius*, 689 F.3d 776, 786 (D.C. Cir. 2012) (Henderson, J., concurring). To determine whether Congress authorized the agency to act, the court instead examines, *de novo*, the "plain terms" and "core purposes" of the statute. *See NRDC*, 894 F.3d at 108; *see also id.* at 112 n.10 (deference "clearly not warranted" when statute "applies to all federal agencies, meaning [the agency] has no special expertise in interpreting its language").

If an agency is not interpreting a statute that it administers but rather its own regulation, it may also be entitled to *Auer* deference. *Auer* deference may apply only if the regulation at issue "is genuinely ambiguous." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019). To determine if a regulation is genuinely ambiguous, "a court must exhaust all the 'traditional tools' of construction." *Id.* (quoting *Chevron*, 467 U.S. at 843 n.9). An ambiguity can only be found when "that legal toolkit is empty and the interpretive question still has no single right answer"; "[i]f uncertainty does not exist, there is no plausible reason for deference." *Id.* Even if a court finds that a regulation is, in fact, ambiguous, the agency's interpretation must still be reasonable to warrant deference. *See id.* And even a reasonable interpretation of an ambiguous rule may not be entitled to deference. For example, "a court should decline to defer to a merely 'convenient litigating position' or '*post hoc* rationalization[n] advanced' to 'defend past agency action against attack,'" because, to receive deference, the agency's interpretation "must reflect 'fair and considered judgment.'" *Id.* at 2417 (alteration in original) (quoting *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 155 (2012)).

B. Discussion

Plaintiffs claim that the Rule exceeds HHS's statutory authority, in violation of 5 U.S.C. § 706(2)(C), in two respects. First, plaintiffs argue that Congress did not delegate rulemaking authority to HHS to promulgate the substantive components of the Rule. *See* Provider SJ at 8–12. Second, plaintiffs argue that Congress did not delegate to HHS the ultimate enforcement power that the Rule claims for the agency—the power to cut off all of recipient's HHS funding for a breach of a Conscience Provision. *See id.* 12–16.

The Court's evaluation of these claims is not unitary—some aspects of the Rule are within HHS's authority while others are not. Nevertheless, for the following reasons, the Court finds that HHS lacked rulemaking authority to promulgate significant portions of the Rule that give substantive content to the Conscience Provisions. The Court also finds that HHS lacked authority to promulgate a Rule empowering it to terminate all of a recipient's HHS funding in response to a violation of one of these provisions.

1. Rulemaking Authority

Congress may delegate rulemaking authority to an agency in either an express or an implied manner. *See Chevron*, 467 U.S. at 843. "The starting point for this inquiry is, of course, the language of the delegation provision itself." *Gonzales v. Oregon*, 546 U.S. 243, 259 (2006). If the delegation provision "explicitly left a gap for the agency to fill," then Congress expressly delegated rulemaking authority to the agency. *Chevron*, 467 U.S. at 843. However, if no explicit delegation exists, then, to determine if there is an implicit delegation, the court must ask whether "Congress would expect the agency to be able to speak with the force of law." *United States v. Mead Corp.*, 533 U.S. 218, 229 (2001). The "delegation must be pertinent to the 'particular question' at issue." *Crowley v. Fed. Bureau of Prisons*, 312 F. Supp. 2d 453, 459 (S.D.N.Y. 2004) (quoting *Mead*, 533 U.S. at 229).

HHS argues that, in a variety of statutes, Congress delegated it rulemaking authority, explicitly and/or implicitly. *See* HHS Reply at 6–7; *see also* 84 Fed. Reg. at 23,183–86. The Court considers, first, HHS's claim of an explicit delegation.

a. Explicit Delegations

HHS acknowledges that the Church, Coats-Snowe, and Weldon Amendments do not expressly grant it rulemaking authority. OA Tr. at 75. Instead, to the extent it claims express authority to engage in substantive rulemaking, HHS relies on: (1) several "housekeeping statutes," *see* 84 Fed. Reg. at 23,183–84; HHS Reply at 6; and (2) rulemaking provisions in other statutes that contain Conscience Provisions, including the ACA, 42 U.S.C. § 18041(a), and Medicare and Medicaid, *id.* § 1302(a); *see* 84 Fed. Reg. at 23,184–85; HHS Reply at 6.

i. The housekeeping statutes

HHS identifies three "housekeeping" statutes as ostensible sources of express authority to promulgate the Rule. It argues that these statutes—and implementing regulations—empower HHS to enforce conditions related to federal funding awards, including when the agency may withhold funds from recipients for non-compliance with the Conscience Provisions. *See* HHS SJ at 23; HHS Reply at 6.

Because these housekeeping statutes apply to multiple federal agencies and HHS does not have particular expertise in interpreting them, *Chevron* deference is not available to HHS as to this argument. *See NRDC*, 894 F.3d at 112 n.10; *see also Forgione v. HCA Inc.*, 954 F. Supp. 2d 1349, 1358 (N.D. Fla. 2013) (denying deference to HHS in its interpretation of 5 U.S.C. § 301, because that statute "delegates authority to enact housekeeping rules to a multitude of agencies" and "no single agency has any particular expertise to interpret" the statute). Accordingly, the Court reviews this claim *de novo* as to each statute. *See NRDC*, 894 F.3d at 108 (examining

"plain terms" and "core purposes" of statute that agency did not administer to determine whether Congress delegated rulemaking authority to agency).[17]

5 U.S.C. § 301: HHS first relies on 5 U.S.C. § 301. It gives rulemaking authority to executive department heads to promulgate regulations governing internal department affairs. But § 301's text and history demonstrate that § 301 does not give HHS authority to make rules regarding the substantive legal obligations of regulated entities. Instead, as the Supreme Court has recognized, § 301 is addressed solely to internal agency administration.

Section 301 states that "[t]he head of an Executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." 5 U.S.C. § 301. The items that § 301 recites as subjects of potential regulations—governance, employees, business, and records—"indicate that the statute is intended to give an agency authority to regulate its own day-to-day affairs." *Koopmann*, 335 F. Supp. 3d at 561. For this reason, the Supreme Court has described § 301 as "simply a grant of authority to the agency to regulate its own affairs." *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979) (examining § 301 in context of "reverse-FOIA" suit considering whether agency disclosures were "authorized by law" for the purposes of the Trade Secrets Act, 18 U.S.C. § 1905, *see id.* 285–86); *see also St. Joseph's Hosp. Health Ctr. v. Blue Cross of Cent. N.Y., Inc.*, 489 F. Supp. 1052, 1057 n.10 (N.D.N.Y. 1979) (recounting Supreme Court's analysis of § 301's "plain language").

[17] Had the Court found *Chevron* deference applicable, it would have reached the same result as to this question, because, for the reasons that follow, a *de novo* and a Chevron step-one analysis would equally reveal, clearly, that these housekeeping statutes did not delegate substantive rulemaking authority to the agency. *See Koopmann*, 335 F. Supp. 3d at 562–63 (finding clear at *Chevron* step one that Congress did not intend agency's interpretation of "employee" in § 301).

Section 301's purpose and history confirm that its delegation of rulemaking authority is narrow, focused on internal agency administration. Congress passed § 301's antecedent in 1789 "to help General Washington get his administration underway by spelling out the authority for executive officials to set up offices and file government documents." *See U.S. ex rel. O'Keefe v. McDonnell Douglas Corp.*, 132 F.3d 1252, 1255 (8th Cir. 1998) (quoting H.R. Rep. No. 85–1461 (1958)). In the nation's early history, statutes of this nature "were enacted to give heads of early Government departments authority to govern internal departmental affairs." *Chrysler Corp.*, 441 U.S. at 309. In 1958, such statutes were consolidated, resulting in the modern version of § 301. *Id.* As the Supreme Court later observed, a 1958 House Report noted that a special subcommittee had "unanimously agreed that [§ 301] originally [had been] adopted in 1789 to provide for the day-to-day office housekeeping in the Government departments" but that "through misuse it ha[d] become twisted into a claim of authority" to do more than mere housekeeping.[18] *Id.* at 310 n.41 (quoting H.R. Rep. No. 85–1461 (1958)).

On the basis of both of § 301's text and its "long and relatively uncontroversial" history, the Supreme Court long ago found that § 301 "is indeed a 'housekeeping statute,' authorizing what the APA terms 'rules of agency organization procedure or practice' as opposed to 'substantive rules.'" *Id.* at 309–10; *see also O'Keefe*, 132 F.3d at 1255. Ensuing courts have repeatedly rejected agency attempts, such as that here, to "twist this simple administrative statute into an authorization for the promulgation of substantive rules." *See O'Keefe*, 132 F.3d at 1255 (collecting cases). HHS's bid to use § 301 to justify substantive rulemaking fares no better.

[18] At the time of the 1958 House Report, that body—the House Special Subcommittee on Governmental Information—was specifically concerned that § 301 had been misused by the government to justify withholding information from the public. That concern was addressed by a 1958 amendment to § 301: "This section does not authorize withholding information from the public or limiting the availability of records to the public." 5 U.S.C. § 301.

40 U.S.C. § 121(c): HHS next relies on 40 U.S.C. § 121(c). HHS Reply at 6. This statute—the Public Health Buildings, Property, and Works Act of 1949—gives rulemaking authority to the General Services Administrator to promulgate the Federal Acquisition Regulation (the "FAR") to carry out "this subtitle"; the subtitle, "Federal Property and Administrative Services," is located within the title of "Public Buildings, Property, and Works." 40 U.S.C. § 121(c)(1); *see also* 84 Fed. Reg. at 23,184. Section 121 gives agency heads the ability to "issue orders and directives that the agency head considers necessary to carry out the regulations." 42 U.S.C. § 121(c)(2). Section 121's text and its placement within the statute suggest that the rulemaking authority relates to property and administration, not to developing substantive rules of private conduct. And the ensuing section, 40 U.S.C. § 121(d), eliminates any doubt as to whether the GSA Administrator may delegate substantive rulemaking power to other agencies, such as HHS. It states that the Administrator "may not delegate . . . the authority to prescribe regulations on matters of policy applying to executive agencies." *Id.* § 121(d)(2)(A). This statute, too, provides no charter to HHS to engage in substantive rulemaking.

42 U.S.C. § 216: HHS finally relies on 42 U.S.C. § 216, which HHS asserts, gives it rulemaking authority related to "grants." HHS Reply at 6. The 2019 Rule, however, does not anywhere cite § 216 as a source of authority. For this reason alone, HHS cannot use § 216 to justify the Rule's substantive components. *See NRDC*, 894 F.3d at 111 (court's "review is limited to the rationales offered by [the agency] at the time it published" rule, as opposed to in later litigation (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87–88 (1943))).

Even if the Rule had invoked § 216, it would not give HHS substantive rulemaking authority, for much the same reasons as with the similarly worded 5 U.S.C. § 301. Section 216 gives the Surgeon General, with the approval of HHS's Secretary, authority to "promulgate all

other regulations necessary to the administration of the [Public Health] Service, including regulations with respect to uniforms for employees, and regulations with respect to the custody, use, and preservation of the records, papers, and property of the Service." 42 U.S.C. § 216(b). Section 216 addresses the day-to-day administration of the Public Health Service. For this reason, a similar attempt by HHS to invoke § 216 as a source of substantive rulemaking authority was rebuffed by a federal district court several years ago. *See Pharm. Research and Mfrs. of America v. U.S. Dep't of Health and Human Servs.*, 43 F. Supp. 3d 28, 40 (D.D.C. 2014) (§ 216 provides rulemaking authority for regulations related to the *administration* of the Public Health Service, not the *implementation* of Public Health Service Act).

The three housekeeping statutes above therefore do not give HHS substantive rulemaking authority.

Also unavailing is HHS's related claim that its enforcement responsibilities gave it the authority to promulgate the Rule. In the Rule itself, HHS asserted that, in adopting the Rule, it was discharging its duties under regulations like the UAR, adopted pursuant to two housekeeping statutes (5 U.S.C. § 301 and 40 U.S.C. § 121(c)). 45 C.F.R. § 75.300; *see* HHS SJ at 24; HHS Reply at 3. The UAR, HHS noted, requires the agency to ensure that the recipient of a federal award comply "with U.S. statutory and public policy requirements." 45 C.F.R. § 75.300(a). On this basis, HHS justified the Rule, including its attempt to define terms within the Conscience Provisions, as a mere "clarifying" measure "for ensuring compliance with Congress's directives." HHS SJ at 24 (definitions in Rule are a "housekeeping matter concerning how HHS interprets the Federal Statutes when it complies and ensures compliance with them").

That argument, too, is foreclosed. The Supreme Court has disallowed federal agencies from using their compliance powers as a basis for substantive rulemaking—to "decide what the

law says." *See Gonzales*, 546 U.S. at 264 ("[T]hough [the statute] does require the Attorney General to decide '[c]ompliance' with the law, it does not suggest that he may decide what the law says."); *cf. New York v. Dep't of Justice*, 343 F. Supp. 3d 213, 230 (S.D.N.Y. 2018) (statute delegating authority to Attorney General over grant application form "does not include the ability to dictate the 'substance' of which laws an applicant must comply with as a condition of grant funding"). HHS does not cite contrary authority.

The Court, finally, addresses at length the core premise underlying HHS's arguments based on the housekeeping statutes: that the Rule is wholly non-substantive. In promulgating the Rule, HHS so depicted the Rule, as it later did, repeatedly, in its briefs in this litigation. *See, e.g.,* 84 Fed. Reg. at 23,185 (Rule "does not substantively alter or amend the obligations of the respective [conscience] statutes"). It is not clear whether this defense of the Rule survives HHS's concession at argument that the Rule has substantive dimensions, including "with regard to the definitions." *See* OA Tr. at 115. But given the centrality of this proposition to HHS's defense of its rulemaking authority, the Court elaborates on the discussion above, *see supra* pp. 30–37, as to why the Rule is heavily substantive.

A rule that announces new rights and imposes new duties—one that shapes the primary conduct of regulated entities—is substantive. *See N.Y.C. Emps. Ret. Sys. v. SEC*, 45 F.3d 7, 12 (2d Cir. 1995) (citing *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993)); *see also Chrysler Corp.*, 441 U.S. at 302 (substantive rules "affect[ ] individual rights and obligations" (internal citations omitted)); *Thomas v. New York*, 802 F.2d 1443, 1447 (D.C. Cir. 1986) (substantive rules "jeopardize or substantially affect the rights and interests of private parties" (internal citations and quotation marks omitted)). In some contexts, the distinction between substantive and procedural rules can be elusive—"one of degree" and not kind. *Elec. Privacy Info. Ctr. v. U.S.*

Dep't of Homeland Sec., 653 F.3d 1, 5 (D.C. Cir. 2011). But not here. At the time the Rule was promulgated, the President stated that it conferred "new protections."[19] And that the Rule recognizes new substantive rights and imposes new substantive duties on regulated entities in the health care sector is apparent from each of the Rule's (1) purpose, (2) definitions, and (3) assurance and certification requirements. HHS's repeated characterizations of the Rule as mere "housekeeping" do not make it so, Lewis Carroll notwithstanding.[20] The Court reviews these features in turn.

The Rule's purpose: In its first sentence, the Rule states that "[t]he purpose of this part is to provide for the *implementation* and enforcement of the Federal conscience and anti-discrimination laws." 45 C.F.R. § 88.1 (emphasis added). The Second Circuit has described rules which "'*implement* the statute'" as substantive. *United States v. Lott*, 750 F.3d 214, 217 (2d Cir. 2014) (emphasis in original) (quoting *Chrysler Corp.*, 441 U.S. at 302–03). There, considering guidelines the Attorney General had promulgated "to interpret and implement" the federal sex offender registration and notification statute, the Circuit held that the act of "interpret[ing] and implement[ing]" the statute had been an act of substantive rulemaking. *Id.* HHS has announced the same objective here—to implement the Conscience Provisions. *See* 45 C.F.R. § 88.1.

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[19] *See* Maegan Vazquez & Jessica Ravitz, *Trump Announces 'Conscience Objection' Rule for Medical Care Is Finalized*, CNN (May 2, 2019, 5:45 PM), https://www.cnn.com/2019/05/02/politics/trump-administration-final-rule-conscience-objections/index.html (quoting President Trump's statement about the Rule: "Just today we finalized new protections of conscience rights for physicians, pharmacists, nurses, teachers, students and faith-based charities. They've been wanting to do that a long time.").

[20] *See* Lewis Carroll, The Hunting of the Snark 3 (1876) ("I have said it thrice: What I tell you three times is true.") (quoted in *Parhat v. Gates,* 532 F.3d 834, 848–49 (D.C. Cir. 2008)).

The Rule's definitions: The Rule's definitions go beyond merely expressing "what [the] statute has always meant." *Guedes v. Bureau of Alcohol, Tobacco, Firearms, and Explosives*, 920 F.3d 1, 19 (D.C. Cir. 2019) (rejecting agency's defense that statutory term "machinegun" had always included bump stocks). That justification applies where a regulatory definition "so closely track[s] the relevant statutory provisions as to make the rule virtually self-evident," so as to "create[ ] no new rights or duties." *Mejia-Ruiz v. INS*, 51 F.3d 358, 364 (2d Cir. 1995). But, as a review of four of the Rule's definitions shows, they do not inexorably follow from the spare terms used in the Conscience Provisions. HHS's definitions impose heretofore unrecognized duties on funding recipients in connection with objections to medical procedures.

1. *"Discriminate or discrimination"*: These terms are used, but are not defined, in the Church Amendment, the Coats-Snowe Amendment, the Weldon Amendment, and the ACA. The Rule's definition of them, *see* 45 C.F.R. § 88.2, adds content. As noted, in the employment context, the Rule foregoes the Title VII defense to a claim of discrimination that accommodating an objection would impose an "undue hardship" on the employer. *See supra* pp. 32–33; 84 Fed. Reg. at 23,191; *see also* OA Tr. at 107. The Rule also foregoes the "reasonable accommodation" framework, allowing an employer to defend an accommodation not accepted by the employee only if it does not require additional action by the employee, does not constitute an adverse action against the employee, *and* does not exclude the employee from her field. *See supra* pp. 33–35; 45 C.F.R. § 88.2(4), (6). The Rule also prescribes, for the first time, limits on an employer's ability to inquire about conscience objections. These limits have clear potential to inhibit the employer's ability to organize workplace arrangements to avoid inefficiencies and dislocations. *See supra* pp. 36; 45 C.F.R. § 88.2(5); *see also* OA Tr. at 59.

Whether any or all of these aspects of the Rule's definition of "discrimination" might have been textually defensible as an act of authorized substantive rulemaking, they cannot be defended as acts of mere "housekeeping" or the mere recapitulation of the terms of an existing statutory provision. HHS in this litigation has stated that Congress, in passing the Conscience Provisions, intended the term "discrimination" to mean what the Rule says. *See* HHS SJ at 59 (asserting that Congress chose not to impose the Title VII framework in the Conscience Provisions). But that declaration is an *ipse dixit.* HHS has not pointed to any evidence that Congress as a whole, or any legislator, understood any Conscience Provisions to embody the content and ground rules that the 2019 Rule assigns to the term "discrimination." At argument, HHS could not point to any evidence of this. *See* OA Tr. at 97–104. That Congress passed the first Conscience Provision, the Church Amendments, a year after it had adopted the reasonable accommodation / undue hardship framework to govern Title VII claims of religious discrimination in employment, without any indication that it perceived a conflict with Title VII, makes it all the more improbable that Congress silently intended effectively to override that framework in the context of the health care industry.[21]

[21] The Supreme Court has disdained a similar attempt to construe an anti-discrimination statute enacted after Title VII as *sub silentio* departing from the Title VII framework. In *Jackson v. Birmingham Board of Education*, 544 U.S. 167 (2005), the Court found unpersuasive the claim that Congress did not intend Title IX to cover retaliation because the later-enacted Title IX did not include an express prohibition against retaliation, whereas the earlier-enacted Title VII had. *See id.* at 175. Title IX, the Court noted, has "a broadly written general prohibition on discrimination," whereas Title VII "spells out in greater detail the conduct that constitutes discrimination." *Id.* Because Congress did not "list *any* specific discriminatory practices when it wrote Title IX," "its failure to mention one such practice does not tell us anything about whether it intended that practice to be covered." *Id.* Similarly, here, while Title VII set out a framework for addressing religious discrimination in employment, 42 U.S.C. §§ 2000e–2(a), 2000e(j), the Conscience Provisions ban "discrimination" broadly in the context of conscience objections, without saying what "discrimination" means. As in *Jackson*, there is no basis to infer that the Congresses that enacted the Conscience Provisions intended to repudiate the familiar Title VII

Simply put, the Rule's definition of "discrimination" is game-changing. Relative to the status quo, it would materially expand the rights of employees articulating objections to covered procedures, and correspondingly enhance the duties of health care employers in this area. This definition is highly substantive.

2. *"Assist in the performance"*: The Rule's definition of this undefined Church Amendment term states that it extends refusal rights to a person engaged in any "action that has a specific, reasonable, and articulable connection" to a particular procedure or research activity, which includes "counseling, referral, training, or otherwise making arrangements for the procedure." 45 C.F.R. § 88.2. HHS defends this definition as textually supportable. HHS SJ at 29–34.

Here, too, whether or not the Rule's definition of this term could be justified textually in the exercise of duly authorized substantive rulemaking, the definition cannot be justified as non-substantive "housekeeping" or as merely recapitulating statutory text. As noted, the definition expands the coverage of the Church Amendments beyond any previously articulated definition, so as, among other things, to confer refusal rights on persons engaged in activities ancillary to a covered procedure (*e.g.*, scheduling and receptionist services, transportation of a patient, and provision of information relating to the procedure) and activities carried out on days before and after these procedures. *See* 45 C.F.R. § 88.2; 84 Fed. Reg. at 23,186–88; OA Tr. at 116–17, 122-–27. Neither the text nor history of the Church Amendments made Congress's intent to reach such activities clear. *See* 119 Cong. Rec. 9,597 (Mar. 27, 1973) (statement of Sen. Church) ("There is no intention here to permit a frivolous objection from someone unconnected with the

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understanding of religious discrimination in employment or the statutory defenses to claims of such.

procedure to be the basis for a refusal to perform what would otherwise be a legal operation."). HHS's withdrawn 2008 Rule did not adopt a definition of such breadth, either.[22]

The 2019 definition of this term is unavoidably substantive. It extends refusal rights to a range of personnel not previously identified as covered by the Church Amendment. And it correspondingly imposes heretofore unrecognized obligations on employers and other providers. It cannot be justified as content-free housekeeping.

3. "*Health care entity*": The Rule's definition of this term—which appears in the Coats-Snowe and Weldon Amendments and the ACA—extends beyond what the face of these statutes disclose. The Coats-Snowe Amendment covers individual physicians, post-graduate physician training programs, and participants in health profession training. 42 U.S.C. § 238n(c)(2).[23] The Rule's definition of "health care entity," however, also covers pharmacists, medical laboratories, entities engaging in medical research, and "any other health care provider or health care facility," creating new rights for a greater number of people and organizations. 45 C.F.R. § 88.2. The Weldon Amendment and the ACA provisions cover physicians, health care professionals, hospitals, provider-sponsor organizations, health care maintenance organizations, health insurance plans, and "any other kind of health care facility, organization, or plan." *See* 42 U.S.C. § 18113(b) (ACA); Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Pub. L. No. 115-245, Div. B., § 507(d)(2), 132 Stat. 2981, 3118 (2018) (Weldon Amendment). These definitions are broader

[22] HHS acknowledged at argument that OCR, the agency's enforcement arm, has never applied a Conscience Provision to protect various activities within the scope of the Rule's definition, such as those of a receptionist, scheduler, or driver. *See* OA Tr. at 123.

[23] It was also enacted in response to a recently enacted ACGME requirement that obstetrician and gynecology residencies provide training for induced abortions. *See* 142 Cong. Rec. S2264 (Mar. 19, 1996) (statement of Sen. Coats).

than that in both statutes. For example, with regard to the Weldon Amendment, Representative Weldon specifically stated that the amendment extended to "health insurance providers," yet the Rule's definition also covers "plan sponsor[s]" (*e.g.*, employers providing employee health benefits) and "third-party administrator[s]" (who process benefit claims and perform other administrative tasks). 45 C.F.R. § 88.2; *see* 150 Cong. Rec. H10,090 (Nov. 20, 2004) (statement of Rep. Weldon) ("This provision is intended to protect the decisions of physicians, nurses, clinics, hospitals, medical centers, and *even* health insurance providers." (emphasis added)).

HHS defends its definition of "health care entity" as textually permissible, on the ground that the definitions in each statute use the term "include," connoting a non-exhaustive list of covered entities. *See* HHS SJ at 38–38 (citing *Lyons v. Legal Aid Soc'y*, 68 F.3d 1512, 1514–15 (2d Cir. 1995)). But whether or not so, the issue here is whether HHS had authority to construe these statutes to cover such entities—imposing substantive obligations on them and conferring corresponding rights on conscience objectors associated with them. This act, too, cannot be justified as a mere "housekeeping" exercise.

4. **"***Referral or refer for"*: The term "referral" appears in the Weldon Amendment, the ACA, and the Medicare and Medicaid provisions; none define this term. The Rule defines "referral" to include:

> [T]he 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, program, activity, or procedure.

45 C.F.R. §88.2.

Here, too, the Rule's definition is broader than what is inherent in the statutory text. Black's Law Dictionary defines "referral" as "[t]he act or instance of sending or directing to

another for information, service, consideration, or decision." Black's Law Dictionary 1471 (10th ed. 2014). In accord with this definition, a common understanding of the term "referral" in the context of the health care industry would include sending a patient to another physician or provider. The text of the Conscience Provisions do not, however, make clear, as the Rule does, that "referral" also covers providing any information that could help the patient obtain the service or procedure at issue. HHS's definition to this effect—whether or not textually defensible—is therefore substantive. It extends the conduct to which these Conscience Statutes apply beyond that inherent in the statutory definition. This definition, too, cannot be justified as a mere act of housekeeping.

The Rule's definitions of all four of these Conscience Provision terms therefore give rise to previously unannounced rights and obligations. All four are substantive, requiring authority for substantive rulemaking.[24]

The Rule's assurance and certification requirements: Finally, the Rule's assurance and certification requirements, *see* 45 C.F.R. § 88.4, impose new obligations and duties on employers and providers. The decision in *Perales v. Sullivan*, 948 F.2d 1348 (2d Cir. 1991), makes clear that these are substantive. In *Perales*, the Second Circuit addressed an HHS "assurance requirement" that a State seeking Medicaid reimbursement for state payments to individuals who

[24] HHS's argument that its definitions merit *Chevron* deference, *see* HHS Reply at 6, implicitly concedes the definitions' substantive quality. *See Guedes*, 920 F.3d at 18 (noting that agency, despite its claim to have promulgated a non-substantive interpretive rule, "further evinced its intent to exercise legislative authority by expressly invoking the *Chevron* framework and then elaborating at length as to how *Chevron* applies to the Rule"). *Chevron* applies only when "Congress delegated authority to the agency generally to make rules *carrying the force of law*, and that the agency interpretation claiming deference was promulgated *in the exercise of that authority*." *Abraham*, 355 F.3d at 200 (emphasis in original) (quoting *Mead*, 533 U.S. at 226–27). To have the force of law, a regulation must be substantive—meaning it affects rights and obligations. *See Chrysler Corp.*, 441 U.S. at 301–03.

became disabled assure that it possessed, at the time of filing its claim, documentation of the finding of disability. *See id.* at 1352–53. The Circuit held that "[t]here [could] be no question that the assurance requirement was a substantive regulation," as it could prevent the States from receiving reimbursement for an otherwise valid Medicaid claim. *Id.* at 1354. The Rule's requirements are indistinguishable. Under the Rule, when an entity applies for funds, it must provide HHS with an assurance and certification that it will comply with the Conscience Provisions. 45 C.F.R. § 88.4(a)(1)–(2). If not, HHS may deny an otherwise valid application for funds or terminate already existing funds. *See id.* § 88.7(j).

As these features confirm, the Rule is therefore heavily substantive. It shapes the rights and obligations of those subject to the Conscience Provisions. It does far more than "alter the manner in which . . . parties present themselves or their viewpoints to the agency." *JEM Broadcasting Co. v. FCC*, 22 F.3d 320, 326 (D.C. Cir. 1994).[25] The substantive components of the Rule cannot be justified based on HHS's authority under housekeeping statutes.

ii. The ACA and Medicare / Medicaid Conscience Provisions

HHS next notes that the ACA and Medicare / Medicaid Conscience Provisions, and certain narrowly targeted Conscience Provisions, supply explicit rulemaking authority.[26] At

[25] In its preamble, the Rule cites *JEM Broadcasting Co.* as support for its assertion that the Rule "does not substantively alter or amend the obligations of the respective statutes." 84 Fed. Reg. at 23,185. *JEM Broadcasting Co.* is inapposite. At issue there were FCC rules that streamlined the process for reviewing radio license applications, requiring the dismissal of applications that contained inaccurate information or were incomplete. *See JEM Broadcasting Co.*, 22 F.3d at 322. The D.C. Circuit held that such rules procedural because they did not change the "substantive standards" by which the FCC evaluated applications. *Id.* at 327 (finding this to be the "critical fact"). HHS's 2019 Rule is a far cry from such a housekeeping rule.

[26] *See* HHS SJ at 40–41 (citing 42 U.S.C. §§ 18041(a)(1) (ACA), 1302 (Medicare, Medicaid, CHIP), 1302 (small rural hospitals), 263a(f)(1)(E) (certification of laboratories), 1315a (Centers for Medicare and Medicaid Services funding instruments)); *see also* HHS Reply at 4 (citing 42 U.S.C. §§ 1302, 18023, 18113, 18041, 263a, 1315a).

argument, HHS helpfully acknowledged that, given the breadth of the 2019 Rule, it cannot be sustained based on the Conscience Provisions targeted to narrow areas of conduct,[27] and that the Rule rises or falls, as to statutory authorization, on the five Conscience Provisions that cover broader subject matters. *See supra* note 1; OA Tr. at 76. As reviewed above, three of these five do not explicitly delegate rulemaking authority: the Church, the Coats-Snowe, and the Weldon Amendments. Whether and to what extent the Rule can be justified based on express rulemaking authority therefore turns on the ACA and Medicare / Medicaid Conscience Provisions.

HHS undeniably had rulemaking authority to implement the ACA and the Medicare and Medicaid Conscience Provisions. *See* OA Tr. at 20 (plaintiffs' counsel, conceding this point). The ACA gives HHS authority to promulgate rules concerning the Exchanges, the reinsurance and risk adjustment programs, and "such other requirements as the Secretary determines appropriate" for "the requirements under this title." 42 U.S.C. § 18041(a)(1). The three ACA Conscience Provisions all fall within "this title."[28] *See id.* §§ 18113, 18023, 18081(b)(5)(A).

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[27] HHS appears to have rulemaking authority to implement the following narrow Conscience Provisions: (1) 42 U.S.C. § 1395cc(f), related to advanced directives, from *id.* § 1395hh(a)(1); (2) *id.* § 1396a(w)(3), related to advanced directives, from *id.* § 1302(a); (3) 22 U.S.C. § 2151b(f), related to abortion and sterilization objections where HHS administers international development funds, from *id.* § 2381; (4) 42 U.S.C. § 1396f, related to protections for individuals who have conscience objections to acquiring general medical treatment, from *id.* § 1302(a); (5) *id.* § 5106i(a), also related to protections for individuals who have conscience objections to acquiring general medical treatment, from *id.* § 5106e; (6) 29 U.S.C. § 669(a)(5), related to employer-administered testing for dangerous substances and illnesses, itself grants rulemaking authority, as does *id.* § 657(g)(2); (6) 42 U.S.C. § 1396s(c)(2)(B)(ii), related to pediatric vaccines, from *id.* § 1302(a); and (7) 42 U.S.C. §§ 1320a–1(h), 1320c–11, 1395i–5, 1395x(e), 1395x(y)(1), 1396a(a), and 1397j-1(b), protections for religious, nonmedical health care providers and their patients from certain Medicare and Medicaid requirements that violate their religious beliefs, from either *id.* § 1302(a) or *id.* § 1395hh(a)(1).

[28] Section 18041(a)(1) provides an exception to this grant of authority—the delegation "shall not apply to standards for requirements under subtitles A and C (and the amendments made by such

Medicare and Medicaid give HHS general authority to promulgate rules "necessary to the efficient administration of the functions with which each is charged" under the Social Security Act. *Id.* § 1302(a). Both the Medicare and Medicaid Conscience Provisions are under the Social Security Act. *See id.* §§ 1396u–2(b)(3)(B) (Medicaid), 1395w–22(j)(3)(B) (Medicare Advantage). The HHS Secretary also has rulemaking authority specifically related to Medicare Advantage. *See id.* § 1395w–26(b)(1).

These delegations of rulemaking authority authorize a subset—but far from all—of the Rule. They empower HHS to implement, and substantively define, the terms used in the Conscience Provisions in the ACA and Medicare and Medicaid.

But this authority does not empower HHS to give content to terms in other Conscience Provisions, including the Church, Coats-Snowe, and Weldon Amendments. An agency's rulemaking authority to "issue regulations . . . to carry out [a] subchapter" of a statute does not empower that agency to define a term in a different subchapter, even when the same term appears in both subchapters. *See Gonzales*, 546 U.S. at 263 (examining *Sutton v. United Air Lines, Inc.*, 527 U.S. 471, 479, 514 (1999) (EEOC did not have rulemaking authority to define "disability" in the ADA)). The same logic applies with even greater force here: If a grant of rulemaking authority in a statutory subsection does not empower rulemaking in another subsection of the same statute, it certainly does not empower rulemaking with regard to a different statute. HHS does not argue to the contrary. HHS did not have authority to extend the definitions of terms used in the ACA and Medicare / Medicaid Conscience Provisions—

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subtitles) for which the Secretary issues regulations under the Public Health Service Act." 42 U.S.C. § 180418(a)(1). That exception is not relevant here.

"discrimination," "referral," and "health care entity"—to govern the same terms as used in the Church, Coats-Snowe, and Weldon Amendments.

This holding has the following implications:

1. HHS lacked authority to promulgate a rule that generally regulates the conduct of recipients with regard to conscience objections involving abortion, sterilization, research programs, health service programs, and abortion training—including defining "discrimination," referral," "health care entity," or "assist in the performance" in connection with all such objections. HHS had authority to substantively rule-make only as to the specific areas of conduct covered by the ACA and Medicare and Medicaid Conscience Provisions.

2. As to Medicare and Medicaid, HHS has authority to promulgate substantive rules, consistent with the applicable Conscience Provisions, to ensure that Medicaid-managed organizations and Medicare Advantage plans are not required to provide, reimburse for, or cover a counseling or "referral" service if the organization or plan objects to the service on moral or religious grounds. *See* 42 U.S.C. §§ 1396u–2(b)(3)(B) (Medicaid), 1395w–22(j)(3)(B) (Medicare Advantage).

3. As to the ACA, first, with respect to assisted suicide, HHS has authority to promulgate substantive rules, consistent with the applicable Conscience Provision, to ensure that providers receiving federal funding under the ACA do not subject any "health care entity" to "discrimination" for failing to provide services that cause death, including assisted suicide, euthanasia, and mercy killing. *Id.* § 18113(a).[29] Second, with respect to abortion, HHS has

[29] This provision authorizes HHS to substantively rule-make to address services that "caus[e]" or "assist[ ] in causing" the death of any individual. 42 U.S.C. § 18113(a). Because the ACA's Conscience Provision does not include the Church Amendment term "assist in the performance," HHS lacks authority to rule-make as to that term. *Compare id.* § 18113(a), *with id.* § 300a–7(b).

authority to promulgate substantive rules to ensure that qualified health plans do not "discriminate" against any provider or facility that refuses to provide, pay for, cover, or "refer for" abortions. *Id.* § 18023(b)(4). However, because the ACA's Conscience Provision does not alter any Title VII rights and responsibilities, *id.* § 18023(c)(3), such rulemaking is bounded by Title VII. Third, HHS may also promulgate substantive rules with respect to the granting of exemptions from the individual mandate based on hardship, *id.* § 18081(b)(5)(A); the Court has no occasion to assess how this authority could apply to conscience objections. Finally, with regard to the ACA, HHS may not promulgate rules that relieve providers of their responsibilities under EMTALA or similar state emergency laws. *Id.* § 18023(d).

b. Implied Delegations

HHS's final argument in support of its claim of broad substantive rule-making authority is that the Conscience Provisions impliedly delegate it such authority. HHS Reply at 7. HHS is unspecific as to which Conscience Provisions do so. The Court assumes HHS to refer to the Church, Coats-Snowe, and Weldon Amendments, given that these provisions do not confer express authority.

At the outset, *Chevron* deference is not due to HHS on the issue of implied delegation here. *Chevron* deference applies where a statute is ambiguous, and the interpretation of that ambiguous statute by the agency charged with its administration is reasonable.[30] *See Chevron*, 467 U.S. at 842–43; *see also King*, 135 S. Ct. at 2488 (*Chevron* deference "is premised on the

[30] It is not clear, in any event, that HHS administers these statutes. The Weldon Amendment, as a "rider to a federal appropriations statute, is 'not within [any agency's] area of expertise' and therefore a particular agency's interpretation thereof 'receives no deference.'" *Sherley*, 689 F.3d at 786 (Henderson, J., concurring) (quoting *U.S. Dep't of Navy v. FLRA*, 665 F.3d 1339, 1348 (D.C. Cir. 2012)). The Church and Coats-Snowe Amendments present closer questions, as neither is specifically addressed to HHS, yet each concerns an area generally within HHS's regulatory ambit. Because the Court finds the claim of implied authority clearly wrong, it has no occasion to resolve whether HHS administers these statutes.

theory that a statute's ambiguity constitutes an implicit delegation from Congress to the agency to fill in the statutory gaps" (citation omitted)). Here, however, the Court, applying the standards governing claims of implied delegation, finds it clear and unambiguous that Congress has not made such an implicit delegation to HHS. HHS's contrary view on this point does not warrant deference.

Courts considering claims of implied delegations "must be guided to a degree by common sense as to the manner in which Congress is likely to delegate a policy decision of such economic and political magnitude to an administrative agency." *FDA v. Brown & Williamson Tobacco Corp.*, 520 U.S. 120, 133 (2000). In particular, when the authority to address major questions is at issue, courts should "hesitate before concluding that Congress intended such an implicit delegation." *King*, 135 S. Ct. at 2488–89 (quoting *Brown & Williamson*, 529 U.S. at 159).

Such hesitance to assume an implied delegation of substantive rulemaking authority to an agency is richly warranted as to the 2019 Rule. Both economically and politically, the Rule is highly consequential.

The Rule stands to affect a large portion of the economy. HHS itself classifies the Rule as "economically significant," meaning it will have an annual economic effect of more than $100 million. 84 Fed. Reg. at 23,227. HHS estimates that it will cost around $1 billion to implement the Rule over its first five years, not including public health costs. *See id.* at 23,240 (tbl. 6) (quantifying costs for familiarization, assurance and certification, voluntary notice, voluntary remedial effects, and enforcement).

Plaintiffs' representations as the costs and burdens that the Rule would impose on them are in accord. They attest that the Rule would impose costs on providers and other funding

recipients in connection with, *inter alia*, retraining employees, revising internal guidance and policies, updating agreements with subcontractors, restructuring billing procedures, and investigating new complaints. *See, e.g.*, Colangelo Decl. 1, Ex. 48 ("Zucker Decl.") ¶¶ 64–66, 175–76, 181–82, 185–86 (describing costs for New York State); *id.*, Ex. 1 ("Adelman Decl.") ¶¶ 10–15 (describing costs for New Jersey); *id.*, Ex. 46 ("Wagaw Decl.") ¶ 18 (describing costs for Chicago). Plaintiffs may also need to double or triple staff to comply with the Rule during emergencies—an "impossible task," given emergency departments' "tight budgets" and limited staffing capacities. Colangelo Decl. 2, Ex. 106 (Am. Coll. of Emergency Physicians Comment) at AR 147982.

The Rule also puts in jeopardy billions of dollars in federal health care funds. *See, e.g.*, States PI at 14. In fiscal year 2018, for example, the State Plaintiffs received $200 billion in federal health care funding. State Compl. ¶ 135. New York alone received $46.9 billion. *Id.* ¶ 151. The Provider Plaintiffs similarly receive hundreds of millions in funding from HHS. *See* NFPRHA Compl. ¶ 20 (Public Health Solutions, Inc., receives $138 million in funds that originate with HHS); PP Compl. ¶ 22 (nearly every Planned Parenthood affiliate participates in Medicaid, which garners hundreds of millions of dollars in reimbursement).

The Rule is also politically significant. It applies across the vast health care industry. It applies to a host of funding recipients, public and private. It sets behavioral standards for those recipients. And it centrally concerns two political hot-button issues: abortion and assisted suicide. Each has long "been the subject of an 'earnest and profound debate' across the country, mak[ing] the oblique form of the claimed delegation all the more suspect." *Gonzales*, 546 U.S. at 267 (internal citation omitted) (finding no implied delegation to Attorney General to regulate assisted suicide).

In a case involving economic consequences and political dynamics on such a scale, the Supreme Court teaches that "[w]e expect Congress to speak clearly" were it to delegate rulemaking authority. *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014) (displaying skepticism when agency finds this power "in a long-extant statute"); *see also Merck & Co. v. U.S. Dep't of Health & Human Servs.*, 385 F. Supp. 3d 81, 96–98 (D.D.C. 2019) (finding no implied delegation to HHS to promulgate rule requiring disclosure of prescription drug prices). Far from speaking clearly here, in none of the three statutes at issue did Congress give any indication that it intended to subcontract the process of legal standard-setting to an administrative agency in general, or HHS in particular. The Church, Coats-Snowe, and the Weldon Amendments do not even mention HHS.

In these circumstances, it is "not sustainable" to conclude that Congress would cede "such broad and unusual authority through an implicit delegation" to HHS. *Gonzales*, 546 U.S. at 267. It is particularly improbable that Congress ceded to an agency authority over such important matters in amendments that were (1) tacked onto the end of a bill in its Miscellaneous section (the Church Amendments); (2) included in the middle of an omnibus bill addressing subjects from prison reform to funding for District of Columbia schools (the Coats-Snowe Amendment); and (3) in an appropriations rider attached to an appropriations act for multiple agencies (the Weldon Amendment). As the Supreme Court has memorably put the point: "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

The Supreme Court's rejection of a similar claim of implied delegation of broad rulemaking authority in connection with Title VII reinforces this result. HHS argues that its

implicit authority to interpret the Church, Coats-Snowe, and Weldon Amendments "stems from its authority to ensure that recipients of HHS funds comply with the terms and conditions associated with the receipt of federal funds." HHS SJ at 26; *see also* HHS Reply at 8 ("Surely Congress did not intend to impose such significant conditions on federal funds without also authorizing HHS to . . . enforce those conditions . . . and, to the extent a term is ambiguous, to clarify such ambiguity."). But, in the context of Title VII, the Supreme Court has rejected just such an argument. In *EEOC v. Arabian American Oil Co.*, 499 U.S. 244 (1991), the Court rejected a claim by the EEOC that its compliance authority presupposed rulemaking authority over the standards the agency enforced. *See id.* at 256–57. The Court acknowledged that the EEOC has "primary responsibility for enforcing Title VII." *Id.* at 256. But,it held, Congress "did not confer the EEOC authority to promulgate rules or regulations" under that title, declining to find any implied delegation. *See id*. at 257; *Gen. Elec. Co. v. Gilbert*, 429 U.S. 125, 141 (1976). Particularly given that these Conscience Provisions substantially address conduct covered by Title VII, it is not credible to claim that Congress tacitly intended to give HHS authority, incident to its compliance responsibilities, to define substantive rules of conduct in this area.

The Court therefore holds that HHS has exceeded its statutory authority in promulgating the Rule insofar as it substantively defines and implements the Church, Coats-Snowe, and Weldon Amendments. HHS's substantive rulemaking authority as to the five principal Conscience Provisions is limited to those in the ACA and Medicare and Medicaid statutes. This authority could sustain only a portion of the terrain that the Rule purports to cover.

2. Enforcement Authority

Plaintiffs separately argue that HHS exceeded its delegated authority in enacting the Rule's most potent enforcement provision—that authorizing the termination of all of a

recipient's federal health care funds. *See* Provider SJ at 12–16. Plaintiffs are correct. Although existing housekeeping statutes appear to empower HHS to terminate a funding stream based on a recipient's violations, the extreme termination power that the Rule claims for HHS exceeds the bounds of the agency's authority, including under the Conscience Provisions.

Section 88.7 of the Rule sets out the enforcement powers that HHS claims under the Conscience Provisions. 45 C.F.R. § 88.7. Relevant here, § 88.7(i)(3) gives OCR, upon finding that an entity has violated the Conscience Provisions, the power to effect "compliance with these laws and this part" through "the following actions, taken in coordination with the relevant Department component, and pursuant to statutes and regulations which govern the administration of contracts (*e.g.*, Federal Acquisition Regulation), grants (*e.g.*, 45 CFR part 75), and CMS funding arrangements (*e.g.*, the Social Security Act)." *Id.* The "following actions" consist of a list of enforcement tools, culminating in "[t]erminating Federal financial assistance or other Federal funds from the Department, in whole or in part." *Id.* § 88.7(i)(3)(iv).[31]

This extreme enforcement remedy exceeds HHS's statutory authority. On its face, § 88.7(i)(3)(iv) allows HHS to terminate *all* of a recipient's HHS funding. The UAR, which plaintiffs do not challenge, authorizes HHS to terminate a portion of the federal funding addressed by § 88.7(i)(3)(iv): "Federal financial assistance." *Id.* § 75.371(c) (allowing for termination of the "Federal award," which § 75.2 defines to include "Federal financial assistance"). The UAR thus exposes to termination, subject to minor limitations, grants,

[31] Under the Rule, HHS also has the ability to temporarily withhold federal funds, deny use of federal funds from HHS, wholly or partly suspend award activities, "deny[ ] or withhold[ ], in whole or in part, new Federal financial assistance or other Federal funds from the Department," refer matters to the Attorney General for enforcement, and "tak[e] any other remedies that may be legally available." 45 C.F.R. § 88.7(i)(3)(i)–(iii), (v)–(vii).

cooperative agreements, non-cash contributions or donations of property, loans, loan guarantees, interest subsidies, and insurance; the UAR does not put in jeopardy Medicare or Medicaid reimbursements.[32] *Id.* Section 88.7(i)(3)(iv), however, would erase these limitations, exposing to the risk of termination, in the event of a breach, all of the recipient's "other Federal funds from the Department," including Medicaid and Medicare reimbursements.[33] 45 C.F.R. § 88.7(i)(3)(iv). The Rule empowers HHS to terminate these funds "*in whole* or in part." *Id.* (emphasis added).

In consequence, under § 88.7(i)(3)(iv), a single violation of § 300a–7(b) of the Church Amendments could cost a State or provider all of its federal health care funding, including Medicaid funding. 42 U.S.C. § 300a–7(b). For New York State, a single violation of the Rule—say, an unconsented-to transfer by a state hospital of a receptionist to a new department for refusing to schedule an abortion—could, in 2018, have cost the State its entire $46.9 billion in HHS funding. *See* State Compl. ¶ 151.

HHS has not pointed to any statute empowering it to terminate all of a recipient's funding streams from the agency for a breach of a Conscience Provision. HHS cites the Church, Coats-Snowe, and Weldon Amendments. But they are silent as to remedy. They cannot be read to authorize this outcome. On the contrary, the Church Amendment's proscription against

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[32] The Rule also defines "Federal financial assistance." *See* 45 C.F.R. § 88.2. The Rule's definition does not appear to have a carve-out, like the UAR, for Medicare and Medicaid reimbursements, as the Rule includes "[a]ny agreement or other contract between the Federal government and a recipient that has as one of its purposes the provision of a subsidy to the recipient."

[33] Plaintiffs argue that § 88.7(i)(3)(iv) would enable HHS to terminate funds from the Departments of Labor and Education. *See* State SJ at 46–47. The Court rejects that reading. The Rule limits HHS's ability to terminate "other Federal funds from the Department." *See, e.g.*, 45 C.F.R. § 88.7(i)(3)(iv). It defines the "Department" as HHS and any of its components. *Id.* § 88.2.

compelling an individual to perform or assist in the performance of an abortion or sterilization applies only to entities receiving federal funding under three statutes—the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act. *See* 42 U.S.C. § 300a–7(b). It cannot be read, for example, to implicate funding streams under Medicaid, which are awarded under a separate statute, the Social Security Act.

HHS also relies on its preexisting administrative regulations. HHS argues that the plenary termination tool claimed by § 88.7(i)(3)(iv) derives from HHS's "preexisting grants and contracts regulations," which "Plaintiffs do not challenge." HHS SJ at 23. But those do not supply authority to terminate HHS funding wholesale. The UAR, the main such regulation on which HHS relies, allows HHS to "[w]holly or partly suspend (suspension of award activities) or terminate the Federal award" if a recipient is found not to comply with a statute. 45 C.F.R. § 75.371(c). But, as HHS conceded at argument, the power to terminate "the Federal award" does not authorize the termination of *all* awards or all HHS funding regardless of source. *See* OA Tr. at 81.[34] HHS has not identified any statute that would do so. Section 88.7(i)(3)(iv) thus asserts enforcement authority in excess of HHS's writ to the extent that it authorizes termination of *all* federal funding.

[34] The UAR defines "Federal award" in several ways. Depending on the context, it can mean the "Federal financial assistance" that an entity receives from HHS or the "cost-reimbursement contract under the Federal Acquisition Regulations" that an entity receives from HHS, or it can mean "the instrument setting forth the terms and conditions" of an award. *See* 45 C.F.R. § 75.2. The "Federal award," however, cannot be construed to reach the entirety of the recipient's HHS funding.

Apparently recognizing that such a remedy would be *ultra vires*, HHS—in its reply brief and at argument—changed tack. It there construed § 88.7(i)(3)(iv) not to expose recipients to potential termination all HHS funding. *See* HHS Reply at 39; *see also* OA Tr. at 79. But the plain language of § 88.7(i)(3)(iv) unavoidably claims this power.[35] In support of this more limited construction, HHS cited the preamble of the Rule, which appears to conflict with § 88.7(i)(3)(iv), in that the preamble states that "[t]he only funding streams threatened by a violation of the [conscience statutes] are the funding streams that such statutes directly implicate." OA Tr. at 79 (quoting 84 Fed Reg. at 23,223). But the "language in the preamble of a regulation is not controlling over the regulation itself." *Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999).[36]

HHS's mid-litigation claim that § 88.7(i)(3)(iv) does not jeopardize all of a recipient's HHS funding is also inconsistent with a justification HHS gave for the Rule when promulgated.

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[35] HHS's mid-litigation construction to save this provision does not merit deference, because the provision is unambiguous on its face. *See Kisor*, 139 S. Ct. at 2415 (*Auer* deference available only where agency regulation is "genuinely ambiguous"). In any event, a court generally need not defer to "agency interpretations advanced for the first time in legal briefs," *id.* at 2417 n.6, as such interpretations can be a "'convenient litigating position' or '*post hoc* rationalizatio[n] advanced' to 'defend past agency action against attack,'" instead of presenting the agency's "fair and considered judgment," *id.* at 2417 (alteration in original) (quoting *Christopher*, 567 U.S. at 155).

[36] Defendant-Intervenors make a separate argument in support of reading the provision narrowly: because § 88.7(i)(3)(iv) allows HHS to use the listed enforcement tools to effect "compliance with *these laws*," they argue, the Rule would allow HHS to withdraw only those funds "authorized by the 'laws' the recipient has violated." DI Reply at 25 (emphasis in original). That, however, is not what the Rule says. In unqualified language, it reserves the right to "[t]erminat[e] Federal financial assistance or other Federal funds from the Department, in whole or in part." 45 C.F.R. § 88.7(i)(3)(iv). And the clause on which Defendant-Intervenors rely contains three words that are fatal to their construction of the provision to jeopardize only funds associated with a particular law. It states that the enforcement tools it provides are to effect "compliance with these laws *and this part*." 45 C.F.R. § 88.7(i)(3) (emphasis added).

A purpose of the Rule, HHS stated, was to enhance the agency's "[i]nadequate enforcement tools" to address discrimination towards conscience objectors. 84 Fed. Reg. at 23,228. But the UAR already empowered HHS to terminate the funding stream(s) implicated by a violation. HHS's claim now that § 88.7(i)(3)(iv) merely affirmed this existing enforcement tool is inconsistent with its claim at the time of promulgation that the Rule would enhance the agency's "inadequate" tools. HHS's justification is coherent only if the Rule expanded HHS's enforcement authority, as it does by exposing the recipient's entire HHS funding to the risk of loss.

HHS undoubtedly has potent existing authority to remedy violations of the Conscience Provisions. Plaintiffs do not challenge HHS's authority under the UAR to terminate a particular "Federal award." *See* OA Tr. at 10–11. But the ultimate penalty claimed by the Rule exceeds that authority, because no law authorizes HHS to terminate all of a recipient's HHS funding for a violation. *See* 45 C.F.R. § 88.7(i)(3)(iv). The Court therefore holds that, as to this enforcement tool, HHS acted outside its rulemaking authority.[37]

V. Did HHS Act "Not in Accordance with Law" in Promulgating the Rule?

The Court next considers plaintiffs' APA claim that HHS acted contrary to law in promulgating the Rule.[38]

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[37] At argument, HHS counsel implied that, even if the Rule authorizes such a remedy, the agency does not intend to pursue it in the event of a violation of a Conscience Provision, and would terminate no more than the funding stream(s) "directly implicate[d]" by that provision. *See* OA Tr. 79. The agency's litigation pledge of forbearance does not, however, narrow the scope of the Rule as promulgated.

[38] Courts sometimes analyze the APA issue of whether a Rule is "not in accordance with law" distinctly from the APA issue of whether it is "arbitrary and capricious," *see, e.g.*, *Henley v. FDA*, 77 F.3d 616, 621 (2d Cir. 1996); *see also FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 304 (2003) (performing standalone "not in accordance with law" analysis), and sometimes combine these inquiries, *see, e.g.*, *Nat. Res. Def. Council v. U.S. EPA*, 808 F.3d 556,

The APA requires that courts "hold unlawful and set aside agency action" that is "not in accordance with law." 5 U.S.C. § 706(2)(A). This "means, of course, *any* law, and not merely those laws that the agency itself is charged with administering." *NextWave Pers. Commc'ns, Inc.*, 537 U.S. at 300 (emphasis in original) (citing *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 413–14 (1971) ("In all cases agency action must be set aside if the agency action was 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law' or if the action failed to meet statutory, procedural, or constitutional requirements.")).[39]

In making this assessment, a court "is not limited to determining whether an agency's decision was 'reasonable' in light of the law as it existed at the time of its decision; instead, the APA requires a court to determine whether a decision is 'in accordance with law' as it exists at the time of review." *Georgetown Univ. Hosp. v. Bowen*, 698 F. Supp. 290, 297 (D.D.C. 1987), *aff'd*, 862 F.2d 323 (D.C. Cir. 1988).

580–84 (2d Cir. 2015). Following the parties' approach, the Court here addresses these issues distinctly.

[39] In contexts where an agency speaks with the force of law and interprets a statute that it administers, courts deciding whether a rule is "not in accordance with law" apply *Chevron* deference to the agency's assessment. *See Military Toxics Project v. EPA*, 146 F.3d 948, 954–55 (D.C. Cir. 1998) (applying *Chevron* deference and finding that EPA rule, promulgated pursuant to its authority under the Resource Conservation and Recovery Act, did not violate that act). Here, however, *Chevron* deference is inapplicable. To the extent that plaintiffs claim that the Rule conflicts with Title VII, HHS does not administer Title VII. To the extent that plaintiffs claim that the Rule conflicts with the Emergency Medical Treatment and Labor Act ("EMTALA"), *see* 42 U.S.C. § 1395dd, the Rule does not purport to interpret EMTALA, and thus HHS cannot be said to have spoken with the force of law as to the existence or not of a conflict with EMTALA. *See NextWave Pers. Commc'ns Inc.*, 537 U.S. at 300–04 (analyzing "not in accordance with law" claim involving FCC license determination in alleged violation of Bankruptcy Code without invoking *Chevron*).

For the following reasons, the Court holds that the Rule is "not in accordance with law" in two significant respects: (1) it conflicts with Title VII; and (2) it conflicts with the Emergency Medical Treatment and Labor Act ("EMTALA"), *see* 42 U.S.C. § 1395dd.[40]

A. Title VII

As reviewed above, *see supra* pp. 14–16, 32–35, the Rule, in its application to the employment context, departs from the framework that Title VII has long used to govern when and how an employer is obliged to accommodate an employee's religious objection.

In particular, the Rule's definition of "discrimination" denies an employer the ability to make two showings available under Title VII to avoid liability: that accommodating the objection would work an "undue hardship" on the employer and that the employer has offered the employee a "reasonable accommodation." *See supra* pp. 32–34; *see also* 42 U.S.C. § 2000e(j). Under Title VII, to establish liability, an employee must first make a prima facie case of religious discrimination, meaning that the employee must first show that "(1) they held a bona fide religious belief conflicting with an employment requirement; (2) they informed their

[40] Plaintiffs argue that the Rule is contrary to a third statute, the Paperwork Reduction Act ("PRA"), 44 U.S.C. § 3507(a), because HHS has not yet received the approval that the PRA requires from the Office of Management and Budget for the Rule's assurance and certification requirements. *See* State PI at 35–36; State SJ at 12. Plaintiffs are, to date, correct as to this critique, because HHS has not yet secured such approval. HHS, however, represents that it expects to receive approval for the assurance requirement by the Rule's effective date, HHS Reply at 23, although HHS appears to have not yet sought approval for the certification requirement, State SJ at 12. And HHS has agreed that, until the OMB approvals required by the PRA have been received, the assurance and certification requirements cannot take effect. *See* 76 Fed. Reg. at 9,971 (noting that 2008 Rule's certification requirement never went into effect because HHS, as of that rule's effective date, had not completed the PRA process). Plaintiffs do not argue that the deferral of the effective dates of the assurance and certification requirements would invalidate the balance of the Rule.

Plaintiffs also argue that the Rule is contrary to other statutes, namely, Title X, section 1554 of the ACA, and the Medicaid informed consent provisions. *See* Provider SJ at 35–40; State SJ at 11. In light of the conflict the Court finds between the Rule and Title VII and EMTALA, and the other infirmities the Court finds with the Rule, there is no occasion to reach these issues.

employers of this belief; and (3) they were disciplined for failure to comply with the conflicting employment requirement." *Knight v. Conn. Dep't of Pub. Health*, 275 F.3d 156, 167 (2d Cir. 2001). The burden then shifts to the employer to show either that it offered a reasonable accommodation or that it could not accommodate the employee because the accommodation would be an undue hardship. *See id.*; *see also Shelton*, 223 F.3d at 224. The Rule eliminates these two means of avoiding liability, permitting a finding of liability to HHS under Conscience Provisions that use the term "discrimination" for conduct that is lawful under Title VII.

While Congress was at liberty to displace these aspects of the Title VII framework and adopt a unique definition of "discrimination" for purposes of the Conscience Provisions, the Conscience Provisions that contain that term do so without elaboration. And HHS has not pointed to any evidence of congressional intent to supersede the Title VII framework. Therefore, even assuming HHS had statutory rulemaking authority to define "discrimination" for purposes of the Conscience Provisions, its latitude to do so in the employment context was bounded by Title VII.

The conflicts that the Rule creates with Title VII are substantial. Although the Rule has applications outside the employment context, its predominant application is in workplaces in the health care sector (*e.g.*, clinics and hospitals), where it seeks to define the conscience rights of employees as to covered medical procedures.

And the two Title VII concepts that the Rule overrides are key components of the framework that Congress adopted in 1972 to address workplace religious objections. The "undue hardship" standard enables an employer to avoid liability for discrimination where the accommodation the employee seeks would pose "more than a de minimis cost" for an employer. *Trans World Airlines, Inc.*, 432 U.S. at 83. But under the Rule, "[u]ndue hardship is no longer

something the employer can trot out under this [R]ule as a defense." OA Tr. at 110; *see* 84 Fed. Reg. at 23,191. The "reasonable accommodation" standard requires an employer, once notified of an employee's religious practice or objection, to offer the employee a reasonable accommodation; if one is offered, "the statutory inquiry ends," and the employer "avoid[s] Title VII liability." *Cosme v. Henderson*, 287 F.3d 152, 158 (2d Cir. 2002); *see also Ansonia Bd. of Educ. v. Philbrook*, 479 U.S. 60, 68 (1986) (explaining that "where the employer has already reasonably accommodated the employee's religious needs, the statutory inquiry is at an end" and the "undue hardship" question need not be reached). But under HHS's Rule, an employer who offers an accommodation can avoid liability only if (1) the employee "voluntarily accepts" an "effective accommodation," *see* 45 C.F.R. § 88.2(4); or (2) the accommodation is not an adverse action, does not require additional action from the employee, and does not exclude the employee from her field of practice, *see id.* § 88.2(6). *See* 84 Fed. Reg. at 23,191 (HHS acknowledging decision not to adopt reasonable accommodation standard); *see also* OA Tr. at 114–15 (HHS counsel acknowledging that the Rules could produce a different outcome than under Title VII).[41]

"[T]he law does not permit [an] agency to regulate away" rights and defenses which were "granted by Congress." *Nat'l Treasury Emps. Union v. Cornelius*, 617 F. Supp. 365, 371 (D.D.C. 1985) (agency attempt to revise statutory appeals process held not in accordance with law). Here, by using a regulation to override Title VII's longstanding framework governing religious accommodations in the workplace, HHS has acted contrary to law.

[41] At argument, Defendant-Intervenors sought to minimize the conflict between the Rule and Title VII by noting HHS's promise that OCR, in evaluating complaints of discrimination under the Rule, will "take into account the degree to which an entity had implemented policies to provide effective accommodations." 45 C.F.R. § 88.2(4); *see* OA Tr. at 151. OCR's pledge to be measured in its implementation does not, however, diminish the facial conflict between the Rule's standards and those of Title VII.

B. The Emergency Medical Treatment and Labor Act

Since 1986, EMTALA has required hospitals that receive federal funds and have emergency departments to provide emergency care to any patient suffering from an emergency medical condition, regardless of the patient's ability to pay. *See* 42 U.S.C. § 1395dd(a). Hospitals must provide medical screening and stabilizing treatment or a medical transfer. *Id.* § 1395dd(a)–(b)(1). If a hospital fails to comply with EMTALA, it may be subject to monetary penalties up to $50,000 per violation, and it may be sued by patients who have suffered harm. *Id.* § 1395dd(d)(1)–(2).

By its terms, EMTALA does not include any exception for religious or moral refusals to provide emergency care. And courts have declined to read exceptions into EMTALA's mandate. *See, e.g.*, *Matter of Baby K*, 16 F.3d 590, 597 (4th Cir. 1994) ("EMTALA does not provide an exception for stabilizing treatment physicians may deem medically or ethically inappropriate."); *Burditt v. U.S. Dep't of Health & Human Servs.*, 934 F.2d 1362, 1375 (5th Cir. 1991) ("[N]othing in EMTALA admits the existence of a good-faith exception."); *cf. Roberts v. Galen of Va., Inc.*, 525 U.S. 250, 253 (1999) (per curiam) (declining to narrow scope of EMTALA's mandate by imposing an "improper motive" element not found in EMTALA's text).

The Rule, however, applies in emergency-care situations. Its definition of "discrimination" exposes a provider (*e.g.*, a hospital, clinic or ambulance service) to liability for failure to accommodate an employee's conscience objection in such situations. *See* OA Tr. at 119 (HHS counsel confirming that, under the Rule, "the employer has to accommodate" conscience objections in emergency situations). The Rule therefore creates, via regulation, a conscience exception to EMTALA's statutory mandate.

To be sure, HHS denies that the Rule is the source of the conflict with EMTALA. It argues that the conflict is the product of the statutory Conscience Provisions themselves, which

the Rule merely implements. *See* OA Tr. at 129. But, as with Title VII, there is no evidence that Congress intended, *sub silentio*, for any of the Conscience Provisions to override EMTALA, a separate statute. On the contrary, there is affirmative evidence that the sponsors of each of the Church, Coats-Snowe, and Weldon Amendments did *not* intend for these to require providers, in an emergency, to be obliged to accommodate an objecting employee. *See* 151 Cong. Rec. H177 (Jan. 25, 2005) (statement of Rep. Weldon) (referencing EMTALA's application to pregnant women and clarifying that Weldon Amendment "prevents Federal funding when courts and other government agencies force or require physicians, clinics and hospitals, and health insurers to participate in *elective* abortions . . . It simply prohibits coercion in *nonlife-threatening situations*" emphases added)); 142 Cong. Rec. S2269 (Mar. 19, 1996) (statement of Sen. Coats) (explaining that ob-gyns still have "sufficient training" to perform abortions "if necessary"); 119 Cong. Rec. 9601 (Mar. 27, 1973) (statement of Sen. Church) ("[I]n an emergency situation—life or death type—no hospital, religious or not, would deny such services.").[42] And the ACA is textually explicit on this point. It states that nothing in it, including its conscience protections, "shall be construed to relieve any healthcare provider from providing emergency services as required by State or Federal law, including . . . 'EMTALA.'" 42 U.S.C. § 18023(d).

HHS's latitude to rule-make in this area, even assuming authority for substantive rule-making, was therefore bounded by EMTALA. And the absence of any exception in the Rule's

[42] Consistent with this, a federal district court, examining the Weldon Amendment in 2008, long before promulgation of the 2019 Rule, noted that "there is no clear indication, either from the express language of the Weldon Amendment or from a federal official or agency that enforcing . . . EMTALA to require medical treatment for emergency medical conditions would be considered 'discrimination.'" *California v. United States*, No. C 05-00328 (JSW), 2008 WL 744840, at *4 (N.D. Cal. Mar. 18, 2008).

mandates for providers confronted with emergency medical situations creates a clear conflict between the Rule and EMTALA.[43]

This conflict, like that between the Rule and Title VII, is consequential. At argument, counsel for HHS acknowledged that the Rule could potentially impose liability on an employer for insisting that an objecting employee assist in urgent care, including for insisting that an ambulance driver complete a mission of transporting a patient to a hospital for an emergency procedure. *See* OA Tr. at 116–20 (addressing scenario in which driver, in Central Park transverse en route to hospital, ceased driving upon learning that patient sought emergency care for ectopic pregnancy). The Rule's limited exclusions from its definition of "discrimination," which require either that the objecting employee accept an effective accommodation or that the employer's accommodation not, *inter alia*, require action from the objecting employee, do not give an employer meaningful leeway to deal with a medical emergency. *See* 45 C.F.R. § 88.2(4), (6). The limits that the Rule imposes on asking employees about conscience objections, *id.* § 88.2(5), could also potentially limit a provider's range of motion in responding to an emergency.

[43] HHS's decision not to include an exception for emergencies was deliberate, as various commenters on the Rule as proposed noted the lack of such an exception or any reference to EMTALA, but the Rule was not thereafter amended. *See, e.g.*, Colangelo Decl. 2, Ex. 87 (N.Y. State Comment) at AR 137927; *id.*, Ex. 90 (Boston Med. Ctr. Comment) at AR 139292; *id.*, Ex. 103 (Anne Arundel Med. Ctr. Comment) at AR 147892; *id.*, Ex. 104 (Disability Coalition Comment) at AR 147954; *id.*, Ex. 113 (Planned Parenthood Comment) at AR 160755; *id.*, Ex. 114 (Ctr. for Reproductive Rights Comment) at AR 160821. These commenters expressed concern that the proposed Rule implied the lack of an "obligation to provide care in an emergency situation," despite EMTALA and similar "state laws reflect[ing] the long-standing obligation of health care institutions to provide assessment and care in an emergency." *Id.*, Ex. 115 (Medicare Rights Ctr. Comment) at AR 161036; *see also* Dkt. 101-1 ("Local Government Amici Br.") at 11–14 (describing shift created by Rule for emergency services provided by EMTs and paramedics).

HHS responds by stating that it plans to read the Rule alongside EMTALA to minimize the extent of conflict. *See* 84 Fed. Reg. at 23,183 (HHS "intends to read every law passed by Congress in harmony to the fullest extent possible" and "to give all laws their fullest effect possible"); *id*. at 23,188 ("[W]here EMTALA might apply in a particular case, the Department would apply both EMTALA and the relevant law under this rule harmoniously to the extent possible."); *see also* OA Tr. at 120. But this pledge does not eliminate the facial conflict with EMTALA presented by the Rule's application to emergency situations. And HHS's stated intention to view complaints involving emergencies with lenity does not, in the crucible, give a hospital, clinic, or unit of state or local government certainty that favoring the patient's needs over the employee's objections will not result in a loss of funding. *See* OA Tr. at 120 (HHS counsel acknowledging that hospital that does not accommodate objector in emergency could risk funding).

HHS's final argument to mitigate the conflict with EMTALA is that providers can double staff to ensure coverage in emergencies. *See* HHS Reply at 18. But that is a non-starter. A hospital, clinic, or ambulance service may lack the funds to hire extra personnel to assure that a conscience-cleared platoon is present or on call for every urgent scenario. And in an emergency, patients "may not have time to wait to be referred to another physician or other healthcare professional." Colangelo Decl. 2, Ex. 106 (Am. Coll. of Emergency Physicians Comment) at AR 147892 (emergency departments do not have the budget or staffing capacity "to be able to have additional personnel on hand 24 hours a day, 7 days a week to respond to different emergency situations that might arise involving patients with different backgrounds, sexual orientations, gender identities, or religious or cultural beliefs").

The Court accordingly holds that the Rule is not in accordance with law, insofar as it conflicts with EMTALA.

VI. Was HHS's Promulgation of the Rule Arbitrary and Capricious?

The Court next addresses plaintiffs' APA claim that the Rule's adoption was arbitrary and capricious.

A. Applicable Legal Principles Under the APA

Under the APA, courts are to "hold unlawful and set aside agency action" that is arbitrary and capricious. 5 U.S.C. § 706(2)(A). Although a court reviewing such action cannot "substitute its judgment for that of the agency," its "inquiry . . . is to be searching and careful." *Overton Park*, 401 U.S. at 416; *see also Nat. Res. Def. Council v. U.S. EPA*, 658 F.3d 200, 215 (2d Cir. 2011); *Nat. Res. Def. Council, Inc. v. FAA*, 564 F.3d 549, 555 (2d Cir. 2009). The court must determine if the agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). The agency must identify a "rational connection between the facts found and the choices made." *Id.* (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). The court must also assess whether the agency has considered the proper factors in taking its action. To that end, agency action is arbitrary and capricious if:

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.

Id.

A reviewing court's "scope of review is narrow." *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019) (internal quotation marks omitted). The court "may not supply a reasoned basis for the agency's actions that the agency itself has not given," *State Farm*, 463

U.S. at 43, because agency action may only be "upheld, if at all, on the basis articulated by the agency itself," *id.* at 50. *See also Overton Park*, 401 U.S. at 420 (noting that "review is to be based on the full administrative record that was before the [agency] at the time [it] made [its] decision"). "[C]ounsel's *post hoc* rationalizations for agency action" are not a valid basis to uphold such action. *State Farm*, 463 U.S. at 50.

B. Discussion

Plaintiffs argue that HHS, in four distinct ways, acted arbitrarily and capriciously in promulgating the Rule. They argue that (1) HHS's justifications for the Rule were contrary to the evidence before it; (2) HHS failed to supply a reasoned explanation for its policy change from the 2011 Rule to the 2019 Rule; (3) HHS failed to consider important aspects of the problem before it; and (4) HHS failed to properly account for the costs and benefits of the Rule. *See* State SJ at 13–38. The Court here considers the first three of these arguments.[44]

1. HHS's Justifications for the 2019 Rule

In the 2019 Rule's preamble, HHS sets out its justifications for promulgating the Rule. The agency stated that two problems caused it to act: (1) a "lack of awareness and . . . confusion" relating to the Conscience Provisions, "leading to possible violations of the law," and (2) the "[i]nadequate enforcement tools" HHS had to address violations of the Conscience Provisions. 84 Fed. Reg. at 23,228; *see also id.* at 23,175 (identifying these problems in "Overview of Reasons for the Final Rule"); *see also* HHS SJ at 53; HHS Reply at 24–25.

Plaintiffs argue that the record before the agency does not support these justifications for the Rule. *See* State SJ at 13–20. Plaintiffs are correct.

[44] Plaintiffs, in their reply brief, did not defend the fourth. And, given the holdings, *post*, as to plaintiffs' first three arguments why the Rule's promulgation was arbitrary and capricious, the Court has no occasion to consider the fourth.

It is hornbook administrative law that an agency must offer a "rational connection between the facts found and the choices made," and that whatever reason it offers, that reason cannot "run[ ] counter[ ] to the evidence before the agency." *State Farm*, 463 U.S. at 43. Here, HHS relied, in part, on the same evidence to show the existence of both problems that it claims justified promulgating the Rule: a "significant increase" in the complaints that HHS had received related to "the laws that were the subject of the 2011 Rule." *See* 84 Fed. Reg. at 23,175. This significant increase in complaints, HHS stated, revealed wide confusion about the Conscience Provisions and "underscore[d] the need for the Department to have the proper enforcement tools." *Id.*

In fact, upon the Court's review of the complaints on which HHS relies, virtually none address the Conscience Provisions at all, let alone indicate a deficiency in the agency's enforcement capabilities as to these laws. And HHS, in this litigation, admitted that only a tiny fraction of the complaints that its Rule invoked as support were even relevant to the Conscience Provisions. *See* OA Tr. at 94. A Court "cannot ignore the disconnect between the decision made and the explanation[s] given." *Dep't of Commerce*, 139 S. Ct. at 2575. As demonstrated below, HHS's central factual claim of a "significant increase" of complaints of Conscience Provision violations is flatly untrue. This alone makes the agency's decision to promulgate the Rule arbitrary and capricious.

a. Lack of Complaints Relating to the Conscience Provisions

In promulgating the Rule, HHS cited "a significant increase" in complaints since November 2016 that "alleg[e] violations" of the Conscience Provisions as demonstrating that the 2011 Rule had created confusion and necessitated agency action. 84 Fed. Reg. at 23,175; *see also* 83 Fed. Reg. at 3,903 (proposed rule seeks to address problem of confusion "leading to increased complaints"). Specifically, HHS stated there had been 34 such complaints between

November 2016 and January 2018, and 343 such complaints during fiscal year 2018. 84 Fed. Reg. at 23,229.[45]

HHS's claim of a significant increase in such complaints proves, however, demonstrably false.

The record before HHS reflects that 358 complaints were filed with OCR between November 2016 and the end of fiscal year 2018. *See* Miller Decl. ¶ 11; Colangelo Decl. 2, Ex. 135-D.[46] Of these 358, 22 are exact duplicates, yielding 336 unique complaints. *See* Miller Decl. ¶¶ 12–13; Colangelo Decl. 2, Ex. 135-E. Of these 336, 266—or 79%—relate to vaccinations, which HHS admits fall outside the scope of the Conscience Provisions and the Rule. *See* 84 Fed. Reg. at 23,183 (explaining that, under the Conscience Provisions and the Rule, States are not required to recognize conscience objections for vaccinations); *see also* Miller Decl. ¶ 15; Colangelo Decl. 2, Ex. 135-F.

[45] These time periods overlap, as the 2018 fiscal year ran from October 1, 2017 through September 30, 2018. *See* Colangelo Decl. 2, Ex. 135 ("Miller Decl.") ¶ 5 n.7.

[46] HHS objects to plaintiffs' submission of "extra-record" declarations, on the ground that APA review is limited to the administrative record. HHS Reply at 47–48. However, the portions of the Miller Declaration and accompanying exhibits cited by the Court do no more than collect and attach the complaints in the administrative record. The declaration is akin to a chart prepared by a summary witness admissible at trial under Federal Rule of Evidence 1006, which allows such charts to be received to make the content of such "voluminous . . . records" available to the finder of fact, where the records "cannot be conveniently examined" otherwise. *See* Fed. R. Evid. 1006. In any event, the Court has independently examined the complaints underlying the summaries in the Miller Declaration. HHS is also incorrect in its claim that the law categorically forbids such materials. Although judicial review on an APA claim is "*[g]enerally*" limited to the administrative record, *see Nat'l Audubon Soc'y*, 132 F.3d at 14 (emphasis added), the court may, at times, consider extra-record materials "to illuminate a complex record and to help the court better understand the issues involved," *New York v. U.S. Dep't of Commerce*, 351 F. Supp. 3d 502, 633 (S.D.N.Y. 2019).

From there, plaintiffs identify an additional 49 complaints that are unrelated to the Conscience Provisions because they, *inter alia*, oppose the Rule, involve entities not covered by the Rule, or do not allege conduct covered by the Rule. *See* Miller Decl. ¶ 16; Colangelo Decl. 2, Ex. 135-G. The Court's review validates plaintiffs' characterization of these 49 complaints.

This leaves 21—or a mere 6% of the 336 unique complaints—that are *potentially* related to the Conscience Provisions. Miller Decl. ¶ 17. And even though HHS quibbles at the margins about which complaints it categorizes as implicating the Conscience Provisions, it conceded, at argument, that only around 20 complaints implicate any of the Conscience Provisions. *See* OA Tr. at 94 ("THE COURT: Yes or no: Are we down to about 20 that actually implicate these statutes as opposed to other problems? MR. BATES: Yes. In that ballpark.").[47]

This conceded fact is fatal to HHS's stated justification for the Rule. Even assuming that all 20 or 21 complaints implicated the Conscience Provisions, those 20 or 21 are a far cry from the 343 that the Rule declared represented a "*significant* increase" in complaints. *See* 84 Fed. Reg. at 23,175 (emphasis added). The record does not reflect that 20 or 21 complaints would be a "significant increase" in complaints; HHS's claim of such an increase, based on a blatantly wrong factual tabulation, is "an unsupported assumption on which [HHS's] decision necessarily relied." *Nat. Res. Def. Council, Inc. v. Rauch*, 244 F. Supp. 3d 66, 95–96 (D.D.C. 2017) (invalidating rule where record "show[s] its critical . . . assumption to be false"). Because HHS

[47] Although HHS's counsel did not make this specific concession until pressed on the point at argument, its counsel, once confronted by plaintiffs' assessment of the administrative record after it was produced in this litigation, never stood by the claim in the Rule's preamble that 343 complaints implicated the Conscience Provisions. HHS instead admitted that "a large subset of [such complaints] complain of conduct that is outside the scope of Federal Conscience Statutes and the Rule," stating only that "*some* do implicate the relevant statutes." HHS SJ at 53 (emphasis added); *see also* HHS Reply at 26.

here relied on a claim—that 343 complaints had "alleg[ed] conscience violations," *id.* at 23,229—that "r[an] counter to the evidence before the agency," *State Farm*, 463 U.S. at 43, the Rule is arbitrary and capricious.

And the record before the agency is even thinner than that. HHS, in its briefing, was able to cite just 11 total complaints as support for the Rule. *See* HHS SJ at 53; HHS Reply at 26 n.5. Seven of these are fairly characterized as implicating the Conscience Provisions.[48] The rest cannot. For example, one complaint was filed by a group of physicians, the Association of Pro-Life Obstetricians and Gynecologists, complaining about an ethics opinion concerning abortion from the American College of Obstetricians and Gynecologists. That entity does not have any legal obligations under any Conscience Provision, and the complaint does not cite any specific instance of discrimination. *See* Colangelo Decl. 2, Ex. 129 at AR 544524–27. A second complaint alleged that Washington State's Department of Corrections had failed to provide a reasonable accommodation of an employee who refused to provide hormone therapy to those who sought to transition genders in prison. The complaint does not allege that this therapy was federally funded, so as to implicate a Conscience Provision. *See id.*, Ex. 127 at AR 544188.

[48] *See* Colangelo Decl. 2, Ex. 130 at AR 544612–16 (nurse complaining University of Vermont violated Church Amendments by coercing her to participate in elective abortions); HHS Reply, Ex. 6 at AR 542025 (unidentified entity complaining that California state agency violated Weldon Amendment by requiring California health care plans to cover elective abortions); *id.*, Ex. 7 at AR 542151–52 (nurse complaining that, after requesting religious accommodation for abortions, Duke placed her on paid leave and did not respond to her request); *id.*, Ex. 8 at AR 542285–87 (pregnancy and counseling center complaining that Hawaii law required pregnancy centers to advertise contraception and abortion); *id.*, Ex. 10 at AR 542337–38 (nurse complaining that Winnebago County Health Department fired her for objecting to abortion); *id.*, Ex. 12 at AR 545932–33 (interviewee complaining Indiana University South Bend did not hire her for full-time faculty position because she was pro-life, in violation of Church Amendments); *id.*, Ex. 13 at AR 542237–40 (physician complaining that Illinois law requires him to participate in and refer women to abortions).

Similarly, a complaint from a pharmacist that he/she was required to fill contraception prescriptions does not, on its face, implicate a Conscience Provision. *See* HHS Reply, Ex. 14 at AR 544945. Unless HHS interprets abortion to encompass contraception,[49] contraception would not fall within the protections for abortion and sterilization under § 300–a7(b), (c)(1), or (e) of the Church Amendments, or the protections for abortion under the Coats-Snowe or Weldon Amendments.[50] And a fourth, filed by the Little Sisters of the Poor, focused on a Pennsylvania lawsuit that challenged HHS regulations interpreting an ACA exemption to its contraception mandate. This question involved the scope of that ACA exemption, not a Conscience Provision. *See* Colangelo Decl. 3, Ex. 139 at AR 542324.

HHS unpersuasively argues that, even setting aside the irrelevant complaints, these shards represented a sufficient increase to justify the Rule. At argument, agency counsel pointed out that before the 2018 NPRM, HHS had received approximately one complaint per year related to the Conscience Provisions, whereas after the NPRM issued on January 26, 2018, that number of relevant complaints (by HHS's tabulation) increased to 10.[51] *See* OA Tr. at 91; *see also id.* at

[49] This was a major concern expressed about the 2008 Rule, although it has not been expressed in connection with the 2019 Rule. *See* 76 Fed. Reg. at 9,973–74 (explaining that one reason for rescinding the 2008 Rule was confusion as to whether "abortion" included "contraception").

[50] This complaint would relate to a Conscience Provision—specifically, § 300a–7(d) of the Church Amendments—only if the prescription were a "health service program" at least partially funded by an HHS program, such as Medicaid. The face of this complaint does not so indicate.

[51] By the Court's review, of the 11 complaints that HHS cited in its briefing, four were filed after the NPRM. *See* HHS Reply, Ex. 14 at AR 544945 (signed September 17, 2018); Colangelo Decl. 2, Ex. 130 at AR 544612 (filed May 11, 2018); *id.*, Ex. 129 at AR 544524 (dated March 23, 2018); *id.*, Ex. 127 at AR 544188 (signed March 6, 2018). All but one of the remainder were filed after the Attorney General's October 6, 2017 memorandum, providing guidance to agencies executing religious liberty laws. *See* HHS Reply, Ex. 6 at AR 542017 (signed October 9, 2017); *id.*, Ex. 7 at AR 542151 (dated December 4, 2017); *id.*, Ex. 8 at AR 542285 (dated January 10,

132. But before the agency issued its NPRM, as HHS acknowledges, there had been *no* increase in complaints. *See id.* at 132. The few complaints implicating the Conscience Provisions after the NPRM are more likely attributed to the 2018 NPRM, rather than an increase, independent of the NPRM, in Conscience Provision violations or, as HHS claimed, in public confusion about these laws. *See* 76 Fed. Reg. at 9,969 (HHS statement that 2008 Rule had caused "greater confusion" in its attempt to clarify the Conscience Provisions).

In all events, far from reflecting a "significant increase" in complaints implicating the Conscience Provisions as claimed by HHS, the administrative record reflects either no increase at all, or that any increase was so small as to be asymptotic to zero. The complaints before the agency, the purported justification for the Rule, do not supply any such justification.

b. Lack of Complaints Indicating Ineffective Enforcement Tools

In promulgating the Rule, HHS also stated that the "significant increase" in complaints since November 2016 "underscores the need for the Department to have proper enforcement tools available to appropriately enforce" the Conscience Provisions. 84 Fed. Reg. at 23,175; *see also id.* at 23,183 ("This rule provides appropriate enforcement mechanisms in response to a significant increase in complaints."). Setting aside the tension between this justification and HHS's statement in defense of the Rule that the Rule did not furnish the agency with any new enforcement power, the complaints do not bear out the contention, either, that new enforcement tools were needed.

To show a "rational connection between the facts found and the choice made," *State Farm*, 463 U.S. at 43, HHS would need to point to *some* facts indicating problems with its

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2018); *id.*, Ex. 10 at AR 542337 (dated January 16, 2018); *id.*, Ex. 13 at AR 542229 (dated January 4, 2018); Colangelo Decl. 3, Ex. 139 at AR 542316 (signed January 11, 2018).

capacity to enforce the Conscience Provisions. HHS has failed to do so. Of *all* the complaints in the administrative record—even including ones filed before November 2016, when HHS claims an increase in complaints began—the record identifies only a small fraction as having even been investigated by HHS.[52] *See* Miller Decl. ¶ 18; Colangelo Decl. 2, Ex. H (identifying 14 resolved complaints). Aside from two pre-2016 complaints,[53] all investigations in the record appear to have been closed. At argument, HHS counsel explained that in the past three years, HHS has made violation findings—formally, informally, or in any other manner—in just three cases. *See* OA Tr. at 87–88. None appeared to raise any concerns about HHS's enforcement capability. *See id.* at 90–91. And the administrative record is devoid of any evidence that HHS, to the limited degree it has ever investigated complaints in this area or attempted to take enforcement action, found its remedial tools wanting.[54]

Given the absence of evidence of any enforcement shortcoming, HHS's claim that the Rule was justified by a need to remedy its "[i]nadequate enforcement tools" is unsubstantiated by the administrative record. *See* 84 Fed. Reg. at 23,228. Where there is "no direct evidence" to support an agency's decision, that decision is arbitrary and capricious. *State Farm*, 463 U.S. at

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[52] Just one of these was filed in fiscal year 2018. *See* Colangelo Decl. 2, Ex. 135-G.

[53] *See* Colangelo Decl. 2, Ex. 132, AR at 545712; *id.*, Ex. 133, AR at 545736; *see also* 83 Fed. Reg. at 3,886–87.

[54] At argument, HHS counsel cited an investigation of the University of Vermont, connected with the complaint at AR 544612, as having raised unspecified enforcement concerns. *See* OA Tr. at 88; *see also* Colangelo Decl. 2, Ex. 130. That investigation was the only one in which HHS appears to have made a formal finding of a violation of the Conscience Provisions. *See* OA Tr. at 88. The investigation, however, occurred after the Rule's promulgation and is thus outside of the administrative record. Because these facts were not before HHS when it decided to promulgate the Rule, the Court cannot consider it in its analysis of whether HHS acted arbitrarily and capriciously. *See Nat'l Audubon Soc'y*, 132 F.3d at 14 ("Generally, a court reviewing an agency decision is confined to the administrative record compiled by that agency when it made the decision.").

52–53 (pointing to lack of direct evidence to support agency finding that detachable automatic seatbelts may not lead to increase in seatbelt usage); *see also Islander E. Pipeline Co. v. Conn. Dep't of Envtl. Prot.*, 482 F.3d 79, 103 (2d Cir. 2006) ("[W]here the record directly contradicts the unsupported reasoning of the agency and the agency fails to support its pronouncements with data or evidence, we may not defer.").

c. Lack of Complaints Supporting the Rule's Scope

Finally, even if the complaints to HHS had demonstrated increasing confusion about the Conscience Provisions, increasing violations of these, or a need for enhanced enforcement tools, the record does not support the breadth of the Rule promulgated by HHS. The Rule's most consequential provisions, as reviewed above, are its definitions of Conscience Provision terms, which would significantly expand the Rule's coverage. But HHS has not pointed to evidence substantiating a need for such definitions. For example, although HHS argues that the "assist in the performance" definition is textually defensible, *see* HHS SJ 29–34, it does not point to any evidence in the administrative record justifying the application of the Conscience Provisions to persons with ancillary connections to a covered procedure—*e.g.*, a scheduler, ambulance driver, receptionist, or billing department clerk. *See* OA Tr. at 123–27. HHS admits that it is unaware of any complaint—in the administrative record or otherwise—of a Conscience Provision violation involving a person in such a role. *See id.* at 127 ("THE COURT: Is the agency aware of any receptionist, ambulance driver, elevator repairman, anybody, who ever complained that their ancillary work, other than on the day of the procedure, was violating their conscience rights? MR. BATES: Not that I'm aware of, Your Honor.").

HHS therefore has not articulated a "rational connection" between the facts before it and the choices it made. *State Farm*, 463 U.S. at 43. Where HHS claimed that the Rule was justified by complaints made to it, the administrative record reflects a yawning evidentiary gap.

Considering these deficiencies in totality, it is clear that HHS's justification for the Rule—that a "significant increase" in complaints called for agency action—is wholly unsupported by the record. Where the record does not support an agency's stated factual basis for a decision, the agency has acted in an arbitrary and capricious manner, and its decision "must be set aside." *Mizerak v. Adams*, 682 F.2d 374, 376 (2d Cir. 1982) ("[A]n agency decision is arbitrary and must be set aside when it rests on a crucial factual premise shown by the agency's records to be indisputably incorrect."); *see also Dep't of Commerce*, 139 S. Ct. at 2575 ("[T]he evidence tells a story that does not match the explanation the Secretary gave for his decision."); *City of Kansas City, Mo. v. Dep't 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, and cannot survive review under the arbitrary and capricious standard."); *Batalla Vidal v. Nielsen*, 279 F. Supp. 3d 401, 427 (E.D.N.Y. 2018) ("This conclusion was also arbitrary and capricious because it is based on an obvious factual mistake . . . This error alone is grounds for setting aside Defendants' decision."); *Choice Care Health Plan, Inc. v. Azar*, 315 F. Supp. 3d 440, 443 (D.D.C. 2018) (explaining that "the facts on which the agency purports to have relied" must "have some basis in the record"); *Rauch*, 244 F. Supp. 3d at 96 ("Suffice it to say, it is arbitrary and capricious for an agency to base its decision on a factual premise that the record plainly showed to be wrong.").

That is precisely what happened here. HHS has promulgated a Rule that did not respond to any documented problem. The Rule represents a classic solution in search of a problem. *See Nat'l Nutritional Foods Ass'n v. Goyan*, 493 F. Supp. 1044, 1046 (S.D.N.Y. 1980) ("[A] 'regulation perfectly reasonable and appropriate in the face of a given problem may be highly capricious if that problem does not exist.'" (quoting *City of Chicago v. Fed. Power Comm'n*, 458

F.2d 731, 742 (D.C. Cir. 1971))); *see also ALLTEL Corp. v. FCC*, 838 F.2d 551, 561 (D.C. Cir. 1988) ("We do, of course, accord deference to a determination by the [agency] that a problem exists within its regulatory domain, but deference is not a blank check."). For this reason alone, the Rule's promulgation was arbitrary and capricious.

Finally, the Court notes that HHS, in its reply brief, cites other evidence ostensibly supporting a new rule, including a 2009 survey, comments from the earlier rulemakings and the 2019 rulemaking, and recent litigation challenging various state laws. HHS Reply at 25. But HHS, like the Rule itself, continues to rely on the purported increase in complaints as a principal basis for the Rule. *See id.* at 25–27 (complaints supported HHS's determination that "'there is a significant need to amend the 2011 Rule to ensure knowledge of, compliance with, and enforcement of' the Federal Conscience Statutes" (quoting 84 Fed. Reg. at 23,175)); *see also* HHS SJ at 53 ("[T]he complaints overall illustrate the need for HHS to clarify the scope and effect of the Federal Conscience Statutes."). Because these complaints do not substantiate HHS's claim of a problem meriting rulemaking, HHS's reliance even "*in part* on the basis of" these patently inapposite complaints is enough to render the Rule arbitrary and capricious. *See Animal Legal Def. Fund, Inc. v. Perdue*, 872 F.3d 602, 619 (D.C. Cir. 2017) (emphasis added) (invalidating agency decision to renew a zoo keeper's license, where agency had relied "in part" on the zoo keeper's false self-certification).[55]

[55] Although a court may sustain agency action "[w]hen an agency relies on multiple grounds for its decision, some of which are invalid," this can only occur "as long as one is valid and 'the agency would clearly have acted on that ground even if the other were unavailable.'" *Batalla Vidal*, 279 F. Supp. 3d at 433 (quoting *Mail Order Ass'n of Am. v. U.S. Postal Serv.*, 2 F.3d 408, 434 (D.C. Cir. 1993)). Here, even if HHS had articulated justifications for the Rule that were supported by the record, it is not at all clear that HHS would have acted without the complaints. Because HHS rested the Rule, "at least in part, on its infirm [complaint] ground," the Rule must be set aside as arbitrary and capricious. *Williams Gas Processing-Gulf Coast Co. v. FERC*, 475 F.3d 319, 330 (D.C. Cir. 2006).

2. HHS's Explanation for Its Change in Policy

An agency generally has latitude to change its policies, as long as it provides a "reasoned explanation" for doing so. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). An agency must "display awareness that it *is* changing position" and "show that there are good reasons" for its new policy, but it need not show that "the reasons for the new policy are *better* than the reasons for the old one." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (emphasis in original).

An agency's "flexibility" to change its policies, however, does have "limits." *United Steel v. Mine Safety and Health Admin.*, 925 F.3d 1279, 1284 (D.C. Cir. 2019). Although an "agency need not always provide a more detailed justification than would suffice for a new policy created on a blank slate," "[s]ometimes it must." *Fox Television Stations*, 556 U.S. at 515. Relevant here, as the Supreme Court has explained, a more detailed justification is required when (1) the "new policy rests upon factual findings that contradict those which underlay its prior policy," or (2) "its prior policy has engendered serious reliance interests." *Id.*; *see also Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015). A "reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Fox Television Stations*, 556 U.S. at 516. An agency must supply such an explanation as "[i]t would be arbitrary or capricious to ignore such matters." *Id.* at 515. An "[u]nexplained inconsistency" in agency policy is sufficient to render agency action arbitrary and capricious. *Encino Motorcars*, 136 S. Ct. at 2126 (alteration in original) (quoting *Nat'l Cable & Telecommc'ns Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)).

Plaintiffs argue that the "more detailed justification" was required here because both alternative conditions identified in *Fox Television Stations* are present. The Rule, plaintiffs argue, rests on factual findings that contradict that on which the 2011 Rule was based; and it

implicates reliance interests of funding recipients. *See* State SJ at 20. For the reasons that follow, that assessment is correct. And while HHS did acknowledge that it was changing course in amending the preceding Rule, *see* 84 Fed. Reg. at 23,175, its explanation for doing so fell short of that required to meet the *Fox Television Stations* standard.

a. Contradictory Factual Findings

In promulgating the 2011 Rule, HHS mostly rescinded the 2008 Rule. As reviewed above, the 2019 Rule largely resuscitated the 2008 Rule. While the 2019 Rule reached farther—it built upon the 2008 Rule, including by defining added terms and by implementing a broader set of Conscience Provisions—the 2008 and 2019 Rules have in common that each interpreted the Church, Coats-Snowe, and Weldon Amendments; contained definitions for "assist in the performance" and "health care entity"; imposed a certification requirement; and granted OCR investigative powers for these three Conscience Provisions.

Salient here, in adopting the 2011 Rule that largely rescinded the 2008 Rule, HHS had articulated its reasons for doing so. These centrally included findings that (1) the 2008 Rule, which attempted to clarify the Conscience Provisions, "instead led to greater confusion," 83 Fed. Reg. at 9,969; and (2) the 2008 Rule "may negatively affect the ability of patients to access care if interpreted broadly," *id.* at 9,974.

As a result, when HHS, in 2019, departed from the agency's 2011 findings, it was obliged to provide a "detailed justification" for doing so. *Fox Television Stations*, 556 U.S. at 515; *see id*. at 537 (Kennedy, J., concurring) (an agency "cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore

inconvenient facts when it writes on a blank slate"). The parties debate whether HHS's 2019 explanations for departing from these two findings were satisfactory.[56]

i. Confusion

A major reason for HHS's implementation of the 2011 Rule was its finding that the 2008 Rule, in "attempting to clarify the Federal health care provider conscience statutes[,] ha[d] instead led to greater confusion." 76 Fed. Reg. at 9,969. In making this finding, HHS relied on comments it had solicited regarding "whether the 2008 Final Rule provide[d] sufficient clarity to minimize the potential harm resulting from any ambiguity and confusion that may exist because of the rule." *Id.* at 9,971. Having received and reviewed "[m]any comments" that "indicated that the 2008 Final Rule created confusion" about what the Conscience Provisions authorized, HHS stated that it "agree[d]" with such comments. *Id.* at 9,973. It rescinded the 2008 definitions—including of "assist in the performance" and "health care entity"—"because of concerns that they may have caused confusion regarding the scope" of the Conscience Provisions. *Id.* at 9,974. HHS in 2011 declined to articulate new definitions. Instead, it stated, it would use individual investigations as "the best means of answering questions about the applications of the statutes in particular circumstances." *Id.*

In promulgating the 2019 Rule, HHS stated that, in fact, the 2011 Rule was the source of enhanced confusion as to the Conscience Provisions' scope. Relying in part on the influx of complaints that the agency claimed to have received, HHS now found that the "2011 Rule created confusion over what is and is not required under" the Conscience Provisions. 84 Fed.

[56] Plaintiffs claim that the 2019 Rule also gave short shrift to another finding underlying the 2011 Rule: that the 2008 Rule's certification requirement had "created unnecessary additional financial and administrative burdens on healthcare entities." *See* State SJ at 21 (citing 83 Fed. Reg. at 9,974). In light of its holdings that HHS's explanations with respect to its changes of view regarding confusion and access to care were fatally inadequate, the Court does not have occasion to reach that claim.

Reg. at 23,175. Its solution was the 2019 Rule, *see id.* at 23,228, which adopted similar definitions to those in the 2008 Rule, despite HHS's having, in between, identified these as creating confusion.

HHS argues that it provided a reasoned explanation for reinstating components of a Rule that it had earlier denounced as confusing. It notes the 2019 Rule stated that, "[a]fter reviewing the previous rulemakings, comments from the public, and OCR's enforcement activities," HHS had concluded that the 2011 Rule had caused confusion that the new Rule would rectify. HHS Reply at 24 (alteration in original) (quoting 83 Fed. Reg. at 3,887); *see also* 84 Fed. Reg. at 23,175.

The Supreme Court, however, has rejected an agency's similarly terse explanation as inadequate to justify a policy reversal. In *Encino Motorcars*, the Court held that a "summary discussion" by the United States Department of Labor had fallen short of the *Fox Television Stations* standard. 136 S. Ct. at 2126–27. The Department, the Court explained, in noting the "good reasons" for its policy change, had "said almost nothing." *Id*. at 2127. The agency had stated, in a conclusory fashion, that it had "carefully considered all of the comments, analyses, and arguments made for and against the proposed changes," and recognized that some comments indicated reliance on the agency's previous policy, but this was not enough. *Id.* at 2126–27. HHS's account here is no more discursive or illuminating. In particular, in acknowledging its reversal of course, HHS did not even acknowledge its previous contrary factual finding. It therefore did not give a reasoned explanation as to why the reinstated terms of the 2008 Rule were needed to rectify, as opposed to being a source of, confusion.

A decision this year from the D.C. Circuit confirms that HHS's failure to acknowledge its earlier contrary factual finding was a rulemaking lapse. *See United Steel*, 925 F.3d at 1284–

85. In *United Steel*, the D.C. Circuit applied the *Fox Television Stations* test to a rule adopted by the Mine Safety and Health Administration ("MSHA"). *See id.* In 2017, the agency had implemented a standard that required safety inspections to occur before miners started working in the mine, which MSHA then determined would enhance safety by "reduc[ing] the variability" of when inspections occurred. *Id.* at 1284. But, in 2018, the agency adopted a new standard that allowed the inspections to occur before or while the miners worked, "reintroduc[ing] that very same variability" the earlier standard had sought to curb. *Id.* The D.C. Circuit held that the MSHA had failed to satisfy the *Fox Television Stations* standard, insofar as it had "completely ignored its previous finding that increased . . . variability . . . does not improve miner safety." *Id.* at 1284–85.

This case is indistinguishable. HHS initially rescinded the 2008 Rule's definitions, finding them to cause confusion; but now it has reinstated these definitions without engaging with, or even acknowledging, its earlier contrary finding. This "unexplained inconsistency" makes the reinstatement of the rescinded provisions arbitrary and capricious. *Encino Motorcars*, 136 S. Ct. at 2126 (alteration omitted).

ii. Access to Care

HHS did a similar about-face in considering the effect of its rules on access to health care. Before the 2011 Rule was promulgated, HHS sought comment as to whether the 2008 Rule ran the risk of "reduce[d] access to information and health care services, particularly by low-income women." 76 Fed. Reg. at 9,971. HHS found that an "overwhelming number" of the 97,000 comments it had received indicated concern that the 2008 Rule could limit access to care. *Id.* HHS then "agree[d] with comments that the 2008 Final Rule may negatively affect the ability of patients to access care if interpreted broadly"; it noted, in particular, the concern that the Rule might limit access to reproductive services and contraception for women, especially in

areas with few providers. *Id.* at 9,974. HHS "partially rescind[ed] the 2008 Final Rule based on [the] concerns . . . that it had the potential to negatively impact patient access" to certain services. *Id.*

In promulgating the 2019 Rule, HHS reached the opposite conclusion: It stated that it "[did] not believe that this rule will harm access to care," 84 Fed. Reg. at 23,180, but instead "expect[ed] the rule to enhance, not impede, access to care," including in areas "with fewer providers," *id.* at 23,182. The agency acknowledged comments regarding access to health care it had received at the time of the *2008 Rule*, and stated that it "agree[d] with its previous response." *Id.* at 23,180. But HHS, in adopting the 2019 Rule, did not once address its intervening 2011 finding that access to care would diminish were the rescinded terms of the 2008 Rule in place. Instead, in the 2019 Rule, HHS shrugged off the issue by noting the absence of "empirical data" regarding how rules in this area would affect access to care. *Id.* at 23,180; *see also id.* at 23,247. It decided that "finalizing the rule is appropriate" in the absence of data bearing on the "competing contentions about its effect on access to services." *Id.* at 23,182.

Given the broad latitude agencies enjoy, HHS's explanation in the 2019 Rule of why it believes the new rule would increase access to care, *see id.* at 23,180–90; 23,246–54, had it been articulated in connection with an original act of rulemaking, might well be sufficiently reasoned to defeat a claim of arbitrary and capricious action. But *Fox Television Stations* requires more for an agency to repudiate a policy based on contrary factual findings. The agency must "provide a more detailed justification than what would suffice for a new policy created on a blank slate," 566 U.S. at 515, and "cannot simply disregard contrary or inconvenient factual determinations that it made in the past," *id.* at 537 (Kennedy, J., concurring). On the issue of

access to care, HHS's rulemaking failed this standard, because HHS failed altogether even to acknowledge its previous contrary finding that a rule along these lines could limit such access.

HHS counters with several arguments, but none are availing.

First, it argues that it was entitled to "give more weight" to concerns raised in its previous rulemakings, and to come to a different decision "even on precisely the same record." HHS Reply at 24 (quoting *Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (en banc)). But this case is not fairly likened to ones in which an agency "simply rebalance[d] old facts to arrive at a new policy," *Organized Vill. of Kake*, 795 F.3d at 968; *see also Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1037–38 (D.C. Cir. 2012) (agency did not need to meet *Fox* standard when it relied not on new, contrary factual findings, but "rather on a reevaluation of which policy would be better in light of the facts"); methodically explained how new pieces of evidence undermined its prior factual finding, *see Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 729–31 (D.C. Cir. 2016); employed a "different method" for addressing access to care, *Mozilla Corp. v. FCC*, 940 F.3d 1, 56 (D.C. Cir. 2019); promulgated a rule as to which an earlier contrary factual finding was unimportant, *U.S. Telecom Ass'n v. FCC*, 825 F.3d 674, 709 (D.C. Cir. 2016); or made a determination on an "entirely new record" that was "supported with new . . . findings," *Ark Initiative v. Tidwell*, 816 F.3d 119, 130 (D.C. Cir. 2016) (distinguishing *Organized Village of Kake*). HHS's flaw here is that, faced with an "overall decisionmaking picture [that] was not substantially different" from that it faced in 2011, it ignored its prior factual finding (that the Rule would decrease access to care) in favor of a new, contradictory one (that a similar rule would increase access to care) without acknowledging or

explaining the inconsistency in its positions. *See Organized Vill. of Kake*, 795 F.3d at 962 (internal quotation marks omitted).[57]

Second, HHS argues that it reached its conclusion regarding access to care by relying on various pieces of evidence, including "its own analysis, the comments it received in response to the NPRM, anecdotal evidence, and . . . [a] 2009 poll," and that it had no obligation to conduct new empirical studies on access to care after the 2011 Rule's promulgation.[58] HHS SJ at 54. That, however, is beside the point. HHS "was not required to refute the factual underpinnings of its prior policy with new factual data," but it was obliged under the APA to acknowledge its prior finding and provide a reasoned explanation for disregarding it. *U.S. Sugar Corp. v. EPA*, 830 F.3d 579, 626 (D.C. Cir. 2016) (holding agency's explanation sufficient where it described why

[57] *Organized Village of Kake*, on which both sides rely, supports plaintiffs' critique. The Ninth Circuit there considered successive "Roadless Rules" imposed by the United States Department of Agriculture which determined which lands should not have roads in order to preserve their "roadless value," such as the lands' "scientific, environmental, recreational, and aesthetic attributes." *Organized Vill. of Kake*, 795 F.3d at 959. At issue was whether Alaska's Tongass National Forest should be exempted from a Roadless Rule. *See id.* at 959–60. In the agency's 2001 Roadless Rule, it found that exempting the Tongass Forest would "risk the loss of important roadless area values." *Id.* at 968. But, after a change of Administration, the agency promulgated the 2003 Roadless Rule, in which it found, "in direct contradiction" to the 2001 rule, that the Tongass Forest should be exempted because including it was "unnecessary to maintain the roadless values." *Id.* The Ninth Circuit held that the agency had failed the *Fox Television Stations* standard, because its 2003 finding as to the Tongass Forest was a directly contradictory factual finding to its earlier one, was "a critical underpinning" of the 2003 Roadless Rule, and was not a case of an agency simply "rebalance[ing] old facts to arrive at the new policy" or of valuing economic concerns over environmental concerns. *Id.* Similarly here, HHS has announced a contradictory factual finding with regard to the impact of a similar rule on access to care—"a critical underpinning" of the 2019 Rule. As *Organized Village of Kake* reflects, an agency must engage with, and provide a justification for, the inconsistency with its prior material assessment.

[58] The parties vigorously dispute the value of the 2009 poll. *Compare* Provider PI at 22–23, *with* HHS SJ at 53–54. The Court does not have occasion to resolve this issue, save to note that the 2009 poll had been part of the record before the agency at the time of the 2011 Rule.

its prior decision "focused too narrowly" on certain facts without consideration of other important facts).

HHS ultimately argues that "it is reasonable to assume" that the 2019 Rule "may, in fact, induce more people to enter or remain in the health care field" and thus the Rule is "reasonably likely to increase, not decrease, access to care." 84 Fed. Reg. at 23,180. Agencies do indeed often deserve deference "in matters implicating predictive judgments," *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009), but, given HHS's prior conclusion to the contrary, such an assumption is insufficient to carry the day. *See Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 708 (D.C. Cir. 2014) (deference must be based on "some logic and evidence, not sheer speculation"); *see also California v. Azar*, 385 F. Supp. 3d 960, 1004–05 (N.D. Cal. 2019) (dismissing HHS's argument that it could rely on predictive judgments to justify a new Title X regulation seeking to prevent abuse of funds, given HHS's contrary assessments in connection with preceding current regulations). In light of the agency's prior factual assessment that its 2008 Rule could impede access to care, HHS's bare contrary *assumption* in 2019 was not the "more detailed justification" required by *Fox Television Stations*. *See Azar*, 385 F. Supp. 3d at 1002–03, 1007 (holding HHS's "speculative justifications" and "belie[f]" that its new Title X regulation would provide "improved client care" insufficient to justify that regulation). HHS's disregard for its prior pronouncement on the same factual point, too, was arbitrary and capricious.

b. Reliance Interests

HHS was also obliged under the APA to consider the "serious reliance interests" engendered by its prior interpretations of the Conscience Provisions. *Fox Television Stations*, 556 U.S. at 515. As reviewed earlier, the 2019 Rule would reshape the substantive contours of the Conscience Provisions, significantly expanding the obligations of employers and other HHS

funding recipients with respect to accommodating conscience objections and creating conflicts with the legal frameworks set by Title VII and EMTALA as to when religious or conscience objections must be accommodated in the health care arena. As explained below, because the 2019 Rule disrupts the reliance interests of various entities based on the status quo, HHS was obliged to consider the Rule's impact on these interests, and give "a more detailed justification" for a disruption of these interests. *Id.*

As the administrative record chronicles in impressive detail, plaintiffs and other funding recipients have relied on—they have shaped their conduct around—HHS's historical application of the decades-old Conscience Provisions, the first of which dates to 1973. Save to a degree during the short-lived 2008 Rule, which prefigured a portion of the 2019 Rule, these statutes have never been read as the 2019 Rule reads them, and the 2019 Rule's transformative definition of "discrimination" is altogether new. The record reflects that HHS funding recipients have relied on a common pre-2019 understanding of the Conscience Provisions in, *inter alia*, making hiring decisions, entering into employee contracts and collective bargaining agreements, implementing staffing arrangements, developing existing practices and policies to accommodate conscience objections, and conducting their general business operations.[59] Were the Rule to take

[59] *See, e.g.*, Colangelo Decl. 2, Ex. 73 (Am. Hosp. Ass'n Comment) at AR 67415 (noting that "[h]ospitals have existing policies, procedures, and best practices" to address accommodations); *id.*, Ex. 81 (S.F. Dep't of Pub. Health Comment) at AR at 134793 (noting that the Rule ignores "contractual obligations" to employees and collective bargaining agreements among employees; and that the Rule "appears to create administrative obstacles to providing employees with religious accommodations"); *id.*, Ex. 89 (NFPRHA Comment) at AR 138109, 138112 (highlighting issues with subrecipient relationships; and separately, with changes that must be made to, *inter alia*, human resource materials, hiring, employee training, and staffing); *id.*, Ex. 90 (Boston Med. Ctr. Comment) at AR 139288–92 (describing existing policies and procedures for accommodating objecting employees, the additional costs to hospitals to come into compliance, and conflicts with current Title VII and EMTALA obligations); *id.*, Ex. 92 (Kaiser Permanente Comment) at AR 139640 (explaining that Rule could "impact the business

effect, however, these entities would need to conform their conduct to it, lest they risk a loss of funding.

The interests of plaintiffs and others here are fairly likened to the reliance interests the Supreme Court recognized in *Encino Motorcars*: "decades of industry reliance" on an agency's "prior policy," where the agency's "new position could necessitate systemic, significant changes" with those who fail to comply facing "substantial . . . liability," "even if this risk of liability" could be diminished by potentially applicable statutory exemptions or defenses. *See Encino Motorcars*, 136 S. Ct. at 2126; *see also Azar*, 385 F. Supp. at 1006–07 (explaining reliance interests for Title X regulation included, *inter alia*, new physical infrastructure, an "overhaul" of programming, "revamp[ing]" of "medical records systems and financial records," and "hir[ing] new staff and personnel"). HHS was therefore obligated to give a "reasoned explanation" for the policy change, taking into account these interests. *Encino Motorcars*, 136 S. Ct. at 2126. That the entities with reliance interests were funded by HHS did not change this obligation: "[C]ourts have recognized serious reliance interests in discretionary grants of

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operations" of hospitals and others in the health care industry, including "rules governing the relationships with employees, contracts with other entities, and systems of compliance"); *id.*, Ex. 96 (BlueCross BlueShield Ass'n Comment) at AR 140271 (describing belief that already-hired health insurance issuer employees were not covered by Conscience Provisions); *id.*, Ex. 99 (N.Y.C. Comm'n on Human Rights Comment) at AR 140486 (describing changes to accommodation procedures and burden of needing to hire more staff); *id.*, Ex. 101 (Greater N.Y. Hosp. Ass'n Comment) at AR 147825–27 (explaining that conscience protections have been in place since the 1970s; "hospitals are familiar with how to balance workers' conscience rights with patients' rights" and have "actual hospital policies and procedures" for accommodations, including an employee duty to notify of objections; and the Rule's expansion of who is covered makes it "more difficult" to "predict[ ] and plan[ ] for scenarios in which conscience rights might need to be exercised"); *id.*, Ex. 106 (Am. Coll. of Emergency Physicians Comment) at AR 147981 (explaining that emergency departments "do not have the staffing capacity" to double staff).

benefits that do not arise from statute." *Azar*, 385 F. Supp. at 1007 (finding reliance interests for HHS's Title X grants).

HHS failed to supply such an explanation here. Indeed, the Rule came close to failing even to acknowledge the existence of such reliance interests. It does not squarely address such interests anywhere in the Rule, and it omits a concrete discussion of even contexts presenting acute reliance interests.[60] HHS did state in the Rule, in its cost-benefit analysis, that it estimates that a little over 5% of "recipients will spend an average of 4 hours to update policies and procedures, implement staffing or scheduling practices that respect an exercise of conscience rights under Federal law, or disseminate the recipient's policies or procedures." 84 Fed. Reg. at 23,241. But the agency then adds the observation that "[i]f entities were already fully taking steps to be educated on, and comply with, all the laws that are the subject of this rule, there would likely not be any costs." *Id.* That statement reflects the agency's central misapprehension—addressed and rejected earlier—that the Rule does not mark a substantive departure from the status quo. That misapprehension calls into grave question the agency's summary assessment of the affected reliance interests as minimal.

HHS's failure to seriously and conscientiously consider recipients' reliance interests, too, made the Rule arbitrary and capricious, consistent with the holdings in numerous cases finding similar deficiencies in agency rulemaking. *See, e.g.*, *Batalla Vidal*, 279 F. Supp. at 431 ("[T]he agency must consider 'serious reliance interests' engendered by the previous policy."); *see also Mozilla Corp.*, 940 F.3d at 63 ("The Commission acknowledged, as it must, the significance of reliance interests as a potential weight against its decision."); *U.S. Telecom Ass'n*, 825 F.3d at

[60] HHS admits in its reply that, for example, it did not consider comments related to the impact of the Rule on collective bargaining agreements. *See* HHS Reply at 30 n.7.

709 (finding that agency "did not fail to 'account' for reliance interests" because "it expressly considered the claims of reliance"); *In re FCC 11-161*, 753 F.3d 1015, 1143 (10th Cir. 2014) (Bacharach, J., concurring in part and dissenting in part) ("It surely would have been arbitrary and capricious if the FCC had disregarded the . . . reliance interests."); *Batalla Vidal*, 279 F. Supp. 3d at 431 (finding arbitrary and capricious the absence of record evidence "that Defendants acknowledged, let alone considered, these or any other reliance interests").

Even if HHS were viewed as having adequately acknowledged the reliance interests implicated by the 2019 Rule, it did not provide the required "more detailed justification" for impinging on these interests. *Fox Television Stations*, 556 U.S. at 515. Most strikingly, the administrative record chronicles that funding recipients subject to the Rule have widely hired employees on the assumption that their duties to accommodate conscience objections from such employees would be shaped by the existing Title VII accommodation framework, and, in the context of emergency medicine, by EMTALA. However, recipients state, under the 2019 Rule, they may in practice be unable to "remov[e] the employee from the position and reassign[ ] them to a comparable position" without breaching the Rule. Colangelo Decl. 2, Ex. 92 (Kaiser Permanente Comment) at AR 139641–42; *see also* OA Tr. at 52. HHS wholly failed to engage with this consequence. The agency acknowledged, in the Rule's preamble, that the Rule deviated from "the approach set forth in Title VII," specifically in eschewing the reasonable accommodation and undue hardship standards. 84 Fed. Reg. at 23,191. But HHS nowhere engaged with the practical administrative problems that its Rule would present for a funding recipient whose hiring and staffing choices had been made on the assumption that these standards would apply. Its sole statement was the summary one that, if a recipient was already

reading the Conscience Provisions as HHS now does, "there would not likely be any costs." 84 Fed. Reg. at 23,241.

HHS's cursory discounting of the reliance issues here was inadequate. As the Supreme Court has held, a "summary discussion" does not suffice when serious reliance interests are at stake. *See Encino Motorcars*, 136 S. Ct. at 2126–27 (faulting agency for not providing "good reasons" for its policy change when weighty interests were implicated by failure to hold category of employees exempt from FLSA). Based on this lapse, too, the promulgation of the 2019 Rule was arbitrary and capricious.

3. HHS's Failure to Consider Important Aspects of the Problem

Agency action is also arbitrary and capricious where the agency "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. Here, the Court holds, HHS failed adequately to consider two vitally important sets of issues flowing from the definitions HHS adopted of Conscience Provision terms such as "discrimination." These issues are ones addressed throughout this decision: (1) the Rule's application to medical emergencies, and (2) the Rule's interplay—and conflict—with Title VII.[61]

a. Emergencies

Plaintiffs argue that HHS, in various respects, failed to consider how the Rule would impact health care delivery in emergency situations. *See* State SJ at 24 (HHS failed to consider disruption in health care delivery, including how its definitions would impede hospitals whose

[61] Plaintiffs argue that HHS failed to consider other important issues, including, as plaintiffs put these points, the Rule's (1) disruption of health care delivery; (2) harm to public health and specific patient populations; and (3) contravention of medical ethics. *See* State SJ at 22–36. Again, in light of the other deficiencies found in HHS's rulemaking, the Court does not have occasion to address every lapse alleged by plaintiffs.

emergency departments have limited staffing)[62]; *id.* at 29–30 (HHS failed to consider Rule's conflict with EMTALA)[63]; *id.* at 31 (HHS failed to consider Rule's conflict with medical ethics, including the duty of health care professionals to provide care in emergencies).[64] To the extent that HHS addressed these concerns at all in the Rule, it did so in passing and in a conclusory manner. HHS's dismissive treatment of these issues ill-suited the gravity of these matters. It was quintessentially arbitrary and capricious.

In response to each concern plaintiffs raise regarding how the Rule would affect medical emergency response, HHS points to two portions of the Rule's preamble. In these, HHS expresses its view that the Rule does not conflict with EMTALA. *See* 84 Fed. Reg. at 23,183; 23,188; *see also* HHS SJ at 59 (response to EMTALA); HHS Reply at 29–30 (response to disruption of health care delivery concern); HHS Reply at 34–35 (response to medical ethics concern).

HHS does not explain there *why* the Rule does not conflict with EMTALA, which, as noted, does not contain an exception for conscience or other objections. *See supra* pp. 74. HHS there states only that it "generally agrees . . . that the requirement under EMTALA that certain

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[62] *See, e.g.*, Colangelo Decl. 2, Ex. 106 (Am. Coll. of Emergency Physicians Comment) at AR 147982 (describing "tight budgets" and limited "staffing capacity" of emergency departments and such departments' inability to "anticipate every possible basis for a religious or moral objection" and "staff accordingly").

[63] *See, e.g.*, Colangelo Decl. 2, Ex. 90 (Boston Med. Ctr. Comment) at AR 139292 (flagging Rule's failure to address conflict with EMTALA); *see also supra* note 43.

[64] *See, e.g.*, Colangelo Decl. 2, Ex. 91 (Am. Med. Ass'n Comment) at AR 139588 (explaining that, according to AMA Code of Medical Ethics, "physicians' freedom to act according to conscience is not unlimited. Physicians are expected to provide care in emergencies."); *id.*, Ex. 94 (Am. Coll. of Obstetricians and Gynecologists Comment) at AR 139750 ("In an emergency in which referral is not possible or might negatively impact the patient's physical or mental health, providers have an obligation to provide medically indicated and requested care.").

hospitals treat and stabilize patients who present in an emergency does not conflict with Federal conscience and anti-discrimination laws," *id.* at 23,183, and that it intends to "apply both EMTALA and relevant law under this rule harmoniously to the extent possible," *id.* at 23,188. Specifically confronted with comments raising concerns about emergency scenarios, such as how the Rule would apply to an ambulance driver seeking to cease assistance while in the process of bringing a woman with an ectopic pregnancy to an emergency room, HHS stated only that the Rule's application "would depend on the facts and circumstances of each case." *Id.*

HHS's meager and non-committal responses are manifestly inadequate to the problems squarely before the agency. For more than 30 years, HHS funding recipients with emergency departments have been subject to a *statutory* requirement to provide emergency care. *See* 42 U.S.C. §§ 1395dd. Many commenters on the 2019 Rule inquired about the apparent conflict between the Rule and EMTALA, and how the agency envisioned its Rule applying to objections affecting emergency situations. *See supra* notes 43, 62–64. Although HHS did not have an obligation to "respond to every comment," it was duty-bound to "explain how the agency resolved any significant problems raised by the comments." *Int'l Ladies' Garment Workers' Union v. Donovan*, 722 F.2d 795, 817 (D.C. Cir. 1983). And the Rule's effect on emergency medical care was unquestionably a "significant problem." Far from providing a reasoned explanation as to how recipients should address emergencies, however, HHS assumed away the problem with conclusory statements that, in its view, the Rule and EMTALA hardly conflicted. *See* 84 Fed. Reg. at 23,183, 23,188.

The comments received by HHS in response to the draft Rule—many in detail, many from medical personnel with duties to emergency patients—should have yielded a thoughtful response from the federal agency responsible for health care, one that engaged with these

important questions. HHS did not provide such a response. HHS's "generalized conclusions" and inadequate responses to these professionals virtually define the APA term "arbitrary and capricious." *AEP Tex. N. Co. v. Surface Transp. Bd.*, 609 F.3d 432, 441 (D.C. Cir. 2010); *see also Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014) ("[C]onclusory statements will not do; an 'agency's statement must be one of *reasoning*.'" (emphasis in original)); *Butte Cnty. v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010) (explaining, in context of 5 U.S.C. § 555(e), that agency must provide a statement "of reasoning; it must not just be a conclusion; it must articulate a satisfactory explanation for its action" (internal quotation marks omitted)).

b. Title VII

Plaintiffs separately argue that HHS failed to adequately explain its departure from the Title VII reasonable accommodation / undue hardship framework, which, as noted, has by statute governed religious accommodation in the health care sector since 1972. *See* State SJ at 34–36; State Reply at 22–23. Numerous commenters raised questions about the conflict between the 2019 Rule, as originally drafted, and the Title VII framework, and the implications of these divergent standards.[65]

It is "a central principle of administrative law . . . that, when an agency decides to depart from decades-long practices," it "must at a minimum acknowledge the change and offer a reasoned explanation for it." *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 923

[65] *See, e.g.*, Colangelo Decl. 2, Ex. 88 (Cmty. Catalyst Comment) at AR 139091–92; *id.*, Ex. 89 (NFPRHA Comment) at AR 138110–11; *id.*, Ex. 90 (Boston Med. Ctr. Comment) at AR 139290–91; *id.*, Ex. 91 (Am. Med. Ass'n Comment) at AR 139591; *id.*, Ex. 100 (ACLU Comment) at AR 147755–56; *id.*, Ex. 101 (Greater N.Y. Hosp. Ass'n Comment) at AR 147826; *id.*, Ex. 103 (Anne Arundel Med. Ctr. Comment) at AR 147891; *id.*, Ex. 104 (Disability Coalition Comment) at AR 147954; *id.*, Ex. 109 (Nat'l Ctr. for Transgender Equal. Comment) at AR 148115–16; *id.*, Ex. 110 (Nat'l Women's Law Ctr. Comment) at AR 149148–49; Colangelo Decl. 3, Ex. 138 (EEOC Former Chair and Former Legal Counsel Comment) at AR 147886.

(D.C. Cir. 2017); *see also W. Deptford Energy, LLC v. FERC*, 766 F.3d 10, 20 (D.C. Cir. 2014); *Office of Commc'n of United Church of Christ v. FCC*, 707 F.2d 1413, 1439 (D.C. Cir. 1983) (agency's "elimination" of a policy that governed "for almost 50 years" required the court "to scrutinize more closely the [agency's] proffered explanations for its actions").

HHS did not do so here. Instead, in response to these comments, HHS modified the draft Rule to provide a small measure of protection to employers. The Rule, as amended, provides that where the employee "voluntary accept[s] . . . an effective accommodation," this "will not, by itself, constitute discrimination." 84 Fed. Reg. at 23,191; *see also* 45 C.F.R. § 88.2(4). The amended Rule also provides that a recipient may ask an employee about her conscience objections after hiring and once per year thereafter, unless "a persuasive justification" exists; and may make an accommodation that does not require the objecting employee to take "any additional action," does not constitute an "adverse action" against the employee, and does not exclude the employee from her "fields of practice." 45 C.F.R. § 88.2(5)–(6). But HHS declined to adopt either Title VII's reasonable accommodation standard or its undue hardship defense. The agency construed Congress's silence on this point as tacitly reflecting its intention that these Title VII concepts not apply to any Conscience Provisions. *See* 84 Fed. Reg. at 23,191; OA Tr. at 103. This response to these comments was inadequate on two levels. First, the agency did not seriously engage with the implications of having differing sets of standards govern the accommodation of objectors—one set by Title VII and the other by the 2019 Rule. And to the extent that the agency justified this on the grounds that Congress intended the agency's 2019 present reading of the Conscience Provisions, this was an *ipse dixit*. As noted, HHS has not pointed to any evidence that Congress intended any Conscience Provision to override Title VII's reasonable accommodation / undue hardship framework. *See supra* pp. 51, 72; *see also* OA Tr.

at 103–104; *Buitrago-Cuesta v. INS*, 7 F.3d 291, 295 (2d Cir. 1993) ("An inference drawn from congressional silence certainly cannot be credited when it is contrary to all other textual and contextual evidence of congressional intent." (alteration omitted)); *United States v. Azeem*, 946 F.2d 13, 17 (2d Cir. 1991) ("Not every congressional silence is pregnant."). And, second, HHS did not address how a health care provider, presented with the conflicting directives of Title VII and the Rule, was to respond.

More broadly, in formulating the Rule, HHS had an obligation to consider alternatives. Here, an obvious alternative was the familiar Title VII reasonable accommodation / undue hardship framework. *See State Farm*, 463 U.S. at 51 (holding arbitrary and capricious agency's failure to consider alternative that was "within the ambit of the existing standard" that the agency rescinded). HHS did not explain why this framework disserved the interests of conscience objectors or was otherwise deficient. In overriding this framework on the grounds that Congress tacitly so intended, HHS failed "'to give sufficient consideration' to the benefits of a more modest possibility" of allowing the extant Title VII framework to inform the meaning of the Conscience Provisions. *See Int'l Ladies' Garment Workers' Union*, 722 F.2d at 818 (quoting *Office of Commc'n of United Church of Christ*, 707 F.2d at 1439 (holding that agency "failed to give sufficient consideration" to alternative that had applied "for almost 50 years")). While HHS was not obliged to adopt that framework, its failure to seriously consider it, instead declaring that Congress had already considered and rejected it, was peremptory. It did not bespeak adequate consideration. That this framework was statutory and longstanding made it all the more appropriate that HHS considered this approach. *See Cape May Greene, Inc. v. Warren*, 698 F.2d 179, 190 (3d Cir. 1983) ("As agency action moves toward the gray area at the outer limits of statutory authority, the arbitrary and capricious nature of the action may be more evident . . .

Another shadow is cast when agency action, not clearly mandated by the agency's statute, begins to encroach on congressional policies expressed elsewhere."); *see also id.* n.16 (collecting cases).

The Court therefore holds that HHS failed adequately to consider two important aspects of the problem—the Rule's application to emergencies, and the Rule's interplay with Title VII. This lapse made the Rule's promulgation arbitrary and capricious. *See Islander E. Pipeline Co.*, 482 F.3d at 103 ("[R]eviewing courts may not 'attempt . . . to make up for . . . deficiencies' in agency decisions." (quoting *State Farm*, 463 U.S. at 43)).

VII. Was the Final Rule's Definition of "Discrimination" a Logical Outgrowth of the Proposed Rule?

The Court next considers plaintiffs' final APA claim: that the Rule's definition of "discrimination" was not a logical outgrowth of the NPRM.

A. Applicable Legal Principles Under the APA

The APA requires that an agency, when engaging in notice-and-comment rulemaking, provide a general notice of proposed rulemaking that includes "either the terms or substance of the proposed rule or a description of the subjects and issues involved." *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007) (quoting 5 U.S.C. § 553(b)(3)). In response to comments received, "agencies[ ] are free—indeed, they are encouraged—to modify proposed rules." *Ne. Maryland Waste Disposal Auth. v. EPA*, 358 F.3d 936, 951 (D.C. Cir. 2004).

There is, however, a limit to the agency's ability to modify its proposed rules: "While a final rule need not be an exact replica of the rule proposed in the Notice, the final rule must be a 'logical outgrowth' of the rule proposed." *Nat'l Black Media Coal. v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986). Although there is "no precise definition of what counts as a 'logical outgrowth,'" *Nat'l Mining Ass'n v. Mine Safety and Health Admin.*, 116 F.3d 520, 531 (D.C. Cir. 1997), it is clear that "if the final rule deviates too sharply from the proposal, affected parties will be

deprived of notice and an opportunity to respond to the proposal," *Nat'l Black Media Coal.*, 791 F.2d at 1022 (citation omitted). The test is "whether the agency's notice would fairly apprise interested persons" of what is at issue in the rulemaking. *Id.* (internal quotation marks omitted).

B. Discussion

Plaintiffs argue that the Rule's definition of "discrimination" was not a logical outgrowth of the Rule as proposed. *See* Provider SJ at 48–53. The Court agrees.

The NPRM defined "discrimination" using only a list of examples of conduct that could constitute discrimination. This list was included in the final Rule at 45 C.F.R. § 88.2(1)–(3). Although there are slight differences in wording between the NPRM and the final Rule as to this list, both the NPRM and final Rule define discrimination as including actions that involve, *inter alia*, withholding, reducing, or denying grants, contracts, titles, positions, or other benefits and privileges. *See* 83 Fed. Reg. 3,892; 45 C.F.R. § 88.2(1)–(3).[66]

Notably, however, the NPRM did not include any provision anticipating § 88.2(4)–(6) of the final Rule. These prescribe the limited latitude that a funding recipient has to accommodate or inquire about conscience objections, including permitting only "effective" accommodations (those to which the objector consents) or accommodations that meet specified standards (*e.g.*, not requiring additional action by the employee, constituting an "adverse action" against the employee, or excluding the employee from her "fields of practice"). Nor had the NPRM asked for comment on these topics. It did not suggest at all that ground rules for the accommodation of employees were in play at all. Instead, the NPRM asked for comment on only one topic: the appropriateness of a Title VI disparate impact analysis in this context. *See* 83 Fed. Reg. at 3,893

[66] The NPRM also included a provision preventing recipients from "otherwise engag[ing] in any activity reasonably regarded as discrimination, including intimidating or retaliatory action." 83 Fed. Reg. at 3,892. This provision was deleted from the final Rule.

("The Department solicits comment on whether disparate impact analysis is appropriate, as a policy or legal matter, to apply to any of the statutes implemented by this rule; whether it is appropriately included in the definition of discrimination, and if so, how disparate impact analysis would be performed in the context of applicable Federal health care conscience and associated anti-discrimination laws.").

This notice was insufficient to "fairly apprise" recipients of the consequential changes HHS later made to the "discrimination" definition. *Nat'l Black Media Coal.*, 791 F.2d at 1022. Although HHS proposed a new definition of "discrimination," and acknowledged that the 2008 Rule had not defined the term, such "general notice that a new standard will be adopted affords . . . parties scant opportunity for comment." *Time Warner Cable Inc. v. FCC*, 729 F.3d 137, 170 (2d Cir. 2013) (alteration omitted) (quoting *Horsehead Res. Dev. Co. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994)). "[G]eneral notice" that an agency "might make unspecified changes in [a] definition" is not sufficient. *Small Refiner Lead Phase-Down Task Force v. U.S. EPA*, 705 F.2d 506, 549 (D.C. Cir. 1983). Instead, as the Second Circuit has observed, an agency's obligation under the APA "is more demanding" than merely to advise that a new standard could be adopted—the agency must "describe the range of alternatives being considered with reasonable specificity." *Time Warner Cable Inc.*, 729 F.3d at 170 (citation omitted) (holding notice insufficient where FCC sought comment on its adoption of "rules to address the complaint process itself" and then adopted a "standstill rule" requiring distributors of video programming "to continue carrying an unaffiliated network under the terms of its preexisting contract until the network's complaint against the distributor" was resolved); *see also Nat'l Black Media Coal.*, 791 F.2d at 1023 ("Unfairness results unless persons are 'sufficiently alerted to likely alternatives' so that they know whether their interests are 'at stake.'" (citation and

alterations omitted)); *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 549 ("Agency notice must describe the range of alternatives being considered with reasonable specificity.").

The only alternative that HHS described was the possibility of incorporating a Title VI disparate impact analysis. But this provided no hint that HHS was considering overriding the *Title VII* reasonable accommodation / undue hardship framework. Nowhere in the NPRM did HHS ever allude to Title VII, accommodations, or inquiries into conscience objections. HHS thus strayed far from its duty to alert the public to the range of alternatives it was considering. *See Kooritzky v. Reich*, 17 F.3d 1509, 1513 (D.C. Cir. 1994) ("Something is not a logical outgrowth of nothing.").

The gap between the NPRM and the final Rule is particularly gaping here, inasmuch as the final Rule, without advance notice, overcomes a longstanding statutory framework, Title VII's, that has governed the health care sector since 1972. *See Nat'l Mining Ass'n*, 116 F.3d at 532 (holding no logical outgrowth where agency gave "no reason to suppose" that regulated party "suspected a change" in the agency's "forty year old practice").

To be sure, HHS's rulemaking lapse was not as extreme as in some reported "logical outgrowth" cases. *See CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1081–82 (D.C. Cir. 2009) (describing paradigmatic logical outgrowth violations, and holding, in a close case, that final rule had not been a logical outgrowth of an NPRM). But even though "the final rule did not amount to a complete turnaround from the NPRM . . . the APA simply requires more." *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 462 (D.C. Cir. 2012) (internal quotation marks omitted).

HHS's changes to the "discrimination" definition far exceeded what a reader of its NPRM could have anticipated, particularly given the lack of notice in the NPRM that the Title

VII framework governing religious objections was up for reconsideration. Logical outgrowth questions require "careful consideration on a case-by-case basis"; here, HHS's NPRM did not come close to foreshadowing the change HHS later made. *See Nat'l Ass'n of Psychiatric Health Sys. v. Shalala*, 120 F. Supp. 2d 33, 39 (D.D.C. 2000) (quoting *BASF Wyandotte Corp. v. Costle*, 598 F.2d 637, 642 (1st Cir. 1979)). Plaintiffs, and others affected by the Rule, cannot be forced to "divine the agency's unspoken thoughts." *Envtl. Integrity Project v. EPA*, 425 F.3d 992, 996 (D.C. Cir. 2005) (brackets omitted). The APA thus prevents HHS from introducing such a change without, at least, providing adequate notice to regulated parties.

HHS presents several counterarguments, none of which are persuasive. *See* HHS SJ at 36–37.

First, HHS points out that the D.C. Circuit has held that "garden-variety" exceptions added to a general rule are logical outgrowths of the proposed rule. HHS SJ at 36 (citing *Timpinaro v. SEC*, 2 F.3d 453, 457 (D.C. Cir. 1993)). It then argues that its changes to the "discrimination" definition were such an exception. *Id.* In so arguing, HHS fails, again, to recognize the substantive quality of the changes worked by the Rule. The provisions at issue, in dispensing with the reasonable accommodation / undue hardship standards of Title VII, are in no sense quotidian. Nor are the provisions limiting the questions a health care provider can put to an employee regarding conscience objections—limits that may handicap the employer's ability to respond to emergencies and comply with EMTALA. A "garden-variety" exception makes "an explicit recognition of what was already an implicit corollary." *Timpinaro*, 2 F.3d at 457 (addressing exception that allowed regulated party "to waive the legal protection of [a] general rule" designed to benefit them, which is "the norm in economic regulation"). These were not that. Instead, the agency imposed, without notice, "a distinctly different and more burdensome

definition" of "discrimination" than ever previously announced. *UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 192 (D.D.C. 2018).

Second, HHS denies that its Rule suffers from a logical outgrowth problem because it added the new terms in response to comments it received on the NPRM's "discrimination" definition. HHS SJ at 36. Circuit courts have repeatedly rejected such a defense. The logical outgrowth question examines not whether the Rule was a logical outgrowth of comments in response to an NPRM, but whether the NPRM gave recipients sufficient *notice* of the direction the agency might take. That "notice necessarily must come—if at all—from the agency." *Nat'l Black Media Coal.*, 791 F.2d at 1023. An agency "cannot bootstrap notice from a comment." *Id.* (quoting *AFL-CIO v. Donovan*, 757 F.2d 330, 340 (D.C. Cir. 1985)); *accord, e.g.*, *Horsehead Res. Dev. Co.*, 16 F.3d at 1268; *Fertilizer Inst. v. U.S. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991); *Shell Oil Co. v. EPA*, 950 F.2d 741, 760 (D.C. Cir. 1991); *Small Refiner Lead Phase-Down Task Force*, 705 F.2d at 549.

Although the D.C. Circuit in *Natural Resource Defense Council, Inc. v. Thomas*, 838 F.2d 1224 (D.C. Cir. 1988), recognized that "comments raising a foreseeable possibility of agency action can be a factor in providing notice," *Shell Oil Co.*, 950 F.2d at 751 (distinguishing *Thomas*), the Circuit there also recognized that it was "stretch[ing] the concept of 'logical outgrowth' to its limits." *Thomas*, 838 F.2d at 1243. *Thomas* is far afield here. In *Thomas*, the agency, having received a comment with a proposal similar to that which it finally adopted, warned regulated parties of the proposal two weeks before it promulgated the final rule. *See id.* This gave petitioners "a limited opportunity to focus a direct attack" on the proposal; as a result, "they managed to file objections 7–10 days before the final regulations were signed." *Id.* No such forewarning occurred here. Even though comments raised issues relating to Title VII, these

did not suggest alternative frameworks to Title VII's. And HHS, for its part, furnished no notice, in any form, to recipients that it was mulling such alternatives.

Third, HHS depicts plaintiffs' objections as "plainly based on policy, not legal, differences," and faults plaintiffs for "not explain[ing] why the definition is an impermissible construction of the statutes." HHS SJ at 37. HHS misses the point. A logical outgrowth challenge goes to the agency's improper *procedure*, not to the *substance* of its rulemaking. *Cf. Thomas*, 838 F.3d at 292 (addressing logical outgrowth claim in "[p]rocedural challenges" section). Regardless whether HHS's additions to the "discrimination" definition are textually defensible, HHS violated the APA by failing to provide regulated parties adequate notice. This alone is sufficient to warrant vacatur of the rule. *See CSX Transp., Inc.*, 584 F.3d at 1078, 1083 (vacating because of "important and potentially prejudicial" lack of notice).

VIII. Is the Rule's Remedial Provision Authorizing the Termination of All HHS Funding Unconstitutional?

Plaintiffs next argue that § 88.7(i)(3)(iv) of the Rule, which authorizes HHS to withhold or terminate all of a recipient's HHS funding as a penalty for non-compliance with a Conscience Provision, is unconstitutional, because it violates (1) the separation of powers and (2) the Constitution's Spending Clause.

A. The Separation of Powers

Plaintiffs argue that § 88.7(i)(3)(iv) is inconsistent with the separation of powers because it allows HHS to withhold congressionally-appropriated federal funds to an extent that neither the Conscience Provisions nor any other statute authorizes. By claiming the power to do so, plaintiffs argue, HHS arrogates to itself, an executive agency, a power the Constitution allocates uniquely to Congress. State PI at 44–45. HHS counters with two arguments the Court has already rejected: that Congress has given HHS the authority to terminate all of a recipient's HHS

funding; or, alternatively, that § 88.7(i)(3)(iv) is more narrow, jeopardizing only a specific HHS funding stream. *See* HHS SJ at 71; HHS Reply at 46.

The "separation of governmental powers into three coordinate Branches" reflects "the central judgment of the Framers . . . that, within our political scheme, [such checks and balances are] essential to the preservation of liberty." *Mistretta v. United States*, 488 U.S. 361, 380 (1989). Accordingly, the Supreme Court has "not hesitated to strike down provisions of law that either accrete to a single Branch powers more appropriately diffused among separate Branches or that undermine the authority and independence of one or another coordinate Branch." *Id.* at 382.

The Constitution vests the spending power in Congress alone. U.S. Const. art. I, § 8, cl. 1. Congress may delegate its spending authority to an executive agency, and the agency, in turn, may exercise a degree of discretion in deciding how to spend appropriated funds. *See, e.g.*, *Clinton v. City of New York*, 524 U.S. 417, 466–67 (1998) (Scalia, J., concurring) (listing examples of spending authority delegated to Executive Branch dating to Founding, and noting that "[t]he constitutionality of such appropriations has never seriously been questioned").

The agency, however, must exercise its delegated spending authority consistent with the specific congressional grant; "the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Whitman*, 531 U.S. at 475; *see also City of Arlington*, 569 U.S. at 296–97 (agency discretion cabined by scope of delegation). An agency may not withhold funds in a manner, or to an extent, unauthorized by Congress. *Train v. City of New York*, 420 U.S. 35, 44–46 (1975); *see City and Cty. of San Francisco v. Trump*, 897 F.3d 1225, 1235 (9th Cir. 2018) ("Absent congressional authorization, [an agency] may not redistribute or withhold properly appropriated funds in order to effectuate its own policy goals [without violating the separation of powers]."); *In re Aiken Cty.*, 725 F.3d 255, 261 n.1 (D.C.

Cir. 2013) (Executive Branch "does not have unilateral authority to refuse to spend . . . the full amount [of funding] appropriated by Congress for a particular project or program"); *City and Cty. of San Francisco v. Sessions*, 372 F. Supp. 3d 928, 947 (N.D. Cal. 2019) (Department of Justice's funding conditions violated separation of powers because Congress had not authorized DOJ to impose such conditions); *New York*, 343 F. Supp. at 238 (same).

HHS's Rule, however, exceeds the agency's authority. Although the other remedies for which the Rule provides do not implicate this concern, § 88.7(i)(3)(iv) claims a power that no Conscience Provision nor other statute has delegated to HHS: to terminate the entirety of a recipient's HHS funding as a penalty for violating a Conscience Provision. Congress nowhere "provid[ed] the Executive with the seemingly limitless power to withhold funds" on this scale. *Train*, 420 U.S. at 45–46. Section 88.7(i)(3)(iv) thus aggrandizes the Executive Branch at Congress's expense. Such an encroachment is inconsistent with the separation of powers. *See, e.g.*, *City and Cty. of San Francisco*, 897 F.3d at 1234–35.

B. The Spending Clause

Separately, the State Plaintiffs argue that even if Congress had authorized this remedy, § 88.7(i)(3)(iv)'s threat to terminate all of a recipient's HHS funding violates the Spending Clause. The Spending Clause gives Congress the power "to pay the Debts and provide for the general Welfare of the United States," U.S. Const. art. I, § 8, cl. 1. But—as reflected in *NFIB*, in which the Supreme Court invalidated a portion of the ACA as a breach of the Spending Clause—there are limits on the conditions that Congress can attach to States' receipt of federal funds. *See NFIB*, 567 U.S. at 575. The State Plaintiffs argue that § 88.7(i)(3)(iv) exceeds these limits.[67]

[67] Plaintiffs have not argued, and the Court therefore has no occasion to consider, whether any other remedy claimed by the Rule (*e.g.*, threats to portions of a recipient's HHS funding) would transgress the Spending Clause.

HHS counters that plaintiffs' Spending Clause claim is not ripe for review, and that the Rule is a permissible exercise of Congress's power to attach conditions to States' acceptance of federal funds. The Court considers these issues in turn.

1. Ripeness

HHS argues that the Spending Clause claim is unripe, and that the Court therefore lacks subject-matter jurisdiction to resolve it, because no enforcement action has been taken against the State Plaintiffs under the Rule. HHS SJ at 18. The State Plaintiffs counter that because the Rule forces them either to make significant and costly changes by November 22, 2019, or risk losing billions of dollars in federal funding, and because they have already begun to make such changes, their claim is ripe.

a. Applicable Legal Standards

A claim is "properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000). A court lacks constitutional authority to adjudicate a claim that is unripe because "[r]ipeness is a jurisdictional inquiry." *Murphy v. New Milford Zoning Comm'n*, 402 F.3d 342, 347 (2d Cir. 2005). "The burden of proving jurisdiction is on the party asserting it." *Daly v. Citigroup Inc.*, 939 F.3d 415, 425 (2d Cir. 2019) (quoting *Robinson v. Overseas Military Sales Corp.*, 21 F.3d 502, 507 (2d Cir. 1994)). Plaintiffs may rely "solely on the pleadings and supporting affidavits," and, although a court "will not draw 'argumentative inferences' in the plaintiff's favor," it is to "construe jurisdictional allegations liberally and take as true uncontroverted factual allegations." *Robinson*, 21 F.3d at 507.

"The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *N.Y. Civil Liberties Union v. Grandeau*, 528 F.3d 122, 130 (2d Cir. 2008) (internal quotation marks and citation omitted). In

its prudential form, the doctrine serves "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967), *overruled on other grounds by Califano v. Sanders*, 430 U.S. 99, 105 (1977). "At its heart is whether we would benefit from deferring initial review until the claims we are called on to consider have arisen in a more concrete and final form." *Murphy*, 402 F.3d at 347.

"[D]etermining whether a dispute is ripe for review requires a two-pronged analysis of (1) whether the issues presented to the district court are fit for review, and (2) what hardship the parties will suffer in the absence of review." *Connecticut v. Duncan*, 612 F.3d 107, 113 (2d Cir. 2010) (citing *Abbott Labs.*, 387 U.S. at 148–49). The "fitness" inquiry addresses "whether the issues sought to be adjudicated are contingent on future events or may never occur." *Grandeau*, 528 F.3d at 132 (quoting *Simmonds v. INS*, 326 F.3d 351, 359 (2d Cir. 2003)). As to that inquiry, the Second Circuit has "dr[awn] a distinction between pre-enforcement judicial review of specific regulations promulgated by [an] agency and judicial review of a nonfinal proposed policy," finding the latter category less likely to present a ripe controversy. *Id.* The "hardship" inquiry addresses "whether the challenged action creates a direct and immediate dilemma for the parties." *Id.* at 134 (internal quotation marks and citation omitted). "The mere possibility of future injury, unless it is the cause of some present detriment, does not constitute hardship." *Simmonds*, 326 F.3d at 360.[68]

[68] The Supreme Court has called into question the "continuing vitality" of the prudential ripeness doctrine, *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 167 (2014), due to the "virtually unflagging" obligation of a court "to hear and decide cases within its jurisdiction," *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 126 (2014) (internal quotation marks omitted). Because the prudential ripeness factors are easily satisfied here, the Court has no occasion to address the doctrine's continued vitality.

b. Discussion

Measured against these standards, the State Plaintiffs' Spending Clause claim here is clearly ripe.

First, where a dispute over agency action "presents legal questions and there is a concrete dispute between the parties, the issues are fit for judicial decision," even where the "factual record is not yet fully developed." *Sharkey v. Quarantillo*, 541 F.3d 75, 89 (2d Cir. 2008). And, when an agency issues "a substantive rule which as a practical matter requires the plaintiff to adjust his conduct immediately . . . [s]uch agency action is 'ripe' for review at once." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990) (citing *Abbott Labs.*, 387 U.S. at 152–54).

Such is the case here. The Rule assigns significant new substantive meaning to the Conscience Provisions. On taking effect, it would require major and immediate changes in the policies and actions of the State Plaintiffs and their subrecipients, including with respect to hiring, staffing, transfer, and other employment decisions. And the Rule announces HHS's intention to assure that States and others comply. *See, e.g.*, 84 Fed. Reg. at 23,227–28 (the Rule "incentivizes the desired behavior" and will cause recipients to "institute proactive measures," including by enhancing HHS's previously "[i]nadequate enforcement tools"); *id.* at 23,269–70 (requiring recipients to sign enforceable assurances and certifications of compliance).

By its terms, the Rule also forces the State Plaintiffs either to adapt their operations by its effective date of November 22, 2019, or risk termination of their federal health care funding. These plaintiffs have chronicled the changes the Rule is forcing them to make. *See, e.g.*, Adelman Decl. ¶ 13 (restructuring New Jersey Medicaid billing systems); Colangelo Decl. 1, Ex. 13 ("Daly Decl.") ¶ 21 (revising conscience objection policy at New Jersey public hospital); *id.*, Ex. 17 ("Ezike Decl.") ¶¶ 33–39, 49–51 (reconfiguring Illinois grants to subrecipients and revising monitoring protocols to ensure subrecipient compliance with Rule); Zucker Decl. ¶¶ 64–

66, 181–84 (retraining staff as to when New York state law can no longer be enforced in light of Rule). Thus, as a substantive and final regulation which raises pure questions of law and requires plaintiffs immediately to conform their conduct, the Rule is fit for immediate review. *See Lujan*, 497 U.S. at 891.

Second, without judicial review, the State Plaintiffs will suffer hardship. A rule that "requires an immediate and significant change in [a party's] conduct of its affairs with serious penalties attached to noncompliance" presents a prototypical instance of hardship. *Abbott Labs.*, 387 U.S. at 153. Where "plaintiffs must either incur great expense to comply with [a regulation's] requirements" or risk "potentially even greater" consequences for non-compliance, they will suffer hardship if the court foregoes review. *Thomas v. City of New York*, 143 F.3d 31, 36 (2d Cir. 1998).

The State Plaintiffs face this predicament. By November 22, they must take major actions—with respect to policy, administration, and personnel—to bring their offices into compliance. Efforts to this end have already begun. *See, e.g.*, Colangelo Decl. 1, Ex. 29 ("Lucchesi Decl.") ¶ 22 (public university hospital planning how to staff emergency room and evaluating which essential hospital functions would have to be cut if Rule takes effect); *id.*, Ex. 45 ("Vanden Hoek & Perna Decl.") ¶¶ 19–20 (public university hospital creating contingency staffing plans and preparing for hiring additional staff so as to maintain adequate level of care while complying with the Rule); Wagaw Decl. ¶ 18 (Chicago Department of Public Health developing and implementing new complaint policy and procedure for conscience objections). In emergency contexts and rural settings involving smaller or remote providers, where a single employee's abstention on account of a conscience objection could pose a heightened threat to patient health and safety, efforts to adapt in advance to the Rule are particularly urgent. *See, e.g.*,

Colangelo Decl. 1, Ex. 5 ("Allen Decl.") ¶¶ 26–30 (emergency care); *id.*, Ex. 38 ("Rosen Decl.") ¶¶ 8, 11–13 (rural care).

HHS's claim that the State Plaintiffs must await an enforcement action against them to challenge the Rule blinks these realities.[69] Plaintiffs "deal in a sensitive industry, in which public confidence in their [services] is especially important," and "[t]o require them to challenge these regulations only as a defense to an action brought by the Government might harm them severely and unnecessarily." *Abbott Labs.*, 387 U.S. at 153. This is especially so here, where noncompliance could cost a State or locality many millions, or even billions, of dollars in federal health care funding.

The Court therefore holds that the Spending Clause claim is ripe for review.

2. Merits

The Spending Clause gives Congress the power "to pay the Debts and provide for the general Welfare of the United States." U.S. Const. art. I, § 8, cl. 1. In exercising this power, "Congress may attach conditions on the receipt of federal funds, and has repeatedly employed the power to further broad policy objectives by conditioning receipt of federal moneys upon compliance by the recipient with federal statutory and administrative directives." *South Dakota v. Dole*, 483 U.S. 203, 206 (1987) (internal quotation marks and citation omitted).

[69] The claim also relies on inapposite case law. HHS cites two cases finding facial challenges to the Weldon Amendments unripe. *See NFPRHA v. Gonzales*, 468 F.3d 826, 827 (D.C. Cir. 2006); *California*, 2008 WL 744840, at *3. But neither involved anything like the concrete immediate consequences and risks that the State Plaintiffs face here as a result of the Rule's new requirements and its wholesale threat to funding. *Cf. Abbott Labs.*, 387 U.S. at 154 ("[T]here is no question in the present case that petitioners have sufficient standing as plaintiffs: the regulation is directed at them in particular; it requires them to make significant changes in their everyday business practices; if they fail to observe the [administrative] rule they are quite clearly exposed to the imposition of strong sanctions.").

But "[t]he spending power is of course not unlimited." *Id.* at 207 (citing *Pennhurst State Sch. and Hosp. v. Halderman*, 451 U.S. 1, 17 & n.13 (1981)). It is a "basic principle" of federalism that the "Federal Government may not compel the States to enact or administer a federal regulatory program." *NFIB*, 567 U.S. at 575 (quoting *New York v. United States*, 505 U.S. 144, 188 (1992)). The States are "independent sovereigns in our federal system," and "[p]ermitting the Federal Government to force the States to implement a federal program would threaten the political accountability key to [that] system." *Id.* at 577–78. For that reason, the Federal Government may not "commandeer a State's legislative or administrative apparatus for federal purposes" or "us[e] financial inducements to exert a power akin to undue influence." *Id.* at 577 (internal quotation marks and citations omitted).

The Supreme Court has thus "repeatedly characterized . . . Spending Clause legislation as 'much in the nature of a *contract*.'" *NFIB*, 567 U.S. at 576–77 (emphasis in original) (quoting *Barnes v. Gorman*, 536 U.S. 181, 186 (2002); *Pennhurst*, 451 U.S. at 17); *see id.* at 676 (Scalia, Kennedy, Thomas, and Alito, JJ., dissenting) (under Spending Clause, "the federal-state relationship is in the nature of a contractual relationship"). The legitimacy of a federal spending program "thus rests on whether the State voluntarily and knowingly accepts the terms of the 'contract.'" *NFIB*, 567 U.S. at 577 (quoting *Pennhurst*, 451 U.S. at 17).

To that end, the Supreme Court has articulated several principles that circumscribe Congress's spending power. Four are relevant here.

First, "the conditions [Congress attaches to the receipt of federal funds] must be set out unambiguously." *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (internal quotation marks and citation omitted). Second, the "financial inducement offered by Congress" must not be "impermissibly coercive." *NFIB*, 567 U.S. at 580 (internal quotation

marks and citation omitted). Third, the conditions must relate "to the federal interest in the project and to the over-all objectives thereof." *Dole*, 483 U.S. at 208 (citation omitted). Fourth, "the power may not be used to induce the States to engage in activities that would themselves be unconstitutional." *Id.* at 210.[70]

The State Plaintiffs argue that § 88.7(i)(3)(iv) causes the Rule to breach each of these standards. The Court agrees that the provision is inconsistent with the first two (although not the third and fourth). It thus is unconstitutional.

a. Ambiguous and Retroactive Conditions

The State Plaintiffs contend that the Rule attaches retroactive and ambiguous conditions to their receipt of federal funds. State SJ at 39.

When the Federal Government "intends to impose a condition on the grant of federal moneys, it must do so *unambiguously*." *Pennhurst*, 451 U.S. at 17 (emphasis added). This requirement flows from the Spending Clause principle that States must "voluntarily and knowingly" accept conditions attached to federal spending. *Arlington*, 548 U.S. at 296 (quoting *Pennhurst*, 451 U.S. at 17). States "cannot knowingly accept conditions of which they are 'unaware' or which they are 'unable to ascertain.'" *Id.* (quoting *Pennhurst*, 451 U.S. at 17). The requirement of unambiguous conditions "enable[s] the States to exercise their choice knowingly, cognizant of the consequences of their participation." *Pennhurst*, 451 U.S. at 17.

Relatedly, "[alt]hough Congress's power to legislate under the spending power is broad, it does not include surprising participating States with post-acceptance or 'retroactive'

[70] An agency which Congress has tasked with implementing a statute that imposes spending conditions is also subject to the Clause's restrictions. *See Lau v. Nichols*, 414 U.S. 563, 569 (1974) (evaluating Spending Clause challenge to regulation implemented pursuant to Title VI of the Civil Rights Act of 1964), *abrogated on other grounds by Alexander v. Sandoval*, 532 U.S. 275, 285 (2001).

conditions." *NFIB*, 567 U.S. at 584 (quoting *Pennhurst*, 451 U.S. at 25). Congress need not "specifically identif[y] and proscrib[e] each condition in Spending Clause legislation." *Jackson*, 544 U.S. at 183 (internal quotation marks and citation omitted). But, once a State has accepted funds pursuant to a federal spending program, the Federal Government cannot alter the conditions attached to those funds so significantly as to "accomplish[ ] a shift in kind, not merely degree." *NFIB*, 567 U.S. at 583; *see id.* at 584 ("A State could hardly anticipate that Congress's reservation of the right to 'alter' or 'amend' the Medicaid program included the power to transform it so dramatically."). In assessing whether States have been given notice consistent with this standard, the Court must view the challenged conditions "from the perspective of a state official who is engaged in the process of deciding whether the State should accept [the] funds and the obligations that go with those funds" and "must ask whether such a state official would clearly understand that" the challenged condition was "one of the obligations [attached to the accepted funding]." *Arlington*, 548 U.S. at 296.

Here, the Rule imposes ambiguous and retroactive conditions on the States.

First, § 88.7(i)(3)(iv) authorizes HHS to withhold, deny, suspend, or terminate previously allocated funding if HHS determines that a State or its subrecipients has failed, even once, to comply with a Conscience Provision as construed by the Rule. But the federal health care funding statutes, including those that the Rule purports to interpret and apply, have specific standards. They condition funding from specific sources on compliance with specific prohibitions. *See, e.g.*, 42 U.S.C. § 300a–7(c)(1) (Church Amendment restrictions that apply to specific statutory funding sources); *id.* § 300a–7(c)(2) (Church Amendment restrictions that apply only to "grant[s] or contract[s] for biomedical or behavioral research). The Rule, however, newly conditions all HHS funding, regardless of source, on compliance with the Conscience

Provisions. And, by adding the substantive conditions announced in the Rule, the Rule exposes a State to a heightened risk, in the middle of a funding period, that funds previously allocated will be withheld or terminated. A State that has organized its programs (*e.g.*, its Medicaid program) in anticipation of a promised outlay of funds could find all its HHS funding streams cut off for its failure to adapt. The State, however, had no way to know at the time it accepted such funds that HHS would later claim the right to close these spigots based on a breach of a Conscience Provision. The Spending Clause concern about retroactivity is very much present here.

Second, the Rule imposes uncertain ground rules for compliance with the Conscience Provisions. It does so, as noted, by imposing standards of conduct that conflict with two major existing laws—Title VII and EMTALA. HHS's pledge that OCR will try to minimize such conflicts does not cure this problem. The Rule instead leaves a State that receives HHS funding "unable to ascertain," *Arlington*, 548 U.S. at 296 (quoting *Pennhurst*, 451 U.S. at 17), its bottom-line legal obligations. The Rule also creates conflicts with dozens of state and local laws, including with regard to emergency care. *See, e.g.*, Colangelo Decl. 2, Ex. 87 at AR 137932–34 (collecting state and local statutes with which the Rule is in conflict); Compl. ¶¶ 103–118 (same). At the time they accepted their current health care funding, the State Plaintiffs could not have foreseen these developments.

Through its new definitions of Conscience Provision terms, the Rule also significantly expands the reach of these laws and—through its assurance and certification requirements—imposes new compliance obligations on States and their subrecipients. These developments, too, could not have been anticipated at the time States agreed to accept their present HHS funding. Relatedly, the Rule's compliance requirements appear likely to "conscript state [agencies] into the national bureaucratic army." *NFIB*, 567 U.S. at 585 (citation omitted). To safeguard existing

HHS grants and awards from termination, state personnel will likely be obliged to implement the Rule's new federal standards of conduct and investigate infractions. This may create friction between States and their citizens. *See id.*, 567 U.S. at 578. The State Plaintiffs did not agree to this, either, when they accepted their current federal funding.

HHS counters that "[w]hen a condition is present but 'largely indeterminate,' the Spending Clause is satisfied if a State nonetheless chooses to accept the federal funds." HHS Reply at 39 (quoting *Mayweathers v. Newland*, 314 F.3d 1062 (9th Cir. 2002)). HHS's argument is that States receiving HHS funding knew that the Conscience Provisions existed, even if they could not anticipate how HHS would later construe them. However, HHS misreads the Ninth Circuit's *Mayweathers* decision, and its position is foreclosed by the Spending Clause analysis in *Pennhurst*, on which *Mayweathers* relied.

In *Mayweathers*, plaintiffs challenged the Religious Land Use and Institutionalized Persons Act of 2000, 42 U.S.C. § 2000cc *et seq.* (2000) ("RLUIPA"), based on an allegedly ambiguous condition in the statute. Plaintiffs termed RLUIPA's condition unpredictable because it had "resulted in different determinations in different courts." *Id.* at 1067. The Ninth Circuit, however, upheld RLUIPA as a lawful exercise of Congress's spending power.

Here, by contrast, the State Plaintiffs' claim is not merely that the Rule may yield unforeseeable or inconsistent outcomes. It is fundamentally that the Rule was an unforeseeable departure from the status quo at the time the States agreed to accept the funding that the Rule puts in jeopardy.

To the extent HHS reads *Mayweathers* as imposing a "caveat emptor" principle on States that accept federal funds in the face of an ambiguous statute, that argument is foreclosed by the Supreme Court's decision in *Pennhurst*. The Court there held that where "a State's potential

obligations under the Act are largely indeterminate," the requirement "that Congress must express clearly its intent to impose conditions on the grant of federal funds so that States can knowingly decide whether or not to accept those funds . . . *applies with greatest force*." *Pennhurst*, 451 U.S. at 24 (emphasis added). Reviewing the statutory language at issue, the Court found it "unlikely that a State would have accepted federal funds had it known it would be bound [by the purported condition]." *Id.* at 25. The Federal Government, the Court held, had failed to provide "clear notice to the States that they, by accepting funds under the Act, would indeed be obligated to comply with [the purported condition]." *Id.* This rendered the funding condition "retroactive," and hence unconstitutional under the Spending Clause. *Id.*

Pennhurst provides an apt analogy here. As in *Pennhurst*, States accepting HHS funding were denied notice that, to sustain existing funding streams, they might need to meet major new unannounced conditions. A state official deciding whether to accept funding would not have "clearly underst[oo]d," *Arlington*, 548 U.S. at 296, that the terms "discrimination" or "assist in the performance" in the Conscience Provision would be given the meaning the Rule gives them. Nor would such an official have foreseen that non-compliance with such a new standard could cost a State all of its HHS funding. The *post hoc* imposition of these standards strains federal-state relations. It is disfavored under the Spending Clause, for the reason noted in *NFIB*: "[I]t may be state officials who will bear the brunt of public disapproval, while the federal officials who devised the regulatory program may remain insulated from the electoral ramifications of their decision." *NFIB*, 567 U.S. at 578 (quoting *New York*, 505 U.S. at 169).

The Court therefore holds § 88.7(i)(3)(iv) of the Rule inconsistent with the Spending Clause requirements that conditions attached to federal funding be unambiguous and not retroactive.

b. Impermissibly Coercive

The State Plaintiffs separately argue that the Rule is impermissibly coercive given the scale of the federal funding that § 88.7(i)(3)(iv) puts at risk. Although "Congress may use its spending power to create incentives for States to act in accordance with federal policies," *NFIB*, 567 U.S. at 577, the "financial inducement offered" must not be "so coercive as to pass the point at which 'pressure turns into compulsion.'" *Dole*, 483 U.S. at 211 (quoting *Steward Mach. Co. v. Davis*, 301 U.S. 548, 590 (1937)). Federal spending that "coerces a State [or local government] to adopt a federal regulatory system as its own" is "contrary to our system of federalism." *NFIB*, 567 U.S. at 577–78. Spending Clause programs instead must provide States "a legitimate choice whether to accept the federal conditions in exchange for federal funds." *Id.* at 578.

Although the Supreme Court has never attempted to "fix the outermost line where persuasion gives way to coercion," *id.* at 585 (internal quotation marks omitted), its decisions in *Dole* and *NFIB* provide guidance as to when a federal financial inducement crosses the line from encouragement to a financial "gun to the head," *id.* at 581.

The federal spending program at issue in *Dole* threatened to withhold five percent of a State's federal highway funds if the State did not raise its drinking age to 21. For South Dakota, the lone challenger in that case, the federal funds at stake (5% of its federal highway funding) "constituted *less than half of one percent of [the State's] budget* at the time." *Id.* (emphasis added) (citations omitted). With only a "small percentage of certain federal highway funds" at risk, the Supreme Court concluded that "Congress has offered relatively mild encouragement to the States to enact higher minimum drinking ages," that left the States with a choice not to comply "not merely in theory but in fact." *Dole*, 483 U.S. at 211–12. Participating States could

therefore be considered to have voluntarily and knowingly accepted the conditions attached to the highway funding.

By contrast, in *NFIB*, the ACA's threat to terminate a State's existing Medicaid funding if the State did not expand its health care coverage was "much more than 'relatively mild encouragement'—it is a gun to the head." *NFIB*, 567 U.S. at 581. Unlike in *Dole*, a non-compliant State would "stand[] to lose not merely a relatively small percentage of its existing Medicaid funding, but *all* of it"—a devastating blow to state budgets. *Id.* The Court concluded that "the threatened loss of *over 10 percent of a State's overall budget* . . . is economic dragooning that [unconstitutionally] leaves the States with no real option but to acquiesce in the Medicaid expansion." *Id.* at 582 (emphasis added).

The threat to funding presented by § 88.7(i)(3)(iv) makes *NFIB* a more apt analogy here than *Dole*. That provision threatens not a small percentage of the States' federal health care funding, but literally *all* of it. Indeed, the Rule allows HHS to initiate a compliance review if it "suspect[s]" noncompliance, § 88.7(c), and to withhold, deny, suspend, or terminate all federal funding from HHS, § 88.7(h)–(j), even during the pendency of voluntary good-faith efforts to come into compliance with the Rule, § 88.7(i)(2).

The State Plaintiffs rely on this federal health care funding, which amounted to nearly $200 billion for these States alone in fiscal year 2018. *See* Colangelo Decl. 2, Ex. 136 at 16 (showing total funding received by States based on information in HHS's Tracking Accountability in Government Grants System ("TAGGS")); States SJ at 44 n.32. Nevada, for example, received more than $2.6 billion in federal health care funding from HHS in the 2018 federal fiscal year. Colangelo Decl. 1, Ex. 40 ("Sherych Decl.") ¶ 3; *see also, e.g.*, Colangelo Decl. 1, Ex. 35 ("Oliver Decl.") ¶ 6 ($6.7 billion for Virginia); *id.*, Ex. 11 ("Clark Decl.") ¶ 2

($1.4 billion out of the Vermont Agency of Human Services' $2.6 billion budget come from federal funds).[71] As the States detail in their declarations, this funding enables a wide range of essential health care programs, including ones on which vulnerable residents rely. *See* States SJ at 44–45 & nn.33–41 (collecting evidence of States' reliance on HHS funding for the provision of key health care services). Wherever "the outermost line where persuasion gives way to coercion" lies, the threat to pull all HHS funding here crosses it. *NFIB*, 567 U.S. at 585.

Also like the Medicaid expansion at issue in *NFIB*, the Rule would substantively transform the existing regulatory regime. *See id.* at 583. As the Court has explained, the Rule changes the "who," "what," "when," "where," "why," and "how" with respect to how regulated entities must respond to conscience-based objections in the health care area, while dramatically raising the stakes of non-compliance. *See NFIB*, 567 U.S. at 580 ("When . . . conditions take the form of threats to terminate other significant independent grants, the conditions are properly viewed as a means of [coercion].").

In *NFIB*, the Supreme Court found the ACA's coercive threat to withdraw state funding repugnant to the federal system because "the States ha[d] developed intricate . . . regimes over the course of many decades to implement their objectives under existing Medicaid." *Id.* at 581. The same is so here. As the State Plaintiffs have demonstrated, their public health institutions have put in place intricate legal frameworks and policies governing employees' religious objections, all premised on the existing legal regime. *See, e.g.*, Allen Decl. ¶¶ 10–19 (describing

[71] The parties have not pointed to record evidence of the State Plaintiffs' total state budgets, as would have allowed a calculation of the percent of a given State's overall budget that the Rule puts at risk. But a court need not know the precise size of a State's overall pie to conclude that the slice of federal health care funding put at risk by the Rule is coercively large. *See NFIB*, 567 U.S. at 582 n.12 ("'Your money or your life' is a coercive proposition, whether you have a single dollar in your pocket or $500.").

existing policies in New York City's municipal hospital system); States PI at 15–16 (collecting affidavit evidence). These policies balance accommodating the beliefs of employees against the goal of providing quality and reliable patient care. *See, e.g.*, Colangelo Decl. 1, Ex. 4 ("Alfredo Decl.") ¶¶ 9–12 (noting, as one feature of this balance, the frequent requirement that employees give advance written notice of an objection, to ensure adequate staffing). The Rule forces these entities to alter their arrangements in the middle of a funding cycle, or else endanger their federal funding.

HHS counters by casting plaintiffs' facial challenge as based on "speculative circumstances." HHS SJ at 66. HHS's suggestion that plaintiffs must await an enforcement action to claim a violation of the Spending Clause, however, is wrong. As *NFIB* teaches, a federal threat to a State to "do this, or else" is coercive at the moment it is uttered; the State's conduct may be influenced long before the "or else" comes to pass. HHS's spending threat here is coercive given the scale of funding it jeopardizes and the new standards of conduct the Rule imposes.

c. Unrelated Funds

The State Plaintiffs separately argue that § 88.7(i)(3)(iv) lacks a nexus between the funds at issue and the Rule's purpose. The Supreme Court in *Dole* noted that "our cases have suggested (without significant elaboration) that conditions on federal grants might be illegitimate if they are unrelated to the federal interest in particular national projects or programs." *Dole*, 483 U.S. at 207 (internal quotation marks and citation omitted).

Here, plaintiffs state that the Rule "appears to condition the receipt of billions of dollars of federal funds that are entirely unrelated to health care on compliance with its provisions." State SJ at 46. This claim, however, presupposes that the Rule "threatens federal funds not only from HHS but from the Department of Labor and the Department of Education as well." *Id.*;

see OA Tr. at 71 (plaintiffs' counsel so acknowledging). But, as the Court has explained, while § 88.7(i)(3)(iv) threatens all of a recipient's HHS funding, it does not threaten funds other than from "the Department" (HHS). *See supra* note 33. In other words, § 88.7(i)(3)(iv) jeopardizes HHS funds only. Plaintiffs' lack-of nexus argument, based on a faulty premise, therefore fails.

d. Violations of Other Constitutional Provisions

State Plaintiffs finally argue that the Rule induces violations of the Establishment Clause. The "'independent constitutional bar' limitation on the spending power" means that "the power may not be used to induce the States to engage in activities that would themselves be unconstitutional." *Dole*, 483 U.S. at 210.[72] For example, "a grant of federal funds conditioned on invidiously discriminatory state action or the infliction of cruel and unusual punishment would be an illegitimate exercise of the Congress's broad spending power" because the Constitution bars the States from so acting. *Id.* at 210–11.

As discussed immediately below, however, the Court does not find the Rule facially to violate the Establishment Clause—the basis on which plaintiffs premise this Spending Clause theory. Therefore, the Rule does not induce the States or their subrecipients necessarily to engage in unconstitutional behavior. *See United States v. Am. Library Ass'n, Inc.*, 539 U.S. 194 (2003) (First Amendment did not facially bar the conditional spending at issue; court defers consideration of hypothetical as-applied scenarios).

* * *

The Court accordingly holds § 88.7(i)(3)(iv) of the Rule breaches the Spending Clause, because of the Rule's ambiguous and retroactive conditions and because of the coercive impact

[72] The cases cited in *Dole* for this proposition did so in *dicta*. They did not find a Spending Clause violation on that ground. *See Lawrence Cty. v. Lead-Deadwood Sch. Dist.*, 469 U.S. 256, 269–270 (1985); *Buckley v. Valeo*, 424 U.S. 1, 91, 96 (1976) (per curiam); *King v. Smith*, 392 U.S. 309, 333 n.34 (1968).

of this provision. *See NFIB*, 567 U.S. at 585–86 (invalidating ACA section that created breach of Spending Clause, as such relief "fully remedies the constitutional violation we have identified").

IX. Does the Rule Violate the Establishment Clause?

Plaintiffs also argue that the Rule facially violates the Establishment Clause. They argue that the Rule does so by defining "discrimination" to inflexibly oblige HHS funding recipients to accommodate religious objections. HHS counters that this claim is not ripe and that the Rule is not facially unconstitutional.

A. Ripeness

The same ripeness standards governing plaintiffs' Spending Clause claim apply to their Establishment Clause claim.[73] And plaintiffs' claim that the Rule facially violates the Establishment Clause is ripe for similar reasons. There is a "concrete dispute between the parties" that is fit for review; delay of review would cause plaintiffs hardship; and the challenge turns on the text of the Rule, such that, unlike in the context of an as-applied challenge, resolution of plaintiffs' claim need not await full development of a "factual record." *Sharkey*, 541 F.3d at 89.

[73] Plaintiffs argue that courts in this Circuit "assess pre-enforcement First Amendment claims . . . under somewhat relaxed standing and ripeness rules." *Nat'l Org. for Marriage, Inc. v. Walsh*, 714 F.3d 682, 689 (2d Cir. 2013); *see* State SJ at 6. HHS argues that this relaxed standard applies only in cases that "deal[ ] with allegations that the plaintiffs' ability to speak had been chilled." HHS Reply at 38. Because plaintiffs' claim is ripe regardless, the Court has no occasion to resolve this debate.

B. Merits

On the merits, however, plaintiffs are wrong to claim a facial Establishment Clause violation. Plaintiffs portray the Rule as an instance of excessive religious accommodation.[74] As the Supreme Court has long taught, religious accommodations are often appropriate and sometimes necessary, including to protect the free exercise of religion. But, "[a]t some point, accommodation may devolve into an unlawful fostering of religion," in violation of the Establishment Clause. *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-day Saints v. Amos*, 483 U.S. 327, 334–35 (1987) (internal quotation marks and citation omitted).

In evaluating whether a statute or rule accommodating religion comports with the Establishment Clause, a key inquiry is whether the provision in question applies neutrally—across different religious faiths and to religious and non-religious parties alike. *See McCreary Cty. v. Am. Civil Liberties Union of Ky.*, 545 U.S. 844, 860 (2005) (citing *Epperson v. Arkansas*, 393 U.S. 97, 104 (1968)); *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005). A statutory or regulatory accommodation may violate the Establishment Clause where it results in "religious concerns automatically control[ling] over all secular interests" and an "unyielding weighting in favor of [religious interests]." *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709–10 (1985). In contrast, a facially neutral enactment that extends common benefits to, or imposes common burdens on, religious and non-religious parties alike is presumptively valid. *See, e.g.*, *Bowen v. Kendrick*, 487 U.S. 589, 608–09 (1988); *Mueller v. Allen*, 463 U.S. 388, 395–99 (1983); *Walz v.*

[74] The Supreme Court has recently described most modern Establishment Clause cases as falling into six categories: involving (1) religious references or imagery in public monuments, symbols, mottos, displays, and ceremonies; (2) religious accommodations and exemptions from generally applicable laws; (3) subsidies and tax exemptions; (4) religious expression in public schools; (5) regulation of private religious speech; and (6) state interference with internal church affairs. *Am. Legion v. Am. Humanist Ass'n*, 139 S. Ct. 2067, 2081 n.16 (2019). The present dispute falls into the second category. *See* 84 Fed. Reg. at 23,170.

Tax Comm'n of N.Y., 397 U.S. 664, 672–73 (1970); *Everson v. Bd. of Educ. of Ewing Twp.*, 330 U.S. 1, 17–18 (1947) (upholding transportation reimbursement program benefitting parents of children attending religious and non-religious schools).

To succeed on a facial constitutional challenge such as that here, "the challenger must establish that no set of circumstances exists under which the [regulation] would be valid." *United States v. Salerno*, 481 U.S. 739, 745 (1987); *accord United States v. Le*, 902 F.3d 104, 117 n.12 (2d Cir. 2018). That a law or regulation might be applied so as improperly to favor or disfavor religion—that it "might operate unconstitutionally under some conceivable set of circumstances"— is insufficient to support facial invalidation. *Salerno*, 481 U.S. at 745.

Plaintiffs' challenge here fails, simply put, because the Rule, on its face, equally recognizes secular ("moral") and religious objections to the covered medical procedures. Like the Conscience Provisions it purports to construe, the Rule equally accommodates *all* conscience-based objections to covered health care services and research activities. That is so whether the individual objector's qualms derive from a religious or a secular moral conviction. The Rule in general, and its definition of "discrimination" in particular, does not elevate religious objectors over others. It cannot be said, on its face, to "command[ ] that . . . religious concerns automatically control over all secular interests." *Thornton*, 472 U.S. at 709.

It is easy here to envision applications of the Rule that are neutral as between religious and secular objections. Persons seeking to dissociate themselves from an abortion or sterilization procedure may or may not act on the basis of a religious, as opposed to a secular, conviction. Inasmuch as a facial challenge requires plaintiffs to "establish that no set of circumstances exists under which the [Rule] would be valid," *Salerno*, 481 U.S. at 745, their challenge here fails. *See Cutter*, 544 U.S. at 725 (rejecting facial challenge to RLUIPA because it was not "factually

impossible" for statute to comport with Establishment Clause). Like the parties, the Court of course recognizes the possibility that an as-applied challenge—*e.g.*, to the implementation of the Rule in a particular setting—could yield a different result. As in *Cutter*, the Court has no occasion to consider under what circumstances, an as-applied challenge based on the Establishment Clause could succeed. *Id.* at 726.

X. Remedy

The Court, finally, considers the appropriate remedy in light of its findings on plaintiffs' APA and constitutional claims.

For the reasons reviewed above, the Court has found the following legal deficiencies with respect to the 2019 Rule:

- With respect to the Church, Coats-Snowe, and Weldon Amendments, HHS was never delegated and did not have substantive rule-making authority. In undertaking substantive rulemaking, HHS therefore acted in violation of § 706(2)(C) of the APA. For purposes of these Conscience Provisions, HHS lacked the authority to define the statutory terms addressed by the Rule ("discriminate or discrimination," "assist in the performance," "health care entity," and "referral or refer for") or to promulgate the assurance and certification requirements, as each of these was an act of substantive rulemaking.

- With respect to all Conscience Provisions, HSS was never delegated and did not have authority to promulgate a Rule authorizing, as a penalty available to the agency for a recipient's non-compliance, the termination of all of the recipient's HHS funds, as § 88.7(i)(3)(iv) of the Rule purports to authorize. In promulgating this provision, HHS also acted in violation of § 706(2)(C) of the APA.

- With respect to all Conscience Provisions, the Rule is contrary to law, in violation of § 706(2)(A) of the APA, insofar as (1) in its application to the employment context, it conflicts with Title VII of the Civil Rights Act of 1964, as amended in 1972 to prescribe a framework governing the circumstances under which an employer must accommodate an employee's religion-based objections; and (2) in its application to emergencies, it conflicts with the 1986 Emergency Medical Treatment and Labor Act.

- With respect to all Conscience Provisions, HHS acted arbitrarily and capriciously in promulgating the Rule, in violation of § 706(2)(A) of the APA, because (1) HHS's stated reasons for undertaking rulemaking are not substantiated by the record before the agency, (2) HHS did not adequately explain its change in policy, and (3) HHS failed to consider important aspects of the problem before it.

- With respect to all Conscience Provisions, HHS did not observe proper rulemaking procedure in promulgating the Rule, in violation of § 706(2)(D) of the APA, insofar as portions of the Rule that define "discriminate or discrimination" were not a "logical outgrowth" of HHS's notice of proposed rulemaking (NPRM).

- With respect to all Conscience Provisions, the Rule's authorization in § 88.7(i)(3)(iv), as a penalty available to HHS's OCR in the event of a recipient's non-compliance of the termination of all of the recipient's HHS funds, violated the Separation of Powers and the Spending Clause of the Constitution, U.S. Const. art. I, § 8, cl. 1.

In light of these rulings, and the Court's corresponding entry of summary judgment for plaintiffs as to these points, three questions are presented as to the proper remedy. First, should the Rule be vacated or, as HHS urges, is some lesser remedy appropriate? Second, if the Court finds vacatur warranted, should, as HHS urges, portions of the Rule that are unaffected by the above rulings, if any, be severed and saved? Third, and finally, does the invalidation of the Rule have nationwide effect and extend to all entities covered by the Rule or, as HHS urges, is the Rule invalid only in this District and only as to the particular litigants in these consolidated cases? The Court addresses these questions in turn.

"When a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated." *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989). Such has long been standard practice under the APA. *See, e.g.*, *Chrysler Corp.*, 441 U.S. at 313 ("[R]egulations subject to the APA cannot be afforded the force and effect of law if not promulgated pursuant to the statutory procedural minimum found in that

Act." (internal quotation marks omitted)); *Camp v. Pitts*, 411 U.S. 138, 143 (1973) ("If [the agency's action] is not sustainable on the administrative record made, then the [agency's] decision must be vacated."); *Am. Biosci., Inc.*, 269 F.3d at 1084 ("If an appellant has standing—which is undeniable here—and prevails on its APA claim, it is entitled to relief under that statute, which normally will be a vacatur of the agency's [action]."); *Nat'l Min. Ass'n v. U.S. Army Corps of Engineers*, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (same); *see also Pennsylvania v. President United States*, 930 F.3d 543, 575 (3d Cir. 2019) ("[O]ur APA case law suggests that, at the merits stage, courts invalidate—without qualification—unlawful administrative rules as a matter of course, leaving their predecessors in place until the agencies can take further action."); *United States v. Goodner Bros. Aircraft*, 966 F.2d 380, 384 (8th Cir. 1992) ("A regulation not promulgated pursuant to the proper notice and comment procedures has no force or effect of law and therefore is void *ab initio*." (internal quotation marks omitted)); *W.C. v. Bowen*, 807 F.2d 1502, 1505 (9th Cir. 1987) ("An agency rule which violates the APA is void.").

That vacatur is appropriate follows from the text of the APA itself: "The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be," *inter alia*, arbitrary and capricious, not in accordance with law, in excess of statutory authority, unconstitutional, or made without observance of procedures required by law. APA § 706(2); *accord Pennsylvania*, 930 F.3d at 575 ("Congress determined that rule-vacatur was not unnecessarily burdensome on agencies when it provided vacatur as a standard remedy for APA violations."). Any one of these APA violations would be a proper basis for vacatur. The Court here has found each.

In urging a lesser remedy than vacatur, HHS relies on three precedents. Each is inapposite. HHS first cites language in *California v. Azar*, 911 F.3d 558 (9th Cir. 2018), which,

HHS argues, suggests that vacatur is not the ordinary remedy for an APA violation. HHS SJ at 78–79; OA Tr. at 136–37. But the Ninth Circuit there was considering the appropriate scope of a preliminary injunction. It was not addressing the proper remedy following the entry of summary judgment on APA claims finding an agency rule defective based on a review of the full administrative record. *See* 911 F.3d at 582–84.

Los Angeles Haven Hospice, Inc. v. Sebelius, 638 F.3d 644 (9th Cir. 2011) similarly has little bearing here. *See* OA Tr. at 137, There, the Ninth Circuit held that the district court had properly found legally deficient an extant HHS regulation pertaining to hospice payments under the Medicare statute. *Id.* at 661. The Circuit took issue with, however, the later instatement by the district court of a nationwide injunction against the rule, which, the Circuit noted, would have the effect of preventing HHS from enforcing a statutorily mandated payment cap, creating "great uncertainty for the government, Medicare contractors, and the hospice providers." *Id.* at 665. There is no comparable circumstance here. The 2019 Rule has not taken effect, and so its invalidation will not disrupt the administration of an extant regulation. And because the Court has resolved the competing motions for summary judgment based on a full administrative record, the Court has no need, as initially appeared potentially necessary before the Rule's effective date was deferred from July 2019 to November 22, 2019, to consider the necessity of preliminary relief pending a full decision on the merits.[75]

Third, HHS points to *Virginia Society for Human Life, Inc. v. Federal Election Commission*, 263 F.3d 379 (4th Cir. 2001), *overruled by The Real Truth About Abortion, Inc. v. Federal Election Commission*, 681 F.3d 544 (4th Cir. 2012). *See* OA Tr. at 137. That case, too,

[75] For this reason, *Weinberger v. Romero-Barcelo*, 456 U.S. 305 (1982), and other cases discussing the appropriate scope of injunctions generally, *see* HHS SJ at 77–79; HHS Reply at 49–50, have little bearing on the Court's analysis in the instant matter.

concerned the appropriate scope of an injunction. After the Federal Election Commission denied a petition for a rulemaking to repeal an FEC regulation, plaintiff sued for a declaratory judgment and injunctive relief. The district court held that the regulation violated the First Amendment and entered a nationwide injunction enjoining its enforcement, without reaching plaintiff's APA claims. *Va. Soc'y for Human Life v. Fed. Election Comm'n*, 83 F. Supp. 2d 668, 676–77 (E.D. Va. 2000). The Fourth Circuit affirmed the district court on the merits—solely on constitutional grounds, *see* 263 F.3d at 381, 392—but determined that the injunction should be limited to enjoining the FEC from enforcing the regulation against the plaintiff, *id.* at 393–94. That situation is far afield from that here. The Court here has found, in addition to constitutional violations affecting § 88.7(i)(3)(iv) of the Rule, multiple APA violations. Under the APA, these provide a sound charter for the remedy of vacatur.

HHS next urges the Court to sever and vacate only the offending provisions of the 2019 Rule. HHS SJ at 79–80; HHS Reply at 49. In doing so, the agency relies on the Rule's severability clause. HHS SJ at 79 (citing 84 Fed. Reg. at 23,226, 23,272). As the Supreme Court has repeatedly held, however, "a severability clause is an aid merely; not an inexorable command." *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2319 (2016) (quoting *Reno v. ACLU*, 521 U.S. 844, 884 n.49 (1997)). The Court has also cautioned that such a clause does not give a court license to "devise a judicial remedy that . . . entail[s] quintessentially legislative work." *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 329 (2006). "Such an approach would inflict enormous costs on both courts and litigants." *Whole Woman's Health*, 136 S. Ct. at 2319.

The Court has carefully considered HHS's application to preserve parts of the Rule that are not compromised by legal deficiencies. Had the Court found only narrow parts of the Rule

infirm—for example, had the Court held invalid only § 88.7(i)(3)(iv), the portion of the remedial provision that authorizes termination of the entirety of a recipient's funding—a remedy tailoring the vacatur to only the problematic provision might well have been viable.

The APA violations that the Court has found, however, are numerous, fundamental, and far-reaching. The Court's finding that HHS lacked substantive rule-making authority as to three of the five principal Conscience Provisions nullifies the heart of the Rule as to these statutes. The Court's finding that the agency acted contrary to two major existing laws (Title VII and EMTALA) vitiates substantive definitions in the Rule affecting the health care employment and emergency contexts. The Court's finding that HHS failed to give proper notice of the definition it adopted of "discriminate or discrimination" voids that central dimension of the Rule. And the Court's finding that the Rule was promulgated arbitrarily and capriciously calls into question the validity and integrity of the rulemaking venture itself. Indeed, the Court has found that HHS's stated justification for undertaking rulemaking in the first place—a purported "significant increase" in civilian complaints relating to the Conscience Provisions—was factually untrue.

In these circumstances, a decision to leave standing isolated shards of the Rule that have not been found specifically infirm would ignore the big picture: that the rulemaking exercise here was sufficiently shot through with glaring legal defects as to not justify a search for survivors. And leaving stray non-substantive provisions intact would not serve a useful purpose. As the D.C. Circuit has observed in the course of invalidating a rule in its entirety, here "it is clear that severing all . . . [of the invalid sections] would severely distort the [Agency's work] and produce a rule strikingly different from" the one HHS promulgated and has fiercely defended in court, making severance inappropriate. *MD/DC/DE Broadcasters Ass'n v. FCC*, 236 F.3d 13, 23 (D.C. Cir. 2001); *see also Nat. Res. Def. Council v. EPA*, 489 F.3d 1250, 1261 (D.C. Cir. 2007)

(vacating two rules in their entirety because, "[a]s a result of our decision today, neither of the two Rules survives remand in anything approaching recognizable form").

And for the Court to preserve isolated parts of the Rule could well deviate from the course HHS would have chosen in the face of the invalidation of the Rule's core provisions. "Severance and affirmance of a portion of an administrative regulation is improper if there is substantial doubt that the agency would have adopted the severed portion on its own." *Nat'l Treasury Emps. Union v. Chertoff*, 452 F.3d 839, 867 (D.C. Cir. 2006) (citation and internal quotation marks omitted). The Court's finding that severance here is inappropriate here ultimately respects

> the fundamental principle that agency policy is to be made, in the first instance, by the agency itself—not by courts, and not by agency counsel. When a court finds that an agency regulation is invalid in substantial part, and that the invalid portion cannot be severed from the rest of the rule, its typical response is to vacate the rule and remand to the agency. Courts ordinarily do not attempt, even with the assistance of agency counsel, to fashion a valid regulation from the remnants of the old rule.

Harmon, 878 F.2d at 494 (footnotes omitted); *accord Chertoff*, 452 F.3d at 867. The Court therefore declines HHS's invitation to sever the invalid portions of the Rule—if such textual surgery were even possible—and instead will vacate the Rule in its entirety.[76]

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[76] This is not a case in which a remand without vacatur is viable, and HHS has not so argued. In a line of cases beginning with *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993), courts have considered two factors when determining whether remand without vacatur is superior to vacatur: "the seriousness of the [rule's] deficiencies" and "the disruptive consequences" of vacatur. *Id.*; *see, e.g.*, *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014); *Advocates for Highway & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1151 (D.C. Cir. 2005); *Milk Train v. Veneman*, 310 F.3d 747, 755–56 (D.C. Cir. 2002); *Nat. Res. Def. Council v. U.S. EPA*, 676 F. Supp. 2d 307, 312 (S.D.N.Y. 2009). Both factors favor "the normal remedy" of vacatur here. *Allina Health Servs.*, 746 F.3d at 1110. First, the Court has found broad and serious APA deficiencies in the 2019 Rule, and it is far from "conceivable that the [Agency] may be able to" remedy these issues without being forced to begin anew. *Allied Signal*, 988 F.3d at 150–51. Second, because the

The Court, finally, considers HHS's argument that any relief from the Rule should be limited either to this District or to the specific plaintiffs in these consolidated actions. HHS SJ at 77–79; HHS Reply at 49–50; OA Tr. at 137–41. That argument is unpersuasive. The plaintiffs in these cases span 19 States, the District of Columbia, several units of local government, and include a number of associations of health care providers. And the Court's decision to invalidate the Rule was based on competing summary judgment motions drawing on the full administrative record. In finding violations of the APA—and, as to § 88.7(i)(3)(iv), of the Constitution—the Court has not relied on facts or considerations specific to this District or particular plaintiffs. Rather, the violations of the APA and the Constitution that were found here would equally imperil the Rule in the face of a similar challenge brought in any District and by any plaintiff with standing.

HHS's argument that relief should be limited to the individual challenger of an unlawful Rule, taken to its logical extreme, would ultimately require a profusion of actions to assure that such a Rule was never applied. More than 30 years ago, the D.C. Circuit foreclosed this audacious argument. It held: "When a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed." *Harmon*, 878 F.2d at 495 n.21. The Circuit reaffirmed this position a decade later:

2019 Rule has not yet taken effect, vacating it before inception ought not to be disruptive. This is not, in other words, a case where "[t]he egg has been scrambled and there is no apparent way to restore the status quo ante." *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002). And vacatur here will not leave a regulatory vacuum. *See Nat. Res. Def. Council*, 489 F.3d at 1265 (Rogers, J., concurring in part and dissenting in part). The 2011 Rule, which has governed HHS's administration of the Conscience Provisions for eight years and is unaffected by this decision, will remain in place, and continue to provide a basis for HHS to enforce these laws, pending any future rule that HHS may promulgate.

> The Administrative Procedure Act permits suit to be brought by any person "adversely affected or aggrieved by agency action." In some cases the "agency action" will consist of a rule of broad applicability; and if the plaintiff prevails, the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual. Under these circumstances a single plaintiff, so long as he is injured by the rule, may obtain "programmatic" relief that affects the rights of parties not before the court.

Nat'l Min. Ass'n, 145 F.3d at 1409 (quoting *Lujan*, 497 U.S. at 913 (Blackmun, J., dissenting)).[77]

HHS does not offer persuasive authority to the contrary. It quotes the familiar general proposition that "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury," *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018); *see also id.* at 1921 ("[A] remedy must of course be limited to the inadequacy that produced the injury in fact that the plaintiff has established." (internal quotation marks omitted)); HHS SJ at 77–78; HHS Reply at 49–50; OA Tr. at 140. But *Gill* was a voting rights case, involving an allegedly unlawful statewide gerrymander, not a challenge to a nationally-applicable agency rule. The Supreme Court there had no occasion to discuss the APA in general or the scope of a vacatur where APA violations affecting a rule on its face have been found.

Far more apposite is a decision earlier this year addressing a similar attempt by a federal agency to limit relief to the particular plaintiffs who had challenged a rule. The district court held that plaintiffs were likely to succeed in establishing the rule's facial invalidity under the APA. Rejecting the agency's bid to limit the scope of relief, and entering a preliminary injunction enjoining enforcement of the rule "to anyone to whom it would apply," the court wrote:

> [T]o remedy an agency's procedural violations of the APA entirely, it is not enough for a court to prevent the application of the facially invalid rule to a particular plaintiff, as [the agency] maintains, because the true gravamen of an APA claim is

[77] The aspect of Justice Blackmun's *Lujan* dissent which the D.C. Circuit quoted was not a point on which he and the *Lujan* majority differed.

> not that the agency has exercised its discretion to select a policy with which the plaintiff disagrees and to promulgate a rule that the plaintiff does not endorse. Instead, under the APA, the plaintiff's claim is that the agency has breached the plaintiff's (and the public's) entitlement to non-arbitrary decision making and/or their right to participate in the rulemaking process when the agency undertook to promulgate the rule. Consequently, to provide the relief that any APA plaintiff is entitled to receive for establishing that an agency's rule is procedurally invalid, the rule must be invalidated, so as to give interested parties (the plaintiff, the agency, and the public) a meaningful opportunity to try again.

Make the Rd. N.Y. v. McAleenan, No. 19 Civ. 2369 (KBJ), 2019 WL 4738070, at *49 (D.D.C. Sept. 27, 2019). This reasoning is compelling. It applies with even greater force to a finding of invalidity under the APA like that here, made on summary judgment.

Accordingly, as a remedy, the Court vacates the 2019 Rule in its entirety, pursuant to APA § 706(2).

The Conscience Provisions recognize and protect undeniably important rights. The Court's decision today leaves HHS at liberty to consider and promulgate rules governing these provisions. In the future, however, the agency must do so within the confines of the APA and the Constitution.

CONCLUSION

For the foregoing reasons, the Court grants plaintiffs' motions for summary judgment; denies HHS's motions both to dismiss and for summary judgment; and denies as moot plaintiffs' motion for preliminary relief. The Court accordingly vacates HHS's 2019 Rule in its entirety.

A separate order will issue shortly terminating these and all other outstanding motions. The Clerk of Court is respectfully directed thereafter to close these cases.

SO ORDERED.

Paul A. Engelmayer
United States District Judge

Dated: November 6, 2019
New York, New York

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, et al., Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	19 Civ. 4676 (PAE) (lead) 19 Civ. 5433 (PAE) (consolidated) 19 Civ. 5435 (PAE) (consolidated)

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT, IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR FOR SUMMARY JUDGMENT, AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

CONSTITUTION

FEDERAL STATUTES

FEDERAL REGULATIONS

RULES

MISCELLANEOUS AUTHORITIES

INDEX

Plaintiffs cite the following short form citations for motions, memoranda of law, and exhibits filed in these consolidated cases (all citations to docket entries are to the docket of the lead action, 19 Civ. 4676 (PAE), unless otherwise specified):

CMDA Mem.	Memorandum of Law of Defendants-Intervenors Dr. Regina Frost and Christian Medical and Dental Associations in Support of Motion for Summary Judgment, and in Opposition to Plaintiffs' Motions for Preliminary Injunction, Dkt. 150 (filed Aug. 14, 2019).
Compl.	Plaintiffs' Complaint for Declaratory and Injunctive Relief, Dkt. 3 (filed May 21, 2019).
Defs.' Mem.	Defendants' Consolidated Memorandum of Law in Support of Defendants Motion to Dismiss or, in the Alternative, Motion for Summary Judgment, and in Opposition to Plaintiffs' Motions for Preliminary Injunction, Dkt. 148 (filed Aug. 14, 2019).
Defs.' Mot.	Defendants' Consolidated Motion to Dismiss or, in the Alternative, Motion for Summary Judgment, Dkt. 147 (filed Aug. 14, 2019).
Ex. __	Citations to Exhibits 1 to 4 and Exhibits 6 to 66 are to the exhibits to the Declaration of Matthew Colangelo, Dkt. 43 (filed June 14, 2019). Citations to Exhibit 5 are to the exhibit to Plaintiffs' Notice of Filing of Corrected Exhibit, Dkt. 44 (filed June 14, 2019). Citations to Exhibits 67 to 136 are to the excerpts from the administrative record and other evidence lodged with the Court as exhibits to the Declaration of Matthew Colangelo, Dkt. 180 (filed Sept. 5, 2019).
Pls.' PI Mem.	Memorandum of Law in Support of Plaintiffs' Motion for Preliminary Injunction, Dkt. 45 (filed June 14, 2019).
Provider PI Mem.	Joint Memorandum of Law in Support of [Provider] Plaintiffs' Motion for Preliminary Injunction, 19 Civ. 5433 (PAE), Dkt. 20 (filed June 17, 2019).
Provider SJ Mem.	Memorandum of Law in Support of [Provider] Plaintiffs' Cross-Motion for Summary Judgment, in Opposition to Defendants' Motion for Summary Judgment, and Reply in Support of [Provider] Plaintiffs' Motion for Preliminary Injunction, Dkt. __ (filed Sept. 5, 2019).

INTRODUCTION

Plaintiffs filed this action to challenge a regulation issued by the U.S. Department of Health and Human Services that—ostensibly in the name of conscience-protection rights—would instead dramatically disrupt the country's entire health care sector by redefining the scope and application of nearly thirty federal statutes, and that would coerce Plaintiffs to carry out the federal government's current policy agenda by subjecting Plaintiffs to the unilateral termination of billions of dollars in federal funds under deeply unclear criteria.

1. Judicial review is warranted now. Defendants argue that Plaintiffs' constitutional claims may not proceed until after the regulation takes effect and the Department initiates a specific enforcement action for noncompliance. But this argument ignores the fact that the purpose and likely effect of the Final Rule is to compel Plaintiffs and others to comply with the Final Rule's unlawful and unreasonable expansion of federal funding statutes. That compliance obligation ripens on November 22, 2019, the effective date of the Final Rule; and, in the meantime, the Final Rule is already affecting Plaintiffs in significant ways, as the Department expected would occur. No further factual development is needed for the Court to discern the clear constitutional violations at issue, and Plaintiffs would be irremediably harmed by delay.

In the face of Plaintiffs' overwhelming showing of drastic and immediate injury—supported by sworn testimony from dozens of national leaders in their fields, with deep experience in medical practice, ethics, public health, epidemiology, health systems administration, and other specialties—Defendants have failed to offer any concrete evidence to the contrary, and instead wave aside Plaintiffs' sworn testimony by mischaracterizing it in broad strokes as "hypothetical" or "imagined." This dismissive approach is unpersuasive; Plaintiffs' challenges are ripe; and the motion to dismiss should be denied.

2. On the merits, the Final Rule is invalid under the Administrative Procedure Act

because it exceeds the Department's statutory authority, is not in accordance with law, and is arbitrary and capricious. Most notably, production of the administrative record following its court-ordered completion reveals that a central factual assertion the Department relied on to support this rulemaking—namely, the number of complaints of discrimination the agency has received in the past three years—is simply false: nearly 95% of the complaints of discrimination that the Department claims formed the basis for the Final Rule in fact *have nothing to do* with the federal refusal statutes. It is hard to find a clearer case of arbitrary agency action than when an agency falsely cites to evidence that it does not actually have to support its action.

Defendants argue that the rule clears APA review because Defendants "considered" the concerns identified in public comments, and that the rule "simply clarifies" the Department's enforcement process. But mere consideration of public comments does not establish a reasoned basis for agency action where that consideration was window-dressing; and counsel's assurances of regulatory modesty contrast starkly with the grand proclamations the federal government has spent two years delivering by Executive Order and in statements from senior officials—including the President and members of his cabinet—regarding the true intended scope and breadth of this rulemaking. The Final Rule should be vacated under the APA.

3. Plaintiffs are also entitled to relief on their constitutional claims. The Final Rule is a paradigmatic example of executive branch overreach that violates the Spending Clause proscription on gun-to-the-head coercion: it retroactively conditions hundreds of billions of dollars of critical federal health care funds on compliance with new and indeterminate policy pronouncements regarding how the federal health care refusal statutes should be broadened and redefined. And the rule violates the Establishment Clause because it impermissibly advances religious beliefs, effectively *requiring* Plaintiffs to hire employees who cannot deliver health

services critical to the entity's mission, and thus to conform their business practices to the employee's own religious practices.

Plaintiffs therefore respectfully request that the Court vacate and set aside the Final Rule.

ARGUMENT

I. Defendants' motion to dismiss should be denied.

Defendants move to dismiss Plaintiffs' Spending Clause and Establishment Clause claims for lack of subject-matter jurisdiction on the ground that Plaintiffs' claims are unripe until Defendants take specific enforcement action under the Final Rule. Defs.' Mem. 18-23. The motion should be denied because the Final Rule (1) requires Plaintiffs to adjust their conduct now, and (2) presents a risk of serious hardship to Plaintiffs absent adjudication of their claims.

A. Legal standard for assessing Defendants' motion to dismiss.

A complaint need only set forth "a short and plain statement of the grounds for the court's jurisdiction," and "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). Under Rule 12(b)(1), Plaintiffs bear the burden of demonstrating that the Court has subject-matter jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Plaintiffs may rely on the pleadings and any supporting affidavits, and the Court should "construe jurisdictional allegations liberally and take as true uncontroverted factual allegations." *Robinson v. Overseas Military Sales Corp.*, 21 F.3d 502, 507 (2d Cir. 1994).

B. Plaintiffs' constitutional challenges are ripe for judicial review.

1. Plaintiffs' claims are ripe because the Final Rule requires Plaintiffs to adjust their conduct immediately.

Defendants assert that Plaintiffs' constitutional claims are not yet ripe because "Plaintiffs have identified no specific enforcement action taken against them under the Rule." Defs.' Mem. 18. But this argument ignores both the explicit purpose and intended effect of the Final Rule,

which is to compel Plaintiffs' and others' *compliance* with Defendants' unlawfully and unreasonably expanded interpretation of federal funding statutes. *See, e.g.*, 84 Fed. Reg. at 23,179 ("Department is . . . required to ensure . . . the compliance of its funding recipients."); *id.* at 23,227-29 (the rule "incentivizes the desired behavior" by expanding enforcement in light of "[i]nadequate [existing] enforcement tools"); *id.* at 23,269-70 (requiring grantees to sign enforceable assurances and certifications of compliance). Defendants' threatened enforcement is merely a means of ensuring that compliance, not the object of the Final Rule. And "agency action is 'ripe' for review at once" when "as a practical matter [it] requires the plaintiff to adjust his conduct immediately." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990).

Plaintiffs' complaint alleges that once the Final Rule becomes effective, Plaintiffs will have no choice but to either acquiesce in the Final Rule's unconstitutional conditions, or risk losing billions of funds that the Final Rule plainly authorizes HHS to terminate or withhold. *See* Compl. ¶¶ 1-4, 80-88, 133-158; Pls.' PI Mem. 10-14; *see also infra* Parts III.B, IV.A. The immediate obligation to comply with the Final Rule—or risk losing billions in critical public health funds—is an immediate harm that this Court can and should address, and constitutes the very threat that the limitations on the spending power proscribe. *See Nat'l Fed'n of Indep. Business ("NFIB") v. Sebelius*, 567 U.S. 519, 580-81 (2012) (underscoring concerns with respect to the "nature of the threat" posed by the Medicaid provisions of the Affordable Care Act); *id.* at 581 (explaining that "[b]y financial inducement the Court meant the threat of losing . . . funds" (internal quotation marks omitted)). When Plaintiffs "ha[ve] no choice, the Federal Government can achieve its objectives without accountability," *id.* at 578, and Plaintiffs' well-pleaded allegations regarding the impact of HHS's fund-termination authority establish a real and imminent claim of unconstitutional government action. *See* Compl. ¶¶ 1-4, 80-88, 133-158.

Defendants also assert that the "scope of funding that may be at risk is unknown," Defs.' Mem. 20, but the Final Rule authorizes HHS to withhold or terminate billions of dollars in federal funding for even suspected violations of the Final Rule and its underlying statutes—as Defendants never contest, and as Plaintiffs clearly pled. *See* Compl. ¶¶ 1-4, 80-88, 133-158. In fact, *all* of Plaintiffs' federal health care funding is at risk, as Defendants elsewhere concede. Defs.' Mem. 4 ("Plaintiffs . . . have the straightforward remedy of no longer accepting the conditioned federal funds."). Plaintiffs are not required to gamble with that critical funding before this Court may adjudicate their constitutional claims. There is no risk of judicial entanglement in abstract disagreements here, *see Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967)); and this Court need not wait until an enforcement action is taken under the Final Rule to conclude that Plaintiffs' claims are ripe for review, *see City of New York v. U.S. Dep't of Commerce*, 739 F. Supp. 761, 766 (E.D.N.Y. 1990).[1] The Final Rule standing alone seeks to compel changes in Plaintiffs' behavior or expose them to the risk of fund termination on the day it takes effect—with extremely disruptive consequences for Plaintiffs and the public health either way. Compl. ¶¶ 80-88, 133-158; Pls.' PI Mem. 13-14.

In any event, even assuming that ripeness depended on HHS's enforcement decisions, the likelihood of enforcement actions to terminate funds is sufficiently high to warrant adjudication of Plaintiffs' constitutional claims. It is hardly "hypothetical[]," Defs.' Mem. 20, that HHS plans to use the threat of funding termination to induce compliance with the Final Rule's new

[1] The cases that Defendants cite with respect to the Weldon Amendment are either inapposite, or further support that Plaintiffs' claims are ripe for review. As Defendants themselves explain, *Nat'l Family Planning & Reproductive Health Ass'n, Inc. v. Gonzalez*, 468 F.3d 826 (D.C. Cir. 2006), dismissed the plaintiff's claims for lack of constitutional standing, which Defendants do not challenge in this case. In *California v. United States*, No. 05-cv-328, 2008 WL 744840 (N.D. Cal. Mar. 18, 2008), the Court made clear that when the federal government either determined that enforcing state law would violate the Weldon Amendment "or refuse[d] to provide an answer, thus leaving California in a difficult position of putting at risk billions of dollars in federal funds if it enforces its own statute, the case then would be ripe for a court to determine this matter." *Id.* at *6. This is exactly the "unfortunate situation" Plaintiffs confront here. *Id.*

requirements; HHS has said so itself, explicitly stating that one purpose in issuing the Final Rule is to address its "[i]nadequate enforcement tools to address unlawful discrimination and coercion." 84 Fed. Reg. at 23,228. Yet, there is no evidence at all in the administrative record that a single complaint of discrimination was unable to be remedied with the Department's existing tools. *See infra* Part II.C.1. This lack of evidence can only suggest that HHS intends to wield its new powers under the Final Rule to induce Plaintiffs to accept its new conditions.

Plaintiffs' Establishment Clause claim similarly presents "a concrete dispute between the parties." *Sharkey v. Quarantillo*, 541 F.3d 75, 89 (2d Cir. 2008); *see also Nat'l Org. for Marriage*, 714 F.3d at 689 (courts "assess pre-enforcement First Amendment claims . . . under somewhat relaxed standing and ripeness rules"). This claim turns on a straightforward legal analysis of the Final Rule's definition of "discrimination." That definition, at subsection (4), provides that an employer "shall not be regarded as having engaged in discrimination" against an objecting employee where the employer offers, and the employee "voluntarily accepts an effective accommodation." 84 Fed. Reg. at 23,263 (§ 88.2). Plaintiffs allege that this definition (as elaborated by the limited discussion in the rule's preamble, *see id.* at 23,190-92) violates the Establishment Clause because it permits an employee an unqualified right to refuse work for religious reasons, and accordingly requires employers like Plaintiffs to conform their business practices to the objecting employee's religious practices. *See* Compl. ¶¶ 73, 198-201. Although HHS disagrees on the merits that the Final Rule violates the Establishment Clause, *see* Defs.' Mem. 67-70, nowhere does the agency assert that the application of this definition is too "abstract" for the Court's review. *Abbott Labs.*, 387 U.S. at 148-49.

2. Plaintiffs face hardship absent the Court's consideration.

In addition, delaying review of these claims would cause immense and immediate harm to Plaintiffs and the public interest. *See id.* at 152-54; *see also New York v. U.S. Dep't of*

Commerce, 351 F. Supp. 3d 502, 626-27 (S.D.N.Y. 2019). Plaintiffs face hardship "where a regulation requires an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance." *Abbott Labs.*, 387 U.S. at 153; *see also Thomas v. City of New York*, 143 F.3d 31, 36 (2d Cir. 1998) (pre-enforcement challenge ripe where "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").

This is exactly the situation Plaintiffs face. Plaintiffs' complaint alleges extensive, imminent, and potentially devastating injuries caused by the Final Rule. *See* Compl. ¶¶ 100-158. Plaintiffs' motion for preliminary injunction and supporting evidence further establish that the Final Rule will cause—and already has begun causing—these imminent harms. *See* Pls.' PI Mem. 10-22. Among these harms are significant administrative, policy, human resources, and other efforts Plaintiffs must undertake to come into compliance prior to the Final Rule's effective date, *id.* at 11-13 & nn.11-14, including efforts that have already begun. *See, e.g.*, Ex. 29 (Lucchesi Decl.) ¶ 22; Ex. 45 (Vanden Hoek & Perna Decl.) ¶¶ 19-20; Ex. 46 (Wagaw Decl.) ¶ 18. Indeed, HHS expressly states that one purpose of the Final Rule is to "institute proactive measures" by grantees like the Plaintiffs. 84 Fed. Reg. at 23,228. And Plaintiffs face "serious penalties attached to noncompliance," *Abbott Labs.*, 387 U.S. at 153, through the risk of losing billions of dollars in federal funds necessary to deliver health care to their residents. *See* Compl. ¶¶ 80-88, 133-158; Pls.' PI Mem. 13-14.

The fact that Plaintiffs must make immediate changes to the conduct of their affairs is not surprising, given the upheaval the Final Rule causes to their direct delivery of health care. As Plaintiffs alleged in their complaint and documented in the motion for preliminary injunction,

their hospitals have policies on accommodating religious objection, many of which track state laws and Title VII. *See* Compl. ¶¶ 112-114; Pls.' PI Mem. 15-16 & n.15. And as Plaintiffs also extensively documented, the Final Rule's definition of "discrimination" departs from the framework underlying their policies by, *inter alia*, allowing an employee to determine whether she has been discriminated against by tying such determination to whether she voluntarily accepts an employer's accommodation—a sea change that requires Plaintiffs' policies to be rewritten, eliminates Plaintiffs' ability to employ efficient and cost-conscious staffing arrangements, and imposes burdens on Plaintiffs' non-objecting staff. *See* Compl. ¶¶ 73-74, 79, 119-132; Pls.' PI Mem. 16-18 & nn.17-18.

Furthermore, changing their religious accommodation policies to permit objections in accordance with the Final Rule will require Plaintiffs to make staffing changes in emergency and rural settings, among others, and such changes threaten irreparable injury to the reputation of Plaintiffs' health institutions. *See* Compl. ¶¶ 119-132; Pls.' PI Mem. 18-22. Plaintiffs "deal in a sensitive industry, in which public confidence in their [services] is especially important," and "[t]o require them to challenge these regulations only as a defense to an action brought by the Government might harm them severely and unnecessarily." *Abbott Labs.*, 387 U.S. at 153; *cf. City of Chicago v. Sessions*, 264 F. Supp. 3d 933, 950 (N.D. Ill. 2017) (risk of reputational injury causes irreparable harm). Indeed, delaying judicial review until *after* Plaintiffs have been either forced to change their policies, stripped of billions of dollars in health care funds, or subjected to federal enforcement action "would result in extreme—possibly irremediable—hardship." *Dep't of Commerce v. U.S. House of Representatives*, 525 U.S. 316, 332 (1999).

Because Plaintiffs' constitutional claims are ripe for judicial review, Plaintiffs

respectfully request that the Court deny Defendants' motion to dismiss.[2]

II. The Final Rule violates the Administrative Procedure Act.

Plaintiffs are entitled to summary judgment on their claims that the Final Rule violates the Administrative Procedure Act ("APA") because "there is no genuine dispute as to any material fact and [Plaintiffs are] entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

The APA provides that courts must "hold unlawful and set aside" agency action that is "in excess of statutory jurisdiction, authority, or limitations"; that is "not in accordance with law"; or that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. §§ 706(2)(A), (C). Defendants assert that under the APA, the Final Rule is "presumed valid." Defs.' Mem. 17, 52. There is no support for this assertion; to the contrary, Congress intended for courts to conduct rigorous judicial review of agency action under the APA in order to maintain the balance of power between the branches of government: "[I]t would be a disservice to our form of government and to the administrative process itself if the courts should fail, so far as the terms of the [APA] warrant, to give effect to its remedial purposes." *Wong Yang Sung v. McGrath*, 339 U.S. 33, 41 (1950); *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 537 (2009) (Kennedy, J., concurring) (in enacting the APA, "Congress confined agencies' discretion and subjected their decisions to judicial review").

Although it is correct that under the APA, "[a] reviewing court may not itself weigh the evidence or substitute its judgment for that of the agency," this standard does not support the claim of presumptive validity Defendants assert; instead, "within the prescribed narrow sphere,

[2] Defendants also argue in general terms that all of Plaintiffs' claims should be dismissed for failure to state a claim, Defs.' Mem. 16, but do not appear to present a distinct argument on Rule 12(b)(6) grounds apart from their arguments on the merits. Defs.' Mem. 23-73. Under Rule 12(b)(6), Plaintiffs "need only allege 'enough facts to state a claim to relief that is plausible on its face.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 n.12 (2011) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). For the reasons stated in Plaintiffs' opposition to Defendants' merits arguments in this memorandum, Plaintiffs easily clear the Rule 12(b)(6) threshold.

judicial inquiry must be searching and careful." *Islander E. Pipeline Co., LLC v. McCarthy*, 525 F.3d 141, 150-51 (2d Cir. 2008) (quotation marks and citation omitted). The Supreme Court has long made clear that the APA requires this Court to conduct "plenary review of the Secretary's decision," *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971), and that this review is to be "thorough, probing, [and] in-depth," *id.* at 415.

Here, there is no dispute of material fact that the Final Rule exceeds the Department's statutory authority, is not in accordance with law, and is arbitrary and capricious.

A. The Final Rule violates the APA because it exceeds the Department's statutory authority.

The APA requires this Court to set aside agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). For the reasons explained in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum, the Final Rule exceeds the Department's statutory authority and violates the APA. *See* Provider SJ Mem., Part I; *see also* Pls.' PI Mem. 25-30.

B. The Final Rule violates the APA because it is not in accordance with law.

The APA provides that the Court shall "hold unlawful and set aside" agency action that is "not in accordance with law." 5 U.S.C. § 706(2)(A). For the reasons explained in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum, the Final Rule is not in accordance with law because it violates the ACA's Non-Interference Mandate and impairs the federal statutory guarantee of access to emergency medical care. *See* Provider SJ Mem., Parts II.A, II.B, II.D; *see also* Pls.' PI Mem. 30-36.

In addition, the Final Rule conflicts with the Medicaid informed consent requirements and violates the Paperwork Reduction Act, as set out below.

1. The Final Rule conflicts with the Medicaid informed consent requirements that apply to counseling and referral services.

The Final Rule conflicts with the Medicaid counseling and referral provision it purports to implement. *See* Pls.' PI Mem. 32-33. That statute provides that Medicaid managed care organizations will not be required to provide counseling or referral services if the organization objects on moral or religious grounds. 42 U.S.C. § 1396u-2(b)(3)(B). Congress, however, expressly cabined these refusal rights by providing that with regard to informed consent, the counseling and referral provision shall not "be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974." *Id.* Because the Final Rule includes no exception for state-law disclosure requirements, 84 Fed. Reg. at 23,266-67 (§ 88.3(h)(1)(ii), (h)(2)(ii)), the Department's implementation of this provision exceeds its authority.

Defendants argue that the Final Rule "does not implicate any state disclosure requirements except to the extent they rely on [§ 1396u-2(b)(3)(B)] for authority," and that the Medicaid informed consent requirement "is simply not implicated here." Defs.' Mem. 49. But nothing in the Final Rule limits its reach in the way Defendants now propose; § 88.3(h)(1)(ii) provides that "[a]ny State agency that administers a Medicaid program is required to comply with," *inter alia*, sub-paragraph (h)(2)(ii); and that sub-paragraph in turn includes a blanket restriction on requiring an objecting Medicaid managed care organization to provide counseling or referral services, with no exception for state disclosure laws. 84 Fed. Reg. at 23,266-67. A regulation may be upheld only "on the basis articulated by the agency itself"—not on "counsel's post hoc rationalizations." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

2. The requirement that Plaintiffs submit written assurances and certifications of compliance is not in accordance with law.

Plaintiffs explained in their memorandum supporting a preliminary injunction that the assurance and certification requirements in the Final Rule, 84 Fed. Reg. at 23,269, are not in accordance with law because the Department failed to comply with the Paperwork Reduction Act ("PRA"). *See* Pls.' PI Mem. 35-36. Defendants' one-sentence response effectively concedes this point, arguing only that *after* the Final Rule was published, the Department belatedly sought to comply with its obligations and "fully expects approval prior to the Rule's revised effective date." Defs.' Mem. 51.

Defendants' response does not cure this legal infirmity. First, as of today, these data collection requirements still have not been approved; and Defendants cannot seriously be asking the Court to ignore a conceded APA violation because the Department "fully expects" that a non-party (the OMB Director) may take action in the future. *Cf. Bellevue Hosp. Ctr. v. Leavitt*, 443 F.3d 163, 179 (2d Cir. 2006) (agency decision was arbitrary where instead of complying with statutory requirement, "agency simply stated its intent to do better the next time").

Second, the Information Collection Request that the Department belatedly submitted to OMB seeks approval only for the assurance requirement, not the certification of compliance. *See* Information Collection Request, *Request for OMB Review and Approval*, at 5 (June 19, 2019), at https://www.reginfo.gov/public/do/DownloadDocument?objectID=92774800 ("Note that this information collection request does not include the related certification of compliance in section 88.4(b).").[3] Defendants' incomplete attempt at post-hoc compliance with its legal obligations renders the assurance and certification requirements invalid under the APA.

[3] *See also* Information Collection Request—Agency Submission, https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201906-0945-003.

C. The Final Rule is arbitrary and capricious in violation of the APA.

Under the APA, the Court must "hold unlawful and set aside" agency action that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A). Agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or [made a decision that] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. Furthermore, agency changes to longstanding policies that have engendered reliance interests over time must "show that there are good reasons for the new policy," and provide a "detailed justification" for its new direction to survive arbitrary and capricious review. *Fox*, 556 U.S. at 515.

The Department's stated reasons for implementing the Final Rule are unsupported and inconsistent with the record evidence; the Department failed entirely to consider the record evidence of significant upheaval the Final Rule would cause; and despite that record evidence, the Department grossly failed to appropriately assess the costs and benefits of its rulemaking.

1. HHS has justified the Final Rule on the basis of asserted problems that do not in fact exist.

HHS's repeated refrain that the Final Rule is necessary to address confusion created by the 2011 Rule, and to adequately provide for enforcement of federal conscience protections, is unsupported by the record and therefore arbitrary and capricious. HHS fails to "acknowledge . . . record evidence directly contradicting its [stated rationales for the Final Rule]," *Islander E. Pipeline Co., LLC v. Conn. Dep't of Envtl. Prot.*, 482 F.3d 79, 102 (2d Cir. 2006), and does not satisfactorily provide a "rational connection between the facts found and the choice made," *State Farm*, 463 U.S. at 43 (internal quotation marks omitted).

First, HHS claims that the Final Rule is necessary to address confusion created by the

2011 Rule. *See* 84 Fed. Reg. at 23,175, 23,228. HHS claims that:

> The 2011 Rule created confusion over what is and is not required under Federal conscience and anti-discrimination laws and narrowed OCR's enforcement processes. Since November 2016, there has been a *significant increase* in complaints filed with OCR *alleging violations of the laws that were the subject of the 2011 Rule*, compared to the time period between the 2009 proposal to repeal the 2008 Rule and November 2016. The increase underscores the need for the Department to have the proper enforcement tools available to appropriately enforce all Federal conscience and anti-discrimination laws.

84 Fed. Reg. at 23,175 (emphasis added); *see also id.* at 23,229 (separately calculating the number of complaints, and stating that OCR received 34 complaints between November 2016 and January 2018, and 343 during fiscal year ("FY") 2018); *id.* at 23,183 ("This rule provides appropriate enforcement mechanisms *in response to a significant increase* in complaints alleging violations of Federal conscience and anti-discrimination laws." (emphasis added)).

But on review of the administrative record, this rationale proves false. Prior to the November 2016 election, evidence of confusion with respect to the underlying statutes and the current regulatory scheme is slim to non-existent: as HHS itself highlights, the Department only received ten complaints alleging violations of federal conscience protections between 2009 and November 2016. *See* 83 Fed. Reg. at 3886. Subsequently, HHS purportedly received 34 complaints between November 2016 and January 2018, and 343 complaints in FY 2018 when it issued the notice of proposed rulemaking. *See* 84 Fed. Reg. at 23,229.[4] However, the vast

[4] HHS misleadingly suggests that the 34 complaints received between November 2016 (after the election) and January 2018 are distinct from the 343 complaints received in FY 2018. The relevant fiscal year, however, is from October 1, 2017 to September 30, 2018. *See* https://www.usa.gov/budget. Accordingly, some of the 34 complaints overlap with the 343 complaints. Given this confusion, Plaintiffs requested that Defendants' counsel direct Plaintiffs to the bates numbers for the 34 complaints, but Defendants never provided that information. *See* Ex. 135 (Miller Decl.) ¶¶ 4-9.

From what Plaintiffs have been able to discern, the administrative record shows 358 unique complaint numbers for the period between the November 2016 election and the end of FY 2018 on the index provided by HHS. *See* Ex. 135 (Miller Decl.) ¶¶ 10-11 & Ex. 135-A. Twenty-two of those complaints are exact duplicates, *see* Ex. 135 (Miller Decl.) ¶ 12 & Ex. 135-B, leaving 336 unique complaints. Ex. 135 (Miller Decl.) ¶ 13. As Plaintiffs explain further, *infra*, the vast majority of these unique complaints are irrelevant to the underlying refusal statutes or the Final Rule.

majority of complaints received after November 2016 reflect a fundamental misunderstanding of what federal conscience laws require or protect.

Tellingly, Defendants now concede that "a large subset of" the complaints received by HHS after November 2016 "complain of conduct that is outside of the scope of the Federal Conscience Statutes and the [Final] Rule." Defs.' Mem. 53. And while the Final Rule expressly claims a "*significant* increase" in complaints alleging violations of "Federal conscience and anti-discrimination laws," 84 Fed. Reg. at 23,175 (emphasis added), Defendants now acknowledge, as they must, that only "*some*" of the complaints "do implicate the relevant statutes." Defs.' Mem. 53 (emphasis added).

These are startling admissions, yet still manage to understate matters. In response to comments that the Final Rule was unnecessary because of the number of complaints HHS had received, HHS made a specific empirical claim that "OCR received 343 complaints alleging conscience violations" in FY 2018. 84 Fed. Reg. at 23,229. Yet a review of the administrative record reveals that the vast majority of these complaints—approximately 79%—do *not* in fact allege conscience violations, and instead relate to vaccinations, *see* Ex. 135 (Miller Decl.) ¶ 15 & Ex. 135-F, which the Department expressly admits is beyond the scope of the Final Rule. *See, e.g.*, 84 Fed. Reg. at 23,183. Numerous other complaints have nothing to do with the topics the Final Rule purports to clarify,[5] and a few vehemently *oppose* issuance of the Final Rule.[6]

[5] *See e.g.*, Ex. 123, AR 542627-36 (complaint filed because federal agencies forced complainant to remove social media ads for "divine cure for cancer"); Ex. 124, AR 543082-90 (parent alleging discrimination against a health care entity because parent did not want newborn to have a newborn screening test); Ex. 125, AR 543879-82 (allegations of identity theft and health care fraud); Ex. 126, AR 544035-43 (complainant upset about needing to purchase coverage for unneeded prescriptions); Ex. 128, AR 544235-43 (allegations of HIPAA violations when an entity posted medical records online); Ex. 131, AR 544753-62 (employee complains of suspension for refusing to meet with board of directors regarding unspecified grievances); *see also* Ex. 135 (Miller Decl.) ¶ 16 & Ex. 135-D.

[6] *See* Ex. 121, AR 542414-22 (explaining HHS's actions are "an appalling, unethical abuse of 'religious freedom' to impose archaic religious ideals on citizens in order to deny them civil liberties and health care"); Ex. 122, AR

Indeed, of the total number of complaints in the record received by HHS since November 2016, a mere *six percent* (21 complaints) allege conduct that is even arguably covered by the refusal statutes or Rule. *See* Miller Decl. ¶ 17 & Exs. 135-F, 135-G.[7]

The mismatch between the agency's stated explanation for the Final Rule and the actual facts in the administrative record cannot be overstated. HHS has woefully failed to substantiate its claim that "allegations and evidence of discrimination and coercion have existed since the 2008 Rule and increased over time." 84 Fed. Reg. at 23,175. It comes nowhere near supporting its assertion that there has been a "significant increase" in complaints related to the refusal statutes. *Id.* The agency's very specific claim of 343 complaints in FY 2018 that allege violations of these laws turns out to be patently false. "Suffice it to say, it is arbitrary and capricious for an agency to base its decision on a factual premise that the record plainly showed to be wrong." *NRDC v. Rauch*, 244 F. Supp. 3d 66, 96 (D.D.C. 2017) (citing *State Farm*, 463 U.S. at 43); *cf. Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2019) (invalidating agency action where "the evidence tells a story that does not match the explanation the Secretary gave for his decision"). That is exactly the case here, as Defendants now all but admit.[8] Far from supporting HHS's contention that the 2011 Rule needed clarification, the record shows that if anything, the Department's proposal to significantly alter the status quo has sown more confusion in the past year than in the previous seven years combined.

542449-57 ("The Current Administration has allowed religious Zealots to run health information agencies.").

[7] Plaintiffs do not concede that all of these complaints are legitimate. And while Plaintiffs do not always agree with HHS's interpretation of the scope of the refusal statutes, *see, e.g.*, 84 Fed. Reg. at 23,178-79 (discussing Weldon Amendment), for purposes of this brief Plaintiffs have erred on the side of including such complaints in this category.

[8] Defendants contend that the supposed increase in complaints was just one of "many metrics" the agency relied on, Defs.' Mem. 53, but Defendants have not here illuminated what those other metrics are, and they do not disagree that complaint volume was in fact a central reason the agency gave for promulgating the Final Rule. A rulemaking that relies a mischaracterization of the actual record evidence is arbitrary. *City of Phila. v. Sessions*, 280 F. Supp. 3d 579, 623-24 (E.D. Pa. 2017).

HHS's second justification for the Final Rule—"[i]nadequate enforcement tools to address unlawful discrimination and coercion," 84 Fed. Reg. at 23,228—also finds no support in the administrative record, and is again counter to the evidence. As explained above, the majority of complaints upon which HHS relies to promulgate the Final Rule do not require enforcement by the Department, or even fall within the scope of the Final Rule or the underlying statutes, as HHS concedes. Moreover, with respect to most of the complaints in the record, there is zero evidence that HHS investigated them at all, or needed more authority to do so.[9] The record further reveals that in the small number of instances where HHS investigated complaints, they were largely unfounded or otherwise satisfactorily resolved.[10] Indeed, HHS highlights the corrective actions health care providers and institutions took in response to OCR investigations. *See, e.g.*, 83 Fed. Reg. at 3,886 (explaining that after OCR conducted investigations of complaints, relevant entities revised policies, posted notices, trained personnel about statutory obligations, and made public announcements indicating changes to practices). Where, as here, the record evidence "directly contradicts the unsupported reasoning of the agency and the agency fails to support its pronouncements with data or evidence," courts will not defer to agency action. *Islander*, 482 F.3d at 103.

Effectively conceding that the Department's reliance on a supposed record of hundreds of conscience complaints is false, Defendants now point to only three complaints in the entire

[9] There is no evidence in the administrative record pertaining to any investigation of the FY 2018 complaints, with the exception of one complaint. *See* Ex. 135 (Miller Decl.) ¶ 18 & Ex. 135-E. And with respect to complaints filed before November 2016, HHS concedes that nearly all have been resolved. *See* 83 Fed. Reg. at 3886. Further, HHS offers no explanation for why two pre-November 2016 complaints remain open, but in any event there is nothing on the face of these complaints to suggest it is because the Department lacks enforcement authority. *See* Ex. 132, AR 545712-16 (Aug. 15, 2014 complaint alleging complainant denied admission privileges because she performed abortions); Ex. 133, AR 545736-40 (Nov. 4, 2015 complaint alleging California's FACT Act violates federal law).

[10] *See, e.g.*, Ex. 120, AR 541967 (OCR closed matter because complaint failed to state a claim of discrimination); Ex. 119, AR 541805 (complaint withdrawn when grantee took actions to come into compliance); *see also* Ex. 135 (Miller Decl.) ¶ 18 & Ex. 135-E (listing record evidence of 14 resolved complaints).

administrative record that purportedly "implicate the relevant statutes." Defs.' Mem. 53. Even this thin showing undermines, rather than supports, the Department's stated reasons for the Final Rule. As noted below, two of the complaints concern issues or entities that are not subject to the underlying statutes; and as to all three, there is nothing in the administrative record to suggest these complaints were even investigated, let alone that they could plausibly form a basis for concluding that the Department needed greater enforcement authority.

Specifically, the first complaint Defendants cite is a 2018 letter from the American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG") to OCR complaining about a decade-old ethics committee opinion by the American College of Obstetricians and Gynecologists ("ACOG") that, according to AAPLOG, leaves ob-gyns "vulnerable to the possibility that his or her conscience-based refusal to participate in abortion could be considered unethical." Ex. 129, AR 544525. The letter fails to refer to a single example of this "discrimination" occurring in the more than ten years since the ethics committee opinion was published.[11] But even if it had, ACOG is a professional organization of doctors and is plainly not subject to any of the refusal statutes. It makes no sense, then, to point to this complaint as evidence of confusion over the scope of the refusal statutes, or of the inadequacy of existing enforcement mechanisms.

The second complaint Defendants cite provides even less support for HHS's stated rationales for the Final Rule. Ex. 127, AR 544188. This 2018 complaint, by an employee of the Washington State Department of Corrections, alleges discrimination based on a refusal to provide hormone therapy to incarcerated transgender persons. Because the objected-to conduct

[11] Moreover, the administrative record includes a statement by ACOG explaining that the committee opinion will *not* be used to determine whether an ob-gyn was entitled to board certification. Ex. 129, AR 544516, at 544557-58; *see also id.* at AR 544555 (letter from American Board of Obstetrics & Gynecology to then-Secretary of HHS Michael O. Leavitt).

has nothing to do with abortion or sterilization procedures, the complaint, by definition, does not implicate the Church (b), (c)(1), (e), Coats-Snowe, or Weldon Amendments. The only refusal statute provisions that could even arguably be at issue here are Church (c)(2) or Church (d). Church (c)(2), however, concerns the rights of employees of entities that receive biomedical and behavioral research funds administered by HHS. *See* 42 U.S.C. § 300a-7(c)(2). However, federal law severely restricts HHS-funding of biomedical or behavioral research on incarcerated persons, subject to discrete and narrow exceptions. *See* 45 C.F.R. § 46.306(a)(2). Meanwhile, Church (d) only applies to a "health service program or research activity funded in whole or in part under a program administered by" HHS, 42 U.S.C. § 300a-7(d), and therefore, "does not encompass . . . medical treatments and services performed by health care providers [that] are not 'part of' a health service program receiving funding from HHS," 84 Fed. Reg. at 23,197. Defendants do not identify any HHS-funded program that provides gender-affirming health care to individuals incarcerated in state prisons and, as such, fail to explain how this complaint implicates any of the federal refusal statutes.[12]

This leaves a single complaint identified in HHS's brief that even arguably states a violation of the refusal statutes. *See* Ex. 130, AR 544612. That is far too thin a reed to rationally support the agency's express justification for the Final Rule: a "*significant increase* in complaints filed with OCR *alleging violations of the laws that were the subject of the 2011 Rule*," 84 Fed. Reg. at 23,175. Nor does the face of this complaint lend any support to HHS's second justification that it has inadequate enforcement tools at its disposal to address the issues it presents. 84 Fed. Reg. at 23,228. Indeed, the administrative record contains nothing with

[12] For example, federal law prohibits states from using federal Medicaid matching funds for health care services provided to adult and juvenile inmates of public institutions, except when the inmate is admitted to an off-site hospital or other qualifying facility for at least 24 hours. 42 U.S.C. § 1393d(a)(29)(A).

respect to HHS's assessment of the complaint, or any investigation thereof.

Defendants' own attempt to identify evidence to support HHS's stated reasons for the Final Rule reveals that HHS's decision is "unsupported by substantial evidence," and therefore arbitrary and capricious. *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018).

2. The Department failed to provide a reasoned explanation for its policy change.

In addition, to survive arbitrary and capricious review, an agency must provide a substantial justification when "its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account." *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015) (internal quotation marks omitted). The Final Rule implicates both concerns: the new policy rests on new factual findings based on substantially the same evidence the Department already considered in 2011 to reach the opposite conclusions; and Plaintiffs have relied on the prior policy as codified in the 2011 Rule, including the Department's previous view that existing "statutes strike a careful balance between the rights of patients to access needed health care, and the conscience rights of health care providers." 76 Fed. Reg. 9968, 9973 (Feb. 23, 2011).

In support of the Final Rule, the Department heavily relies on the same evidence that the agency considered in promulgating the 2011 Rule, which largely rescinded the 2008 Rule that had included many of the same onerous provisions found in the 2019 Final Rule.[13] *See, e.g.*, Pls.' PI Mem. 4-9. Yet in 2011, after considering this information, HHS found that (1) "the 2008 final rule attempting to clarify the Federal health care provider conscience statutes ha[d] instead led to greater confusion," 76 Fed. Reg. at 9969; (2) "the 2008 Final Rule may negatively affect

[13] This evidence includes a 2009 survey, 2009 journal article, news reports in 2010, and comments the Department received in response to the proposed rescission of the 2008 Rule. *See, e.g.*, 84 Fed. Reg. at 23,175-76.

the ability of patients to access care if interpreted broadly," *id.* at 9974; and (3) the certification requirements imposed by the 2008 Rule "created unnecessary additional financial and administrative burdens on health care entities," *id.* The Department's reliance on the same evidence more than eight years later to reach precisely the opposite conclusions—with no explanation of why the Department's assessment of those facts in 2011 was incorrect—is arbitrary and capricious. *See Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (en banc) (holding an agency's decision arbitrary and capricious when "it made factual findings directly contrary to" its previous policy following a change in presidential administrations, and "expressly relied on those findings to justify the policy change"); *see also Fox*, 556 U.S. at 515-16; *Islander*, 482 F.3d at 103.

The Department claims that it did "acknowledge that it was changing its policy," Defs.' Mem. 52, but far more than an "acknowledgement" was required by the APA. The Department was required to provide "a reasoned explanation" for its dramatic change in course, which it failed to do. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Instead, in responding to the many comments explaining that the Final Rule would jeopardize patient access to care[14]—one of the key findings underlying the 2011 Rule—the Department concluded "that finalizing the rule is appropriate *without regard to whether data exists* . . . about its effect on access to services." 84 Fed. Reg. at 23,182. But "[a]n agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore

[14] *See, e.g.*, Ex. 87, AR 137920 (Comment, Attorneys General of New York, et al.) ("New York Comment"); Ex. 89, AR 138102 (Comment, Nat'l Family Planning & Reprod. Health Ass'n) ("NFPRHA Comment"); Ex. 99, AR 140484 (Comment, New York City Comm'n on Human Rights, et al.) ("NYC Comment"); Ex. 100, AR 147746 (Comment, Am. Civil Liberties Union) ("ACLU Comment"); Ex. 110, AR 149141 (Comment, Nat'l Women's Law Ctr.) ("NWLC Comment"); Ex. 113, AR 160751 (Comment, Planned Parenthood Fed. of Am.) ("PPFA Comment"); Ex. 117, AR 161476 (Comment, Lambda Legal) ("Lambda Comment").

inconvenient facts when it writes on a blank slate." *Fox*, 556 U.S. at 537 (Kennedy, J., concurring).

The Department's lack of reasoned explanation is particularly egregious given that the Final Rule's radical departure from long-established policy will upend strong reliance interests. Plaintiffs and many others have developed staffing patterns and scheduling practices, hired personnel, entered into collective bargaining agreements, signed contracts with subrecipients, and otherwise structured their operations around HHS's longstanding interpretation of the refusal statutes.[15] HHS acted arbitrarily in disregarding these strong reliance interests of Plaintiffs, their health care institutions, and the populations they serve. *See Encino Motorcars*, 136 S. Ct. at 2126; *see also Chamber of Commerce v. U.S. Dep't of Labor*, 885 F.3d 360, 387 (5th Cir. 2018) (vacating agency rule as arbitrary where it "transform[ed]" the "market . . . and . . . regulate[d] in a new way the thousands of people and organizations working in that market").

3. In promulgating the Final Rule, the Department entirely failed to consider important aspects of the problem.

The APA requires this Court to set aside Defendants' decision as arbitrary if Defendants "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

a. HHS failed to consider the Final Rule's radical disruption of health care delivery.

A failure to address serious harms presented to the agency—with widespread impact on a regulated industry—constitutes arbitrary decisionmaking. *See, e.g., SecurityPoint Holdings, Inc. v. Transp. Sec. Admin.*, 769 F.3d 1184, 1188 (D.C. Cir. 2014) (vacating agency order where

[15] *See, e.g.*, Ex. 72, AR 67173 (Comment, Wash. Dep't of Health) ("WA DOH Comment"); Ex. 76, AR 71138 (Comment, Ass'n of Am. Med. Colls.) ("AAMC Comment"); Ex. 86, AR 137905 (Comment, Calif. Dep't of Justice); Ex. 87, AR 137920 (New York Comment); Ex. 89, AR 138102 (NFPRHA Comment); Ex. 96, AR 140265 (Comment, BlueCross BlueShield Ass'n) ("BCBS Comment"); Ex. 97, AR 140350 (Comment, Calif. Dep't of Insurance) ("CA Insur. Comment"); Ex. 99, AR 140484 (NYC Comment); Ex. 100, AR 147746 (ACLU Comment); Ex. 101, AR 147824 (Comment, Greater New York Hospital Ass'n) ("GNYHA Comment"); Ex. 113, AR 160751 (PPFA Comment).

agency failed even to consider potential harms of its changes to an airport advertising program); *Stewart v. Azar*, 313 F. Supp. 3d 237, 263 (D.D.C. 2018) (vacating HHS Secretary's waiver of several requirements of expanded Medicaid because "[f]or starters, the Secretary never once mentions the estimated 95,000 people who would lose coverage, which gives the Court little reason to think that he seriously grappled with the bottom-line impact on healthcare."). Courts also consider agency action arbitrary and capricious when the agency "fail[s] to address the commenters' concerns." *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 449 (D.C. Cir. 2012).

Here, as discussed in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum, the Final Rule defines key statutory terms in a manner that dramatically expands the scope and applicability of the underlying federal statutes and that will have a widespread impact on the health care industry. *See* Provider SJ Mem., Part II.A; *see also* Pls.' PI Mem. 25-30, 37-38. The new definitions of "assist in the performance," "referral," and "discrimination" drastically expand the universe of individuals, entities, and conduct regulated by the refusal statutes, and radically disrupt Plaintiffs' and other providers' basic operations and ability to deliver care—including emergency care. Taken together, these definitions create a dangerous double bind for providers: "assist in the performance" and "referral" increase the number of prospective objectors from clinical staff to a potentially limitless group of workers, while "discrimination" prescribes unworkable limits on a provider's ability to learn about possible objections among this expanded group of workers, thereby limiting providers' ability to provide undisrupted patient care.[16]

[16] Pursuant to the Final Rule, an employee (1) may not be asked, pre-hire, whether she can execute core functions of her job without objection; (2) has no affirmative duty to disclose an objection to any aspect of her work; (3) may object at any time to any task, without advance notice to her employer and regardless of the effect on patient health;

The administrative record contains evidence that the Final Rule would do serious damage to Plaintiffs and other providers around the country in just this way. Major industry organizations and health provider systems, representing or employing millions of health care workers, raised the following operational concerns to HHS:

- Expanding the universe of potential objectors beyond clinicians to other workers, *e.g.*, janitorial, scheduling, or other administrative staff, "could significantly impact the smooth flow of health care operations for physicians, hospitals, and other health care institutions and could be unworkable in many circumstances." Ex. 91, AR 139590 (Comment, Am. Med. Ass'n) ("AMA Comment"); *see also* Ex. 72, AR 67174 (WA DOH Comment); Ex. 111, AR 151667 (Comment, California Med. Ass'n) ("CMA Comment").

- An employee's affirmative disclosure of an objection with meaningful advance notice to the employer is essential to the operations of hospitals and health providers, and its absence or restriction would disrupt business operations and jeopardize patient care. *See* Ex. 73, AR 67415 (Comment, Am. Hosp. Ass'n) ("AHA Comment"); Ex. 81, AR 134793 (Comment, San Francisco Dep't of Pub. Health) ("SFDPH Comment"); Ex. 84, AR 137611 (Comment, Ohio Hosp. Ass'n); Ex. 92, AR 139641-42 (Comment, Kaiser Permanente) ("Kaiser Comment"); Ex. 101, AR 147825-26 (GNYHA Comment); Ex. 102, AR 147872 (Comment, Massachusetts Health & Hosp. Ass'n);

- Confusion as to how an objecting employee's exercise of her right to refuse, pursuant to the expanded definitions of "assist in the performance" and "discrimination," affects existing collective bargaining agreements governing employees, and whether a health provider could legally administer the rule's requirements. *See* Ex. 81, AR 134793 (SFDPH Comment) (noting "problems with the fair administration of labor contracts between employees asserting conscience rights and those who do not"); Ex. 92, AR 139649 (Kaiser Comment); and

- The double bind of the definitions is especially destructive to "emergency departments, ambulance corps . . . and other urgent care settings" with extremely limited staffing, which cannot successfully plan for employee objections, consistent with the rule. Ex. 99, AR 140486 (NYC Comment) (noting the "very real financial impact on healthcare facilities, including government-run and subsidized clinics and hospital systems"); *see also* Ex. 106, AR 147982 (Comment, Am. Coll. of Emergency Physicians) ("ACEP Comment") (observing the rule requires "an impossible task that jeopardizes the ability to provide care, both for standard

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and (4) should an employer seek to accommodate an expressed objection, the employee has the categorical right to reject the accommodation as not "effective," with no consequence to her employment. *See* 84 Fed. Reg. at 23,263 (definition of "discrimination).

emergency room readiness and for emergency preparedness").

Despite this extensive evidence in the administrative record, the Department entirely failed to consider disruptions to the operations of health providers, including Plaintiffs. None is mentioned or discussed in the Final Rule. Contrary to the Department's argument, Defs.' Mem. 55, these examples are not "hypothetical"—they are documented disruptions presented directly to the agency through the administrative record by major health systems and industry organizations, concerning the drastic effect the Final Rule will have on the delivery of health care by their institutions and members.[17] The Department's failure to consider these consequences is arbitrary. *See Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017) (agencies must "adequately analyze . . . the consequences" of their actions); *see also SecurityPoint Holdings*, 769 F.3d at 1188; *Stewart*, 313 F. Supp. 3d at 263.

Second, HHS claims that it satisfied its obligations under the APA because it "modified each definition in response to the comments it received." Defs.' Mem. 56. But those modifications utterly failed to address the concerns raised.[18] *See, e.g.*, *Duncan*, 681 F.3d at 449. This is true as to each definition, and the change to "discrimination" is illustrative. In finalizing the rule, HHS added subsections (4)-(6) to the definition as proposed, purportedly to address commenters' concerns about the Rule's interaction with Title VII. *See* 84 Fed. Reg. at 23,190-92, 23,263. Yet nowhere does the agency address concerns that advance notice of an objection is essential to provider operations and patient care. And HHS does not dispute that, consistent with the Final Rule's definition of "discrimination" (even as modified), an employee may object at

[17] Though HHS describes Plaintiffs' examples as "extreme," it appears to endorse just such an extreme scope with respect to the definition of "assist in the performance." Without in any way addressing the definition's operational consequences or burdens on providers, HHS appears to agree that, *e.g.*, an employee who schedules an abortion would assist in the performance of that procedure. *See* 84 Fed. Reg. at 23,186-87.

[18] Indeed, on this score HHS itself concedes that its modification of the definition of "referral" from the 2018 Proposed Rule to the 2019 Final Rule is "relatively minor." 84 Fed. Reg. at 23,199.

any time to performing even core job functions—without advance notice and irrespective of patient harm—with no consequence to her employment. Nor does HHS anywhere address the "double bind" or cumulative effect of its definitions upon health providers, though this was set out squarely before the agency. *See, e.g., WildEarth Guardians v. Salazar*, 741 F. Supp. 2d 89, 102-03 (D.D.C. 2010) (agency action is arbitrary where the agency failed to consider "cumulative effect" of factors individually considered). The Final Rule is arbitrary and capricious because of the Department's failure to consider the severe operational harms to providers that are extensively documented in the administrative record.

b. HHS failed to consider harms to public health and specific patient populations.

The Final Rule is arbitrary for the additional reason that the Department failed to consider, or to conduct a reasoned analysis regarding, the Final Rule's impact on reducing access to care for large numbers of people—*e.g.*, women, LGBTQ people, immigrants and refugees, people living with HIV/AIDS or disabilities—who already face barriers to access. HHS "does not dispute that people in such demographic categories face health care disparities of various forms," 84 Fed. Reg. at 23,251, and indeed such disparities and the harmful impacts of the Final Rule are documented in the administrative record through comments citing statistics, data, first-hand accounts from medical providers, and other evidence.[19]

Nor does the Final Rule account for the financial, physical, and mental harms—among other serious and wide-ranging negative effects—that patients who are denied care will suffer.

[19] *See, e.g.*, Ex. 80, AR 134731-738 (Comment, Nat'l Ctr. for Lesbian Rights); Ex. 83, AR 135825-32 (Comment, Callen-Lorde Cmty. Health Ctr.); Ex. 108, AR 148073-74 (Comment, N.Y. State LGBT Health & Hum. Servs. Network); Ex. 109, AR 148096-107 (Comment, Nat'l Ctr. for Transgender Equality); Ex. 110, AR 149142-43, 149150-53 (NWLC Comment); Ex. 112, AR 160566-69 (Comment, GLMA: Health Professionals Advancing LGBT Equality) ("GLMA Comment"); Ex. 113, AR 160752-54 (PPFA Comment); Ex. 117, AR 161485-92 (Lambda Comment).

See, e.g., Provider Pls.' PI Mem. at 18-19. These harms include adverse health outcomes for patients who are denied information about or access to care; increased costs and burden related to the need to obtain care from other sources; and the harms of forgone medical assistance when patients fear refusal by a provider.[20] The failure to account for these documented harms is arbitrary. *See Humane Soc'y of U.S. v. Zinke*, 865 F.3d 585, 606 (D.C. Cir. 2017); *see also Stewart*, 313 F. Supp. 3d at 263.

In the face of this evidence, HHS makes three arguments. First, the agency argues that commenters failed to identify suitable data allowing for reliable quantification of the Final Rule's effects, Defs. Mem. 57-58, ignoring that it is the *Department's* burden to establish a "rational connection between the facts found and the choice made."[21] *Nat'l Treasury Emps. Union v. Horner*, 854 F.2d 490, 498 (D.C. Cir. 1988) (internal quotation marks omitted).

Second, HHS discounts the record evidence on this point as "anecdotal accounts . . . unfit for extrapolation," Defs. Mem 58, but this explanation is fatally inconsistent. The agency itself cites to anecdotal evidence in support of its belief that the Final Rule will increase the number of available providers, *see, e.g.*, 84 Fed. Reg. at 23,247, 23,252; and "[o]f course it would be arbitrary and capricious for the agency's decision making to be 'internally inconsistent.'" *NRDC v. U.S. Nuclear Regulatory Comm'n*, 879 F.3d 1202, 1214 (D.C. Cir. 2018). HHS also discounts the record support of harms to patients because the Department did not consider it "empirical

[20] *See, e.g.*, Ex. 72, AR 67173 (WA DOH Comment); Ex. 73, AR 67413 (AHA Comment); Ex. 76, AR 71138 (AAMC Comment); Ex. 87, AR 137920 (New York Comment); Ex. 91, AR 139587 (AMA Comment); Ex. 94, AR 139749 (Comment, Am. Coll. of Obstetricians & Gynecologists) ("ACOG Comment"); Ex. 97, AR 140350 (CA Insur. Comment); Ex. 98, AR 140460 (Comment, Am. Acad. of Pediatrics); Ex. 99, AR 140484 (NYC Comment); Ex. 100, AR 147746 (ACLU Comment); Ex. 106, AR 147981 (ACEP Comment); Ex. 107, AR 148056 (Comment, Nat'l Immigration Law Ctr.); Ex. 110, AR 149141 (NWLC Comment); Ex. 113, AR 160751 (PPFA Comment); Ex. 116, AR 161178 (Comment, Inst. for Policy Integrity) ("IPI Comment").

[21] *See also infra* Part II.C.4 (concerning HHS's cost-benefit analysis); Provider PI Mem. 17-18.

evidence," 84 Fed. Reg. at 23,251; but here too, the Department has chosen to selectively credit non-empirical evidence that happens to support the Final Rule, including a summary of an outdated 2009 poll based on predictions about the effects of an entirely different rule (the 2011 Rule).[22] *See* Defs.' Mem. 54 ("There was nothing unreasonable, arbitrary, or capricious in HHS considering the poll among other non-empirical evidence."). Selective reliance on non-empirical evidence only when supportive—combined with the refusal to consider like evidence when it undermines the agency's position—is arbitrary. *See Water Quality Ins. Syndicate v. United States*, 225 F. Supp. 3d 41, 69 (D.D.C. 2016) (reversing agency decision that "cherry-pick[ed] evidence").

Third, HHS argues that the majority of comments on this topic "focused on *preexisting* discrimination in health care and did not attempt to answer the question of how the Rule itself would affect access to health care." Defs.' Mem. 58. As an initial matter, evidence of preexisting discrimination in health care is self-evidently germane to the agency's consideration of how a new health care policy will affect already-vulnerable populations. *Cf. Friends of Back Bay v. U.S. Army Corps. of Eng'rs*, 681 F.3d 581, 588 (4th Cir. 2012) ("A material misapprehension of the baseline conditions existing in advance of an agency action can lay the groundwork for an arbitrary and capricious decision."). In addition, among the handful of arguably pertinent complaints HHS cites to justify the specific need for the Final Rule, *see supra* Part II.C.1, is an objection that mirrors the very record evidence HHS discounts concerning the rule's impact on access to care. To the extent that HHS believes a complaint from a correctional employee—who objected to providing hormone therapy to a transgender inmate—warrants new

[22] Intervenors' argument that Plaintiffs "do not challenge the survey's methodology or results," CMDA Mem. 24, is curious given that the record includes no information regarding the poll's methodology. All that exists in the record is a two-page summary of the poll, Ex. 118, AR 537609-10; which makes HHS's reliance on it as part of its justification for the Final Rule all the more arbitrary.

HHS enforcement powers under the Final Rule, the underlying facts are similar to the record evidence before the agency concerning barriers to access for transgender patients and heightened discrimination since HHS first proposed the rule.[23] The agency's arguments about the evidence before them reflects either a complete failure to address these population-based patient harms or, at the least, the absence of a "reasoned analysis" and "satisfactory explanation of its action."[24] *State Farm*, 463 U.S. at 42-43; *see also Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) ("[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions") (emphasis in original).

c. HHS failed to consider the Final Rule's interference with EMTALA.

The Final Rule is arbitrary and capricious because HHS failed to consider an important aspect of the problem that health care providers and entities repeatedly raised in response to the notice of proposed rulemaking—namely, how to reconcile the Final Rule with the Emergency Medical Treatment and Labor Act ("EMTALA").

Commenters stressed that it was critical for HHS to confirm that the Final Rule would not affect EMTALA's requirement that covered hospitals treat and care for patients in emergency situations.[25] As noted in the Provider Plaintiffs' summary judgment memorandum, the Final

[23] *See, e.g.*, Ex. 112, AR 160568 (GLMA Comment) ("Since the Department issued the proposed regulation, GLMA members have shared with us the ways they have seen religious objections used to the detriment of the healthcare of LGBT patients," citing multiple accounts of barriers to access); Ex. 117, AR 161490-91 (Lambda Comment) (citing instance of clinic doctor refusing to provide hormone replacement therapy to a transgender woman, based on a religious objection).

[24] This defense also fails because it is inconsistent with the Department's own reasoning in support of the Final Rule—in particular, HHS's reliance on the "preexisting" CMDA poll, which did not attempt to answer the question of how *this* Rule would affect access to care, or even whether the 2011 rescission of the 2008 rule actually led to the exodus of health care providers that the 2009 poll predicted.

[25] *See, e.g.*, Ex. 87, AR 137926-928 (New York Comment); Ex. 90, AR 139288 (Comment, Boston Med. Ctr.); Ex. 103, AR 147892 (Comment, Anne Arundel Med. Ctr.); Ex. 104, AR 147954 (The Disability Coalition); Ex. 113, AR 160755 (PPFA Comment); Ex. 114, AR 160821-22 (Comment, Ctr. for Reprod. Rights); Ex. 115, AR 161036-037 (Comment, Medicare Rights Ctr.).

Rule completely fails to address these significant and potentially life-threatening concerns. *See* Provider SJ Mem., Part II.B; *see also* Pls.' PI Mem. 33-34.

The Final Rule's four-sentence response to comments regarding EMTALA contains only curt and unreasoned factual statements (*e.g.*, "[t]his final rule . . . does not go into detail as to how its provisions may or may not interact with other statutes"), and generalities (*e.g.*, "[t]he Department intends to give all laws their fullest possible effect"), 84 Fed. Reg. at 23,183, that are insufficient to meet the APA's requirement of reasoned decisionmaking. *See Citizens for Responsibility & Ethics in Washington v. FEC*, 316 F. Supp. 3d 349, 411 n.48 (D.D.C. 2018). HHS fails to provide any non-conclusory explanation of its unsupported conclusion that EMTALA's requirement "does not conflict with Federal conscience and antidiscrimination laws." 84 Fed. Reg. at 23,183. Instead, the Department merely references the reasoning in the preamble of the 2008 Rule. *See id.* By "relying only on generalized conclusions," the Department's assessment is arbitrary and capricious. *AEP Tex. N. Co. v. Surface Transp. Bd.*, 609 F.3d 432, 441 (D.C. Cir. 2010).

d. HHS failed to consider the Final Rule's contravention of basic medical ethics.

HHS's adoption of the definitions discussed above is also arbitrary and capricious because the agency failed to consider, or at minimum failed to conduct a reasoned analysis of, how those definitions violate basic ethical canons of the health professions. *See, e.g.*, *Am. Acad. of Pediatrics v. Heckler*, 561 F. Supp. 395, 399-400 (D.D.C. 1983) (invalidating HHS regulation on arbitrary-and-capricious grounds where the administrative record showed no attempt to balance "the malpractice and disciplinary risks that may be imposed upon physicians and hospitals caught between the requirements of the regulation and established legal and ethical guidelines"). In particular, the definition of "discrimination" permits an employee to object

without notice—irrespective of her duty of care or the needs of a patient—and the definitions of "assist in the performance" and "referral" violate the fundamental concept of informed consent by permitting health care entities and providers to withhold basic information from patients—even in emergencies. *See* 84 Fed. Reg. at 23,263-64 (definitions).

The administrative record contains evidence from organizations tasked with developing codes of ethics within the health professions, *e.g.*, the American Medical Association ("AMA"), American Nurses Association, and the Association of American Medical Colleges. These groups and others unequivocally informed HHS that:

- Current codes and professional standards allow individuals to refuse to provide services to which they object, but such objections are not unlimited and "must be balanced against the fundamental obligations of the medical profession"—*i.e.*, the needs of the patient; *see* Ex. 91, AR 139588 (AMA Comment);[26]
- Physicians have a duty to provide medically indicated care in an emergency, irrespective of their moral or religious beliefs, and may not abandon a patient, *see id.*;[27] and
- Physicians and other health professionals have a duty to inform patients about all relevant options for treatment, including options to which they object, *see id.*;[28]

Despite notice from organizations that have codified the ethical standards of the health professions—in the case of the AMA, for over a century—HHS failed to consider how its

[26] *See also* Ex. 70, AR 56915, at 56918 (Comment, Am. Nurses Ass'n) ("ANA Comment") (nurse's first duty is to the patient, citing Association's code of ethics and World Medical Association standards); Ex. 101, AR 147824-25 (GNYHA Comment) (principle that objections must not compromise "standards of professional care and the rights of patients" reflects "broad consensus in health care professions and health care ethics"); Ex. 106, AR 147981, at 147983 (ACEP Comment) (noting "one of the major, unacceptable flaws in the rule: it does not focus on the needs of patients or our responsibility as providers to treat them").

[27] *See also* Ex. 94, AR 139749, at 139750 (ACOG Comment) ("In an emergency in which referral is not possible or might negatively impact the patient's physical or mental health, providers have an obligation to provide medically indicated and requested care . . . . The Proposed Rule disregards these rigorous standards of care established by the medical community."); Ex. 105, AR 147963 (Comment, Ass'n of Women's Health, Obstetric and Neonatal Nurses) (discussing abandonment).

[28] *See also* Ex. 76, AR 71138, at 71141-42 (AAMC Comment) (noting rule's definition of "referral" is "incongruous with the standards of medical professionalism that are the core of a physician's education and the practice of medicine").

definitions contravene basic medical ethics. As a general matter, substantive references to "ethics" within the Final Rule overwhelmingly relate not to the patient, nor to what a health professional owes as a duty to that patient, but rather to the situation of the objector refusing to providing health care services—which the agency failed to "balance[] against the fundamental obligations of the medical profession." Ex. 91, AR 139588 (AMA Comment).[29] Specifically regarding the agency's expansive definition of "discrimination," HHS entirely failed to consider or address the Final Rule's implication for standards of professional ethics, by permitting an employee to object to a wide range of health care services at any time—without notice, even in emergency contexts—with no affirmative duty to disclose that objection or provide advance notice of any intent to object. *See supra* Part II.C.3.a.

Regarding the definitions of "referral" and "assist in the performance," the Final Rule's combination of these terms *itself* violates principles of medical ethics. The Final Rule identifies "referral" as an action that "may" constitute "assist[ance] in the performance" and thus form the basis of a protected objection. *See* 84 Fed. Reg. at 23,188-89. Yet this combination turns a basic principle on its head. As the AMA communicated to HHS, the provision of information about options for treatment is a method by which the health professions balance ethical duties, *i.e.*, allowing a practitioner to honor her own religious convictions about a health procedure, while simultaneously fulfilling her duty of care to a patient. *See* Ex. 91, AR 139587-88 (AMA Comment). AMA's Code directs physicians to "inform the patient about all relevant options for treatment, including options to which the physician morally objections," and should a physician decline to offer a referral, the physician should, at minimum, "offer impartial guidance to

[29] *See, e.g.*, 84 Fed. Reg. at 23,171, 23,174-77, 23,181, 23,183, 23,189, 23,199-200, 23,204, 23,208, 23,246, 23,249-250.

patients about how to inform themselves regarding access to desired services."

Yet the Final Rule prevents this carefully calibrated balancing of ethical duties. Its definition of "referral" includes the "provision of information in oral, written, or electronic form" where "the purpose or reasonably foreseeable outcome . . . is to assist a person" in "obtaining . . . a particular health care service." 84 Fed. Reg. at 23,203. But if a patient "desires" a service—as stated in the AMA Code—it is a reasonably foreseeable outcome that the health service will result from a physician providing the patient guidance on how to inform herself on access—*e.g.*, from providing information resources. Thus, as HHS was well aware, the Final Rule's definition of "referral" expressly permits a doctor to object to her minimally required ethical duty under the AMA's Code. *See id.* at 23,253 (noting information the Final Rule "may allow" providers to abstain from providing).

Where HHS purports to address providers' duties to patients in the Final Rule—or the balancing of these duties described above—it does so in conclusory fashion. Referring generally to comments about the Final Rule and principles of informed consent, HHS pastes a near-verbatim answer into its discussions of both "assist in the performance" and "referral." The agency states that "medical ethics have long protected rights of conscience alongside the principles of informed consent" and, accordingly, it "does not believe that enforcement of conscience protections . . . violates or undermines the principles of informed consent." 84 Fed. Reg. at 23,200; *see also id.* at 23,189. Yet HHS sidesteps the fact that the Final Rule's definitions are precisely what undermine the method by which medical ethics harmonized those principles, as discussed above. HHS knew this, because the professional organizations that developed this method clearly stated it to the agency. HHS's "belief" reflects a complete failure to address the Final Rule's conflict with medical ethics or, at the least, the absence of a

"reasoned analysis" and "satisfactory explanation of its action." *State Farm*, 463 U.S. at 42-43.

e. HHS failed adequately to explain its departure from Title VII's framework for workplace religious accommodation.

The Final Rule is also arbitrary because, in departing without adequate rationale from the framework for religious accommodations in the workplace provided by Title VII of the Civil Rights Act of 1964, the Final Rule is not based on a "reasoned analysis" indicating that HHS "examine[d] the relevant data and articulate[d] a satisfactory explanation of its action." *State Farm*, 463 U.S. at 42-43. In failing to explain why existing remedies against discrimination are insufficient, the Department has not met its "duty to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives." *City of Brookings Mun. Tel. Co. v. FCC*, 822 F.2d 1153, 1169 & n.46 (D.C. Cir. 1987) (internal quotation marks omitted).

Title VII has long governed the assessment of claims for religious accommodations in the workplace, with a central focus on a balancing of all interests at stake. Existing employment discrimination law requires employers to accommodate employees' religious beliefs "unless an employer demonstrates that he is unable to reasonably accommodate to an employee's or prospective employee's religious observance or practice without undue hardship on the conduct of the employer's business." 42 U.S.C. § 2000e(j); *see also id.* § 2000e-2(a); 29 C.F.R. § 1605.2 (discussing reasonableness and undue hardship). This framework permits an employer simultaneously to consider the needs of the requesting employee, other employees, and its business and customers—in this context, patients in need of care.

Title VII thus protects individuals' religious beliefs while balancing employers' and employees' interests. The Final Rule departs from this framework uniquely in the context of the refusal-of-care statutes, but the Department has not explained why a departure from the Title VII

framework—to which Plaintiffs have long conformed their employment practices—is necessary. First, the definition of "discrimination," at subsection (5), prohibits an employer from inquiring, pre-hire, whether a prospective employee objects to performing or assisting in types of work, making it impossible for the employer to determine whether hiring that individual would pose an undue hardship on the business—*i.e.*, if the individual is unwilling to perform core job functions. *See* 84 Fed. Reg. at 23,263. Second, the definition, at subsection (4), provides that an employer does not discriminate when it offers and an objecting employee "voluntarily accepts an effective accommodation"—thus providing an employee a veto right over accommodation. *Id.* Under Title VII, an employee does not have this unilateral right to a religious accommodation of his or her choosing at the expense of all the other interests at play in the workplace.

Indeed, HHS concedes that it rejected "incorporating the additional concept of an 'undue hardship' exception for reasonable accommodations under Title VII." *Id.* at 23,191. But the agency dodges any reasoned explanation for this rejection, and instead merely asserts its belief that, because Congress "did not adopt an undue hardship exception" expressly within the various conscience protection statutes interpreted by the Final Rule, this reflects a legislative intent "to take a different approach."[30] *Id.* However, Congress's "silence in this regard can be likened to the dog that did not bark," and should not be interpreted as an intent to depart from Title VII's established framework for religious discrimination claims. *Miller v. Clinton*, 687 F.3d 1332, 1350 (D.C. Cir. 2012) (internal quotation marks omitted) (rejecting claim that silence in Basic Authorities Act altered provisions of Age Discrimination in Employment Act); *see also* Provider

[30] HHS argues that this purported legislative intent is "consistent with the fact that Title VII's comprehensive regulation of American employers applies in far more contexts, and is more . . . potentially burdensome . . . than the more targeted conscience statutes that are the subject of this rule," *id.*, apparently overlooking the fact that the agency's inclusion of "plan sponsor" in the definition of "health care entity" sweeps within the Final Rule's ambit virtually any employer that offers health insurance to its employees. *See* 84 Fed. Reg. at 23,195.

SJ Mem., Parts II.A.1, IV.

HHS's reliance on this congressional silence likewise does not constitute a reasoned analysis or satisfactory explanation for departing from a legislative policy that has set the standard for workplace religious accommodation for decades. *See City of Brookings Mun. Tel. Co.*, 822 F.2d at 1169 & n.46 ("[T]he failure of an agency to consider obvious alternatives has led uniformly to reversal."); *Action on Smoking & Health v. Civil Aeronautics Bd.*, 699 F.2d 1209, 1216, 1218 (D.C. Cir. 1983) (agency's decision failed to give sufficient consideration to narrower alternatives). To the contrary, "[a]nother shadow is cast when agency action, not clearly mandated by the agency's statute, begins to encroach on congressional policies expressed elsewhere." *Cape May Greene, Inc. v. Warren*, 698 F.2d 179, 190 (3d Cir. 1983) (holding EPA action arbitrary and contrary to law for "failure to give sufficient weight to congressional admonition in the Coastal Zone Management Act"). HHS's failure to explain why Title VII's framework is insufficient to address the harms the refusal-of-care statutes seek to prevent is arbitrary and capricious.

4. The Department's analysis of the costs and benefits of the Final Rule is counter to the evidence before the agency.

The Final Rule should be vacated as arbitrary and capricious for the independent reason that the Department relied on a cost-benefit analysis so flawed that it cannot be viewed as anything other than an effort to "put a thumb on the scale" by overvaluing the benefits and undervaluing the costs. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008); *see* Pls.' PI Mem. 38-43; Provider PI Mem. 23-24; Br. of the Inst. for Policy Integrity as *Amicus Curiae* 4-24, Dkt. 52-1 (filed June 21, 2019).

The Department casts this detailed presentation of the many flaws in its quantitative and qualitative analysis as nothing more than Plaintiffs' preference "to impose their own standard of

research on the agency before it can act." Defs.' Mem. 57. Not so: the "consideration of costs is an essential component of reasoned decisionmaking under the Administrative Procedure Act," *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732-33 (D.C. Cir. 2016); and agency action is invalid where it "fail[s] to adequately account" for relevant costs and benefits. *Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 53-55 (D.D.C. 2019).

For example, Plaintiffs identified the agency's significant mistake in underestimating the number of covered persons and entities, *see* Pls.' PI Mem. 41-42: the agency concluded that the Final Rule may increase the number of regulated entities by only about 0.02%, *see* 84 Fed. Reg. at 23,233-35 & tbl.2, even though the Final Rule's definition of "health care entity" both expands *and was intended to expand* the number of regulated persons and entities considerably. *See id.* at 23,194-96, 23,264 (§ 88.2). This is a significant miscalculation that results in a failure to present the true costs of the Department's policy choice. Yet Defendants' only response is that "New York provides no alternative evidence of its own" regarding the number of covered entities. Defs.' Mem. 59-60. But the administrative record that was before the agency when it was developing the Final Rule did provide the agency ample evidence of the expanded universe of regulated entities the rule's definitions would encompass.[31] And it is the agency's obligation to account for those costs, and show that it "examine[d] the relevant data" and can "articulate . . . a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43; *Council of Parent Attorneys & Advocates*, 365 F. Supp. 3d at 54-55.

The Department finally seeks to excuse its inadequate cost-benefit analysis by protesting that "[m]any of these questions . . . are difficult to answer." Defs.' Mem. 60. But "[a]n agency

[31] *E.g.*, Ex. 68, AR 52459 (Comment, N.Y. Dep't of Fin. Servs.); Ex. 91, AR 139587 (AMA Comment); Ex. 96, AR 140265 (BCBS Comment); Ex. 97, AR 140350 (CA Insur. Comment); Ex. 113, AR 160751 (PPFA Comment); Ex. 116, AR 161178 (IPI Comment).

may not avoid an obligation to analyze . . . consequences that foreseeably arise from [its action] merely by saying that the consequences are unclear . . . ." *Kern v. U.S. Bureau of Land Mgmt.*, 284 F.3d 1062, 1072 (9th Cir. 2002). The Department's "conclusory statements" regarding the costs and benefits of the Final Rule do not constitute reasoned decisionmaking. *Getty v. Fed. Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1057 (D.C. Cir. 1986).

III. The Final Rule is unconstitutional.

A. The Final Rule violates the constitutional separation of powers.

The Constitution vests the spending power in Congress. U.S. Const. art. I, § 8, cl. 1. The Executive Branch "does not have unilateral authority to refuse to spend . . . funds" already appropriated by Congress. *In re Aiken Cty.*, 725 F.3d 255, 261 n.1 (D.C. Cir. 2013).

In the context of the refusal statutes, Congress has chosen to tailor the conditions it has placed on the receipt of federal funds to specific procedures, involvement in those procedures, and health care providers or entities. *See* Pls.' PI Mem. 44-45. Defendants' wholesale refusal to address this argument is telling, especially because Defendants cannot dispute that the text of the Final Rule allows HHS to withhold all of the federal funding that Plaintiffs receive from the Department based on any perceived violation of any of the underlying statutes that it purports to implement. *See* Fed. Reg. at 23,272 (§ 88.7(i)(3)(i)-(iii)).

Although Congress may delegate some discretion to the Executive Branch to decide how to spend appropriated funds, *see Clinton v. City of New York*, 524 U.S. 417, 488 (1998), this discretion is cabined by the scope of the delegation, *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013). When Congress provides agencies with broad authority to withhold funds, it does so clearly. *See* Providers' SJ Mem., Part I. Defendants cannot find support in any of the underlying statutes for HHS's claim of broad power to terminate all federal funding. For example, the Weldon Amendment—on which Defendants rely—does not even mention HHS, let alone

expressly grant the Department this authority. Defs.' Mem. 71. Simply put, "Congress does not hide elephants in mouseholes." *Cyan, Inc. v. Beaver Cty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1071-72 (2018) (internal quotation marks omitted).

B. The Final Rule violates the Spending Clause.

The Final Rule violates the Spending Clause because it (1) attaches retroactive and ambiguous conditions to Plaintiffs' receipt of federal funds; (2) is coercive; (3) lacks a nexus between the funds at issue and the Final Rule's purpose; and (4) induces Plaintiffs to engage in unconstitutional violations of the Establishment Clause. Pls.' PI Mem. 45-53; *see South Dakota v. Dole*, 483 U.S. 203, 207-08, 211 (1987).

Defendants' assertion that Plaintiffs' "real objection is to the underlying substantive law," Defs.' Mem. 60-61, is incorrect—Plaintiffs argue that the Final Rule substantially departs from the underlying statutes that it purports to implement by, among other things, redefining and dramatically expanding key definitions within those statutes, and threatening the termination of all HHS funds for a perceived violation of a new regime that HHS creates out of whole cloth. Plaintiffs' challenge is not to Congress's authority to enact the underlying statutes that Plaintiffs have complied with for years; it is instead to HHS's legislative fiat to create a new federal conscience regime in violation of the Spending Clause.

1. Plaintiffs did not knowingly accept the new and confusing conditions imposed by the Final Rule.

The Final Rule violates the Spending Clause's requirement to provide clear notice to Plaintiffs by retroactively and ambiguously imposing conditions on the receipt of federal funds. Pls.' PI Mem. 46-50. *See Dole*, 483 U.S. at 203 (explaining that when conditions are placed on federal funds it must be done "unambiguously" so that states and local jurisdictions determining whether they agree to accept such funds may "exercise their choice knowingly, cognizant of the

consequences of their participation").

"States cannot knowingly accept conditions of which they are 'unaware' or which they are 'unable to ascertain.'" *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981)). The Final Rule violates both of these principles. First, as Plaintiffs explained in detail in their opening brief, the Final Rule contorts the underlying statutes that it purports to implement to such a degree that Plaintiffs were not and could not have been aware of the new conditions when agreeing to accept the relevant funding. Specifically, the Final Rule (1) includes new definitions of key terms in the underlying statutes that dramatically expand the scope of those statutes; (2) imposes new, retroactive, and burdensome compliance requirements that apply immediately to all recipients of federal funds; (3) disregards that Congress in the relevant statutes conditioned funding from specific sources with specific prohibitions; and (4) purports to conflict with literally dozens of state and local laws on a variety of substantial issues related to health and patient care. Pls.' PI Mem. 47-48.

Defendants fail to address the import of any of these new conditions, and instead claim confusion as to the meaning of "retroactive." Defs.' Mem. 63. But as the Supreme Court has explained, "though Congress's power to legislate under the spending power is broad, it does not include surprising participating States with post-acceptance or retroactive conditions." *NFIB*, 567 U.S. at 584 (alterations and internal quotation marks omitted); *see also Mayhew v. Burwell*, 772 F.3d 80, 88 (1st Cir. 2014) ("[T]he anti-retroactivity rule . . . provides that Congress may not surprise states . . . with post-acceptance or retroactive conditions." (alterations and internal quotation marks omitted)). This is exactly what the Final Rule does. Pls.' PI Mem. 47-48. Indeed, Plaintiffs "could hardly anticipate that" HHS would claim authority to patch together

thirty statutes on a variety of topics scattered throughout the United States Code and appropriations riders to "transform" the landscape of health care provision and regulation "so dramatically." *NFIB*, 567 U.S. at 584; *see also Cty. of Santa Clara v. Trump*, 250 F. Supp. 3d 497, 532 (N.D. Cal. 2017) (where conditions are not "unambiguous condition[s] that the states and local jurisdictions voluntarily and knowingly accepted at the time Congress appropriated these funds, [they] cannot be imposed").

Second, the Final Rule is ambiguous in that it fails to make clear what conduct it prohibits or requires, what funding streams are at stake, and how recipients can avoid its penalties. *See* Pls.' PI Mem. 48-50. Rather than attempt to defend or clarify *any* of the Final Rule's opaque requirements, Defendants merely state, without support or explanation, that the Final Rule is "necessarily clearer and less ambiguous than the statutes." Defs.' Mem. 62. Defendants are wrong. For example, in sharp contrast to the underlying statutes, the Final Rule expands the scope and applicability of federal conscience protections in a way that significantly disrupts health care and creates an unworkable morass of potentially-life threatening situations for Plaintiffs. *See* Pls.' PI Mem. 15-30; Provider SJ Mem., Part II.A. Moreover, again in contrast to the underlying statutes, Plaintiffs have the impossible task of reconciling the Final Rule's requirements with conflicting provisions of other laws like EMTALA and Section 1554 of the ACA. *See* Provider SJ Mem., Parts II.A, II.B, II.D. And unlike the underlying statutes—which clearly identify the funds at stake for violations of the statutes—Plaintiffs stand to lose all HHS funds for any perceived misstep under the Final Rule.

Defendants' nearly singular reliance on the Ninth Circuit's decision in *Mayweathers v. Newland*, 314 F.3d 1062 (9th Cir. 2002) is misplaced. Defs.' Mem. 62-63. First, Plaintiffs take no issue with the fact that Congress may exercise its Spending Clause power to foster religious

freedom and deter religious-based discrimination. *Id.* at 62. As *Mayweathers* makes clear, however, in advancing these interests the limitations to the Spending Clause power—the same limitations that the Final Rule violates here—apply. *See Mayweathers*, 314 F.3d at 1066. Second, unlike the plaintiffs in *Mayweathers*, Plaintiffs here do not challenge Congress's "express conditional language" as "perhaps unpredictable." *Id.* at 1067. Instead, Plaintiffs challenge Defendants' contortion of clear and well-settled statutory conditions because they are unworkable, nonsensical, and contrary to both the statutes HHS purports to interpret and others on which Plaintiffs rely and with which they must comply.

HHS falls "well short of providing clear notice to [Plaintiffs] that they, by accepting funds . . . would indeed be obligated to comply" with Defendants' radical departure from congressional intent and the status quo. *Pennhurst*, 451 U.S. at 25. For these reasons, Plaintiffs could not have "exercise[d] their choice" to accept funds "knowingly, cognizant of the consequences of their participation." *Dole*, 483 U.S. at 203 (internal quotation marks omitted).

2. The Final Rule creates a new program and coerces Plaintiffs to comply.

The Final Rule also violates the Spending Clause because far from "creat[ing] incentives for [Plaintiffs] to act in accordance with federal policies," its "financial inducement . . . is a gun to the head." *NFIB*, 567 U.S. at 577, 581 (internal quotation marks omitted); *see* Pls.' PI Mem. 50-51.

Defendants' attempts to distinguish *NFIB* fall flat. First, as Plaintiffs explained in their opening brief, the Final Rule creates an entirely new regime that accomplishes "a shift in kind, not merely degree." *NFIB*, 567 U.S. at 583; *see* Pls.' PI Mem. 51. Defendants' only response is to once again point to the fact that the underlying statutes have been in effect for decades. Defs.' Mem. 65. This is no answer at all. *See NFIB*, 567 U.S. at 541 (noting Medicaid's enactment in

1965, and analyzing whether its expansion was coercive). Instead, the relevant inquiry is whether the challenged provisions have expanded those in the original statute to such a degree as to create a new program. *Id.* at 583. The Final Rule does just that: it weaves together disparate and distinct anti-discrimination prohibitions, 84 Fed. Reg. at 23,264-69 (§ 88.3); redefines terms to include newly covered individuals, entities, and procedures, *id.* at 23,263-64, (§ 88.2); and creates a compliance and enforcement scheme that substantially alters Congress's efforts to tailor specific requirements to specific sources of funds, *id.* at 23,269-72 (§§ 88.4, 88.6, 88.7). *See NFIB*, 567 U.S. at 583 (expansion of the original program "for four particular categories of" individuals beyond those categories was a shift in kind).

Second, Defendants are wrong that "it is far from clear that noncompliance with the conscience statutes and the [Final Rule] would impact all of the funding sources that New York identifies." Defs.' Mem. 64. The Final Rule's enforcement scheme plainly threatens billions of dollars in funding that Plaintiffs receive for a failure or suspected failure to comply with its provisions and those of the underlying statutes. Specifically, the Final Rule's enforcement scheme allows the Department to initiate a compliance review or a complaint investigation of Plaintiffs if it "suspect[s]" noncompliance. 84 Fed. Reg. at 23,271 (§§ 88.7(c),(d)). If the Department determines that "there is a failure to comply" with any provision of the Final Rule or the statutes it implements, the Department may refer the matter to the Department of Justice for enforcement, or the Department may itself withhold, deny, suspend, or terminate federal funds. *Id.* at 23,271-72 (§§ 88.7(h), (i)(3), (j)). The compliance process for the Department to follow is described by citations to three disparate administrative procedures. *Id.* at 23,272 (§ 88.7(i)(3)). And no matter Defendants' assurance that "HHS will always begin by trying to resolve a potential violation . . . through informal means," Defs.' Mem. 64, the Department is expressly

authorized to terminate a recipient's federal funds even *during* the pendency of good-faith voluntary compliance efforts. *Id.* at 23,271-72 (§ 88.7(i)(2)). Moreover, if the Department believes a recipient has "fail[ed] or refuse[d] to furnish an assurance or certification" required by § 88.4, the Department may suspend *all* HHS funding during any efforts at resolution and even before a finding of noncompliance. *Id.* at 23,272 (§ 88.7(j)). Accordingly, Plaintiffs stand to lose "not merely a relatively small percentage of its existing [HHS funding], but *all* of it." *NFIB*, 567 U.S. at 581 (internal quotation marks omitted).

Plaintiff States collectively received approximately $192 billion in federal funding from HHS in fiscal year 2018 based on publicly available information from the Department's Tracking Accountability in Government Grants System ("TAGGS").[32] This funding is critical to a wide range of essential programs and services that Plaintiffs use to promote the health and well-being of their residents, including: (1) Medicaid and the Children's Health Insurance Program;[33] (2) services to promote the health of women, infants, and children;[34] (3) family planning and contraception;[35] (6) treatment of substance use disorders;[36] (7) treatment and screening for arthritis, asthma, and other cancers, and heart disease;[37] (8) medical services to

[32] *See* Ex. 136 (TAGGS Recipient Search). Plaintiffs generated this number by filtering "Fiscal Year" to "2018," "Recipient Class" to "State Government," and "State" to each State Plaintiff represented in this lawsuit. The Court may take judicial notice of this publicly available material, *see Force v. Facebook, Inc.*, No. 18-397, 2019 WL 3432818, at *3 n.5 (2d Cir. July 31, 2019), and Defendants also rely on data from TAGGS to justify the Final Rule, *see, e.g.*, 84 Fed. Reg. at 23,232 & n.182, 23,235-36 & n.224.

[33] *See* Ex. 1 (Adelman Decl.) ¶ 5; Ex. 5 (Allen Decl.) ¶ 8; Ex. 11 (Clark Decl.) ¶ 8; Ex. 20 (Forsaith Decl.) ¶¶ 7, 10; Ex. 33 (Miller Decl.) ¶¶ 14, 16-18; Ex. 38 (Rosen Decl.) ¶ 7; Ex. 44 (Turnage Decl.) ¶ 7; Ex. 47 (Zimmerman Decl.) ¶ 7; Ex. 48 (Zucker Decl.) ¶¶ 93-94.

[34] *See* Ex. 9 (Brancifort Decl.) ¶ 16; Ex. 15 (Elnahal Decl.) ¶ 9; Ex. 17 (Ezike Decl.) ¶¶ 25-29; Ex. 19 (Foley Decl.) ¶¶ 5-6; Ex. 20 (Forsaith Decl.) ¶ 8; Ex. 28 (Levine Decl.) ¶¶ 11-14;

[35] *See* Ex. 2 (Alexander-Scott Decl.) ¶ 9; Ex. 10 (Charest Decl.) ¶¶ 3, 5; Ex. 17 (Ezike Decl.) ¶¶ 14-23; Ex. 35 (Oliver Decl.) ¶ 5; Ex. 37 (Rattay Decl.) ¶ 15; Ex. 42 (Swartz Decl.) ¶ 8.

[36] *See* Ex. 15 (Elnahal Decl.) ¶ 11; Ex. 20 (Forsaith Decl.) ¶¶ 7, 9; Ex. 28 (Levine Decl.) ¶ 28(vi); Ex. 40 (Sherych Decl.) ¶ 7; Ex. 44 (Turnage Decl.) ¶ 8.

[37] *See* Ex. 2 (Alexander-Scott Decl.) ¶ 8; Ex. 9 (Brancifort Decl.) ¶ 15; Ex. 17 (Ezike Decl.) ¶¶ 14-23; Ex. 28

residents with HIV;[38] (9) funds for bioterrorism and Ebola preparedness, and other disaster response;[39] (10) student health services;[40] and (11) biomedical and health-related research, education, and training funds to universities.[41] Plaintiffs simply cannot gamble away some or all of this funding by hoping the Department will exercise with restraint its expansive authority under the Final Rule to withhold these funds in full. *Cf. United States v. Stevens*, 559 U.S. 460, 480 (2010) ("We would not uphold an unconstitutional statute merely because the Government promised to use it responsibly.").

Finally, Defendants' protest that Plaintiffs cannot succeed on a "facial challenge by identifying a handful of implausible and speculative circumstances" that "*might* have a coercive effect," Defs.' Mem. 66, fail for the same reason. The Final Rule's provisions and the authority that they provide to HHS are real, and they are currently set to take effect in only a few months. Nor do Plaintiffs take comfort in Defendants' note that HHS has never terminated substantial funding before. *Id.* Far from offering any reassurances that it will exercise restraint, HHS has made clear that it issued the Final Rule precisely *because* of "[i]nadequate enforcement tools to address unlawful discrimination and coercion," 84 Fed. Reg. at 23,228, without offering any explanation for why the tools it had—including informal resolution of complaints—were inadequate. *See supra* Part II.C.1. Accordingly, any nod to past HHS practice is irrelevant.

More fundamentally, Defendants' argument misunderstands the Spending Clause's constraint on the agency's rulemaking authority. The constitutional prohibition on coercion does

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(Levine Decl.) ¶ 14.

[38] *See* Ex. 5 (Allen Decl.) ¶ 8; Ex. 7 (Anderson Decl.) ¶ 8; Ex. 15 (Elnahal Decl.) ¶¶ 7-8; Ex. 17 (Ezike Decl.) ¶¶ 33-35.

[39] *See* Ex. 28 (Levine Decl.) ¶¶ 14, 28(ii), 28(iv); Ex. 35 (Oliver Decl.) ¶ 7; Ex. 46 (Wagaw Decl.) ¶ 6.

[40] HIV/STD prevention, contraception, and abortion referrals, *see* Ex. 24 (Hirata Decl.) ¶¶ 5-7; Ex. 34 (Nichols Decl.) ¶¶ 5-7.

[41] *See* Ex. 22 (Hedges Decl.) ¶ 6; Ex. 23 (Herbst Decl.) ¶¶ 13-14; Ex. 29 (Lucchesi Decl.) ¶ 7.

not spring into effect only after the devastating consequences Plaintiffs confront because of the Final Rule—*i.e.*, the termination of substantial amounts of federal health care funds—come to fruition. Instead, it is the *threat* of terminating those funds that the limitations on the spending power proscribe. *See NFIB*, 567 U.S. at 580 (underscoring concerns with respect to the "nature of the threat" posed by the Medicaid provisions of the Affordable Care Act); *see also id.* (explaining that "[b]y financial inducement the Court meant the *threat* of losing . . . funds" (emphasis added)). This threat in the form of "economic dragooning" leaves Plaintiffs with "no real option but to acquiesce" in the Final Rule's new regime. *Id.* at 582.

3. The Final Rule violates the Spending Clause's relatedness requirement.

As Plaintiffs explained, through the Weldon Amendment, the Final Rule appears to condition the receipt of billions of dollars of federal funds that are entirely unrelated to health care on compliance with its provisions. Pls.' PI Mem. 51-52. This violates the Spending Clause's requirement that any conditions imposed on spending must be related "to the federal interest in . . . [the] program[]." *Dole*, 483 U.S. at 207 (internal quotation marks omitted); *see also City & Cty. of San Francisco v. Sessions*, 349 F. Supp. 3d 924, 959-61 (N.D. Cal. 2018).

Defendants do not even attempt to dispute that by its terms, the Final Rule threatens federal funds not only from HHS but from the Department of Labor and the Department of Education as well. Nor do they defend that these funds have anything at all to do with the federal conscience statutes. Instead, Defendants' only response is an unsupported suggestion that Plaintiffs have an evidentiary burden to show Labor or Education funds "will actually be at risk." Defs.' Mem. 67. To the extent that Defendants suggest that HHS can constitutionally force Plaintiffs to choose whether to acquiesce to the Final Rule's provisions or take the risk that

HHS will terminate the Labor Department and Education Department funds the Final Rule authorizes it to do, this argument fails. *See supra* Part III.B.2.

4. The Final Rule violates the Spending Clause's prohibition on unconstitutional conditions.

For the reasons explained in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum, the Final Rule requires Plaintiffs to engage in conduct that would violate the Establishment Clause, thus violating the Spending Clause's prohibition on unconstitutional conditions. *See* Provider SJ Mem., Part II.E; Pls.' PI Mem. 53.

C. The Final Rule violates the Establishment Clause.

For the reasons explained in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum, the Final Rule is unconstitutional because it impermissibly advances religious beliefs in violation of the Establishment Clause. *See* Provider SJ Mem., Part II.E; *see also* Pls.' PI Mem. 29-30, 53.

IV. Plaintiffs are entitled to a preliminary injunction before the effective date of the Final Rule.

For the reasons set out herein (as well as in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum), Plaintiffs are entitled to summary judgment that the Final Rule is invalid and should be set aside. The Court recognized, however, that the scale of the administrative record or other factors "may prevent a reliable final determination on the merits" before the Final Rule's current effective date of November 22, 2019. Dkt. 121. Plaintiffs request that in the event the Court determines not to enter final judgment on the merits before November 22, the Court should in the alternative grant Plaintiffs' request for provisional relief, and enjoin Defendants from implementing the Final Rule pending ultimate resolution of the merits. Plaintiffs are entitled to a preliminary injunction because they will suffer irreparable harm absent provisional relief; they are likely to succeed on the merits;

and the balance of equities and public interest favor a preliminary injunction.[42]

A. The Final Rule irreparably harms Plaintiffs.

1. Plaintiffs are irreparably harmed by "the Hobson's choice" of "whether to suffer this injury or else decline much-needed grant funds." *New York v. U.S. Dep't of Justice*, 343 F. Supp. 3d 213, 244 (S.D.N.Y. 2018); *see* Pls' PI Mem. 9-14. Defendants argue that the efforts Plaintiffs must undertake to comply with the Final Rule are merely "ordinary compliance costs [that] are typically insufficient to constitute irreparable harm." Defs.' Mem. 75 (quoting *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005)); *see also* CMDA Mem. 5. But Plaintiffs have documented why compliance-related harms are unique here: in addition to the time, administrative burdens, and money that cannot be recouped, any changes Plaintiffs make to their policies and procedures before the Final Rule's effective date could have irreversible effects on the health of Plaintiffs' residents.[43]

Defendants also argue—citing no authority—that this forced choice fails to establish irreparable injury because "a long chain of events" would have to take place before fund termination could occur. Defs.' Mem. 75. Defendants' argument misses the point: the "long chain of events" they describe entail efforts to modify Plaintiffs' practices to comply with the Final Rule through measures short of fund termination, *see id.*; it is this precise compulsion—being forced to choose between changing policies to comply with an illegal regulation, or risking the loss of billions of dollars in health care funds—that causes irreparable harm to Plaintiffs. Courts have agreed, over objections identical to those Defendants raise here. *See, e.g.*, *New*

[42] *See Winter v. NRDC*, 555 U.S. 7, 20 (2008). For the same reasons, Plaintiffs are entitled, in the alternative, to a stay under § 705 of the APA. *See Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016).

[43] *See* Pls.' PI Mem. 11-13 (noting changes that may be required to New York State's guidance to physicians and nurse practitioners concerning statutorily-mandated provision of information to terminally ill patients about palliative and end of life care) (citing, *e.g.*, Ex. 48 (Zucker Decl.)).

York, 343 F. Supp. 3d at 244; *City of Phila. v. Sessions*, 309 F. Supp. 3d 289, 340-42 (E.D. Pa. 2018) (citing *City of Phila.*, 280 F. Supp. 3d at 655-57); *City of Chicago*, 264 F. Supp. 3d at 950; *Cty. of Santa Clara*, 250 F. Supp. 3d at 536-38. The risk of loss need not be tomorrow or absolutely assured; rather, irreparable harm is established where a plaintiff receives federal funds "knowing that the [plaintiff] *may be later deemed out of compliance with*" federal conditions on those funds. *City of Phila.*, 280 F. Supp. 3d at 656 (emphasis added); *see* Pls.' PI Mem. 11 n.9.

2. Plaintiffs are also harmed by the damage the Final Rule will cause to their health institutions and direct delivery of health care. Defendants contend that Plaintiffs' evidentiary showing is "purely speculative and based on a misunderstanding of what the Federal Conscience Statutes and the Rule actually require." Defs.' Mem. 74. But the grave operational harms identified in the dozens of declarations from Plaintiffs' health providers and other fact witnesses are concrete and specific, not speculative. *See* Pls.' PI Mem. 15-22.[44] Instead of addressing Plaintiffs' evidence, HHS merely restates snippets of the Final Rule—for example, tautologically arguing that an objecting employee could not cause a staffing problem because Plaintiffs are allowed to accommodate the employee by moving her, as long as she voluntarily accepts the move, but is under no obligation to do so, no matter how reasonable. Defs.' Mem. 74.

HHS similarly argues that a need for advance notice of an objection poses no problem for Plaintiffs as health providers, because they may require an employee to inform them of an

[44] These declarants include national leaders in their respective fields whose written testimony is supported by detailed and specific evidence. *See* Exs. 1-48. Defendants have not contested a single paragraph from this written testimony, and have conceded that they will not seek to cross-examine a single witness at the preliminary injunction hearing in this matter. *See* Paragraphs 3(K) and 5(C)(i) of this Court's Individual Rules and Practices. Intervenors separately quibble at the margins with the likelihood that a particular physician will object to treating a woman with an ectopic pregnancy, or Plaintiffs' lack of identifying a specific ambulance driver or helicopter pilot who has made a religious objection in the past. CMDA Mem. 5-6, 9. These arguments again miss the point detailed by declarants from numerous hospital systems: they have policies in place requiring sufficient advance notice of religious objections to *avoid* crises that arise when objections are made at the time a patient needs treatment, and it is precisely these policies that the Final Rule limits and undermines to the point of inoperability. *See* Pls.' PI Mem. 15-22.

objection—leaving out the fact that the Final Rule permits this to happen only once a year (barring an undefined "persuasive justification"), and places no duty upon the employee to inform the employer of any change in the employee's religious views over the course of that year. But HHS remains silent as to how such a rule could safely be implemented in sensitive emergency or medical transit settings, or in rural settings with personnel shortages, though Plaintiffs documented their imminent injuries in just these settings. *See* Pls.' PI Mem. 18-20.[45]

3. Finally, the Final Rule irreparably injures Plaintiffs as regulators and insurers. *See* Pls.' PI Mem. 22-23. These injuries alone support injunctive relief, because "a state's inability to implement its laws constitutes irreparable harm." *New York*, 351 F. Supp. 3d at 675-76 (citing *Abbott v. Perez*, 138 S. Ct. 2305, 2324 n.17 (2018)). Defendants' and Intervenors' oppositions to preliminary injunction did not contest or respond at all to this showing of irreparable harm, Defs.' Mem. 73-76, CMDA Mem. 5-10, thereby conceding these injuries. *See, e.g.*, *Rodriguez v. Carson*, No. 17-cv-4344, 2019 WL 3817301, at *4 (S.D.N.Y. Aug. 14, 2019) (holding that a party's failure to raise an issue in an opposition brief waives the issue).

B. Plaintiffs are likely to succeed on the merits of their claims.

Plaintiffs have also established the required merits showing to entitle them to preliminary relief. In the Second Circuit, Plaintiffs may obtain a preliminary injunction by showing irreparable harm and either a likelihood of success on the merits or "sufficiently serious questions going to the merits to make them a fair ground for litigation . . . ." *Citigroup Glob. Mkts., Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 35 (2d Cir. 2010) (quoting *Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979)).

[45] HHS later argues that Plaintiffs assert harms against third parties, citing to a discussion of Plaintiffs' direct delivery of health care. *See* Defs.' Mem. 76. As discussed, Plaintiffs directly provide care as operators of health institutions, and administer insurance laws as health regulators; both such functions are impeded by the Final Rule.

For the reasons already briefed, Plaintiffs are likely to succeed on the merits of their claims that the Final Rule violates the APA and the Constitution. *See supra* Parts II, III; *see also* Pls.' PI Mem. 24-53; Provider SJ Mem., Parts I, II, III. In addition, given the overwhelming evidence that the "balance of hardships tip[s] decidedly" in Plaintiffs' favor—as discussed above and as Defendants hardly contest—this Court may also apply the "serious questions" standard and conclude that if nothing else, Plaintiffs have presented "a fair ground for litigation" on the merits. Under either standard, Plaintiffs readily clear the showing required for preliminary relief.

C. The balance of equities and public interest favor preliminary injunctive relief.

As to the final factors for a preliminary injunction, "there is a substantial public interest 'in having governmental agencies abide by the federal laws that govern their existence and operations.'" *League of Women Voters v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (quoting *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994)). Defendants argue that the federal government suffers irreparable injury if it is "enjoined by a court from effectuating statutes enacted by representatives of its people." Defs.' Mem. 76 (quoting *Maryland v. King*, 133 S. Ct. 1, 3 (2012)). But as Defendants point out repeatedly, Plaintiffs have not challenged the underlying refusal statutes, *see* Defs.' Mem. 1, 3, 61, 65-68, so there is no risk those statutes will be enjoined. Nor can the Department support its claim of injury where it asserts continuing investigative and enforcement authority under the refusal statutes independent of the Final Rule. *See* Defs.' Mem. 80; *see also* 76 Fed. Reg. at 9975 (acknowledgment in the 2011 Final Rule that "none of these statutory provisions require promulgation of regulations for their interpretation or implementation").

Intervenors claim that an injunction would cause their members distinct injury because they object to procedures on religious grounds, *see* CMDA Mem. 10-12, yet they fail to (1)

address that the refusal statutes will not be enjoined by this action, or (2) allege any instance of discrimination a member has faced, other than the general results of a survey cited in the Final Rule's preamble, the flaws of which have been addressed previously.[46] *See* Pls.' PI Mem. 40-41.

The Court should therefore grant Plaintiffs' motion for preliminary injunction.

V. Plaintiffs are entitled to vacatur of the Final Rule as well as declaratory and injunctive relief to remedy Defendants' violations of the APA and the Constitution.

A. The Court should vacate the Final Rule.

The APA mandates that the Court "shall" "hold unlawful and set aside agency action" that is arbitrary and capricious, contrary to law, or in excess of the agency's statutory authority. 5 U.S.C. § 706(2)(A), (C). When a regulation is not promulgated in accordance with the APA, challengers are "entitled to relief under that statute, which normally will be a vacatur of the agency's [decision]." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001).

Vacatur is the appropriate remedy under the APA both when an agency acts contrary to law, *e.g.*, *NRDC v. EPA*, 489 F.3d 1250, 1261 (D.C. Cir. 2007) (vacating rule that "conflicts with the plain meaning of the statute"), and when an agency action is arbitrary and capricious, *e.g.*, *Camp v. Pitts*, 411 U.S. 138, 143 (1973) ("If [the agency's] finding is not sustainable on the administrative record made, then the [agency's] decision must be vacated . . . ."). Vacatur

[46] Intervenors now attempt to shoehorn in the results of a new survey that post-dates the Final Rule, is not part of the administrative record, and cannot, therefore, be used to uphold the Final Rule. *See* CMDA Mem. 10-12; Norman Decl., Dkt. 153. The Court should also disregard this new evidence in light of Intervenors' failure to comply with Rule 56(c)(4), which requires a declaration to "set out facts that would be admissible in evidence." The Norman Declaration fails to do so because either: (1) it is opinion testimony that fails to meet the standard for such testimony, *see* Fed. R. Evid. 702, and Intervenors failed to fulfill the disclosure requirements of Rule 26, *see* Fed. R.Civ. P. 26(a)(2); or, alternatively, (2) it is opinion testimony by a lay witness, only admissible if it is "rationally based on the witness's perception," and "not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701(a), (c). The Norman Declaration fails both requirements, and especially 701(c), because public opinion polling and survey methodology are clearly "scientific, technical, or other specialized knowledge within the scope of Rule 702." *See, e.g.*, *United States v. Garcia*, 413 F.3d 201, 215 (2d Cir. 2005) (if the purported lay opinion "rests in any way upon scientific, technical, or other specialized knowledge, its admissibility must be determined by reference to Rule 702, not Rule 701") (quoting 4 Weinstein's Federal Evidence § 701.03[1]).

reflects the sound principle that an agency action that violates the APA "'cannot be afforded the force and effect of law,' and is therefore void." *Air India v. Brien*, No. 00-cv-1707, 2002 WL 34923740, at *14 (E.D.N.Y. Feb. 14, 2002) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979)). Because the Final Rule violates both the APA and the Constitution, the Court should order the typical relief mandated by the APA and vacate the Final Rule. 5 U.S.C. § 706(2).

Contrary to Defendants' contention, nationwide relief is the usual course in an APA action because when "agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed." *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989); *see also Pennsylvania v. President of the United States*, 930 F.3d 543, 575 (3d Cir. 2019) ("[O]ur APA case law suggests that, at the merits stage, courts invalidate—without qualification—unlawful administrative rules as a matter of course . . . . Congress determined that rule-vacatur was not unnecessarily burdensome on agencies when it provided vacatur as a standard remedy for APA violations.").

An order vacating the Final Rule under the APA thus inherently has nationwide application, and Defendants' concerns about nationwide injunctive relief are misplaced. *See NAACP v. Trump*, 315 F. Supp. 3d 457, 474 n.13 (D.D.C. 2018). Nationwide relief is further required here to provide a complete remedy to the Plaintiffs in these consolidated cases, who collectively operate health centers nationwide. *See* Pls.' PI Mem. 54-55; Provider PI Mem. 51.

B. In the alternative, the Court should order provisional relief under Rule 65(a) or 5 U.S.C. § 705.

Alternatively, if this case is not resolved on the merits by the Final Rule's effective date, the Court should grant Plaintiffs' request for interim equitable relief as the public interest requires, or stay the effective date of the Final Rule pending resolution on the merits, per 5 U.S.C. § 705. *See* Pls. PI Mem. 54-55.

Whether the Court proceeds to enter a preliminary injunction, or to postpone the effective date of the Final Rule pending judicial review, any relief granted would properly apply nationwide, as noted in Part V.A. The scope of preliminary injunctive relief "is dictated by the extent of the violation established." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). Plaintiffs have demonstrated a likelihood of success on the merits, and the usual nationwide relief granted in APA actions applies here. *See Harmon*, 878 F.2d at 495 n.21; *NAACP*, 315 F. Supp. 3d at 474 n.13. This is especially true in light of "the equities of [this] case." *California v. Azar*, 911 F.3d 558, 584 (9th Cir. 2018). Together, Plaintiffs are twenty-three state and local governments and two nationwide organizations operating hundreds of health centers in all fifty states, the District of Columbia, and the U.S. territories. Far from a case where "the record is not sufficiently developed on the nationwide impact of the [agency action]," *City & Cty. of San Francisco v. Trump*, 897 F.3d 1225, 1245 (9th Cir. 2018), Plaintiffs have described irreparable harms that are geographically expansive in scope. *See supra* Part IV.A; *see also* Pls.' PI Mem. 10-23. An injunction without geographic limitation is necessary to provide Plaintiffs with complete relief.

C. The Court should vacate and enjoin the Final Rule in its entirety because the challenged portions of the regulation are not severable from the remainder.

The Court should likewise reject Defendants' skeletal suggestion to vacate or enjoin only part, but not all, of the Final Rule. Defs.' Mem. 79-80. "Whether the offending portion of a regulation is severable depends on the intent of the agency *and* upon whether the remainder of the regulation could function sensibly without the stricken provision." *MD/DC/DE Broad. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2000) (citation omitted). Defendants' cursory explanation that the Final Rule covers a wide variety of statutory provisions and defines several terms that "can operate independently of one another" does not establish that the Final Rule would function if unspecified pieces of it were severed. Defs.' Mem. 79-80. Nor have Defendants explained

how the Court "might craft a limited stay." *Texas*, 829 F.3d at 435.

To the contrary, the Final Rule's provisions are co-dependent, which hinders the regulation's ability to function sensibly without all component parts. Several sections cross-reference and rely on one another. *See, e.g.*, 84 Fed. Reg. at 23,264-69 (mandating compliance with §§ 88.4, 88.6); *id.* at 23,269-70 (assurance/certification compliance requirements dependent on funds to which § 88.3 applies, and failure to submit assurances/certifications are subject to enforcement under § 88.7). And the Department makes clear that compliance with certain provisions of the Final Rule will inform its execution of its powers pursuant to other sections. *Id.* at 23,216 ("OCR will consider the posting of notices [described in § 88.5] as non-dispositive evidence of compliance . . . ."). At minimum, if the Court vacates parts of the Final Rule but believes others may be severable, Plaintiffs request the opportunity to brief the issue after receiving the benefit of the Court's judgment regarding which parts of the rule are invalid.

D. The Court should reject Defendants' request for an advisory opinion on the lawfulness of undisclosed investigations.

Finally, the Court should reject Defendants' invitation to opine on ongoing unspecified investigations not before the Court. Plaintiffs have challenged the Final Rule, not the underlying statutes on which the Department purportedly relies for its activities. Any type of declaratory relief concerning unidentified investigations not at issue in this litigation is without basis. *See* U.S. Const. art. III, § 2, cl. 1.

CONCLUSION

Plaintiffs respectfully request that the Court vacate and set aside the Final Rule, or in the alternative, enter a preliminary injunction pending resolution of Plaintiffs' claims on the merits.

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Respectfully submitted,

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