UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

MAYOR AND CITY COUNCIL OF BALTIMORE, Plaintiff, v. ALEX M. AZAR, III, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES; and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Civil Action No.: 1:19-cv-01672-GLR Judge George L. Russell, III

NOTICE OF SUPPLEMENTAL AUTHORITY

On Wednesday, November 6, 2019, the U.S. District Court for the Southern District of New York (Engelmayer, J.) vacated in full the rule promulgated by the United States Department of Health and Human Services 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"). The decision is attached here as Exh. A (*New York v. U.S. Dep't of Health & Human Servs.*, 19 Civ. 4676, Dkt. 248 (S.D.N.Y. Nov. 6, 2019)) (the "SDNY Opinion"). The transcript of the hearing, at which Defendants made representations regarding the issues in dispute in this case is attached as Exh. B and Mayor and City Council of Baltimore (the City) requests that the Court take judicial notice of this transcript.

The SDNY Opinion granted summary judgment for plaintiffs and vacated the Rule in full pursuant to the Administrative Procedure Act, 5 U.S.C. § 706, and the United States Constitution – the exact relief the City seeks in this case. The SDNY Opinion held: (1) that the Rule exceeds Defendants' statutory authority with respect to the substantive and enforcement components of the

Rule; (2) that the Rule is contrary to law in that it conflicts with Title VII, 42 U.S.C. § 2000e(j), and the Emergency Medical Treatment and Labor Act ("EMTALA"), 42 U.S.C. § 1395dd; (3) that HHS acted arbitrarily and capriciously because its justifications for the Rule were contrary to the evidence, HHS failed to supply a reasoned explanation for its policy change, and HHS failed to consider important aspects of the problem before it; (4) the constitutional claims are ripe, and the enforcement provision of the Rule authorizing HHS to withhold or terminate all HHS funding for noncompliance violates the United States Constitution's Spending Clause; and (5) the Rule must be vacated in its entirety. *See* SDNY Op. *generally*; *see also id.* at 137-138 (summarizing grounds for vacating Rule); *id.* at 141-143 (explaining why Rule must be vacated in full).

DATED: November 7, 2019

Respectfully submitted

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CERTIFICATE OF SERVICE

I hereby certify that on November 7, 2019 the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system and all counsel of record will receive an electronic copy via the Court's CM/ECF system.

/s/ Elisha B. Barron
Elisha B. Barron

EXHIBIT A

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

[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

EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
----------x

STATE OF NEW YORK, et al.,

Plaintiffs,

v. 19-cv-4676 (PAE)
19-cv-5433 (PAE)
19-cv-5435 (PAE)

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants. Argument

----------x

New York, N.Y.
October 18, 2019
9:32 a.m.

Before:

HON. PAUL A. ENGELMAYER

District Judge

APPEARANCES

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The State of New York
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AMANDA MEYER, ESQ

PLANNED PARENTHOOD FEDERATION OF AMERICA
BY: DIANA SALGADO, ESQ
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BY: DAVID M. ZIONTS, ESQ

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BY: DANIEL BLOMBERG

(In open court)

THE COURT: Good morning everyone.

I will have some words of introduction in a moment but before I do I want to just take the roll to make sure I understand who is who. Who do I have appearing for the provider plaintiffs?

MS. KOLBI-MOLINAS: Alexa Kolbi-Molinas for plaintiffs National Family Planning Reproductive Health Association and Public Health solutions.

THE COURT: Good morning, Ms. Kolbi-Molinas.

MR. ZIONTS: Good morning, your Honor.

David Zionts for the Planned Parenthood plaintiffs.

THE COURT: Good morning, Mr. Zionts.

Anyone else for the provider plaintiffs?

MS. SALGADO: Yes, your Honor. Diana Salgado on behalf of the Planned Parenthood plaintiffs.

THE COURT: Good morning, Ms. Salgado.

For the New York State and other state plaintiffs.

MS. SALGADO: Good morning, your Honor. Matthew Colangelo from the New York Attorney General's Office on behalf of the governmental plaintiffs.

There are a number of other plaintiffs' counsel in the courtroom but not near a microphone. They include Marie Soueid for the State of New Jersey, Jonathan Burke for Massachusetts, Cynthia Weaver for New York City, Lisa Landau for New York

State and Justin Deabler for New York State.

THE COURT: Good morning, Mr. Colangelo.

I appreciate your putting those names on the record. I take as a given that a number of the people who are here are lawyers who have worked in one way or the other on the case. Solely in the interest of economy, I'm taking appearance only from those in front of the bar but I very much value, as I'll say in a moment, the contributions by everybody here and behind the scenes.

MS. MEYER: Good morning, your Honor. Amanda Meyer on behalf of the governmental plaintiffs.

THE COURT: Good morning to you, Ms. Meyer.

Now for the defense, who do I have for HHS?

MR. BATES: Christopher Bates from the U.S. Department of Justice representing HHS but you're asking about counsel from HHS?

THE COURT: Yes. Well I was asking for the government. Thank you, Mr. Bates. Good morning.

MR. KEVENEY: Good morning, your Honor. Sean Keveney with HHS.

THE COURT: Very good. Good morning, Mr. Keveney. Anyone else for the government?

MR. VOLTAIRE: Jean-Michel Voltaire for HHS.

THE COURT: Very good, it's Mr. Voltaire?

MR. VOLTAIRE: Yes.

THE COURT: Very good. Good morning, Mr. Voltaire.

Anyone else for HHS?

MS. ANDRAPALLIYAL: Vinita Andrapalliyal from DOJ representing HHS.

THE COURT: Good morning, Ms. Andrapalliyal.

Anyone else for HHS?

MR. TAKEMOTO: And Benjamin Takemoto for the Department of the Justice.

THE COURT: Good. Very good. Good morning Mr. Takemoto. All right.

And for the intervenor defendants, who do I have?

MR. DUNN: Good morning, your Honor. Robert Dunn for the Christian Medical and Dental Association.

THE COURT: Good morning, Mr. Dunn.

MR. BLOMBERG: Daniel Blomberg for intervenor defendants.

THE COURT: Good morning, Mr. Blomberg.

You may all be seated.

Let me begin just by welcoming everyone in this courtroom and to the extent there is anybody following in the overflow courtroom, although at this point it doesn't appear necessary, welcome to you as well.

We're here today for argument on a rule promulgated earlier this year by the Department of Health and Human Services. The rule is entitled Protecting Statutory Conscience

Rights in Health Care Delegations of Authority. It is scheduled to take effect on November 22.

In the consolidated lawsuits before me several groups of plaintiffs challenged the rule on various grounds, including based on The Administrative Procedure Act and on several provisions of the Constitution.

Before argument begins I want to take a moment and thank and compliment counsel. I have received, it is safe to say, extensive briefing from the parties. The briefs have been absolutely first rate. Really absolutely first rate. They are as good as it gets. And I have benefited enormously from counsel's thoughtful and close attention to the many complex issues in the case.

I've also received a large number of amicus briefs. They too have been thoughtful and very valuable to me.

So thank you to all of those who worked on the briefs. And I'd ask the lead counsel here to please kindly, on my behalf, acknowledge all of the lawyers and staff on your teams who worked on these briefs and associated materials and please thank them for me for a job very, very, very well done.

In terms of argument, here is how we will proceed. And earlier this week I issued an order to this effect so this will not come as a surprise to the counsel in front.

First of all, I'm going to hear argument from the plaintiffs. I've allocated 75 minutes for that.

Plaintiffs have divided their time and topics according to a letter I received from them among four advocates. The first two are on behalf of the provider plaintiffs, which is to say Planned Parenthood and the National Family Planning and Reproductive Health Association, et al. The second two are on behalf of the governmental or state plaintiffs and are from the New York State Attorney General's office.

As I did in my order, I had asked plaintiffs' counsel to please watch the clock and be sure to leave sufficient time for the later of your four advocates because I expect I'll be active in asking questions that may get you off script. I need you, nevertheless, to be mindful of the time just so that important topics that happen to be batting third and fourth don't get squeezed for time.

After I hear from the plaintiffs, we'll then take a short comfort break and I will then hear from the defendants to whom I've also allocated 75 minutes. Specifically, I've allocated 65 minutes for HHS and ten minutes to the intervenor defendants, specifically counsel for Dr. Regina Frost and the Christian Medical and Dental Association.

I hope afterwards we will have time for rebuttal and follow-up. I certainly expect that I will have a lot of questions for all counsel throughout.

So with that preface, let's begin with the provider

plaintiffs and I understand that I'll hear first from Mr. Zionts.

MR. ZIONTS: Thank you, your Honor.

THE COURT: Go ahead.

MR. ZIONTS: Thank you, your Honor. And good morning. I'm mindful of your Honor's instruction in terms of time allocation. Just to let you know in advance my plan here is to speak for about 15 minutes and each of my colleagues plan to speak for about 20 minutes although, of course, we'll be in your hands in terms --

THE COURT: Thank you. That's helpful to know.

MR. ZIONTS: Your Honor, I'll be spoking about HHS's authority or rather lack of authority to issue this regulation. I'd like to start with a basic but fundamental point.

The heart of HHS's position is that the rule is just housekeeping. The agency says it is just letting everyone know how it interprets the refusal statutes and how it enforces them so it doesn't need any delegation of substantive rule-making authority.

Your Honor, the best answer to this argument is in the text of the rule itself. At every step it is clear from the face of the rule that it is legislative, imposing substantive requirements on regulated parties.

So with the Court's permission, I would like to very briefly walk through the rule's key provisions.

THE COURT: If I may. I know -- I know what the key provisions are. Let me see -- I understand your point that components of the rule are substantive and legislative and I understand those to involve the definitions of discriminate and assist in the procedure and the like.

But let's focus on the other side of the equation. Is there some part of the rule that you would acknowledge is housekeeping and that can properly be done under the housekeeping statute?

MR. ZIONTS: Your Honor, what I would say is there are parts of this rule that could have been done in a way that would be consistent with housekeeping.

For example, if the agency had simply said: Go look at the UAR; we are letting you know that we will follow to the letter the UAR and that is how we will enforce, I think that would indeed be housekeeping.

But the way this rule is structured at every step of the way it's hard to disassociate the pieces of this that impose substantive requirements from other provisions that might for example, if done differently, could be genuine housekeeping.

THE COURT: Well let me pushback on that. You say repeatedly in your briefs that you're not challenging the conscience provisions that are in the statutes, correct?

MR. ZIONTS: Correct, your Honor.

THE COURT: Let's assume for argument's sake, imagine whatever scenario you would concede would be a between-the-eyes blatant violation of those statutes. Right now I take it the law is silent as to remedy.

Imagine a violation of the statutes. Put aside any gloss on those statutes by rule. Just imagine a between-the-eyes violation.

MR. ZIONTS: Right.

THE COURT: What does HHS do without rule-making to explain how the process of adjudicating a violation is and what the consequences would be and is that something that HHS can properly rule-make on?

MR. ZIONTS: Well, your Honor, there was a 2011 rule, that we do not challenge its validity, that provided a complaints mechanism and we don't dispute the agency's power to do that.

THE COURT: Now let's suppose the complaints process results in a finding of a between-the-eyes violation or set of violations. Is there anything out there right now that would set out the consequences?

MR. ZIONTS: Your Honor, we also do not challenge the existing regulatory grant procedure.

So, for example, if OCR, through that 2011 complaint procedure, determined that there was a square violation of the statute -- not the rule, of the statute -- then the agency's

position, and we don't have any problem with this, is that they would go through the ordinary procedures under the UAR. Remedies would be limited to that. There would be notice and due process and there would be -- one key feature of the UAR is the remedy is generally limited to the specific source of funding at issue. And they could do that. We're not disputing that.

THE COURT: So if there were a violation, let's say, of any or all of the ACA, Medicaid, or the other three primary statutes that are our main focus here, you don't dispute that under existing authority the agency, if it crossed its Ts and dotted its Is, it could ultimately get to the place of retracting federal funding limited to the funding stream attributable to that statute?

MR. ZIONTS: Right, your Honor. It would be limited to the funding stream.

And one just additional crucial point would be that in terms of -- I think in this hypothetical we're talking about a square, everyone-would-agree violation. And just one key proviso I would put would be: HHS would have its view of what the statute means and it would go through this procedure and it would be free -- it would be upon the regulated party to potentially go to court and say it doesn't mean this. And there would be no deference at that point. The Court would decide.

THE COURT: Give me an example of something you would agree is a between-the-eyes violation of the conscience statutes.

MR. ZIONTS: Your Honor, I think Ms. Salgado may be able to speak to this a bit more when she addresses discrimination. If, for example, just turning to the Church Amendments, speaking of discrimination of employment because someone performed or refused to perform.

If you had someone who was -- who an employer demanded you must perform an abortion or you'll be fired, there is no hardship to the employer to find someone else to do it. There is really no reason for purposes of patient care. There is no emergency, etc. It's essentially: Person standing there. Do it or you're fired. No good reason, no hardship preventing that. I think we would all agree that that violates the statute.

THE COURT: Under the UAR suppose there's a singular violation, one violation to that effect. But it's absolutely adjudicated perfectly and there is no question that exactly that happened.

If the agency, crosses its Ts and dots its Is, at the end of that possess for that single violation does the existing statute and the existing regulations, do they permit the agency to pull the entity's entire funding under that statute?

MR. ZIONTS: The agency's entire funding, I don't

think so, your Honor.

THE COURT: Under that statutory -- under that one statute?

MR. ZIONTS: Well, your Honor, I think it's not just -- I distinguish between the statute itself.

So, for example, the Church Amendments which might impose obligations across a range of funding stream grants, etc. Generally the way the UAR works is that it speaks of the cost of the specific federal award or activity. So in general if there was -- we're speaking hypotheticals -- if there were to be an actual health care entity that committed this violation and committed a violation, of course, of a particular funding stream, I think what the UAR would say is you could lose that. Of course, there's voluntary remedies. The UAR is phrased a little differently from this rule in that it is intended to escalate and to give various offramps for voluntary remedies and cessation. But ultimately you could lose funding under the particular grant at issue. We don't think anything in the UAR provides for just wiping out all federal funds.

THE COURT: Go ahead.

Sorry. Just explain to me just a little more the meaning of funding stream, as you concede, it could be implicated by a violation. The Church Amendment covers a number of different funding streams. I want to be sure that I understand what you're acknowledging and what you're resisting.

How would HHS ultimately, if we got to the end of the series of enforcement events, how would they go about defining the funding stream that is jeopardized by such a brief?

MR. ZIONTS: Your Honor, I think just looking at the language of Church, and it applies based on receiving a grant contract, loan, or loan guarantee under the Public Health Service Act. So I think you would go grant-by-grant, contract-by-contract. And, again, you would have to see how this would play it, and it could vary depending upon the circumstances. I think you would look at the grant.

THE COURT: Let's look at a big one. Let's suppose it's Medicare or Medicaid. Let's use New York State as an example, although they'll have an opportunity to defend their own perspective on this. But imagine, again, a between-the-eyes violation of the sort that you hypothesize and assuming that no offramp applies or is activated, at the end of the day for one error like that, can New York State lose its entire let us say Medicaid funding?

MR. ZIONTS: Your Honor, I do not want to stand here and bind the State of New York.

THE COURT: Choose some other state.

MR. ZIONTS: Particularly when they are sitting right here.

What I would say, it's an interesting problem that the agency itself has not clarified. Their position here has been

this is all part of existing regulations. And they're fairly specific about the UAR, which is about grants in particular.

THE COURT: Why can't -- go ahead.

MR. ZIONTS: I was going to say with respect to Medicaid, we're actually not sure how the agency believes it would go about withdrawing federal funding; not in terms of the rule, in terms of if it believes it as the existing statute.

So in the part of the rule where it speaks to: For grants, see the UAR; for contracts, see this. For Medicaid, it just says in the rule: See the Social Security Act. They don't point to a provision. They don't point to a regulation. So we're not really sure how they think existing regulations would allow --

THE COURT: Well then that begs the question. It's the agency's existing regulations don't clarify the universe. What is it that prevents the agency, whether in the context of this rule or another, from sharpening up its guidance even if, perhaps, having a more muscular approach to these problems and saying at least in this area where we're talking about violations of religious or moral conscience rights recognized by statute, we're going to have a particularly strong penalty and deterrent. Why can't they do that?

MR. ZIONTS: Your Honor, we think -- well, first of all, the statute itself, just looking at the Church Amendment, Church B-- this may not be a good example because it doesn't

apply to Medicaid funds but Church D may. Church D is simply written as individuals have a right not to do acts. And it doesn't say anything about: Or else you lose X or Y or X, Y, and Z or everything under the sun.

So in our view -- we acknowledge there are things that HHS can do under its existing authorities in a careful step-by-step way, in a way that has been done for as long as these statutes have been on the books and, in particular, under the 2011 Rule.

But when Congress intends the Draconian remedy of you lose all your federal funding, a state loses Medicaid, it says so. Title VI says so. It says agencies have the authority to promulgate regulations, provide for the termination of funding, provide adaptors to process. There's even notice to congressional committees. And it doesn't say anything like this. So while -- we're happy to concede that there is some level in the administration of these grant programs that it can do, it would be quite anomalous if we're -- in Title VI Congress was very explicit in saying you can take money but only up to here and with these protections. Here, the Congress didn't say anything but HHS has free reign to say we can take it all.

THE COURT: Very helpful. I want to give you a chance in a moment just to turn to the more substantive dimensions of the regulation, but one final housekeeping-type question.

The rule has new assurance and certification requirements imposed on recipients. Are those compatible with the housekeeping statutes?

MR. ZIONTS: We don't think so, your Honor. And, again, if you look at the rule, here's how Section 88.6 is written. Parties shall, in quotes, shall. Excuse me. It's 88.4. Requires that the applicant or recipient to comply with applicable federal conscience and discrimination laws and this part, and this part is referring to this part of the CFR.

So, first of all, that certification does not just certify that you comply with the underlying statutes. It's saying what we just added to the CFR, which are substantive legislative requirements, you have to certify --

THE COURT: Fair. Fair point. Strip away the substantive components of the rule and focus just on the violations or not of the statute.

Could HHS under its housekeeping authority require the hospital, state, etc. to comply with assurance and certification if those -- if that's limited to compliance with the statute?

MR. ZIONTS: Your Honor, I think there are -- in the existing UAR there are much more general certifications. This is a bit different in that --

THE COURT: But the UAR is a measure of what the agency can do. It's one thing the agency has done but they may

or may not be able to do more.

MR. ZIONTS: Agreed, your Honor.

The main point I would make is that this is, in our view, a substantive requirement: You shall complete the certification. And that has legal consequences. A certification raises issues under the False Claims Act. You could potentially be sued if someone thinks that you have made a certification for compliance with these statutes and someone believes that that was false and that led to receiving federal funds. And so when an agency legislates and says you must do this -- and when you look at the enforcement provisions as well, 88.7, the enforcement provisions, they say they will take your money away if you violate this part, and that includes certification.

So even if you haven't done anything substantively wrong, if you just don't do the certification the way they say, they say you violated the regulation, we will enforce it, that's a substantive force of law rule.

THE COURT: All right. Let's turn to the substantive parts of the statute. And I think I understand from your briefs the definitions of all the various statutory terms are ones that you intend, and I understand why, are substantive.

MR. ZIONTS: Right. Your Honor, I think I'm about at fifteen minutes. I will just say one word. The -- we do think it is clear when you look at the way this rule is framed,

including with the definitions and the way they work with what the rule calls applicable requirements and prohibitions, this is a federal agency telling regulated third parties: Do this or you will be in trouble. Do this or we will enforce against you.

The one point, just because it's not in the briefing, I wanted to alert your Honor to a decision, fairly recent decision from the D.C. Circuit called Guedes v. ATF. The citation is 920 F.3d 1. It's somewhat similar in the sense that there you had an agency insisting that all it was doing was interpreting, telling people -- this had to do with the bump stocks regulation -- it was just telling people how it interprets this rule.

The agency said: No. It says shall. It's in this CFR. The agency was claiming Chevron deference. Everything about it said legislative substantive rule-making. And the Court said yes. And I think the Court, if you look at the opinion, you'll find a number of parallels. The one difference in that statute was the agency was actually delegated authority to issue a legislative rule. Here, we have all the indicia of a substantive legislative rule. We just don't have any source of authority to do that.

THE COURT: Final point on that. That appears to be so, at least explicitly with respect to Church and Coats-Snowe and Weldon. But under the Affordable Care Act and Medicare and

Medicaid there is some grant of substantive rule-making authority.

Suppose the rule had simply defined terms like discriminate or refer, etc., within the framework of the statutes that do have substantive rule-making authority delegated to the agency. Could the agency have done that, had it confined the definitions to the statutes that have the explicit delegation of rule-making provisions?

MR. ZIONTS: We may have other problems with that, but in terms of statutory authority, we absolutely agree. The ACA says you can regulate on this topic. It can't --

THE COURT: So while you're not happy with the definitions, as it relates to those statutes, the ACA, Medicare, Medicaid, you're not making a lack-of-authority challenge with respect to the definition of those statutory terms for those statutes.

MR. ZIONTS: That's right, your Honor.

THE COURT: Thank you.

MR. ZIONTS: In the interest of keeping everything moving, I'll turn things over to Ms. Salgado, unless your Honor has any other questions on the rule-making issue.

THE COURT: No. I think there will be an issue about remedy and severability that is very much implicated by our last exchange. But I think it's better to move on and we'll touch on that later. Very helpful. Thank you.

So next up I think is Ms. Salgado.

MS. SALGADO: May it please the Court, Diana Salgado on behalf of plaintiffs.

Your Honor I'm going to focus my time on two plaintiffs' claims: That the rule is contrary to law and, if time permits, that the final rule is not a logical outgrowth of the proposal.

There are several reasons that the rule is contrary to law but I'd like to start with conflict with the underlying statutes. In promulgating this challenge regulation, not only has the agency given the rule the force of law but it has also stretched the terms of the statutes beyond their limit and far exceed what Congress intended.

Starting with the term discrimination, which is found in nearly all of the underlying statutes, HHS has taken a general prohibition on nondiscrimination and promulgated a regulation that defines the term to mean that health care entities, such as the plaintiffs here, have an absolute duty to accommodate employees who have objections to performing or assisting in the performance of, and depending on the statute, abortion or sterilization and must do so regardless of the burden on employers and the patients they're seeking to serve.

THE COURT: So pause on that for a moment.

Let's focus on the part of the rule that affects employees and employers. I take it your view is that up to

this point the Title VII framework has governed that.

MS. SALGADO: That's correct, your Honor.

THE COURT: And Title VII requires that ultimately at the end of the sequence if there is an undue hardship essentially the employer is allowed to refuse to accommodate the religious objector.

MS. SALGADO: Yes.

Title VII requires that an employer provide a reasonable accommodation unless there is an undue hardship on that employer.

THE COURT: So is the point here then at least as to the employment dimension of the world covered by the rule, we've got a square conflict with a statute, Title VII.

MS. SALGADO: Well, your Honor, we haven't -- that's true. There is -- that the statutes or actually that the agency, in the way that they have interpreted the statutes in this rule, seeks to abrogate Title VII's application.

THE COURT: I have read with great interest your briefs that focus on the emergency care and Title X and whatnot. Why isn't the most explicit example or, as good an example you have, Title VII where since 1972 we have a statute that appears to encode the hardship exception and, therefore, it has much more of a carve-out than the rule does in allowing an employer that needs to exist to insist.

MS. SALGADO: I'm sorry, your Honor. Are you

asking --

THE COURT: It's a softball but it's an important question. But the reason I'm asking is from your briefs I did not get the impression you were pushing nearly as frontally on the conflict with the statute, and a familiar one at that, Title VII, as a basis for your contrary-to-law argument.

MS. SALGADO: Well it is true, your Honor, as you know, we have brought many claims in this case and one specific one is not that the rule itself conflicts with Title VII; rather, that the term discrimination and the way that the agency has interpreted that rule here is not a faithful application of the underlying statutes; that the agency has exceeded what Congress intended when it passed the refusal statutes.

THE COURT: Right. I'm just trying to understand why the argument isn't being made flat-out that at least as to the definition of discriminate it can't stand because that aspect of the rule is contrary to a separate law, not the law under which the agency purports to have but Title VII, which predates even the first of the conscience statutes, has given employers an opportunity -- a hardship basis for refusing to accommodate.

Why isn't the simple answer -- and I'll obviously be eager to hear the government's perspective -- why isn't the simple answer Title VII is law; the agency by regulation can't contravene that?

MS. SALGADO: That is our position. That's absolutely our position, your Honor, is that in interpreting this -- the statutes that the agency has promulgated a definition of discrimination that is in conflict with Title VII.

THE COURT: If I were to agree on that, what part of the rule would be unaffected by it? Would it be the parts that simply don't affect the employment context?

MS. SALGADO: Your Honor, absolutely those parts would be affected. I think that raises a fair question, which is: Are there other applications of the agency's definition of discrimination that are not a faithful application of the statute beyond the employer and employee context.

And as a whole, your Honor, we believe that the term discrimination is always sensitive to context and circumstance. It always considers whether there is a justification for the treatment that's being complained of.

So as a broader matter, the term discrimination that the agency has put forth here in this rule as a whole is not a faithful application of the statutes.

THE COURT: So let's get down to brass tacks. Your agency employs medical professionals, correct?

MS. SALGADO: That's correct.

THE COURT: Pre-rule, if you had a religious objector who didn't want to participate in an abortion, didn't want to hand the forceps over or something like that, how would --

within the Title VII framework and in the real world how does your agency deal with an objector like that?

MS. SALGADO: Well, your Honor, you're correct that we have health care professionals that would be subject to this rule in medical centers all across the country, in every state of this country. And how a religious objections are dealt with are through the Title VII framework.

THE COURT: So a nurse says: I've been on the job for a while. I've now developed a sincere religious view that prevents me from assisting in an abortion. Let's put the nurse in the operating room so we're not dealing with more distended ways of assisting. The nurses says: No can do.

What is it that the -- how does the agency -- how does your -- as an employer, how does your client deal with that problem now within the Title VII framework?

MS. SALGADO: Well, your Honor, it's a hard question to answer because the -- in terms of how a very specific objection would be dealt with, I think it would depend on a number of factors. It would depend on whether the agency or the plaintiffs in this case have a duty to try to reasonably accommodate the nurse.

So the question would be: Is there is a way to accommodate this particular individual's objections by, for example, if abortions were only performed on a certain day then that nurse -- there would be perhaps a conversation about

whether that nurse would be willing to work on the days when abortions are not provided.

THE COURT: You would reallocate responsibility so the nurse worked on non-abortion procedures?

MS. SALGADO: Exactly, yes.

Or there might be a question of whether instead of actually working in a room where abortions are being provided, whether the nurse would actually be -- whether be able to work in a different room.

But all of those decisions have to be balanced with whether accommodating that nurse would impose a hardship.

And if I may, your Honor, just add that the record evidence, what it shows is that the plaintiffs in this case operate several clinics where there is only one medical professional.

THE COURT: That's where I was going to go in the rural hypothetical or the short-staffed hypothetical that appear here. Maybe it hasn't, in fact, arisen in the real world, but how -- under the current framework what would your client do if in the end there wasn't an alternative person to fill in?

MS. SALGADO: Well, your Honor, I do think there is a question of whether -- what the individual has been hired to do as one of their primary or substantial duties to perform, then I think there is a question of whether that individual was

qualified for that position.

THE COURT: Right. And I'm using the hypothetical in which a sincere religious conviction develops after the point of hire. And so we're the actually -- you've got an employee -- is it your view ultimately that under the Title VII framework, in our hypothetical rural hospital, if the person cannot do an essential part of the job and there's nobody else, in the end that could be a basis for something up to discharge?

MS. SALGADO: Depending on the facts and circumstances, yes. I mean I guess I would say that many of Planned Parenthood's affiliates operate several health centers in a particular region. So perhaps there would be -- and not every one of those centers offers abortion so there would be a conversation of whether that person could be transferred to a different health center. And, yes, your Honor, if what the nurse was hired to do was to assist with -- assist in the performance of abortion services or in states that actually allow it provide abortion services and the individual developed a religious objection and was not able to perform the primary duties of their position and was not willing to work on other days or be transferred to another health center, then, yes, your Honor, I think the Title VII framework does allow for consideration of undue hardship.

THE COURT: And under the rule, same hypothetical, if the rule were to take effect, how does it work as you

understand the rule?

MS. SALGADO: I think the rule has no consideration or the term -- the rule's definition of discrimination has no consideration of a balancing of interests, the interests of the employer in seeking to provide care, or the interests of their patients. And it doesn't allow for any consideration of hardship. The only thing that the rule references is, quote, an effective accommodation, which is one that the employee must voluntarily accept. And isn't lost on anyone than an effective accommodation is different than a reasonable accommodation that allows for some consideration of the balancing of interests.

THE COURT: But in the end there is no hardship exception to the rule is your point.

MS. SALGADO: That's correct, your Honor.

I would say as an example of, a real world example, because we've been talking about hypothetical situations, a real world example of how the rule would work, if I may, a reference the Court to the Shelton case.

THE COURT: I was -- I've got that on my list for the defendants.

MS. SALGADO: And in that case the nurse refused to assist in emergency abortions. The second time the patient was standing in a pool of blood and the nurse still refused to perform an emergency abortion. It took the hospital 30 minutes to find another person to fill in. And even after that the

hospital offered the nurse an accommodation to the NICU department. She refused and the hospital had no other option but the terminate her. She brought a Title VII claim and the Court found against her because the hospital had offered a reasonable accommodation.

THE COURT: Your point is under the rule if the rule were law Shelton comes out the other way?

MS. SALGADO: That's right.

And certainly the agency has not said otherwise.

THE COURT: All right. Thank you. Very helpful. I realize I've taken you off topic. Focus on other ways, apart from the Title VII conflict, that the rule is contrary to law.

MS. SALGADO: Yes, your Honor.

So I think the -- as we were just discussing in the context of emergency abortions, the rule has no exception for cases where there is a need to provide emergency treatment. And the parties agree that under the Emergency Medical Treatment and Labor Act there is a duty for providers to provide stabilizing treatments or a transfer, if possible. And defendants don't dispute that in some cases patients need emergency abortions. But the rule doesn't have any exception for that. All the agency has said is that it will -- it will seek to harmonize the statutes to the extent possible. That isn't -- EMTALA doesn't say that it can be applied, quote, to the extent possible. There is no exception.

THE COURT: When was EMTALA enacted, if you know?

MS. SALGADO: I don't, your Honor. I know that it predates -- I am sure that it predates Weldon and I don't know -- I'm being told 1985 or 1986.

THE COURT: So it comes after Church. It comes after the first of the conscience provisions but not some of the later ones. I guess the question is whether there's anything in the legislative history of the later ones that suggested an intention to modify the state of play under EMTALA, emergency statute.

MS. SALGADO: Yes, your Honor. Each of the statutes there was discussion about -- well Weldon specifically Representative Weldon specifically noted that EMTALA forbid health care facilities to abandon patients with medical emergencies and particularly pregnant women. Senator Church also made clear: We're not permitted to shield a hospital from denying services in, quote, in emergency situations, life or death type. And Senator Coats also stressed in his amendment which was, as I've said in the briefing, the Coats amendment was actually focused on abortion training, so it was a little bit more removed, but Senator Coats did stress that the amendment wouldn't prevent physicians from being able to provide -- or being trained to provide emergency treatment.

THE COURT: One thing I'm couldn't quite figure out was the interplay between EMTALA and Title VII under current

law. In other words, in practice is the way EMTALA applied in the use of undue hardship notes from Title VII but in an emergency context the employer has a particular deference, or the hardship concern comes particularly before you can't have somebody, you know, stopping in a transverse on the way to the hospital because they realize they're driving somebody to an abortion.

MS. SALGADO: Absolutely, your Honor. I think the Sheldon case highlights this; is that the hospital, after having two serious incidents in which a nurse was not providing care to a patient that had life-threatening conditions, the hospital had to remove the nurse. I'm not -- honestly, I'm not quite sure whether that decision discusses EMTALA, but I think that is an example where the hospital -- that it would have been an undue hardship for the hospital if -- to keep that staff and not be able to comply with EMTALA.

THE COURT: So I have your points on Title VII and EMTALA. Just come back just for a moment to the ACA.

The ACA does have a substantive ruling provision and it specifically says that nothing in the Act shall be construed to have any effect on federal laws regarding conscience protection.

Given that, what's the contrary-to-law argument you have with respect to the ACA?

MS. SALGADO: Well in the ACA, in Section 1554 of the

ACA specifically, that statute prohibits HHS from promulgating regulations -- or shall not promulgate any regulation that creates any unreasonable barrier, impedes timely access to health services. And specifically Section 1554 of the ACA what it says is: Notwithstanding any other provisions of this Act the Secretary of Health shall not promulgate any regulation that does these six different things.

So, your Honor, I think that it was clear that Section 1554 was meant to trump any other provision of the Act including section -- I think you're referring to Section 1303, 42 U.S.C. 1823. So I think it's clear by the face of the statute that Section 1554 was meant to trump any other provisions of the Act including that provision.

I would also note that in Section 1303 --

THE COURT: In other words, the ACA leaves in place all the conscience provisions that were there by statute. Your issue is that if the agency substantively expands the reach of those provisions, then you're not only -- whatever other rule-making issues there may be, you're now encroaching into a space that the ACA limits the agency's room to run in.

MS. SALGADO: Yes, your Honor. Section 1554 has been on the books for nearly nine years, coexisting with refusal statutes. So our position isn't that 15 -- defense counsel has tried to argue this but our position isn't that 1554 conflicts with the statute. It conflicts with the rule or, better yet,

the rule conflicts with the statute because the rule itself does -- it does create unreasonable barriers to the ability of individuals to obtain appropriate medical care. It does impede timely access to health care services. And the most clear example of that is by not having exceptions for emergency services. But I think that there are other ways in which the rule also violates 1554, right, even outside of emergency care. The rule also restricts full -- requires full disclosure of all relevant information to patients. But through the expansive definition of assist in the performance, which includes referral. And the way in which they have defined referral means that just the mere provision of information if that person believes that it will assist someone in performing an abortion is a referral, that would lead individuals to be able to deny people basic information such as if a patient faced with an unplanned pregnancy asked about abortion --

THE COURT: The rule reaches back to events, days, weeks, months before the procedure, including a phonecall, a conversation -- a chat with a receptionist.

MS. SALGADO: Exactly, your Honor. We think in those ways, by allowing refusals or individuals to refuse to provide basic information is another way in which it violates the clear mandate of Section 1554.

THE COURT: Why don't you in the remaining time just deal with logical outgrowth briefly. Your argument is that the

agency in it's notes and rule-making didn't, among other things, telegraph the possibility that it will be repudiating the Title VII accommodation framework. I get the argument. Nevertheless, a lot of commentators clearly understood that that was in play because a lot of the comments on the rule are addressing just that.

Doesn't that suggest that while the agency could have been more precise it was understood that the accommodation framework was in play in the rule-making process?

MS. SALGADO: Well I have two responses to that, your Honor.

The first is that, as a legal matter, the agency cannot bootstrap notice from the comments; otherwise, that would turn notice into an elaborate treasure hunt of which interested parties would have to search the record for the sort of buried treasure.

But you are right, your Honor. There were several commenters that submitted comments imploring the agency to make clear that it was not taking away the reasonable accommodation undue hardship framework. Those comments came from the plaintiffs in this case but they also came from major medical organizations, American College of Emergency Physicians, The American Medical Association, The American Hospital Association.

But they were in response -- what they were in

response to was the fact that the proposed rule actually -- it only had -- I think it had four sections. But the proposed rule gave a definition of discrimination that just listed out certain types of actions that would be deemed discrimination like the withdrawal of a benefit or termination. And that's all it said.

THE COURT: In other words, the rule was silent about the other side of the equation?

MS. SALGADO: Exactly.

And in response to the comments, where the plaintiffs and other organizations and other medical providers weren't sure what the rule meant, in response to that they submitted comments asking for the reasonable accommodation undue hardship framework, explaining that it would --

THE COURT: But from an administrative law perspective, the fact that the agency is essentially talking about a bright line ban and not talking about an offset, a hardship, a carve-out, an exception, why isn't that notice enough that the agency's not talking about a hardship or an exception; i.e., that's it's rethinking the whole framework?

MS. SALGADO: You're right, your Honor in that the -- we were on notice that the agency was rethinking or might have been, I guess, really, right; that the agency might have been rethinking the framework because our position is that when -- is that the term discrimination in the employment context

inherently requires a balancing of interests; it inherently, certainly in the context of religious accommodation, for decades that term has meant to include the reasonable accommodation undue hardship framework.

So what I would say what the public was on notice of was that the agency may be thinking that it was going to strip away Title VII protections. But what they weren't on notice of was the unusual ground rules that the agency has put into the rule in subsections four through six; not only that, there is this, quote, effective accommodation, which is a term that the agency has made up; but also that you can only ask employees about their objections once perfect calendar year or you can't ask potential hires unless there is persuasive justification. You might be able to post notices but only unless it's adverse action.

The public had no notice of those unusual groundworks.

THE COURT: This shows up in the final rule and not before.

MS. SALGADO: Exactly.

And the reason why I think -- the agency tries to push these away as just details, but at every turn through its briefing it points to those subsections as the agency's -- the framework that it is created and the reason why the rule is justifiable and reasonable. And so we believe that the agency's failure to put the public on notice of this new

framework it created does violate the notice of common procedures and the APA.

THE COURT: Ms. Salgado, I want to come back to contrary law. There's an establishment clause challenge. For argument's sake assume that the Court were to conclude that there was not a facial establishment clause problem here but there are all sorts of imaginable hypotheticals that could give rise to as-applied challenges. Does that then become a basis to argue that the rule is contrary to law or does the fact that any establishment clause problem on my hypothetical conclusion could only be as applied, prior view to the ability to identify the establishment clause violation as contrary to law?

MS. SALGADO: If the Court -- I just want to follow your hypothetical. If the Court found --

THE COURT: There is no facial establishment clause problem but as applied you could have any number of such problems but on its face it's not a violation of the establishment clause, does that prevent you as a matter of Administrative Procedure Act Doctrine, does that prevent you from arguing that on that basis the law is contrary to law -- that the rule is contrary to law?

Do as-applied violations count?

MS. SALGADO: Well, we don't believe this is an as-applied violation. But I will confess that you have stumped me and if I may confer with my colleagues and get back to you.

THE COURT: There will be a chance for -- I expect a chance for rebuttal. That is of interest to me. Thank you, Ms. Salgado. Very helpful.

Next up is Mr. Colangelo.

MR. COLANGELO: Good morning, your Honor.

Matthew Colangelo from the New York Attorney General's Office on behalf of the plaintiffs. And I will argue the arbitrary and capricious claims for relief in these consolidated challenges.

Your Honor, to meet the standard for reasoned decision making the agency must examine relevant data and articulate a rational connection between the facts found and the choice made. The agency fails this test and its decision must be set aside as arbitrary where its explanation runs counter to the evidence before the agency, the agency entirely failed to consider important aspects of the problem, or the agency doesn't justify its reversible unsettled policy.

Here, HHS fails each of these tests of a rational agency's action, first, because the agency's explanation is counter to the evidence in the administrative record.

In multiple critical respects the agency relied on a factual claim of evidence that examination shows to be either mischaracterized or flatly untrue.

THE COURT: I'm eager to have you get into it in just a moment. One threshold question. It looks as if it has been

ping pong ball between administrations here. You have the 2008 rule, which prefigures part of the current rule. It's retracted to say that at some point the administrative component in 2009 is substituted by a 2011 rule that, again, is more housekeeping and now there's a change of administration and there's a new policy.

To what degree does the agency have to -- let me put it this way. You're arguing that there's a change in effect from the 2011 rule and I appreciate that, but there is some harmony, some extension, but some harmony with the 2008 rule. Why isn't that also a relevant point of comparison here? Why is the only test here how this compares with what the agency had done and thought at the previous chapter which you go back to two administrations ago they're more in sync?

MR. COLANGELO: It doesn't inform the Court's analysis for two reasons, your Honor. First, if we're looking at the chapters in the story, I think the story most reasonably told is that for nearly the entire 46-year history, starting with the enactment of the first Church Amendment in 1973, there was no need at all for any regulatory implementation for any of these statutes. The 2008 rule, published in December of 2008, was the first effort to regulate these statutes at any point and never took effect. So as a practical matter I don't think the 2008 rule is --

THE COURT: Why did it never take effect? It was that

the implementation date was into the next administration and it was tabled or was there an injunction?

MR. COLANGELO: There was an implementation date that was to take effect I believe the day before the inauguration of the new president. The incoming administration suspended effective dates. There was litigation in the District of Connecticut. But then the agency said that it was not -- both not enforcing the regulation and was not completing the paperwork production act process to implement the certification requirement in the 2008 rule. So as a practical matter that rule was never enforced and didn't inform the state of play.

So I think the more realistic assessment of the state of play is that for nearly five decades no regulations had been necessary and, in fact, that's what the agency said in 2011 when it completed the rescission of the 2008 rule.

Your Honor to go to the many ways that this rule is counter to the evidence, there is no specific example where this error is more egregious than with respect to HHS's claim that it relied upon a, quote, significant increase in complaints filed with OCR alleging violations of the laws that were the subject of the 2011 rule. The administrative record makes clear, after we moved to compel its completion, that those assertions are factually false. And a factually false evidentiary claim can't be the basis for reasoned agency decision making. Now for context, your Honor --

THE COURT: There are a lot of complaints but they deal with extraneous matters like vaccinations, right.

MR. COLANGELO: Yes, your Honor.

Nearly 80 percent of the 343 complaints the agency said it relied on deal with vaccinations which the defendants now concede have nothing to do with the underlying statutes. Another 15 percent of the complaints are irrelevant because they either oppose the rule-making. They don't allege prohibitive conduct like the complaint that the state attorney was failing to prosecute a voyeur. They don't cover a protected entity like the complainant who said that the FDA was acting like the Mafia because it required the removal of social media ads for divine cancer care. That leaves just 21 complaints, only six percent of what the agency said in the final rule that they were relying on, that even potentially allege a violation.

Now we quarrel with some of those complaints. But even if you accept them all, to say that you've relied on 343 complaints of discrimination when the record -- the uncontested record shows you relied on at most 20 in a two-year period.

THE COURT: Is there any indication of how many complaints had been there before just by way of comparison?

MR. COLANGELO: So the administrative record shows that the agency received, I believe it was either nine or ten complaints from 2010 to 2016. So the figure that I believe the

agency cites is one or two each year for the years before 2016 and then they claim 343 in fiscal year 2018. In point of fact they received only 20 in a merely two-year period from the November 2016 election until the end of fiscal year 2018.

It's the definition of arbitrary to rest a decision so consequential on claims that are factually untrue or can be so readily disproved. The Second Circuit reached that conclusion three-and-a-half decades ago in the Mizerak v. Adams case. An agency's 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.

Your Honor, to emphasize, this mismatch between what the agency says they relied on and what the record shows is only known because we sued and only known because after suing we moved to compel completion of the record. It should go without saying that it's not a rational basis for agency decision making to fail to disclose the true facts.

THE COURT: Put another way, the administrative record shows that this is a solution in search of a problem.

MR. COLANGELO: Yes, your Honor. I think that's exactly right.

There are a number of other ways in particular that the record shows that the rule is a solution in search of a problem. So, for example, the harms that the agency identifies, and by their own analysis HHS estimates that this

is a billion-dollar rule, costs more than nine hundred million dollars to implement over the first five years, so nearly a billion-dollar rule in quantifiable costs.

THE COURT: What would make it so costly?

MR. COLANGELO: The most significant component of those costs, your Honor, are the assurance and certification requirements. I believe they estimate about $150 million a year to implement the certification and assurance requirements. And then the additional costs that they quantify are other costs regarding familiarization with the rule and other compliance procedures.

One of the harms that they fail entirely to examine in any adequate way is the overwhelming showing of harm to specific patient populations in particular vulnerable communities like immigrants, poor people, women, people of ill health, the LGBT community. The administrative record includes overwhelming evidence from not only advocacy organizations but the nation's leading medical associations and health care providers that access to care would be undermined by this rule and the agency does not quantify those costs.

THE COURT: Come back for a moment though to your first point which had to do with the falsity in the stated number of complaints.

What should I take away from the fact of not just the falsity but the number of complaints? Why so few complaints?

What does that mean about the world as it's working?

MR. COLANGELO: So, your Honor, I think that the fact that there is so few complaints shows that the fundamental justifications for this rule are not well founded.

Now the agency says that they needed greater enforcement authority and they needed to clear up confusion. And they also make the assertion that the relative absence of complaints before 2016 was really only a function of the prior administration sending the signals that they weren't open for business. They didn't want to hear from complainants regarding violations of conscience rights.

Now, two-and-a-half years after the agency has attempted to send the opposite signal, to receive only ten complaints a year when, remember, your Honor, OCR receives in the last fiscal year for which we have records 30,000 complaints of the other statutes that they --

THE COURT: OCR is Office of Civil rights within HHS?

MR. COLANGELO: Yes, your Honor.

THE COURT: So what would be the paradigm complaint that that office gets?

MR. COLANGELO: So OCR investigates HIPAA complaints for violations of health care privacy. They investigate Title VI complaints for discrimination on the basis of race, color, or national origin which can include complaints regarding a denial of language access. OCR also investigates Title IX

complaints as well as, I believe, Section 504 which relates to disability.

So when the evidence here shows that less than three one-hundredths of a percent of their annual complaint volume relates to the statutes that they are enforce here, your Honor, I think to answer your question directly, I think it shows, again, that this is a solution in search of a problem.

THE COURT: I take your point about the number of complaints. A separate justification which I guess applies more to the enforcement architecture that the rule sets up as opposed to the substantive standard, but focus on that for a moment. Agency says essentially it's opaque. Where do you go and how do you get this enforced?

Does the record reflect any instance in which the agency did an investigation leading to enforcement action of the sort that we see from other federal agencies, whether DOJ, SEC, FCC, FTC. All sorts of agencies have enforcement apparatuses which result in notices of potential violations, evidence gathering, often a pre-allegation of what the charges would be and then ultimately a charge either brought administrative or either in litigation. I'm having difficulty in the record figuring out whether any such complaint ever reached the end line of that.

What have you found?

MR. COLANGELO: Your Honor, the final rule mentions

agency action with regard to a Hawaii state statute that the agency believe violated the Church Amendments. And the Hawaii Attorney General said she would not enforce the statute.

I believe my next example would not be in the record because it's more recent but within the last several months OCR, the Office for Civil Rights, issued a notice of violation regarding employment practices at the University of Vermont Medical Center.

THE COURT: That's based on the complaint at tab 130, right?

MR. COLANGELO: Yes, your Honor.

And then a third example I believe is the instance -- and the agency cites this in connection with litigation by affected employees, but the instance of the nurse at Mount Sinai Hospital here in New York. That nurse's complaint was ultimately resolved by a successful OCR investigation.

THE COURT: I guess the question is I'm trying to figure out whether there has been enough of a developed enforcement process to conclude -- to allow us to conclude whether there is clarity as to how it works and what the rules are so as to bear on the need for enforcement clarification.

MR. COLANGELO: Well I think, your Honor, we don't need to -- we don't necessarily need to look at some significant extant body of investigations and resolutions regarding the conscience protection because the question, as it

pertains to arbitrary and capricious review of the rule, is whether the agency has sufficiently connected the facts they found to the procedures and substantive prohibitions that they're implementing here. And the record does not show anything close to a need for the enforcement procedures and the intrusive mechanisms that they're implementing in this rule.

THE COURT: Even if the number of complaints investigated doesn't get you there, is there any place a person would go pre-rule to explain, for example, what the consequences or the outer bound consequences could be of a violation of one of the conscience statutes.

MR. COLANGELO: Yes, your Honor. I think the 2011 rule which delegates the authority to enforce these statutes to the HHS Office for Civil Rights sets out the assignment and delegation of that authority and someone could go to the Office for Civil Rights with a complaint or an inquiry --

THE COURT: Where would you go if you are a entity that is covered and, therefore, whose conduct could subject somebody to the loss of a funding stream, where would you go that spells out pre-rule what the consequences are of having on your watch an employee of yours or a subrecipient of a grant or whatnot violate a conscience statutory provision.

MR. COLANGELO: I think, your Honor, there are two answers to that question.

The first is that you would go to OCR, which has been

assigned authority to enforce these statutes, and one could request technical assistance. I should say three answers.

Second is that the statutes themselves setout what the contours of the prohibitions are.

THE COURT: Sorry. But that's the contours of the prohibitions. I'm asking about the consequences.

Assume a violation of the statute. Let's use the hypo from the first discussion I had. Is it clear right now to a provider or to a state that receives funding what is in jeopardy, concretely what funding stream is in jeopardy from a violation in a particular area or is that something where clarity could be enhanced by a rule.

MR. COLANGELO: I think -- there are two answers to that question. The first is that OCR has provided guidance regarding what funds are in jeopardy, including through the 2011 rule; but the second and more import answer, your Honor, is that even if it is true that the agency had reason to believe that greater clarity was needed in terms of what funds are at risk, for which violations of which statutes, the agency still has to connect this final rule to that concern. And they haven't done that. The focus of the rule, including on the complaints that they purport are at risk, and as implemented through these Draconian enforcement provisions, the expansion of liability to sub-recipients, the assurance and certification requirements, the recordkeeping obligations and the expanded

definitions of terms like health care entity, assist in the performance of discrimination, none of those mechanisms are necessary or at least not rationally connected in this record to any interest in clarifying what the consequences are of a violation of the statutes that the agency says here that they're implementing.

So I guess a different way to put it, your Honor, is that the agency --

THE COURT: Does the existing rule -- pre-rule, is it clear what the liability would be, for example, for New York State -- for a violation by a subrecipient, some -- you use your Medicare funds or whatnot fund, a hospital and somebody on their watch -- I may have a bad hypothetical, but essentially a subrecipient's violation, does the rule clarify the consequences, for example, to New York State if a subrecipient breaches one of the conscience statutes?

MR. COLANGELO: The 2019 rule does assign responsibility to every recipient for the activity of its subrecipients.

THE COURT: Does anything beforehand clearly speak to that? I'm trying to figure out if there are gaps or lacunas here that could properly be clarified by rule.

MR. COLANGELO: I don't believe the 2011 rule speaks to subrecipient conduct and a recipient's vicarious liability at all, your Honor.

There are, of course, preexisting mechanisms under the general grant-making and acquisition regulations and frameworks where recipients do have some obligation to ensure, for example, anti fraud protections in how a subrecipient uses the funds.

I will say, your Honor, there is no evidence in this administrative record, certainly not that the agency has pointed to, that either recipients or subrecipients or complainants were asking: What are we going to do about a subrecipient violating the conscience statutes?

Your Honor, I think the best way to think about this is that even if one believes that there are other aspects of the implementation of the refusal statutes that could fruitfully be clarified, the agency has articulated a justification that is based on specific claims of evidence that are untrue. And it has implemented specific provisions to enforce particular statutes that prohibit particular kinds of conduct in connection with particular funding with no record that there is any underlying justification for those -- for those prohibitions as to that particular conduct.

THE COURT: One of the points you make in your brief is that the agency didn't properly consider what you call reliance interest.

MR. COLANGELO: Yes.

THE COURT: I couldn't quite tell concretely what you

meant. What reliance interests should the agency have considered that it didn't?

MR. COLANGELO: So, your Honor, and I think the Court touched on this a moment ago with a question to my colleague regarding Title VII. But the regulated entities, which include the states and cities and providers that are plaintiffs in your courtroom this morning, your Honor, regulated entities have conformed their operations around the way HHS has implemented these statutes for nearly five decades in a number of ways. And this is evident both from the administrative record --

THE COURT: Pause on that. You said that HHS has implemented these statutes. The overall portrait I get is that the statutes have existed but that this is an area of relative inactivity. Has HHS done much to enforce these statutes over these decades or have plaintiffs essentially treated Title VII, for example, as applicable but not because HHS has done something but because Title VII is on the books.

MR. COLANGELO: Your Honor, the administrative record shows that the plaintiffs have aligned their policies to the refusal statutes consistent with how HHS has interpreted those refusal statutes.

So, for example, the governmental plaintiffs discuss this in our briefs in connection with how we have organized our personnel practices, the typical requirements for advanced notice of objections, the staffing procedures in terms of what

to do when somebody raises an objection that was unanticipated.

THE COURT: Sure. But I mean that's a matter of changing your procedures. Reliance interest I would think would be more: We've hired a bunch of people whom we thought we had the flexibility to move around and we're now stuck with them as parts that will prevent effective delivery of medicine in particular areas. Is there a reliance interest along those lines that hasn't been considered?

MR. COLANGELO: Yes, your Honor.

There certainly is reliance interest on exactly what the Court just articulated. And, in addition, if one thinks about the expansion of the definitions of health care entity to include nonmedical personnel, including plan sponsors, there is no plaintiff in the courtroom right now, your Honor, that has ever considered a clerk in the billing department, a receptionist at the check-in desk --

THE COURT: What about the ambulance drive?

MR. COLANGELO: The ambulance drivers are not typically considered in most employers' practices someone who assists in the performance, for example, of an abortion if the person they are transporting to the hospital may have a miscarriage that may result in an abortion.

THE COURT: I mean plaintiffs may have conceived of the rule a little differently but -- conceived of the statutes differently. But pre-rule, if you can generalize, how did the

providers and states treat the outer bound systems of performance? Was it in effect within the operating theater? Did it extend beyond that? How was it widely understood pre-rule?

MR. COLANGELO: What the administrative record shows is that, at least as to governmental plaintiffs, assist was widely understood within the rule as providing a typically medical aid in specific connection with and furtherance of a particular procedure. So the medical staff performing a procedure, the nurse assisting the medical stuff or performing procedures themselves, that would be considered assisting. The billing clerk at the insurance company after the fact who sends the bill, that's not -- no plaintiff --

THE COURT: And somebody who is giving patient guidance in the days or weeks beforehand that may inform the decision whether undertake the procedure, was that considered pre-rule assisting the performance?

MR. COLANGELO: Not typically, your Honor, no, it has not been.

THE COURT: And the scheduling -- not the scheduler, no?

MR. COLANGELO: Certainly not, your Honor.

For these reasons the rule is arbitrary and capricious. We're happy to address anymore questions on rebuttal.

THE COURT: Just one moment.

MR. COLANGELO: Yes.

THE COURT: Just explain to me you mentioned disadvantaged populations. What's the reason to infer that this rule would disproportionately affect particular populations?

MR. COLANGELO: So there are two reasons, your Honor. First, there is a documented existing pervasive disparities in health care as to discrete and identifiable populations including people of color, low-income families, the LGBT community, and immigrants.

So the first reason is that any rule that affects the delivery of health care will necessarily bear more heavily on disadvantaged populations. And the administrative record includes a number of examples. Both because those populations are already subject to discrimination in health care, but because in many instances they are also located in areas where the provision of health care is strained by other factors, whether it's rural communities or whether because of lack of financial resources their most common vehicles for delivery of care are in the emergency setting which is also stressed by this rule. So that's one reason why the vulnerable populations are likely to be particularly affected.

And the second reason, as a number of the administrative record comments point out, is that as a

historical matter many of the religious refusals to provide care have arisen in the context of circumstances that distinctly affect vulnerable populations like the LGBT community. So, for example, an objection to gender reassignment surgery or hormone therapy that would likely apply to only a transgender individual --

THE COURT: But your point as to that, and I thought this was in the context I think of one of the complaints, I think it's the Washington State complaint, I thought your point was that procedure is not implicated by these statutes at all.

MR. COLANGELO: Yes, your Honor. In connection with the Washington Department of Corrections complaint, it's pretty clear from the record that there is no connection between that complaint and that complainant's concerns and what the statutes are prohibiting. I'm trying to make a broader point that the record is full of evidence that transgender individuals face significant and extreme discrimination in health care.

THE COURT: Right. But the particular procedures that are implicated by these statutes are primarily abortion and sterilization, right?

MR. COLANGELO: Yes, your Honor.

THE COURT: To what extent do the statutes include, for example, what you're talking about now which is change of gender, procedures, that sort of thing?

MR. COLANGELO: Well, your Honor, there has been

religious objections to that kind of procedure on the ground that it would functionally result in sterilization.

THE COURT: So that's how it becomes within the scope of these statutes?

MR. COLANGELO: Yes, your Honor.

THE COURT: Final question. HHS, as to the issue of denial of access of care, says: No, we did respond to your concerns, you just don't agree with us. Their statement is that by making the health care world a more receptive one to people with strong religious views you'll actually increase the population of people who choose to participate in an area who are right now deterred by the possibility of being in effect stuck performing a procedure to which they object.

Is your objection to that simply that that's unpersuasive or that the agency didn't consider the issue?

MR. COLANGELO: Your Honor, the plaintiffs' objection to that is that its counter to the evidence and that they've failed adequately to consider the issue and although -- although your Honor is correct that the defendants do say, particularly in litigation, that this is simply a policy disagreement and that they have reached a contrary view that we disagree with, I think the fairest reading of what the agency actually said in the final rule was that after considering the overwhelming record evidence regarding access to care, including the agency's own determination just eight years ago

that expansion of the conscience protection rights would affect detrimentally access to care, the agency said, quote, that they should finalize the rule without regard to whether it exists on the effect of access to care.

So although your Honor is correct that the rule purports to walk through some of these analyses, I do think the fairest reading is that they ultimately concluded that the effect on access to care was immaterial.

I think the other reason why that conclusion is irrational is that they discount the record evidence regarding the effect on access to care for the same reasons that they credit record evidence that supports the conclusions that they -- we believe that they have predetermined that they wanted to reach.

So, in other words, they dismiss some of the concerns that your Honor and I have just been discussing regarding risks to the LGBT community, they dismiss those concerns as anecdotal and qualitative but they credit Kellyanne Conway's survey conducted on behalf of the Prison Medical Association as a qualitative survey because they thought it was informative. It's irrational to be internally inconsistent. If you believe qualitative evidence has some persuasive force, you can't dismiss qualitative evidence when it cuts against your --

THE COURT: Thank you, Mr. Colangelo. Very helpful. Finally, I'll hear from Ms. Meyer.

MS. MEYER: Good morning again, your Honor.

THE COURT: Good morning.

MS. MEYER: I want to first address both the ripeness and merits of the governmental plaintiffs --

THE COURT: The last thing you said?

MS. MEYER: Discuss the scope of relief of the plaintiffs.

Plaintiffs' spending clause claim is ripe for judicial review. On November 22 if the rule takes effect plaintiffs will need to adjust their conduct immediately and significantly or face risk -- or risk losing billions of dollars of funds that the rule authorizes HHS to withhold or suspend.

THE COURT: So let's assume the rule takes effect November 22. Right away what are the most primary, most significant transformative things you would need to do to meet the rule?

MS. MEYER: So if the rule takes effect the compliance requirements go into effect immediately because the threat of funding termination springs into effect immediately. So specifically the plaintiffs have submitted over 48 declarations containing hundreds of patients' sworn testimony from preeminent leaders across the country in the health care sector. And these leaders have testified that the harm stemming from the final rule is real and immediate.

For example, plaintiffs' institutions have various

policies and procedures in place that have balanced conscience objections with patient care for decades. For example, many of the institutions require that employees with conscience objections provide their employer with advanced notice in writing so that they can make accommodations in advance based on objections to care.

An employee may not object in real time or abandon a patient in need of care and an employee could face consequences for failing to abide by these critical notice requirements.

THE COURT: The employer could?

MS. MEYER: The employee under plaintiffs' policies exist -- that currently exist, if they do not provide advanced notice of an objection, they could face consequences.

THE COURT: Explain that. In other words, I thought your primary concern was really on the employer, that the employer suddenly has to scramble to meet a new framework and if it doesn't ask questions, for example, of employees to smoke out potential objections, the employer then could be stuck in a situation where it has somebody with a bona fide right to object who the employer has to accommodate in a situation which could affect care. I thought that was the primary argument. I didn't perceive a separate impact on the employee. Can you explain that?

MS. MEYER: Correct, your Honor. That is our primary argument. The only point with respect to the fact that an

employee could be disciplined for not giving an advanced notice requirement is that is a provision that allows employers to enforce these particular notice requirements that are now implicated by the final rule. When the final rule does take effect or if it does take effect on November 22, plaintiffs to comply with this are going to have to overhaul those policies and procedures in significant ways.

THE COURT: Give me a scenario of something that could happen in the first week after the rule takes effect that could affect let's say a funding stream but for the employer's quick adaptation to the rule.

MS. MEYER: Many of our declarants have testified, for example, in the emergency context that a women presenting with an obstetrics problem would face -- would encounter anywhere from 12 to 16 hospital employees. So our declarants have testified that if the final rule goes into effect, they need to be prepared to deal with objections on the spot from those various 12 to 16 employees. And this is because of, for example, the expansion of the definition of discrimination and the expansion of the definition of assisting performance.

THE COURT: Let's focus on the employers' ability under the rule to smoke out, if you will, from employees or applicants what they object. Under the rule what can the employer do in the hiring process to determine, if anything, whether an employee is going to be off limits for certain

procedures?

MS. MEYER: So in the hiring process the employer cannot ask the hire whether there's any objection.

THE COURT: And that's true even in our rural hypothetical even in the situation where accommodating may be impractical.

MS. MEYER: Correct.

Once the employee is hired, the employer may ask once per calendar year or with persuasive justification.

THE COURT: Let's suppose we don't know what persuasive justification is. I take it that's undefined.

MS. MEYER: Correct.

THE COURT: Let's assume that the process of adapting to the rule itself is a persuasive justification; that the fact that there's a new regulatory framework in place almost necessarily allows the employer right out of the gate to ask employees who's eligible for what, on a conscience perspective, for what areas of work.

Assume that the employer is allowed, at least, to ask that and that would clear a persuasive justification bar, what happens next? How is -- how is your primary conduct affected?

MS. MEYER: So assuming that that is a persuasive justification which, frankly, our declarants cannot rely on because they have not received that clarification from HHS so they have to proceed under this regime of one calendar per

year. But assuming that is a persuasive justification, there's still the extreme financial burdens that are imposed on institutions for needing to basically double or triple staff certain departments or going to an employer and asking if they will accept an accommodation like a transfer to a different department. If that employee says no, then our institutions have to have backup or shadows.

THE COURT: Is there anything out there in the world that would guide me in the record as to the number of employees, in fact, who work appertinent to procedures at issue who actually would object in them?

In other words, there are a lot of hypotheticals that have populated everybody's briefs. One thing that's a little less clear is, assuming a widespread regulatory right to object, assuming even a statute that said that, any information out there about in practice what that would mean?

MS. MEYER: The exact number of people who holds religious objections?

THE COURT: Right. Or number of people who both hold those religious objections and are let us say presently in jobs where those objections might be triggered.

MS. MEYER: We don't have those exact numbers in the record, your Honor, but the objections to procedures do exist and this is exactly why these policies and procedures are in place, to make sure that employers can accommodate those

conscience objections while protecting patient care.

THE COURT: Does the rule have any safe harbor, any unramped period in effect where an employer gets some period of time to adapt its procedures without being subject to loss of funding because the procedures have not been fully developed or implemented?

MS. MEYER: No, your Honor. HHS explicitly rejected comments requesting that it allow for compliance in one year after the effective date of the rule or for a one-year safe harbor. So HHS explicitly made this choice. And, in fact, one of the key reasons that HHS issued this final rule was to affect compliance with --

THE COURT: So going back to the hypothetical earlier, in the hypothetical situation in which a subrecipient of a New York Medicaid grant, let us say, breaches the rule by following a Title VII accommodation approach that's now been eclipsed by the rule, if that happens on November 23 subject to how the enforcement process plays out, at the end of that process New York's failure to adapt its subrecipient's policies to the new rule could cost New York its Medicaid funding?

MS. MEYER: Correct, your Honor.

THE COURT: Which is billions of dollars a year.

MS. MEYER: Yes. Yes, it is.

THE COURT: So I take -- I think I take the argument as to ripeness. Let's focus on the merits of the spending

clause point.

MS. MEYER: With respect to the final -- the merits, the final rule violates each of the four limitations placed on the federal government's use of funds in violation of this spending clause. Critically the rule conditions plaintiffs' compliance with HHS's new federal conscience reviews on 192 billion in federal health care funding. Specifically the rule gives the department the authority to withhold funding in the whole or part to deny use of federal financial assistance or funds from the department in whole or part, to wholly or partly suspend award activities, to terminate federal financial assistance or other federal funds from the department in whole or part, or to deny in whole or part new federal funds from the department. This all includes based on any indication that a recipient has failed to comply with the rule and during pendency of good faith compliance efforts or for failure to comply with the new assurance and certification requirements in the rule.

THE COURT: May I ask you. One of the situations that can give rise to a spending clause problem involves a situation where the rule would violate another constitutional provision. I'm going to come back to a question I asked one of your colleagues earlier. Focus on -- one thing that you argue is that the rule would violate the establishment clause. Indulge the hypothetical that it might in some applications but it

doesn't on its face and that that was the Court's determination.

Is the spending clause implicated by that problem in which one can imagine scenarios where you have an establishment clause problem but that on its face the rule doesn't?

MS. MEYER: It is, your Honor, especially in the context of this rule where if liability is imposed on the states for the activity of their staff recipient. So, for example, as a practical matter our declarants have testified that they will have to review their contractual arrangements with various subrecipients to ensure compliance with the final rule because they are now subject to vicarious liability. And in doing so, in reviewing those contracts and imposing conditions if necessary on subrecipients, if those conditions present a constitutional problem, what defendants are subjecting plaintiffs to is imposing those unconstitutional conditions on its recipients.

THE COURT: OK. Another dimension of spending clause analysis involves retroactively. Articulate for me why the rule has a retroactive effect. Right now are you able to hire people -- are you able to ask the conscience question in hiring?

MS. MEYER: We are, your Honor.

THE COURT: And is the retroactive point that you're now stuck with people -- so if -- that doesn't work. In other

words, if you were able to fence out people who simply couldn't do core parts of the job by virtue of asking that in hiring, how is there a retroactive application of the rule, meaning you are getting punished for past conduct or decisions?

MS. MEYER: So one of the prohibitions of the spending clause is retroactivity in the fact that plaintiffs need to knowingly and voluntarily accept the conditions of the funding streams. And when plaintiffs accepted these particular funds they had no idea that HHS would expand their substantive requirements to, for example, broaden definition of discrimination in such a way that it would severely curtail plaintiffs' current policies and procedures.

THE COURT: But you accept funding typically on a year-to-year basis.

MS. MEYER: That's correct.

THE COURT: So we're in right the middle or early part of the fiscal year right now. Suppose on November 23 comes the violation. Suppose it's adjudicated in full on January 1. Presumably the image -- I'm telescoping the process here just for purposes of a hypothetical, I know the world doesn't work that fast, but assuming that it did. If the agency were to cut off your funding from January 1 through the end of the fiscal year, why is that retroactive? Yes. You took the money not knowing that the regulatory world would change, although the notice was out there, but you would only be cutoff

prospectively unless the agency is threatening to clawback the money going back to the beginning of the fiscal year, how is that retroactive?

MS. MEYER: A couple of responses, your Honor.

First, let me clarify that various contracts and grants govern the administration of all of these underlying funds. And so I don't think that it is accurate to say that we renew, for instance, on a yearly basis. I think the underlying funds are governed by various provisions of the grants and contracts.

With respect to why this particular provision is, in fact, retroactive is the obligations that are imposed on day one go into effect on day one. And so the funding streams that are threatened are the funding streams that we currently operate under now and the policies and procedures that we have to change are policies --

THE COURT: You have hired people and engaged subcontractors and the like on the premises that the funding stream is intact at least through the end of that grant or installment whether it's yearly or whatnot. The point is there's an architecture that develops around the expectation that your Medicare grant isn't going to be yanked in the fiscal year.

MS. MEYER: Yes, your Honor. And, in fact, we have declarants that testified as to the expectation of the spending

streams the governs had budgeted for them in 2019 and 2020 and 2021 and so you have those reliance interests as well.

In addition, the written assurances and certifications of compliance with the final rule are new and retroactive conditions that plaintiffs may be subject to immediately. The final rule authorizes HHS to require certification if OCR suspects a violation and it makes that certification an explicit condition of continued receipt. So that's another way in which this rule is retroactive.

THE COURT: I realize there are multiple ways in which the spending clause could be violated but one of the things you say is that -- one of the concerns implicated is that retraction of spending is unrelated to the federal interests at issue.

Assume for argument's sake a small dose of conscience statutory violations. Just put aside the issue whether the rule faithfully implements the statute and just let's take our hypothetical of the no-doubt-about-it violation.

How would one go about narrowing the scope of the financial penalty to get rid of your concern about the penalty being Draconian or unrelated?

Is it literally just the salary of that employee? Is it real -- does the fit have to be that tight as to what the hospital or state uses or is there some broader retraction of funds that it would still be considered in effect related to

the violation?

MS. MEYER: So we think that under current procedures for any type of funding with withholding or suspending or termination that those procedures are tied to specific funding streams. So if a violation came up HHS would look to the specific funding stream that was implicated.

THE COURT: So right now assuming a violation of a conscience statute which is litigated to completion and procedurally sound, you would not contend there's a spending clause problem with the retraction of the entirety of the funds from that funding stream even if you only had one bad act or one bad apple in the hospital?

MS. MEYER: We would -- we would rely on the regulations and provisions that are already in place. So we do not take issue in the underlying statutes that say certain funding --

THE COURT: No. I appreciate that. But I'm trying to understand your constitutional argument based on the spending clause and I understand that you've argued ambiguity, coerciveness, violation of other constitutional provisions.

I'm just focusing now on the problem which you say also exists here of the penalty in effect, the spending clause -- spending retraction being unrelated to the problem.

I think what you're saying to me is that you don't have a problem with that as long as if -- even if the entire

funding stream is taken away on the basis of a single violation of the conscience statutes. Am I hearing you right?

MS. MEYER: So we're not quibbling with the fact that HHS has options through provisions like the UAR at its disposal. But here the amount of funding on which HHS conditions compliance in the final rule is a much larger pool.

THE COURT: Right. Let's suppose there's a Medicaid funding stream. I have the numbers handy somewhere. One moment.

New York received -- well it's not clear. I don't have it broken out by Medicaid. New York received many billions of dollars in health care funding, but certainly billions in Medicare. Let's just take Medicare for a moment.

Is it really your position that all of that could properly be taken away based on a violation of the conscience statutory provision applicable to Medicare by a single violation by a single person? Is that the way we define funding stream? And is that really your view that the spending clause concept of unrelatedness is not offended by that?

MS. MEYER: Your Honor, our view is not that -- that a small violation would jeopardize all of our Medicare funding, which is exactly what the final rule says here.

THE COURT: So, is there a case that helps define the relatedness concept?

If you're saying that there's a separate problem here

that the funding -- that the threat to the funding stream implicated by a singular violation, if what you're saying to me is that presents a spending clause problem of an unrelated penalty, what's the case that helps me with that?

MS. MEYER: So I think that there is a distinction between our relatedness argument which we are saying that the termination scheme plainly violates that requirement because the rule conditions funds on things that have nothing to do with health care like the Department of Labor and Education.

THE COURT: Right. That's your point which is that we're going outside the scope of HHS or going to funding streams not implicated by a particular violation.

MS. MEYER: Yes, your Honor.

THE COURT: But you're not making that argument even if it costs you an entire funding stream that that is a spending clause problem?

MS. MEYER: No, your Honor.

We are arguing separately that this scheme here is coercive; it has combined funding streams. And it also puts the final rule's new provisions and conditions those compliance with new provisions on that funding stream.

THE COURT: Final couple questions just on remedy.

Hypothetically assume that portions of the rule are problematic for one reason or another, including the ones that have been articulated today, but that portions are not,

including ones that sound in a more housekeeping nature, or where the application of a certain term is authorized by a rule-making grant as in ACA or Medicare or Medicaid.

Why shouldn't, given the severability provision in the rule itself, the definitions that are statutorily authorized, assume that we don't have the other APA problems that Mr. Colangelo addressed, why shouldn't those definitions be permitted to stand and why shouldn't the portions of the regulatory administrative structure that I conclude are fair and housekeeping, why shouldn't those stand?

MS. MEYER: The rule's provisions, your Honor, are codependent. So, for example, several sections rely on one another and cross-reference one another. For example, the posting of notices in 88.5 is evidence of compliance for purposes of enforcement in 88.7.

We don't believe that severability is appropriate. So, for example, as to the definitions this rule is already incredibly ambiguous, as we argued in our papers. And the little explanation that HHS gives as to various situations in the preamble is predicated on their understanding of multiple interpretations and definitions in this rule working together. And so where this rule provides very little clarity for plaintiffs on how to comply in the first instance, if the Court were to sever certain definitions but leave others, we would be left with even less clarity.

In terms of the severability clause itself, there are several cases that say -- and we've cited them in our papers -- that the severability clause is not an indication by itself that the rule should not be vacated in its entirety. Instead, we look to the intent of the agency. And the agency made clear here that it was trying to address confusion created by the 2011 rule. The confusion created by the 2011 rule, it claims, stem from the 2011 rule's interpretation of Weldon, Coats-Snowe and the Church Amendments. And so if the Court were to, for instance, strike certain provisions with respect to those statutory provisions, it's not clear at all that HHS would have made the same decision to promulgate this rule absent those core statutes.

THE COURT: Thank you very much.

In a moment we'll take a break. Let me just ask counsel for defendants who will be arguing for each side and who will be arguing first.

MR. BATES: Your Honor, I will be arguing for HHS. Christopher Bates.

THE COURT: That's Mr. Bates. And you'll be going first, I take it?

MR. BATES: Yes your Honor.

THE COURT: Who will be arguing for the intervenor?

MR. DUNN: I will, your Honor.

THE COURT: That's Mister?

MR. DUNN: Dunn.

THE COURT: OK. Very good. We'll take a fifteen-minute comfort break. I'll see you in fifteen minutes. Thank you counsel.

(Recess)

THE COURT: Welcome back. Be seated.

I'll hear now from counsel for the government. That's Mr. Bates.

MR. BATES: Thank you your Honor. Would you like me to speak from here?

THE COURT: Podium, kindly, please.

MR. BATES: Good morning, your Honor.

THE COURT: Good morning.

MR. BATES: HHS promulgated a conference rule, a law that exercises at its core, in order to provide clarity and ensure robust protections for rights of conscience that are protected under federal statute. I'd like to begin with the agency's authority for this rule.

There are expressed delegations of authority to the agency in a number of statutes to ensure compliance with grant conditions, other conditions, and to insure clients under applicable law. There's been some discussion about today there are some limiting authority with regard to Medicare and Medicaid and CHIP, which we have cite in our briefs, 42 U.S.C. 1302. There is limiting authority with regard to the ACA that

applies to implementation of the ACA's conscience provisions which we've cited in our briefs as well. It's in 42 U.S.C. 18 -- these are expressed delegations of authority for the agency promulgated or related to --

THE COURT: But I take it with respect to Church, Weldon and Coats-Snowe it's not disputed that there is no express delegation.

There is not express delegation, you said, for those three?

MR. BATES: That's correct.

THE COURT: The question just to take -- just to focus our discussion. In total, there are about 30 or so statutes that contain conscience provisions. Having looked at the others, each is really targeted to a rather narrow scope type of activity. Can I assume that for the purposes of discussion we're really talking about the several you just mentioned that have express delegation provisions and the three that I just mentioned that do not, that the others are really targeted to small corners of the world?

MR. BATES: So the intersections that do have expressed limiting authority are -- do apply to a more discrete subject.

THE COURT: So for the purpose of this discussion am I safe to really treat us as talking about the ones you identified a moment ago and the three that I identified in my

statement to you?

MR. BATES: So in terms of rule-making as it pertains to those three conscience statutes that you mentioned.

THE COURT: The heart -- the rule covers a broad set of conduct. It, to be justified, would have to be justified saving those discrete areas' conduct by one of either the statutes you mentioned, Medicare, Medicaid, ACA, or the ones that I identified to you as lacking express rule-making authority. We're not for the most part relying on any of the other three.

MR. BATES: For the other three conscience statutes, that's correct, your Honor. There's also the other housekeeping statute which we point to as authority for the rule here. I would note for the Court's information that the general housekeeping statute is the authority for the UAR; it is, in fact, the only statute that the agency cites as authority for the UAR. UAR is a comprehensive regulatory scheme. It governs the agency's administration of grants and processing the AG uses for ensuring compliance with grants. It is a comprehensive scheme set for the UAR. The statute ability for the UAR is solely general housekeeping statutes. That doesn't indicate that the housekeeping statute does provide broad authority in terms of assuring compliance.

THE COURT: Has HHS ever taken away anybody's funding for violation of a conscience statute?

MR. BATES: Agency counsel informed me no.

THE COURT: Has HHS ever threatened to do that?

MR. BATES: HHS has issued notice. It has issued warning letters, notices of enforcement, has taken enforcement actions under the conscience statutes. In terms of the --

THE COURT: What actions has it taken that are -- if it's never taken away somebody's funding, what enforcement action has it taken?

MR. BATES: So, your Honor, I'm looking over here at agency counsel now for specifics.

THE COURT: Rather than your looking, agency counsel, if there's an answer to the question that you want to furnish, Mr. Bates, would write it out rather than our going --

MR. BATES: Certainly in the vast majority of instances, conscience statutes, civil rights statutes as well, the resolution that is reached is a voluntary resolution that's worked out throughout informal processing, informal means between the agency and the -- its only in instances where those informal processes do not result in voluntary compliance that further enforcement action is taken. As to the specifics of -- I'll wait for --

THE COURT: I'm eager to come back to get a quantification as to the number of full enforcement actions in this area. If it's not something you're immediately facile with it, we'll come back to it, but it is of interest to me.

Go ahead.

MR. BATES: So the general housekeeping statute is as well exclusive authority for HHS's actions here. And then there is also, as HHS explained in the rule, there is inherent in Congress's adoption of the conscience statutes to require recipients of federal funds from the department to comply with statutes, the authority of the department to take measures to ensure compliance with those statutes. The Supreme Court has been clear that delegations of authority to --

THE COURT: Let me ask you this. The very last page of your regulation -- and I take it this must be justified with your housekeeping statute -- states that as a remedy for a violation the agency can -- the remedies include, quote, terminating federal financial assistance or other federal funds from the department in whole or in part.

Putting aside what you say in the briefs, that appears to be stating that for a singular violation of a conscience statute, as interpreted in the rule, an entity such as New York could lose all of its federal funding from HHS and perhaps from other agencies.

Is there -- does the housekeeping statute UAR authorize a rule like that, a consequence like that?

(Continued on next page)

MR. BATES: So in terms of the last point about funds from HHS for other entities, HHS has been clear in the rule that the funding streams that are impacted by the rule are only funds that are administered through HHS. So it would not subject funding through other agencies for violations.

THE COURT: Does the rule say that?

MR. BATES: So, it says -- let me just turn to my notes here. There are a number of places where it says that the funds that are at issue in the rule are tied to specific funding streams.

So I can provide a couple of quotes here for the court's information. Page 23223: "The only funding streams threatened by a violation of the conscience statutes are the funding streams that such statutes directly implicate."

On page 23192: "The prohibition discrimination is always conditioned on and applied in the context of violating a specific right of protection, and each protected right is typically associated with the particular federal funding stream or streams."

THE COURT: Those are comments. The actual reg itself on the last page, on its face, it has no limitation as to funding stream. I appreciate that it can be read not to implicate policies of the Department of Education or of Labor. But on the face of it, what I just read to you seems to say that, for a singular violation by New York State, it could lose

the entirety of, let's say, the $46.9 billion it got from HHS in healthcare funding in fiscal year 2018. In the face of the reg itself, where does it limit the threatened consequence to a particular funding stream?

MR. BATES: So this is not a way in which the regulation is different from the UAR, your Honor. The UAR also uses somewhat broad language here, as well. HHS --

THE COURT: Does the UAR use the language that I quoted to you from the last page?

MR. BATES: So the UAR does not use identical language, but the UAR speaks about terminating funding in whole or in part.

THE COURT: It says here "other federal funds from the department." It's hard to read the words "other federal funds from the department" as, given that it is unlimited, as unlimited.

MR. BATES: So, again, your Honor, the agency made clear in the preamble to the rule.

THE COURT: Preamble is not the rule. The text of the rule appears, on an unlimited basis, to leave open the possibility that, in an extreme case, the -- the agency could seek to terminate all federal funds from the department. It doesn't have any limitation in there. Would the UAR permit that? Would the UAR permit as a matter of housekeeping the agency to enforce the conscience statute so as to, without

limitation to a particular funding stream, deprive a recipient of the entirety of HHS funding for a singular violation?

MR. BATES: So, your Honor, I'm going to look to agency counsel now to answer --

THE COURT: You have to stop looking at HHS counsel. In baseball we call that sign stealing. You have to give me the answer. This is a fundamental question. It is all over the briefs. Yes or no: Do the funding statutes authorize you to adopt a rule that on its face threatens the entirety of HHS funding for a single violation? I take it the answer might be different for a particular funding stream, but I'm reading the text of the regulation now.

MR. BATES: So first point, your Honor, is that the regulation would not do that. For the purposes -- for the terms of the UAR, my understanding is that the UAR would not do that either. The rule is similar to the UAR here in the sense that it is tied to the specific funds that are at issue with regard to the specific statute that the agency has found a potential violation.

THE COURT: All right. So if I am understanding you right, so we can proceed with the balance of the discussion, your position, at least in this litigation, is that "all" that is in jeopardy -- quote/unquote around "all" -- is the specific funding stream implicated, right?

MR. BATES: That's correct, your Honor.

THE COURT: So if, hypothetically, within the scope of activity under Medicaid, there was a singular violation, you would reserve the right or HHS would reserve the right to withdraw the entirety of the Medicaid funding scheme, but that wouldn't extend to, let's say, Medicare.

MR. BATES: That's correct, your Honor. And in practice, HHS's practice is to tie or limit those enforcement mechanisms to the specific grant report or funding stream that's at issue.

THE COURT: But that's never happened in the context of the conscience statute. It's happened in other contexts, right?

MR. BATES: Yes.

THE COURT: How often does HHS terminate funding midstream for a violation, civil rights violation?

MR. BATES: So my understanding, your Honor, is that it is not common. My understanding is that there are approximately 12 to 13 enforcement actions that are taken each year, that this is under the civil rights statutes as well as under the conscience statutes and HIPAA as well, which OCR also administers. And agency counsel just confirmed that they have never -- that they have never terminated funding for a violation.

THE COURT: For a violation of this statute or anything else?

MR. BATES: Of any of them.

THE COURT: So HHS has never terminated funding of any recipient for any civil rights violation?

MR. BATES: That's correct, your Honor.

THE COURT: So this would be a first if that were -- if what is threatened here, whatever the scope, were to transpire?

MR. BATES: If HHS took an enforcement action under the rule that resulted in the termination of funds, that would be the first time that the agency had done that. But the agency has authority, under other statutes, to do it in other instances as well. So that is not unique to the rule or to the conscience statutes.

THE COURT: May I ask you, do any of the conscience statutes say anything about a remedy?

MR. BATES: I'm sorry. Say that again.

THE COURT: Do any of the conscience statutes say anything about the remedy for a violation?

MR. BATES: So the conscience statutes provide that -- that none of the funds made available in the funding streams that are specified in the various conscience statutes may be used or made available to an entity that engages in discrimination or other prohibited acts under the statute in terms of what the -- a specific remedy for such violations are. The conscience statutes themselves, or at least the three

statutes that you identified, setting aside other conscience statutes that you have more detailed -- the three that you have identified do not specify those remedies. And so, again, for purposes of that aspect of this, we would look to the housekeeping statute and to other statutes that provide authority for ensuring compliance with applicable laws.

THE COURT: Why is it that -- and I am now going -- I have a question beyond conscience statute violations, but to other civil rights violations that are within the ambit of OCR, why is it that none of them ever reached a point by way of a remedy of retraction of funding? What are the lesser remedies that tend to be deployed?

MR. BATES: The funding component in HHS?

THE COURT: Right. In other words, I am now asking you, beyond conscience statutes, you have told me that for no violation has the department ever retracted or cut off funding. What do they do to a violater?

MR. BATES: So under the UAR, there are various remedies that are set off. The first point, again, your Honor, I think, would be that it is uncommon for there to be a formal enforcement remedy actually imposed. The vast majority of these are worked out between the agency and the regulated entity. And so at least in terms of the context of the UAR, so the UAR sets out various penalties or enforcement mechanisms that could come into play, such as temporarily withholding

payments --

THE COURT: Has that ever happened?

MR. BATES: -- disallowing matching funds.

THE COURT: Sorry. I took you to be saying essentially that there hasn't been a financial hit for violations. Maybe I misread you. Has there been some lesser financial consequence to violaters of any of these conscience statutes?

MR. BATES: So agency counsel informed me no.

THE COURT: Let's deal with the enforcement part of our argument now, and we will get back to the authorization.

To what degree has HHS ever investigated complaints of violations of the conscience statute? How often does that happen?

MR. BATES: So there are obviously more investigations per year than there are, you know, further action or further enforcement actions taken. I know that in this most recent year there were three enforcement actions that were brought. I believe that those were mentioned earlier.

In terms of the number of investigations beyond that, obviously the answer is higher. HHS does review complaints when they come in, institutes investigations of those complaints.

And in terms of a discrete number, with your Honor's indulgence, I'm going to wait for if agency's counsel has a

specific number to give me on that. I do know that the number --

THE COURT: Would it be useful just to take a moment and have agency counsel at the podium? Because I am interested in, in practice, how enforcement works and how it has worked. That's an important backdrop here. You tell me, but at some point I want to have that discussion about the history of enforcement of these statutes within HHS. If that's not something that you are familiar with, but agency counsel is, would that make sense?

MR. BATES: Yes, your Honor.

THE COURT: Let's just take a moment. I will come back to you, because I realize there are many categories and topics for us to discuss, but I would welcome briefly to hear from agency counsel.

MR. TAKEMOTO: Can we pause for a moment so that we can converse with --

THE COURT: No. No. You have prepared for months. Let's get agency counsel. Come on.

MR. KEVENEY: Sean Keveny, your Honor, with HHS.

THE COURT: Sorry, that is Mr.?

MR. KEVENEY: Keveney, your Honor.

THE COURT: Mr. Keveney.

Just tell me about the history of the actual enforcement of these statutes. How often does HHS investigate

a complaint for a violation of these statutes?

MR. KEVENEY: With the caveat that I have only been at HHS for about eight months, your Honor --

THE COURT: But you were the counsel assigned to this important case.

MR. KEVENEY: Correct, your Honor, and I have asked these questions within the agency.

There are approximately 35,000 complaints per year that come into OCR. Those cover the full range of areas for which OCR has enforcement authority, traditional civil rights cases, Title VI, Title IX, 504 of the Rehabilitation Act, HIPAA, and the conscience statutes.

THE COURT: Focusing on the conscience statutes, how many investigations have been undertaken, if you know, of the violations -- alleged violations of the conscience statutes?

MR. KEVENEY: It is my understanding, your Honor, that there are approximately 20 open investigations. It is my understanding that in the last three years there have been four formal or informal notices of violation issued in connection with the conscience statutes, including in Hawaii, Mt. Sinai Hospital here in New York, Vanderbilt University, and most recently the University of Vermont Medical Center.

THE COURT: That's the one that trips off of the complaint that I referenced earlier, the UVM one.

MR. KEVENEY: That's correct, your Honor.

THE COURT: How often has a violation been found by OCR of a conscience statute?

MR. KEVENEY: A formal finding has only occurred in the University of Vermont Medical Center.

THE COURT: Over the course of what period of time?

MR. KEVENEY: Over, to my knowledge, the last three years. But it is important to distinguish, too, your Honor, the difference between formal findings of violation and informal communication of concerns or potential violations to a covered entity -- and, by way of analogy, to put this in helpful light, I will point the court to the Justice Department's enforcement of Title VI the 1964 Civil Rights Act. That's been on the books for years, it covers a wide range of federal funding, and the Justice Department has never pulled federal funding for a violation of the '64 Act.

THE COURT: Tell me, with respect to the investigations of conscience violations, how many times has the agency determined that there was a violation even if it is not in an informal way?

MR. KEVENEY: To my knowledge, there are the four that I referenced, your Honor.

THE COURT: Over what period of time?

MR. KEVENEY: Over the last three years.

THE COURT: All right. And was there, in the course of that work, was there -- did the agency encounter problems

presented by limited enforcement authority or ambiguous enforcement authority, did the agency have any hiccups in doing its work.

MR. KEVENEY: Yes. I can point the court specifically, and I hesitate because we are in ongoing negotiations with the University of Vermont, so to the extent some of those negotiations may had been covered by the rules of evidence, but the University of Vermont specifically --

THE COURT: As of the date the rule had been promulgated here --

MR. KEVENEY: Yes.

THE COURT: -- what, if any, problems had the agency encountered in the enforcement of the conscience provisions?

MR. KEVENEY: I can tell your Honor the University of Vermont particularly challenged the agency's authority to enforce any of these statutes, and that is an issue over which we are engaged in ongoing discussions.

THE COURT: Was the University of Vermont experience or your experience with the University of Vermont a reason for this regulation? Does the rule say that; and, if not, is there a basis on which to represent that that was a reason for this rule?

MR. KEVENEY: Yes and no. So the rule, again, obviously wouldn't specifically refer to the situation with the University of Vermont, because it hadn't come up yet; but the

concerns that arose in dealing with the University of Vermont were very much on the agency's mind.

So, specifically, your Honor, the university, understandably, has questioned what the procedures are, what the procedures are for withdrawing funds, which portion -- which component of HHS would be ultimately responsible for withdrawing any particular grant funds that the university receives. Those are questions that this rule answers.

THE COURT: Prior to the University of Vermont issue, and I'm not eager to get into anything that's confidential in that case, but had the agency experienced any practical problems investigating or enforcing allegations of violations of conscience statutes?

MR. KEVENEY: Without knowing the details of the Mt. Sinai investigation, your Honor, I can't answer that definitively.

THE COURT: Can you answer it nondefinitively? I'm trying to understand whether any part of this rule has its anchor in learned experience from enforcing the statutes.

MR. KEVENEY: So I can tell you, your Honor, that much of this rule is anchored in OCR and the federal government's experience enforcing civil rights protections generally. Obviously the rule draws upon the Title VI enforcement framework and the federal government has -- and across the federal government, including at HHS, has long experience

enforcing Title VI. And it obviously has been useful over the years to make sure the covered entities are aware of the procedures the agencies will follow. The Justice Department has its Title VI manual available online for covered entities to see, so they are aware of what the potential consequences of violations are. So in that sense, the agency's long experience of enforcement does inform the architecture of this rule.

THE COURT: All right. In a moment I will let Mr. Bates get back, but this question, you mentioned that there are currently four notices of violation pending. How does that compare to the previous three-year period or the three-year period before that? Is the number four greater, lesser, or about the same?

MR. KEVENEY: Greater.

THE COURT: It grew to four from what?

MR. KEVENEY: There was approximately, as is set forth in the preamble of the rule, one complaint per year prior to the issuance of the MPRM that is increased by a thousand percent. There are approximately ten complaints per year.

THE COURT: That has happened since the notice of rule-making in this case.

MR. KEVENEY: That's correct.

THE COURT: And without going out on a limb, is it safe to assume that it was the notice of rule-making by the agency itself that may have been causative in the increase in

complaint.

MR. KEVENEY: That is certainly the agency's view, setting aside difficulties --

THE COURT: All right.

MR. KEVENEY: -- in cause and effect generally.

THE COURT: So prior to the notice of rule-making was there any empirical data that suggested an increase in complaints actually made to the agency in this area?

MR. KEVENEY: Not that I am aware of.

THE COURT: I think if --

MR. KEVENEY: I think the answer is no.

THE COURT: If there is no one else in the room who would be more aware of it, is the answer to that no?

MR. KEVENEY: I think the answer is no, your Honor. I hesitate because there very may well have been statements from the agency that it intended to start enforcing these statutes. The Office of Civil Rights stood up a new unit, and I think that predated the issuance of the MPRM.

THE COURT: All right. Mr. Keveney, I appreciate your help. Is there anything else responsive to what I have asked so far that you, given your familiarity as agency counsel, wish to clarify?

MR. KEVENEY: No, your Honor.

THE COURT: Thanks very much. I appreciate you didn't come here today expecting to argue, and I appreciate the

helpful answers under fire.

MR. KEVENEY: Absolutely. You're welcome, your Honor.

MR. TAKEMOTO: Your Honor, may I say one thing? I just want to formally object to the record just on the basis of APA case are limited to the record and not based off of agency testimony.

THE COURT: I appreciate that, so why don't we turn to the record?

Mr. Bates, let's go to what Mr. Colangelo was saying about the number of complaints. The record that Mr. Colangelo recites suggests that the number of complaints that were presented to the agency was not nearly the quote/unquote significant increase that the agency represented. Factually, over the course of your briefs, the number has gotten smaller and smaller and smaller.

How many complaints does the agency say it received in the ramp-up to this rule?

MR. BATES: So the agency stated in the rule that it received 343 alleging violations.

THE COURT: That's what it said, but once we strip away things like vaccinations, what are we left with that actually implicate this rule?

MR. BATES: So it is a smaller number, your Honor. We have cited a number of them in our reply brief. I believe that we cited about ten in the reply brief, and I know that

plaintiffs have stated that they believe that there are about 20 or 21. In terms of the exact number of complaints, there are -- we didn't cite all the ones in our reply that we would say fall in here, but it would be something probably relatively similar to the number that the plaintiffs provided.

THE COURT: So you are not directionally disagreeing with Mr. Colangelo's numeric representations.

MR. BATES: Not to the extent that plaintiffs have identified that a number of the complaints of those 343 did not allege violations that were relevant to the --

THE COURT: I'm sorry. Let's go back to the 343. The agency at the time it proposed the rule represented that there had been a significant increase in the number of complaints that it used the 343 as a measure of that. If I am hearing you right, that 343, once we strip away complaints that deal with extraneous problems like vaccination, we are down to something like 20, correct?

MR. BATES: In terms of the complaints that would have dealt more directly with rights that were protected under the conscience section.

THE COURT: I going to drill down a little more until I get a direct answer. 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, your Honor.

THE COURT: Now, your brief, your brief ultimately, I think it is your reply, identifies actually three at one point that you say are responsive. I took a look at the three and, unless I am missing something, two of the three aren't even responsive.

There is a complaint from a law firm on behalf of an adequacy group -- this is at tab 129 -- that doesn't cite any specific instance of discrimination. There is a complaint at tab 27 from the doctor at the Washington State Department of Corrections that deals with the sex transformation procedure, but there's no HHS funding that appears to be implicated. And the third one seems actually to fit the paradigm here, and that's the nurse at the University of Vermont who says she was coerced into participating in an abortion. Am I misreading you as to those three?

MR. BATES: So we also cited some additional complaints in our reply brief, your Honor. That's at page 26, note 5.

THE COURT: I have got that. But at one point you highlighted those three. Am I right that two of the three actually drop away?

MR. BATES: Two of the three would not implicate violations of the conscience statutes. Those complaints I believe would have alleged violation of the conscience statute; and, in part, the rule here, as the agency explained in the

preamble, was to help to increased understanding and awareness of the rights that are protected under the conscience statute. So the fact that there may have been complaints filed did not actually implicate is still relevant here, because it shows some confusion about what the statutes do cover.

THE COURT: All right. I took you off script. I know you wanted to talk initially about authority and rule-making authority. Thank you. Go ahead.

MR. BATES: So turning back to my notes here, so I think that I also, as we explain in our briefs, in addition to the express delegations of authority, there are also implicit delegations that are relevant. The Supreme Court has made clear that delegations of authority can be both explicit and implicit, and in the process of enacting the conscience statutes and imposing obligations on regulated entities, placing obligation on the agency to ensure compliance with those statutes, there was implicit delegation to the agency to ensure that the agency complies with requirements of those statutes. And so that is relevant --

THE COURT: What is the basis for arguing implicit delegation for the three statutes I mentioned earlier that would substantively define, for example, a term like "assist in the performance" to capture, for example, the range of services or acts that are covered? That seems substantive. That deals with the range of people whose primary conduct implicates the

rule. What's the basis for arguing that implicitly Congress meant HHS to fill that gap and define that?

MR. BATES: So HHS is the agency that's tasked with ensuring compliance with the statutes. So in the process of ensuring compliance, HHS has authority to set forth definitions for what those terms are in the statute.

THE COURT: But, so you say. I mean, isn't the other way to look at it that if Congress was able to affirmatively give you substantive rule-making authority for Medicare, Medicaid, ACA for terms like "discrimination" or "aid and assist in the performance," as the case may be, its silence on that, as to the Church and Weldon and Coates-Snowe amendments, implies that it wasn't intended to give, other than housekeeping, rule-making authority to the agency.

MR. BATES: So, again, delegations can be both explicit and implicit. The various statutes you have discussed here, they were passed at different times by different Congresses as parts of different public laws. So attempting to engage in some sort of intertextual comparison among the different statutes passed at different times doesn't necessarily show that --

THE COURT: Be that as it may, what's your affirmative evidence that when Frank Church put forward the Church amendment, after *Roe*, he intended HHS to rule-make? 1972, the year before Title VII adopts the accommodation framework with

the hardship exception, allowing the employer to insist on somebody's performance of the task. Frank Church was presumably well aware of that, as was Congress. They passed the Church amendment. There was not word one about Title VII and there is not one word about delegating to the agency the ability to rule-make in this area, let alone to supervene Title VII. What's the basis for implying that intention on Congress's part? It's the very next year.

MR. BATES: Well, that's, I think, the nature of an implicit delegation, your Honor. That there is not --

THE COURT: No, but that is circular. Give me something that suggests that HHS, in Congress's eyes, was free to roam around and define those terms, including in a way that would supervene a statute that Congress passed the previous year. I mean, you keep saying it is implied, but implied from what? Otherwise it is just a say-so. What's the evidence?

MR. BATES: Well, in terms of the question of supervening Title VII, your Honor, again, conscience statute, Church amendment was passed after Title VII. Congress chose not to include certain aspects of Title VII in the Church amendment. So that doesn't necessarily --

THE COURT: That doesn't mean that they disagree with it. Maybe they liked what they had previously done. I mean, in Title VII, as of 1972, you have an amendment that, at least in the context of the religion protection in Title VII, as

opposed to morality-based conscience objections, explicitly deals with this problem at a level of greater specificity than does Church or Coates-Snowe or Weldon. What is the basis for inferring in those very short conscience provisions that post date the 1972 amendment of Title VII that Congress was *sub silentio* saying, you know, be done with this hardship exception?

MR. BATES: So there is a difference in the statutory text there, your Honor. And I apologize, I have lost my train of thought here for a moment.

THE COURT: I'm focusing -- look, I want to engage with you on the basis for implying that -- for implying an intent on Congress's part to allow the agency to substantively rule-make here, let alone substantively rule-make in a way that would cover what were a different outcome and a different test, what Congress itself had dealt with the previous year in Title VII.

MR. BATES: I think that what you are speaking to here, your Honor, may be a statutory gap. So this question of how Congress set forth the scene in Title VII, how that's going to interact here with the conscience statute, that may be an example of a statutory gap that then is left for the agency to fill.

THE COURT: But it's not -- it would be perhaps a gap if there weren't conflict. But let's engage, then, with the

issue of how the rule intersects with the area of conduct covered by Title VII. So let's focus just on the employment context as opposed to, for example, benefits situations. In the context of employment, do you disagree with the way that plaintiffs portrayed, pre-rule, the operation of the hardship exception?

MR. BATES: In terms of?

THE COURT: How it worked.

MR. BATES: In terms of its application here?

THE COURT: How an employer, presented with an employee who asserted an objection to, let's say, assisting in an abortion. Do you disagree with the portrait, given by plaintiffs, as to how the dynamic worked under Title VII, that there would be an attempted accommodation, but in the end, if there was a -- forgive me, I'm forgetting the adjective modifying hardship. Undue hardship. Thank you. Do you agree that that was the standard that applied in terms of an employer's latitude to insist on an employee's performance of a task under Title VII?

MR. BATES: So that may have been the standard that the -- that employers of the plaintiffs were applying. That exception does not apply in the text of the conscience statutes.

THE COURT: No, no, no, no. Do you disagree that under Title VII the employer was able to overcome in effect a

religious-based objection to a procedure based on undue hardship?

MR. BATES: Under Title VII, yes.

THE COURT: Okay. So had any court ever held that the conscience statutes in the context of employment overcame that framework, the Title VII framework?

MR. BATES: I am not sure that that issue ever had been presented, your Honor.

THE COURT: Except in the *Shelton* case, which goes the other way, Third Circuit, right? That's exactly the Third Circuit. The Third Circuit in *Shelton* is an employment context involving the nurse who refuses to participate in the abortion and declines the accommodation, gets fired, sues, and loses, essentially based on the Title VII hardship framework, right?

MR. BATES: So, that question would then depend, your Honor, on if the plaintiff in that case raised the conscience statutes and what the court decided about the interplay of the conscience statute for Title VII in that case.

THE COURT: In other words, *Shelton*, you think, would have come out differently if the lawyer in that case had had the wisdom to invoke the conscience statute as having *sub silentio* overcome the Title VII framework.

MR. BATES: That the conscience statutes are more specific and address a more discrete instance, which is conscience protections in the healthcare arena, and that

therefore they apply there in that instance.

THE COURT: But the conscience statutes don't get to this level of granularity. They use words like "discriminate," which, by the way, is also used in Title VII. But beyond the words like "discriminate," they don't get granular as to the operation of the statute as applied to workplace context. They don't say there is or isn't an undue hardship. They just say "don't discriminate," right?

MR. BATES: Yes, that's correct.

THE COURT: So what is the basis for inferring in that that they meant discriminate in some way other than by then the very familiar Title VII framework? I understand that might have been preferred by some, but the statute itself just doesn't say that.

MR. BATES: Congress chose not to include an undue hardship exception in the conscience statutes.

THE COURT: When did they choose that? They use a general term, but they don't -- they simply don't spell out the details. But on what basis can you say that Congress affirmatively chose Frank Church and all the others to not afford an undue hardship exception? Was it a choice or was it simply silence?

MR. BATES: I mean, they knew that that provision was in Title VII. They could have included that provision in the conscience statutes if they chose to --

THE COURT: And they could have indicated in some way in the legislative history or a committee report or the text a disagreement with the existing framework and didn't do that either.

The point is, it seems like it's an *ipse dixit* to say that their silence means that they chose to quietly overcome this very familiar framework. I am looking for some dollop of evidence beyond your say-so that that's what Congress intended. Do you have anything?

(Pause)

MR. BATES: I am just turning to my notes here, your Honor.

THE COURT: Go ahead.

MR. BATES: So the absence in the text is a point, your Honor. As I also mentioned, there are also differences between what Title VII covers and what the conscience statutes cover. And Congress may have determined based on difference in scope not to include the exception there.

THE COURT: They might have done a lot of things. The issue is what they actually did. To a large degree, the conscience statutes cover the employment world, *i.e.*, the world covered by Title VII. I'm asking you, last time, if there is any reason to think, anything specific you can point to that indicates that anybody at Congress intended to overcome the Title VII framework with the conscience statutes in the area

the Title VII framework otherwise applies to.

MR. BATES: Just in the statutory text, your Honor.

THE COURT: May I ask you, up until this rule, I know that the Bush era 2008 rule doesn't define "discrimination," so it didn't seek to overcome the Title VII framework, correct?

MR. BATES: So I have here the rule in front of me, your Honor, the 2008 rule. I would need to review that specific provision of the rule. I will take your Honor's --

THE COURT: Well, it doesn't define "discriminate." It defines other terms, but it doesn't do that, right?

MR. BATES: I -- I'll -- I'll take your Honor's correct on that.

THE COURT: As you understand here now, can you think of any time prior to the promulgation of this rule when HHS, either in the context of a rule-making or in the context of the application of the conscience statutes to a particular scenario, ever took the position prior to this rule-making that the Title VII framework didn't apply to conscience objectors covered in the employment setting?

MR. BATES: I'm not aware of HHS having previously taken that position, your Honor.

THE COURT: So if Congress intended *sub silentio* to overcome Title VII, it was first discovered in or about 2019? Is that the point?

MR. BATES: That?

THE COURT: All those people have been dead for a while who passed -- it's the early parts of the statutes. What's the basis in 2019 for saying that archeology discovers that the framers of these statutes going back to 1973 intended to override Title VII?

MR. BATES: I mean, I, I, I, I apologize. It seems to be the same back-and-forth here, your Honor. It is based on the statutory text. There is a difference in the statutory text. Title VII explicitly has the exception that is not present in the statutory text in any of the conscience amendments which were passed at various times across various Congresses and various public laws. There were multiple times that Congress considered rights of conscience and in none of those instances did they incorporate an undue hardship exception.

THE COURT: Congress was surely aware with the second and third and fourth and all of those up to the 30 conscience statutes that there was apparently no authority out there that read the conscience statutes as intentioned with Title VII or as overcoming it. Given that Congress is presumed to be aware of the facts on the ground, wouldn't one have expected in conscience statutes 2 through 30 to then circle back and say, hey, wait a minute, you know nothing of our work, you don't know what we -- we obviously meant the first of these statutes to override Title VII. You have misread us, so we are going to

be clearer in each of the ensuing statutes.

Isn't there some mileage we can get out of the fact that they didn't do that?

MR. BATES: I mean, it would depend on the extent to which the issue had been brought to Congress's attention, your Honor. I mean, the fact that Congress, time after time, has enacted conscience statutes without this protection -- I suppose one could draw the inference both ways. Here in the text, we would say that the absence in the text, you compare Title VII -- and I apologize if we are just going round and round here, your Honor, but it is a difference in the statutory text, and the question is, what is the inference that you draw from the absence in the statutory text?

THE COURT: What inference do you draw from the fact that the ACA, Affordable Care Act, 2010 says that it doesn't conflict with Title VII?

MR. BATES: What do you mean, your Honor?

THE COURT: Doesn't the ACA, isn't the ACA, doesn't it contain the explicit language harmonizing itself with Title VII?

MR. BATES: It also says that nothing in the act -- let me just turn to. . .

THE COURT: That's one of your examples of substantive rule-making authority. But the ACA, it is hard to read that as, given its reference to Title VII, overcoming Title VII.

MR. BATES: The ACA also says that nothing in the act shall be construed to have any effect on federal laws regarding conscience protection.

THE COURT: Sure. But that assumes the conclusion. If you assume the conscience provisions overcame Title VII, I suppose that's right. If you start with the opposite conclusion, that Congress, in referencing Title VII, presumably, if it intended to override Title VII, would have said something different than it said, you come up to a very different place.

All right. Let's go back to other issues of authorization, unless there is something else you want to tell me about Title VII.

MR. BATES: Just one point. To the extent there is an issue you have identified here, your Honor, I think that it would apply to that specific aspect of the definition of "discrimination." And so to the extent that you find an issue here, that is not a basis to sort of go beyond that specific issue in terms of the scope of relief with regard to plaintiffs' challenge.

THE COURT: As to that, do you agree that the rule adopts a different framework with respect to discrimination and then Title VII?

MR. BATES: The rule does not include the undue hardship.

THE COURT: Give me a concrete example in which that difference would result in a different outcome.

MR. BATES: So the Title VII framework says that the employer has to provide a reasonable accommodation unless doing so would result in undue hardship. And so some of the examples we have talked about, where an employee raises an objection to a procedure and the employer offers an accommodation or the employee seeks an accommodation and the employer determines that the accommodation would be, you know, problematic, would result in the employer having to spend some more money or complicate their staffing decisions --

THE COURT: Let's be concrete. Suppose an employee now says she has been a nurse or he has been a nurse assisting in abortions and does not want to do so anymore, develops that objection, and the employer says, fine, you are now going to no longer be working in OB-GYN, but you can work in orthopedics, you can work in pediatrics, you can work in neonatal; and the employee says -- and same pay, same title, same perks -- and the employee says, no, I insist on staying in OB-GYN. Under the statute, under the rule, who wins?

MR. BATES: Under the conscience rule, your Honor?

THE COURT: Yes.

MR. BATES: So that will depend on whether that reassignment constitutes discrimination.

THE COURT: But doesn't discrimination -- if the

employee rejects the accommodation and the employee is being transferred because of the religious objection to performing a particular procedure in his or her department, doesn't that, under the rule, constitute discrimination?

MR. BATES: So the rule says that the acceptance of the accommodation, that that does not itself -- so it creates a safe harbor. It says the accommodation is not itself discrimination. It doesn't necessarily -- they will set in place the converse or --

THE COURT: Right.

MR. BATES: -- that's going to be a fact-dependent scenario depending on what the assignment entails that's going to be a question for the agency in the first instance to determine what the difference is between the responsibilities and --

THE COURT: In my scenario, here, though, the OB-GYN nurse is transferred to neonatal work, and every other mete and bound of the employment is the same, and the only reason for the transfer is, from the employer's perspective, it is functionally a challenge to have somebody there who is saying on a procedure-by-procedure basis, yes, I can, no, I can't. You would rather have somebody who is available for all procedures that come through the department. You can understand the functional reasons for that.

But if the employee refuses to get out of that

department than be transferred to another equally estimable reputable department, isn't that, under the rule, in terms of discrimination, there is nothing in the rule that gives the employer comfort that in doing so they are not jeopardizing their federal funds, correct?

MR. BATES: So again, your Honor, it is fact specific, and it is going to be a determination by the agency based on the facts of the scenario what the outcome is.

THE COURT: In the hypothetical I gave, though, does that mean that the employer could be, depending on how the agency views that problem, the employer could have violated the conscience statutes as interpreted by the agency under my scenario?

MR. BATES: Yes, your Honor.

THE COURT: Whereas, if, under the Title VII framework, there was an undue hardship determination, the employer would be free to do what it did, right? Undue hardship is no longer something the employer can trot out under this rule as a defense.

MR. BATES: That's correct, your Honor.

THE COURT: All right. So what defense does the employer have if it's being candid in saying, yeah, of course it is your objection to this procedure that is causing you to be moved, it is nothing else, but we have a job to do and it is much more functional to have somebody who is reporting for duty

for all aspects of the job to be in that department, we honor your work, we honor your religious conviction, but you are a better fit for pediatrics and neonatal than for handling an ectopic pregnancy. What defense does the employer have under the rule?

MR. BATES: What do you mean by defense, your Honor?

THE COURT: Well, if you claim that it was a violation and the employer admitted that the reason for the transfer was because of the conscience objection and what it -- the complications it presented for the workplace, under Title VII the complications in the workplace have a doctrinal home. It's called undue hardship. Maybe you meet it, maybe you don't. But under the rule, is there anything that the employer can point to to avoid liability for that behavior, for that transfer?

MR. BATES: Not in terms of the possibility of an undue hardship. The question would come down to what the nature of the reassignment is and whether the nature of the reassignment falls within the definition of the --

THE COURT: Right, but doesn't the rule essentially say that in the event -- the rule doesn't say that only a diminution of responsibility or a diminution of salary, or something like that, constitutes discrimination. It is the transfer itself, the accommodation itself, if it isn't accepted by the employee, that is the discrimination. I'm asking you,

can you point to something in the rule that you would, if you were the general counsel or the employer, point to and say, ah-ha, we have comfort. We can move this valued employee to an area in which he can do equally valued and equally paid work and not complicate our mission. Is there anything in the rule that gives the employer a legal hook to hold on to?

MR. BATES: So the rule sets forth what constitutes discrimination. The rule does not say *per se* that reassignment is discrimination. It talks about adverse impact and those sorts of things. I think that in the scenario that you posit, the best practice might be to contact the agency and discuss the situation with the agency and seek the agency's guidance.

THE COURT: I see. How long does that take?

MR. BATES: It could vary, your Honor. I mean, there is information on the agency's website about how to get in contact with the agency. I would presume it would vary depending upon the complexity of the question and those sort of things.

THE COURT: Would *Shelton* come out the other way under your reading if the rule were determinative?

MR. BATES: So in terms -- so if you had a scenario where you had a nurse who objected to performing an abortion and did not accept a reassignment to another unit, the question is --

THE COURT: And got fired.

MR. BATES: So it would depend on, your Honor, whether that reassignment constitutes discrimination.

THE COURT: No, it would be whether the termination constitutes discrimination. Remember in *Shelton* she gets fired and she sues for being fired after refusing the accommodation. And I am asking you, under the rule, isn't it clear that *Shelton* would come out the other way as long as providing the employee made the right argument under the rule.

MR. BATES: Well, it does depend on whether the reassignment is discrimination. Because if the employee were terminated for refusing to accept something that is not discrimination, then that wouldn't come within the ambit. There has to be discrimination in order for the rule to be --

THE COURT: Maybe this is circular, but I'm trying to figure out, it is HHS that has defined "discrimination." I'm trying to figure out what in the definition of "discrimination" gives the employer some latitude in dealing with this type of problem.

MR. BATES: So the definition sets forth what can constitute discrimination. It talks about -- let's see here. It talks about withholding, reducing, excluding, terminating employment, title, position, utilizing criterion, method of administration.

THE COURT: So there is terminating employment. *Shelton* nurse terminated employment. It is checkmate, isn't

it, under the rule?

MR. BATES: Not if the reassignment itself was not discrimination. So if the employer --

THE COURT: If the employee doesn't like being in pediatrics or neonatal and says no, under the rule, isn't it discrimination?

MR. BATES: Only if -- the reassignment. So the termination in this hypothetical is triggered by the rejection of the reassignment.

THE COURT: Right.

MR. BATES: So if the reassignment is discrimination, the consequence that follows from that would also be discrimination.

THE COURT: And under the rule, isn't the fact that the reassignment is triggered by the refusal to accommodate a -- it's triggered by the refusal to allow the morally objecting or religiously objecting nurse to stay in his or her job, isn't that itself an act of discrimination?

MR. BATES: I'm sorry. Can you repeat that, your Honor?

THE COURT: Let me put it this way. You are, I take it, at this point unprepared to give an answer to the question under the *Shelton* scenario, which is the case and the case law that is the most clear, how it would come out under the rule. You certainly can't assure me to come out the same way.

MR. BATES: No, your Honor.

THE COURT: Throughout your brief, you repeatedly tell the court that this is just about housekeeping. Is it really the agency's position that there is no substantive component to any part of this rule?

MR. BATES: No, your Honor. The agency does take the position that the rule is substantive, that it does impose obligations on regulated entities.

THE COURT: Is that a change from what was said in the brief? I think we collected about ten sound bites that say the opposite. I'm not going to waste your time reading them to you, but it was housekeeping, housekeeping, housekeeping throughout the brief. I think this dialogue explores and demonstrates that, for better or worse, there are substantive changes in the sense that the law applies different or potentially different consequences to the same primary conduct.

MR. BATES: And there are different elements at play here, your Honor, so I think with regard to the definitions, there are some substantive elements there. With regard to compliance and enforcement of grant conditions and those sorts of things, which, like the UAR, the agency has taken pursuant to the housekeeping statute, those are housekeeping matters.

THE COURT: Okay. There certainly are some housekeeping matters in here, but the brief depicted the rule as entirely housekeeping.

Let me continue to understand how this rule would apply in some workplace context.

Let's take a clinic that unwittingly hires a receptionist who objects to abortions. The clinic largely does work that includes a lot of abortions. The receptionist refuses to schedule abortions and refuses to switch jobs. Business slows to a halt. Can the clinic fire the receptionist without potentially breaching the rule?

MR. BATES: So in the rule, the agency said that scheduling an abortion can constitute assistance in the performance, so that would then bring this action within the ambit of the rule.

THE COURT: Right.

MR. BATES: So that therefore the agency could not -- I'm sorry, not the agency -- the employer could not discriminate on the basis of that which would include termination.

THE COURT: Meaning that the termination, then, would appear to be a violation of the rule.

MR. BATES: That's correct, your Honor.

THE COURT: All right. A pregnant woman takes an ambulance across Central Park to Mt. Sinai Hospital and, midway through, from conversation with the ambulance driver, it becomes clear that she is headed there to terminate an ectopic pregnancy. The driver tells her to get out in the middle of

the park, and the employer fires the ambulance driver for that. Is the ambulance driver assisting in the performance of the procedure if the ambulance driver takes her to the hospital?

MR. BATES: So the agency did say in the rule that transporting an individual to a hospital for the purpose of having a procedure that falls within the ambit of the rule, that that would constitute performance.

THE COURT: So the --

MR. BATES: I think that that might implicate other issues as how the ambulance driver dealt with that situation.

THE COURT: Right. It's certainly not a best practice. But the issue is, is the conduct of the ambulance driver, in refusing to drive any further because of the ambulance driver's sincere religious objection to the procedure, is that protected by the rule?

MR. BATES: The rule protects an ambulance driver's ability not to assist in the performance of a procedure to which the driver has an objection.

THE COURT: So play out for me what is supposed to happen in that scenario under the rule, if the ambulance driver simply says, I'm breaching my convictions to get to the other end of Central Park.

MR. BATES: So employers have an obligation, under EMTALA, to provide sufficient staffing and recourse in the event of emergencies that are implicated so the agency -- or,

sorry, I keep saying "agency" when I mean to say "employer" -- so the employer, under EMTALA, should already have in place procedures to handle that situation, and so therefore would put into place whatever --

THE COURT: Right now --

MR. BATES: -- ambulance procedures were and would have had the ability to ask the ambulance driver about his objections, so that they would then be aware to know what the proper way would be to deal with that situation.

THE COURT: So the employer, you are saying, would have known before the ambulance mission began -- the employer is allowed to ask the ambulance driver in the driver's employment whether or not he objects to any particular procedures, such as abortion, on religious grounds --

MR. BATES: Yes.

THE COURT: -- or other moral grounds.

And if the driver has said yes, then the employer is allowed to task the driver with nonabortion ambulance drives? I'm trying to understand just how this works.

MR. BATES: The employer would need to have in place a procedure to handle a situation just as your Honor has posited.

THE COURT: And now, look, we are talking about emergencies. It is a bleeding ectopic pregnancy, and the driver realizes in the middle of the park what the nature of this is. It's not, by the nature of emergency, something which

calm deliberation or all facts are brought to bear at the outset. So in the middle of the transverse in the park, the driver realizes what is going to happen when the ambulance hits the hospital, and the driver then says "no can do" and refuses to drive any further. Can the employer take action against the ambulance driver under this rule or is the employer risking its federal funding by taking action against the driver?

MR. BATES: So, again, the employer should have had in place procedures to deal with this, whether it be another driver in place or something in place to deal with this situation, and then to the question of what then happens to the driver, the driver would be protected under the rule because it would have had a right, under the conscience statutes, not to assist in the performance of a procedure as to which the driver has objection.

THE COURT: And in my scenario in which the -- we have an emergency situation that pops up in the middle of the drive that we have this problem, in other words, it can't be anticipated at the outset, the employer cannot say to the driver: We have somebody who is bleeding. You have to get to the hospital. Sorry. The employer can't do that, you are saying. The employer has to, quote, accommodate in the crucible.

MR. BATES: So the employer has to accommodate, that's correct, under the rule. HHS also made clear that if it

intends to read EMTALA harmoniously with the requirements under the rule, so that if it came to questions of enforcement by the agency, working out sort of what to do in the scenario, that's not necessarily to say, then, that the most extreme measures are necessarily going to come into play because the agency has said it intends to read them as harmoniously as possible.

THE COURT: Right. What that means is the agency may, in its grace, choose not to cut off billions of dollars of funding, but it also might, it still reserves the right to do so, correct?

MR. BATES: The rule would not prohibit that, but the agency is clear that it intends to read them harmoniously wherever possible, that it will begin -- it says it will begin with informal enforcement, informal communications, and only take further action when voluntary compliance cannot be reached. So there is a long series of events that has to take place before any of these more extreme eventualities come into play, and --

THE COURT: When, under the new rule, can the employer even ask about these matters? I gather once a year or if there is a persuasive justification, but not on a more regular basis, right?

MR. BATES: Yes. After hiring, and once a year, unless there is a more -- absent a persuasive justification.

THE COURT: What about the rural hypothetical? That's

the classic example that's given for undue hardship, where you have got a very limited number of personnel. You really need to have somebody there who is a full spectrum, you know, nurse, scheduler or whatnot. It is not realistic to have a substitute in the wings or something like that. How does the rule apply in that setting?

MR. BATES: It applies the same as it applies in other settings, your Honor. It sets forth the various responsibilities for employers. It doesn't create an exception or other conditions that apply in rural instances.

THE COURT: Okay. So meaning that essentially if there is an employee there who asserts religious objections to a range of procedures and it is economically impractical, you know, to have a platoon situation for objectionable and non-objectionable procedures, where you have different employees filling that role, the employer is -- simply has to find a way to pay for a second job there, even if it is impractical, right? The employer intends to continue performing that service and the one person who works there, the one scheduler, the one operating room nurse, that sort of thing, the employer is stuck.

MR. BATES: So with regard to the specific discrete service or discrete procedure that the employee may have an objection to, yes, the employer would in that instance not be able to force the employee to perform the procedure; and so if

the employer wished to continue providing that service, it would need to find an alternative way to do so.

THE COURT: Let's pivot now from discrimination, which has been largely the focus of this line of hypotheticals and questions, to "assist in the performance."

From your perspective, substantively, how does the rules definition of "assist in the performance," insofar as it spells out the range of people who are assisting in some sense with a medical -- with an abortion, just to be direct, how does it change, in your view, from prior definitions or understandings? There really wasn't a definition of "assist in the performance," but I take it the agency had never acted so as to apply the term to people, for example, who did something the day before a procedure. Is that correct?

MR. BATES: I believe so, your Honor.

THE COURT: So in what ways does "assist in the performance" expand the scope of that term from what was previously applied or understood?

MR. BATES: So in terms of the relationship between the term and the statute, we have argued in our briefs that the term is consistent, claiming in the statute, in terms of how HHS has applied that term in the past. I think that is a question that goes to prior enforcement actions.

THE COURT: So in any prior enforcement action, has HHS ever even investigated somebody for -- where the objection

was made by somebody who had a role in a procedure that didn't involve the same day?

MR. BATES: So, your Honor, I don't want to ask to bring agency counsel back up here, so I am going to say --

THE COURT: I'm sure agency counsel doesn't want to come back up either, but --

MR. BATES: So I'm going to say no, with the caveat that I would ask agency counsel to correct me if that's incorrect.

THE COURT: You would say what?

MR. BATES: I would say no with the caveat that agency counsel would correct me.

THE COURT: Agency counsel, if you have got an example in mind where there was a -- an enforcement action or interpretation taken where the conscience objection was to something on a day other than the date of the procedure, I would welcome your letting me know.

MR. BATES: No, your Honor.

THE COURT: I will construe silence that at least offhand you don't have such an example.

That is a not inconsequential change. Whether or not it is linguistically supportable by the text of the conscience statutes, you will agree that that is a consequential change in the way going forward these statutes would be applied, would you not?

MR. BATES: So your question is would that be -- to the extent that HHS has not brought an enforcement action in that scenario previously --

THE COURT: Or to the extent it is not announced that people who perform previous-day or post-day support roles are covered by the conscience statute, yeah, I mean, in other words, whether or not it can be linguistically supported by the text of the conscience statutes and the words "assist in the performance of," it is a newly articulated interpretation that doesn't have its anchor in anything that's been articulated or acted upon before. Is that much correct?

MR. BATES: Not previously by the agency.

THE COURT: Well, by anybody else? Who else?

MR. BATES: Well, there is the text of the statute which sets forth the term "assisted performance." HHS administers that statute. So insofar as HHS has not taken enforcement action pursuant to that scenario then --

THE COURT: Do you know if HHS has even been presented with the scenario before in all the years of these statutes, where somebody who was distressed about the possibility of non-same day steps or assistance towards an abortion felt that that religious objection, that conscience objection wasn't being respected, has the agency even been presented with that as a problem in any of the complaints presented?

MR. BATES: Not to my knowledge, your Honor, and we

would be happy to submit briefing to the court about these sort of specifics.

THE COURT: Let me ask you, you were relying on all these vaccination complaints. Did any one of those complaints even involve somebody who was scheduling a vaccination or doing something as to even a vaccination other than on the day of the vaccination?

MR. BATES: I don't know the answer to that, your Honor, not to my knowledge.

THE COURT: In terms of the rule-making process here and the factual basis, you heard me engage with Mr. Colangelo about the number of complaints. Can you point to a single complaint that the agency has ever gotten in connection with a failure to accommodate somebody whose connection to the abortion or sterilization procedure was other than on the day in question? Is there a single example of that?

MR. BATES: In terms of the complaints, not that I am aware of, your Honor.

THE COURT: So how can the agency be said to have a factual basis for that dimension of its work?

MR. BATES: Because "assistance in the performance," that term --

THE COURT: No, no, no, no. I understand that if we are playing the textual game that one can use -- one can construe "assist" in a variety of ways, and I understand the

linguistic basis for saying that assistance goes all the way back to, you know, a person who paid for the nursing school of the nurse, I get all that, you can do that. I am asking you factually why the rule was enacted? The agency said we have got the significant number of complaints. Well, that's all fine and good, but how does that sync up to the broadened definition of "assist in the performance"? Even if you had a lot of complaints, that might justify rule-making in the area of the ambit of the complaints, but if there literally wasn't anybody who complained that their conscience rights were being offended by participating in some non-same day way, I'm trying to understand if there is any factual way to prompt for that, for engaging in this space? Why rule-make on that point?

MR. BATES: So an agency does have authority and ability to use its expertise to engage in rule-making and set forth definitions, and I don't believe it is the case your Honor that, in setting forth the definition in this context or in another context, an agency must sync up every single individual piece of a definition that sets out with some complaint or a piece of evidence that was brought. It doesn't have to rate some massive chart where it is linking up all of the definitions with all of the complaints or evidence that was brought forward to the agency.

THE COURT: But arbitrary and capricious review turns, as Mr. Colangelo pointed out, on a factual basis. I am trying

to test the factual basis for this consequential part of the rule. That's all. And I take it the answer is that although there is a textual justification, there is not a factual basis for rule-making on that point.

MR. BATES: On the point that action taken a day before a procedure can constitute assistance in the performance of the procedure, so on that discrete point, there is not, to my knowledge, a complaint that addresses that issue.

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.

THE COURT: All right. Is this statute consistent with EMTALA or not?

MR. BATES: May I add one point, your Honor?

THE COURT: Please go ahead.

MR. BATES: Getting back to that hypothetical you have identified a specific scenario, that doesn't necessarily then mean the definition itself as a whole is invalid. You have identified sort of one application that, to the extent it raises issues, may be a potential issue, but that would go to the application as to that specific factual scenario, like an as-applied challenge as opposed to a facial challenge, which is what we face here.

THE COURT: It would be facial as to parts of the definition but not to, perhaps, parts of the definition that involve the nurse handing over the forceps, right? In other words, it is not that -- it is not that the distant, remote assistance is in any scenario justified by an empirical basis before the agency, it is that there are parts of the definition that are not made problematic by that failure of evidence, *i.e.*, the nurse who is immediately in the operating theater.

MR. BATES: That's correct.

THE COURT: Just briefly, counsel for the plaintiffs says that, on the contrary to law point, the statute is inconsistent with EMTALA, the Emergency Medical Act.

Putting aside the agency's promise to do its best to harmonize them, on the face of the rule how is the rule -- is the rule, on its face, consistent with EMTALA?

MR. BATES: On this question, the rule is, like the conscience statutes themselves, the conscience statutes themselves do not discuss the interaction of those statutes with EMTALA. So this question applies equally to the conscience statutes themselves. And the agency said it intends to read them harmoniously. It applies both to the rule and to the conscience statutes.

THE COURT: Isn't there all sorts of legislative history, including Weldon and Church, that, if we consider it, makes clear they had no intention of compromising the execution

of emergency medicine? I recognize there are issues about the extent to which one can consider legislative history, but put that aside for a moment, doesn't the legislative history to the extent that it exists make clear that emergency medicine was intended to be cordoned off from the impact of the conscience statute.

MR. BATES: So there is legislative history indicating that the individuals who made those statements did not -- were not expecting for the conscience statutes to impact the requirements to provide emergency services under EMTALA.

THE COURT: Like Frank Church.

MR. BATES: That's correct.

THE COURT: All right.

MR. BATES: And the rule implements those statutes, and so the interaction between the statutes and EMTALA is going to be the same as the interaction between the rule and EMTALA.

THE COURT: It depends how one construes the statute. Has the agency -- prior to the rule, had the agency been presented by any complaint from anybody practicing emergency medicine?

MR. BATES: So there were complaints. There were complaints by various nurses. I don't know that those complaints specified whether the nurse participated in emergency services or not.

THE COURT: Why -- what was the agency's basis for

interpreting the rule so as not to carve out the emergency situation? Given that EMTALA is out there as a federal statute, what was the agency's reasoning in not correspondingly carving out the emergency space in terms of the ambit of the rule?

MR. BATES: I think it was consistent with the conscience statutes, which don't explicitly do that either. It was implementing the conscience statutes. Conscience statutes don't have that explicit carveout. So, again, it is a question of the interaction between the rule and EMTALA is going to be the same as the interaction between the statutes and EMTALA. So I don't think the agency found it necessary to carve that out because it wasn't in the statutes either, and the interaction is going to be the same between the two of those.

THE COURT: *Shelton*, of course, applies in the emergency context. It is at once a Title VII case and an emergency medical case. Did the agency consider *Shelton* explicitly in its rule-making as a federal appellate court application of these concepts in the Title VII context? Did it engage with that? What was its reasoning for, in effect, coming up with a different framework?

MR. BATES: So I believe that the agency did cite *Shelton* at some point in the footnotes. I don't know the exact footnote that that was at, your Honor.

But getting to your question about, again, the

interaction between the rule and EMTALA, again, I apologize if I am repeating myself, I think the agency determined reasonably that the interaction between the rule and EMTALA would be the same between the interaction between the conscience statutes and EMTALA, and so that it wasn't necessary, then, to provide an explicit carveout because the extent that there is tension there, it is the tension with the conscience statutes as well, so that resolving that tension is the same between the statutes and the rule, and so it wasn't necessary to provide a carveout that wasn't in the statutes that was implementing itself.

THE COURT: All right. Go ahead. I have taken you off. I think we have covered a lot of what I am sure you intended to cover, but I want to make sure that you have enough air time for the points you wanted to make to me.

MR. BATES: Thank you, your Honor. How much time do I have remaining?

THE COURT: I have taken you off script. You have got what you need.

MR. BATES: So let me just go through my notes here, your Honor.

So we talked about the evidence that the agency can serve. We talked about the complaints. I noted that, as we did cite in our reply, that a number of the complaints did implicate violations of the conscience statutes. So there was, before the agency, evidence of the complaints, as agency

counsel mentioned, that there was an increase in complaints, even setting aside the vaccination complaints, they went from, like, one year to around ten or so a year, so there was a substantial increase.

THE COURT: But that was after the notice of rule-making. Prior to the notice of rule-making, which presumably was prompted by -- I mean it is a Heisenberg principle you have here, right? Where you -- once you throw out the notice of rule-making, you are stirring the pot. Prior to the notice of rule-making, was there any increase in complaints?

MR. BATES: So not prior to the notice of the rule-making, but the rule-making, to the extent it did increase its knowledge or awareness of these rights --

THE COURT: But it's not laboratory conditions. In other words, if you say, We are open season for new complaints, you can't then treat the new complaints as reflecting that concern over an area as growing. You are responding to the invitation.

MR. BATES: Well, it could also be an indication that when individuals are made aware of these issues, that they will then respond by filing complaints. So, yes, there may have been a causal relationship between the MPRM and the complaints, but the fact that complaints were then filed and people were made aware may indicate that there had been problems going on

for a while, but just folks weren't aware of their rights. So once they were made aware of their rights by the MPRM that they then sought to bring them to the attention of the agency.

THE COURT: You said there were ten complaints after the notice of rule-making. With as much specificity as possible, what scenarios did they implicate?

MR. BATES: So among the ones that we cite in our reply, it depends on the level of specificity that is included in the complaints themselves. There was a nurse who was placed on administrative leave by a hospital on the ground -- she alleges this -- that she was placed on administrative leave by a hospital on the ground that she sought a religious accommodation for having to perform abortions.

THE COURT: The actual performance, in other words, operating theater apparently.

MR. BATES: She had not gone to that level of granular detail, but performance of abortions.

Complaint by a nurse alleging that she was terminated from a hospital for her unwillingness to participate in the provision of abortion-related services.

Complaint by a nurse alleging she was --

THE COURT: Do we know what that means, what services those were?

MR. BATES: She does not spell that out in the complaint.

Complaint by a nurse alleging that she was coerced into performing an abortion after previously notifying her employer of religious objections to performing abortions.

Complaint by a nursing professor alleging that she was not hired for a full-time faculty position because of her views on abortion.

So these are just a few examples, your Honor, that do show that there are instances where employers are not abiding by their obligations under the conscience statutes, and so this is evidence before the agency that there were problems and --

THE COURT: What would the reason be, if any, for an uptick if one was to credit that in disrespect for conscience-based -- sincere conscience-based objections? In other words, if the premise is this is a growing problem in our country, can you theorize why that would be? We are dealing with a quite small numbers here, so I am not blind to that. But if one accepts the premise that there had been a consequential increase not generated by the notice of rule-making, any idea why?

MR. BATES: So the fact that -- it is not necessarily going to be the case that there was an uptick in the actual violations of rights under the statute, although that might be the case, it may have been the case that there were -- even if the amount was consistent, going back 20 or 30 years, the folks were not aware of their obligations under the statute so that

they were not aware of their rights under the statutes, then that would be equally a problem as if there was a change in how employers dealt with requests --

THE COURT: So why not just have a public awareness campaign? Why not if you see something say something? Why isn't that the answer if people don't understand their rights? Why do we need this whole apparatus of the rule?

MR. BATES: That could have been one way that the agency could have addressed the problem, your Honor. The agency, in the exercise of its expertise, in the exercise of its authority, after having reviewed the situation, decided that, in addition to the notice requirements under the rules that would advise individuals of their rights, that the best way to address the problem was through the policy as implemented in the rule. The agency has the authority and the ability to, in the exercise of its expertise, to decide what the best way is to address a policy, and the court, upon review, need not agree with the agency that it was the best policy or even that it was better than the alternative policies, but merely that the agency gave a -- considered the relevant data and gave an explanation -- rational explanation for -- in connection between the data and the decisions that it made.

THE COURT: Can I come back "to assisting in the performance," that definition. Am I right that that is

actually only in the Church amendment or is that somewhere else?

MR. BATES: So I'm just comparing here Church, Coates-Snowe, and Weldon, because I know those are the ones we have been talking most about. So in those three, that is the only -- that is the only --

THE COURT: And that has no substantive rule-making delegation explicit.

MR. BATES: Church does not.

THE COURT: All right. I want to make sure I give a little time to our intervenors. Is there anything further you wanted to say to me? If not, I have got one or two more questions.

MR. BATES: I think I might just note, there was not a great deal of discussion today about the establishment clause. I would just point to -- point your Honor to our argument about the state or forum is distinguishable here.

And in terms of the scope of relief --

THE COURT: Yes. That's what I was going to get to.

MR. BATES: Okay. Just real quickly there, your Honor, plaintiffs have asserted that sort of a standard procedure when a court finds a rule invalid is vacatur of the rule in its entirety in nationwide application. I believe they cited some D.C. Circuit cases to that effect. We cited the California case, *California v. ASR*, out of the Ninth Circuit,

that vacated the nationwide scope of an injunction under a facial challenge under the APA.

Just for your Honor's information, in that *California v. ASR* case, that cites another Ninth Circuit case, *Havens Hospice*, which is relevant here and there is also a Fourth Circuit case, *Virginia Society for Human Life,* that I think has some very helpful language about in a similar instance where a plaintiff made an argument that, under the EPA, the standard remedy is vacatur in the entirety, nationwide relief, and the Fourth Circuit rejected that argument there.

So to the extent plaintiffs are saying that the normal -- the usual practice, there is authority out of both the Ninth and Fourth Circuits saying that is not in fact --

THE COURT: So there are two questions. One is severability and one is if there were an injunction, whether it applies on a more limited basis. Let's just take the second one. What is your view as to the proper geographic scope of any injunction or any relief in this case?

MR. BATES: So it would be the scope necessary to afford relief to the parties in this case, so there are various state and various municipal plaintiffs in this case. So it would be --

THE COURT: There are 23 states, right?

MR. BATES: 23 states and municipalities. I don't know that all of the government plaintiffs are states.

THE COURT: All right. But, in other words, by your lights, if the court were to rule against the government in whole or in part, and let's move out of the world of injunctions and focus on the merits, the summary judgment dimension, is it your view that that should be -- invalidation should only be as to those 23 states and as to the activities of the named plaintiffs in other states?

MR. BATES: That's correct, your Honor.

THE COURT: So the rule would still stand in 27 states, plus territories, less -- but not as applied to, for example, Planned Parenthood to the extent that it has a presence in those 27 states. Is that what you are saying?

MR. BATES: So it depends on who the plaintiffs are. So -- and that depends on sort of the relationship between Planned Parenthood writ large and its -- I don't know the exact terminology to use here, your Honor, but the sub-entities that it contracts with and sort of who are plaintiffs in the case and who are not, but our position would be that the remedy should be limited to the plaintiffs in this case. So it would be --

THE COURT: So other people in New York State who haven't joined the lawsuit could still have the rule enforced against them. Even if I found that it was arbitrary and capricious, contrary to law, all of that stuff, other people in New York State could still have the rule applied because they

didn't join this lawsuit.

MR. BATES: Other --

THE COURT: I thought what you were saying was 23 states it is invalid, 27 states somebody has got to sue in those states. I think you are now actually saying that unless this turned into a class action or an opt-in class involving every medical entity in the United States, you haven't actually sued in this case, you can't get the benefit of relief. Is that what the United States is telling me?

MR. BATES: That the relief should be limited to the plaintiffs as the regulated parties here.

THE COURT: So.

MR. BATES: To the extent New York is a regulated entity --

THE COURT: Right. You are telling me that to get relief, let's suppose, just indulge the hypothetical, that the rule is found by the court to be for one reason or another invalid. Is what you are really telling me is to get the benefit of that rule there now have to be follow-on lawsuits by every hospital and doctor and clinic and, you know, farmhouse, you know, to get relief as opposed to the invalidation of the rule having operation of law across the board? Is that really what the United States thinks is the right approach here? I get the problems with nationwide injunctions, but you are going way beyond that. You are telling me that you actually have to

be a party to the case to get relief. Was there thought given to that position before this argument began?

MR. BATES: So, your Honor, we have cited to the court the *Gill* case of the Supreme Court that instructed that the remedy should be limited to the inadequacy that produced the injury, tailored to redress the plaintiffs' particular injury. The remedy here should be tied to the injury that the plaintiffs have alleged. And my understanding is that the states and municipalities have brought this suit in their capacity as regulated entities.

THE COURT: Is there any reason why the arguments that have been made today and in the briefs apply any differently to the other 27 states or to medical providers in -- to covered entities by the rule in any -- in the 23 states who haven't filed suit or anywhere in the 27? The rule -- the infirmities that have been alleged about the rule rise or fall without respect to the identity of the plaintiff who sues, no?

MR. BATES: In terms of the arguments about why the rule is legally invalid in terms -- the harms that are alleged against the rule, those do relate to what services regulated entities provide, what policies those regulated entities have in place in terms of the alleged harms that are --

THE COURT: But that's more of a preliminary injunction notion, and I get that. That's a little different. But in the context of the relief that the parties reciprocally

seek on summary judgment, it is a unitary calculation. Regardless of whether you are affected a little or a lot, the rule either is valid or it is not, correct?

MR. BATES: Yes.

THE COURT: Okay. All right. Thank you very much. Appreciate the helpful argument under substantial fire. Thank you.

All right. I will hear now from Mr. Dunn.

MR. DUNN: Thank you, your Honor. Robert Dunn for defendant intervenors. Thank you for granting us intervention and the chance to present argument today.

THE COURT: As you know, the reason I granted intervention was substantially on the basis that the case might need to be resolved as a preliminary injunction and, as such, I wanted to make sure there was a voice given to parties who could be harmed by an injunction stopping the rule. I don't know whether or not we will go in that direction, but the unique value that the intervenors add is in bringing to bear in a real world sense the experiences of the people whose rights are affected by the rule.

MR. DUNN: Understood, and appreciate that. Hopefully our briefing contributed to that.

THE COURT: It did very much.

MR. DUNN: So a couple of points on that and then we can pivot to discussing the definition of discrimination which

might be helpful as well.

But the two quick points I want to make and advance, with respect to CNDA and its members, they treat patients of every religion, every race, every gender, sexual orientation, etc. There have been some insinuations in the brief that the rule is essentially a cloak or a cover for the expression of animus and bigotry, and I hope that plaintiffs' counsel will confirm that that's not the case, but the briefing suggests that --

THE COURT: I don't think plaintiffs' counsel said anything like that, and I take the conscience statutes as directed at protecting very valid interests, which is the legitimate desire of people, in good faith, for moral or religious reasons, not to participate in various procedures. I don't think that's at issue, and I appreciate as well your point that renaming the statutes, the refusal statutes may be seen by some as not fully respecting the legitimate conscience interests. I read that. I understood what you were saying.

MR. DUNN: So we are all agreed this is about protecting folks who have objections to specific procedures, not patients. With that in mind, our position is that the rule is important. I think there has been some discussion of is it a solution in search of a problem? In the rule-making, on pages 23175 to 179, I think the agency does a good job of looking back at some of the prior comments that were submitted

both in the 2008 and the 2011 and the current rule-making. Beyond complaints filed at OCR, these are comments from healthcare providers -- doctors, nurses in the profession -- who have personally experienced discrimination or pressure. There was some of discussion in the briefing about the 2008 CMDA survey. In that survey, the respondents -- we are talking about doctors and nurses primarily -- 40 percent of them said I have experienced personal pressure or some form of discrimination.

THE COURT: And I read that with interest. What was less clear to me was what their experiences had been in front of HHS.

MR. DUNN: And from what I gather, most do not proceed in front of HHS.

THE COURT: Is that because they are unaware of their legal right to do so?

MR. DUNN: I think it is probably because HHS cannot do much for them. There is no private right of action. HHS cannot get them reinstated, cannot provide them damages.

THE COURT: But your co-counsel, counsel for HHS, says that to the degree that there have been cases, in effect, some solution, some accommodation has often been worked out, whether in this or other civil rights areas, short of an ultimate adjudication in which simply reporting to the agency gets the mighty HHS on the side of the objector and often results, in

practice, in getting relief. And what was striking to me from what you submitted was not the number of people who say that they have had discomfort in the workplace because their conscience objections haven't been treated seriously, but any argument that the regulatory apparatus is not up to the task or that they have had bad experiences with it. Can you help me with that?

MR. DUNN: Yeah. I think that from the comments submitted to the agency, the uniform theme of those comments are there are no teeth in the actual existing regulation.

THE COURT: Has any member of CMDA -- there are 20,000 -- brought a complaint before the agency?

MR. DUNN: Not to my knowledge.

THE COURT: So maybe they should try. In other words, how can they say the agency is not up to the task if they haven't given it a whirl.

MR. DUNN: If you uphold the rule, I am sure they will.

THE COURT: But with respect, the justification for the rule is a greater number of complaints. I have heard about that. But that somehow or other there is a -- the agency has proven toothless or incapable of action. If this is a concern of your membership and none of them has ever gone to the agency, how do we know if that is true?

MR. DUNN: Well, I mean, you look at the existing

rule, the 2008 rule that was, you know, a blip in time, and the 2011 rule, which essentially, you know, wiped out all of the substantive provision of the 2008 rule --

THE COURT: But, sorry, it is your co-counsel who says the statutes are the source of all this authority and that the application by the agency is merely explaining what Congress meant by the rule, by the statutes. If you buy that, if you believe that, all along the statutes have had meaning consistent with what is being articulated today. That was an invitation for somebody to go before the agency and say, I shouldn't have had to hand over that forceps, I should have been respected when I said I didn't want to do it, or even other ways of assisting. I'm having difficulty with the premise that there is an enforcement gap here that is demonstrated other than stated. Is there anything you can point to?

MR. DUNN: Yeah. I think what it comes down to is if you are a physician or a nurse and you have been discriminated against or terminated or transferred, you have to put your career a little bit on the line to run to HHS and sort of flag yourself as a thorn in the side of a hospital that wants to provide these types of services. You are kind of putting your career in jeopardy. Once you have done that, you basically can be blacklisted essentially from the profession, and it is unclear what HHS can do for you, you know, absent the rule. So

you can run to HHS and say, hey, the Church amendment says they can't do this if they receive federal funds, and my understanding is my employer received federal funds, do something for me.

THE COURT: But HHS says that in the limited number of cases it has done something for people, just as it says it has done so with respect to other civil rights violations. Is the problem a public education problem? Do your clients know of either the conscience statutes or the existence of HHS or that there is a remedial place, procedure and a place to go? Do the members of the organization, Dr. Frost and the other 20,000, do they know about all this?

MR. DUNN: I'm quite certain that there is an information problem and that this is not something that is well known both for the employers and the employees. I think there were comments submitted to the effect that even in the enforcement proceedings some of the hospitals were made aware of the statutes and said, We didn't even know about these statutes. So I think there is a lack of awareness of the statutes themselves and certainly lack of awareness of HHS's role in them.

THE COURT: Am I correct to assume that most of your members probably fit into the employment box?

MR. DUNN: Almost all of them.

THE COURT: So what has their experience been with the

Title VII framework? How does that work for them?

MR. DUNN: Unclear. I think an employer who is fired probably has -- there have been undoubtedly Title VII claims in that context, you know, less clear when we are talking about transfers or other types of hiring, you know, I didn't get hired, difficult to --

THE COURT: Are they finding that the undue hardship exception, if you will, under Title VII has been applied to capaciously so as to, in effect, unneedlessly override legitimate conscience objections? Is that what they are saying?

MR. DUNN: I think that's a concern that's been expressed. It puts the burden quite heavily on them to prove that it wasn't an undue hardship. Because the employer can invoke the undue hardship standard and it is difficult for an employee to combat that.

I think the bigger concern is that many of these instances sort of evade Title VII, where people are feeling like they are pressured to do something, they do it, don't feel like they have a recourse under Title VII when they have sort of done it, and part of the thing that the rule provides is it gives them a recourse with the agency.

THE COURT: But they haven't -- but the -- they have had recourse, even the 2011 rule which you are not pleased with gave the recourse and presumably it was there before, but it

certainly is clear who you call, right? The rule is consequential here because of its interpretation of discrimination, aid in the performance, and referral and the like, but can it really be said that, after the 2011 rule, members of your organization didn't know where to go if they were concerned that their statutory conscience rights were being infringed?

MR. DUNN: Well, there are sort of two answers to that. The first is, I think there was probably a lack of confidence in the agency administering the rule at that point, and that's an issue of sort of, as you mentioned, the political ping-ponging, how serious is the administration and the agency taking conscience protections. You know, we had litigation all over the country regarding the contraception mandate and the agency was taking positions there that indicated it was not terribly sympathetic to, you know, sort of rights of conscience and religious freedom. So that I think probably plays a role. And I think the other part is just you go to the agency for what? And it is a big step for someone to sort of invoke the power of the federal government if you don't know what you are going to get or what the agency can do for you.

THE COURT: But isn't that exactly what the rule does? It just gives the agency -- it broadens, perhaps, the scope of the prohibitions beyond certainly what was previously understood and it may give the agency more muscle if you accept

the face of the rule that said all HHS funding is in play, but in the end there is still no private right of action. The statute still doesn't allow you to go to court if you are the ambulance driver or the nurse in *Shelton*. You have to bring your lawsuit under something else, like Title VII. The rule still directs you to the agency. So to the extent that that is a deterrent, what's changed?

MR. DUNN: Well, the specific power that HHS has invoked to step in and address funding streams, you know, regardless of how broadly you construe that, there is an extreme. You can cut off funds that the Labor Department supposedly administers. That would be an extreme version. But even if it was just a narrow funding stream to the specific offending employer, that's muscle.

THE COURT: It's because the agency is putting at risk, at least -- depending on how we construe this, at least the funding stream that the rule has teeth you were saying.

MR. DUNN: Yes. I think that's more or less it.

THE COURT: Doesn't that help plaintiffs on their spending clause argument?

MR. DUNN: They have to still prove all of the retroactivity and the unexpected nature of it, and we have addressed that in our briefing. But there is a spending element here. The agency specifically invoked its spending power, so I think the fact that it is putting spending at

risk --

THE COURT: The agency says that essentially under the UAR it had the same authority with or without the statute to implicate the spending stream.

MR. DUNN: But nobody knew that.

THE COURT: That's public education, right? There is a remedy other than a statute for that, than a rule.

MR. DUNN: If that's true, then the challenge to HHS's authority to strip funding under this rule is also irrelevant, because if they had that power all along, what are we talking about?

THE COURT: Understood. I get that.

From your perspective as an advocate for the religious or moral objector, what do we do with the *Shelton* scenario? What's the right answer to that?

MR. DUNN: I think that's a great question. I think I read the rule slightly differently than plaintiffs' counsel. Possibly I read the rule differently than DOJ. I don't think so. The way I look at it, if you take a look at the definition of discrimination in 88.2, you have to prove some sort of adverse treatment or some sort of penalty to even say this is discrimination. But paragraph 4, the point of paragraph 4, notwithstanding paragraphs 1 through 3, is to basically incentivize employers to provide reasonable or effective accommodations to provide them. Now there is a safe harbor if

it is accepted, so that's one thing. Provided it is accepted, there is no issue here.

THE COURT: But in *Shelton*, the nurse refuses to be transferred.

MR. DUNN: Yes. And I take the next sentence to basically say "in determining whether any entity has engaged in discriminatory action with respect to any complaint or compliance review under this part, OCR will take into account the degree to which an entity had implemented policies to provide effective accommodations for the exercise of protected conduct," etc., etc.

THE COURT: But it doesn't say we will take into account the impact on the entity of continuing the employee in the present job. In other words, it removes the Title VII undue hardship. It focuses on something else.

MR. DUNN: It does. But to the extent that, in *Shelton*, the accommodation offered appeared to be in effect an accommodation that appeared to be offered in good faith.

THE COURT: And was rejected.

MR. DUNN: And was rejected. I take the rule to say OCR will take that into consideration when even deciding if there was discrimination, and it might well decide in that particular situation that there was no discrimination.

THE COURT: Well, we don't know.

MR. DUNN: We don't know.

THE COURT: We can't.

Final question for you, and I realize this is a hypothetical, but the rural hypothetical and the ambulance in Central Park hypothetical, how does your client base view those?

MR. BATES: Sorry, say --

THE COURT: How would your client base view those scenarios where, in a very real world sense, there are adverse health consequences to patients from the Central Park driver refusing to bring the bleeding ectopic patient to the hospital because of an objection or in the rural scenario where the person refuses an accommodation and is essentially occupying a singular position.

You know, it is easy in the real world to understand adverse medical or treatment availability consequences. I welcome your view as an advocate for the people with religious objections, how you view those scenarios? I appreciate they are extreme, but they are out there in the briefing.

MR. DUNN: So with the ambulance hypothetical, that one strikes me as about as extreme as you can get, because nobody calls 911 and says, I am having an ectopic pregnancy. They say, I am having abdominal pain with bleeding. So the driver isn't going to ascertain what's going on, what the treatment is on the back end and make the decision to kick the person out. It's hard to deal with something quite that

extreme.

But the rural situation, that, I think, is a real issue, because you could have a doctor, the only physician in a hospital that itself permits abortions to be provided, and he or she objects and says --

THE COURT: And Title VII framework would presumably permit the person to be screened to allow the hiring of somebody who is able to do the full job or the termination of somebody who refuses to do a good portion of it in those circumstances. Just from a human perspective, how does your client -- do you object to the Title VII framework application to that scenario? Is there something problematic about that?

MR. DUNN: I don't object to the Title VII application, but with respect to the rule, I mean, I think the consequence of that is to say, well, you know, Christian doctors or religious doctors can never serve in those positions. So I think that would have some real world effects, too, if you are going -- and nurses, like no nurse can serve in a rural hospital if she has a religious objection to abortion. And I recognize this is a balancing, and there are winners and losers on both sides, but clinics closing down, nurses leaving their profession, doctors leaving the profession, that has an adverse impact on patients as well, and I think the agency tried to balance that.

THE COURT: All right. Thank you. Very helpful. I

appreciate the very thoughtful briefing as well.

Is there any rebuttal from plaintiffs?

MR. ZIONTS: Your Honor, we are very conscience of the time, and I think a couple of us have very, very few points to make, subject to any questions that you have.

THE COURT: Go ahead.

MR. ZIONTS: In terms of regulatory authority, really just two points, your Honor.

One, we have heard a lot of assurances this morning. We really aren't going to do that. The agency is not going to go that far. It's not going to take every last dime of New York's $45 billion in Medicaid. The rule says what it says. It says "terminating federal financial assistance from the department in whole or in part" and our clients can't say, well, in open court a lawyer from the Department of Justice did say they are probably not really going to do it. Our clients have to adjust their conduct based on what it says in the C.F.R.

The only other point I would make, your Honor, in terms of where the agency gets this implicit authority that it believes it has to issue substantive rules with authoritative interpretations, I think the closest we heard to something was essentially inferring it from their enforcement role, you know, they have to enforce these statutes so that, by implication, they bootstrap onto that the idea that they need to issue

substantive rules and authoritative interpretations.

Respectfully, your Honor, that is just flat out inconsistent with how Title VII and the EEOC have operated for half a century. It's been very clear, the Supreme Court has said it multiple times, EEOC obviously has a role to play in the enforcement of Title VII. But Congress did not delegate a substantive rule-making authority. It can issue binding force-of-law interpretations. that doesn't mean that agency is toothless. It issues guidance. It issues interpretive opinions. It tells -- you know, your Honor mentioned public awareness campaigns. The EEOC has no shortage of ways to let it be known how it views Title VII.

The exact same thing could be said of HHS here. HHS and other agencies, all the time they issue guidance documents. They have a big box at the front that says: This is not binding, a court may interpret this differently, but this is how we see the world, this is how we see is the statutes, this is how we are going to interpret it. There is nothing preventing HHS from doing that. It just didn't do it.

THE COURT: All right. Thank you. Anything else from plaintiffs?

MS. SALGADO: Yes, your Honor.

THE COURT: Go ahead.

MS. SALGADO: Your Honor, I wanted to get back to the question that you asked me, the last question you asked me.

There was some confusion about what the court was concerned about, but the question is whether, here, if the court believes that there is a constitutional violation, but that it is as applied to the plaintiffs --

THE COURT: It was that one could imagine constitutional applications that would be unconstitutional but that the rule was not facially invalid under the establishment clause. That was the hypothetical.

MS. SALGADO: Right. And I think here plaintiffs have shown that the rule is unconstitutional as to plaintiffs here because it does require plaintiffs to put above all other interests the day the rule takes effect those of religious beliefs that were put into this rule. So just take as a concrete example, on the day the rule takes effect, plaintiffs are required to change their hiring practices. The record shows they have open positions, they are hiring, and the record shows that through that process they ask questions. The rule prohibits that from doing so because it -- because -- well, I'm not really sure why the rule does that, but it prohibits covered entities from asking prospective employees whether they have religious objectives to performing the services that they are being hired to do. So in that example, your Honor, we believe that the rule is putting above all other interests those of religious beliefs and does violate the establishment clause. So the question about whether there is an as

applied -- the question about as applied versus facial --

THE COURT: Your premise is not that it is in fact an as-applied violation as to your client. That was not what I was -- I was not so finding but, rather, just positing that there are possible applications that could be unconstitutional. That was the question. If that's all we have got, is it contrary to law?

MS. SALGADO: The relief under the APA is under its nature the relief must be set aside.

THE COURT: Thank you.

MS. SALGADO: The only other question I wanted to -- oh, and just one last point about the question about as applied versus facial is that, even setting that aside, your Honor, I just wanted to say that the canon, the constitutional avoidance would still prohibit the agency from defining the term "discrimination" in the way that it has here.

THE COURT: All right. Thank you.

MS. SALGADO: Thank you.

THE COURT: Anything else from plaintiffs?

(Continued on next page)

MR. COLANGELO: Thank you, your Honor.

The justice department made a number of arguments attempting to pare back the Draconian scope of the enforcement provisions here and in particular mentioned the intent to pursue voluntary compliance efforts.

I want to point out that the rule itself expressly disclaims any need to wait for the resolution of voluntary compliance efforts before funds can be terminated. That's at 88.7(i)(2).

Attempts to resolve matters informally shall not preclude OCR from simultaneously pursuing any action described in the other paragraphs.

Your Honor, my second point. There has been considerable discussion regarding Title VII and the import for the Court's analysis of the rule's departure from the Title VII framework.

One argument that we just wanted to point out, your Honor, is the particularly on-point case that we've cited in our papers is Chamber of Commerce v. United States Department of Labor. This is a Fifth Circuit case from 2018 where the Court held that it was arbitrary for the Labor Department to interpret a long extant statute, in that case ERISA which was enacted in 1974, more or less contemporaneously with the amendments we're talking about here.

It was arbitrary for the Department of Labor to

interpret ERISA to regulate in a new way the thousands of people and organizations working in that market or to discover in a long extant statute an unheralded power to regulate a significant portion of the economy.

So for all the reasons the Court has been discussing, the concerns about Title VII bear directly on the arbitrary and capricious analysis.

Finally, your Honor, the agency has conceded in this courtroom that the complaint -- the volume of complaint evidence it was looking at was ten complaints a year, not 343. And of those ten complaints a year the agency has deemed only three or four complaints worthy of investigation.

That alone is fatal to the final rule. It is unsupportable for the agency to claim that this rule is necessary to enforce in a context where they've only pursued three or four a year and where it's not the explanation that they gave.

Thank you.

THE COURT: Thank you.

Ladies and gentlemen, we're going to adjourn now but before we do I just want to say something for the benefit of all the people out here which is you have all had the privilege of seeing some truly excellent lawyers all around and I think we judges don't often give shout-outs, not often enough. But the quality of the briefs I got in this case was extraordinary

and the quality of the advocacy I've gotten here was extraordinary and invaluable to me in making sense of what is really a series of complicated problems.

So thank you very much for the excellence of the advocacy and all the hard work.

We stand adjourned.

(Adjourned)