

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

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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

Plaintiffs-Appellees,

(Caption continued on inside cover)

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

BRIEF FOR DEFENDANTS-APPELLANTS UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, II; AND UNITED STATES OF AMERICA, AND CONSOLIDATED-DEFENDANTS-APPELLANTS ROGER T. SEVERINO AND OFFICE FOR CIVIL RIGHTS, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Consolidated-Plaintiffs-Appellees,

v.

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

Defendants-Appellants,

DR. REGINA FROST AND CHRISTIAN MEDICAL AND DENTAL ASSOCIATIONS,

Intervenors-Defendants-Appellants,

ROGER T. SEVERINO, in his official capacity as Director, Office for Civil Rights, United States
Department of Health and Human Services; AND OFFICE FOR CIVIL RIGHTS, UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Consolidated-Defendants-Appellants.

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INTRODUCTION

Numerous federal statutes protect individuals and entities with religious or moral objections to providing certain health-care-related services in connection with government-provided or government-funded health-care programs. The statutes place conditions on federal funding, barring recipients from discriminating against individuals and entities based on protected conscience objections.

The Department of Health and Human Services (HHS) in 2019 issued a final rule (the Rule) that collects in one place all applicable statutory requirements, provides HHS's understanding of key statutory terms, and clarifies its procedures for ensuring HHS-administered funds are expended in compliance with these requirements. In so doing, the Rule serves various interests, including increasing awareness of the conscience statutes and their protections and addressing public confusion regarding the statutes and HHS's enforcement of them.

The district court vacated the Rule in its entirety and universally, holding that the Rule exceeds HHS's authority, conflicts with other provisions of law, and violates the separation of powers and the Constitution's Spending Clause. But properly understood, the Rule merely gives effect to the conscience statutes, which plaintiffs do not challenge. For that reason and others, the Rule is within HHS's statutory authority; is consistent with other laws, including the Administrative Procedure Act (APA); and raises no constitutional concerns. At the very least, the court should have vacated only the parts of the Rule it found unlawful and only as to plaintiffs.

STATEMENT OF JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331. The district court entered judgment on November 6, 2019. Government appellants filed a timely notice of appeal on January 3, 2020. JA 2764-72; *see* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the district court erred in holding that the Rule is contrary to statute, violates the APA, and is unconstitutional.
2. Whether the district court erred in vacating the Rule in its entirety, in all of its applications and against all persons.

STATEMENT OF THE CASE

This appeal arises from consolidated lawsuits challenging a final rule that HHS promulgated in 2019. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 84 Fed. Reg. 23,170 (May 21, 2019). Judge Engelmayer of the District Court for the Southern District of New York granted summary judgment to plaintiffs and vacated the rule in its entirety. *See New York v. HHS*, 414 F. Supp. 3d 475 (S.D.N.Y. 2019); SA 1-147.

A. Statutory Background

Congress has enacted numerous statutes to protect freedoms of conscience and religious exercise in the health-care context. The Rule gives effect to those statutes, including the five key laws discussed below.¹

1. The Church Amendments

In the 1970s, Congress enacted the Church Amendments. In their current form, these provisions protect those who hold religious beliefs or moral convictions regarding sterilization procedures, abortion, or health-care or research activities against discrimination (1) by entities that receive certain federal funds and (2) in HHS-funded health service programs and research activities. *See* 42 U.S.C. § 300a-7. The Amendments include several provisions.

Subsection 300a-7(c) states that no entity which receives a grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act may, with respect to “any physician or other health care personnel,” “discriminate” in (1) the person’s “employment, promotion, or termination of employment” or (2) “the extension of staff or other privileges” because the person either “performed or assisted in the performance of a lawful sterilization procedure or abortion” or refused to do so because his performance or assistance “would be

¹ The Rule implements other statutes as well. *See* 45 C.F.R. § 88.3.

contrary to his religious beliefs or moral convictions” or “because of his religious beliefs or moral convictions respecting sterilization procedures or abortions.” 42 U.S.C. § 300a-7(c)(1). Section 300a-7(c)(2) imposes similar obligations on entities receiving grants or contracts for biomedical or behavioral research under any HHS-administered program. *See id.* § 300a-7(c)(2).²

Subsection 300a-7(d) provides protections not limited to sterilization or abortion, stating that “[n]o individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by [HHS] if” doing so “would be contrary to his religious beliefs or moral convictions.” 42 U.S.C. § 300a-7(d).

Subsection 300a-7(e) prohibits entities that receive certain funds or benefits under the statutes identified above or a successor statute from discriminating against applicants for training or study because of their “reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant’s religious beliefs or moral convictions.” 42 U.S.C. § 300a-7(e).

² Section 300a-7(b) makes clear that the receipt by an individual or entity of funds under the statutes identified in subsection (c)(1) does not permit any court, public official, or “other public authority” to require such an individual to “perform or assist in the performance of any sterilization procedure or abortion,” or such an entity to make facilities available or provide personnel for such purposes, if it would be contrary to the recipient’s religious beliefs or moral convictions. *See* 42 U.S.C. § 300a-7(b)(1)-(2).

2. The Coats-Snowe Amendment

Section 245 of the Public Health Service Act, enacted in 1996 and known as the Coats-Snowe Amendment (Coats-Snowe), prohibits abortion-related discrimination in training and accreditation among other contexts. *See* 42 U.S.C. § 238n.

Specifically, Coats-Snowe prohibits the federal government, and any state or local government that receives “Federal financial assistance,” from discriminating against any “health care entity” because such entity (1) “refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions” or (2) refuses to make arrangements for those activities. 42 U.S.C. § 238n(a)(1)-(2). Coats-Snowe also forbids such governments from discriminating against any “health care entity” that “attends (or attended) a post-graduate physician training program, or any other program of training in the health professions” that does not “perform induced abortions or require, provide or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.” *Id.* § 238n(a)(3).

In addition, Coats-Snowe provides that “[i]n determining whether to grant a legal status to a health care entity” or “to provide such entity with financial assistance, services or other benefits,” covered governments “shall deem accredited any postgraduate physician training program that would be accredited but for the accrediting agency’s reliance upon an accreditation standard[] that requires an entity to

perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training.” 42 U.S.C. § 238n(b)(1).

3. The Weldon Amendment

Since 2004, Congress has included a rider known as the Weldon Amendment in every appropriations act for the Departments of Labor, HHS, and Education. *See* 84 Fed. Reg. at 23,172. The Amendment provides that none of the appropriated funds “may be made available to a Federal agency or program, or to a State or local government,” if it “subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.” Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, div. A., § 507(d)(1), 133 Stat. 2534, 2607.

4. The Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (ACA), Pub. L. No. 111-148, 124 Stat. 119 (2010), also protects health-care-related conscience rights.

Section 1553, for example, prohibits the federal government, any state or local government or health-care provider receiving federal financial assistance under the ACA, and any health plan created under the ACA from discriminating against a health-care entity because “the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the

death of any individual, such as by assisted suicide, euthanasia, or mercy killing.” 42 U.S.C. § 18113(a).

Section 1303 provides that nothing in title 42 requires “qualified health plans”—*i.e.*, health plans that meet criteria permitting their sale on exchanges established under the ACA, *see* 42 U.S.C. § 18021(a)(1)—to cover abortion services as “essential health benefits for any plan year.” *Id.* § 18023(b)(1)(A)(i). Furthermore, “[n]o qualified health plan offered through an [ACA] Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions.” *Id.* § 18023(b)(4). Section 1303 also clarifies that nothing in the ACA should be construed to affect “Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.” *Id.* § 18023(c)(2)(A).

5. Medicare and Medicaid Advantage Programs

Congress has specified that organizations offering Medicare+Choice plans (now known as “Medicare Advantage” plans, *see* 84 Fed. Reg. at 23,173) may not restrict a “covered health care professional” from advising a patient of her “health status” or “medical care or treatment for the individual’s condition or disease, regardless of whether benefits for such care or treatment are provided under the plan,” so long as “the professional is acting within the lawful scope of practice.” 42

U.S.C. § 1395w-22(j)(3)(A). The provision, however, “shall not be construed as requiring a [Medicare Advantage] plan to” provide or cover counseling or referral services if the organization offering the plan notifies prospective enrollees that it “objects to the provision of such service on moral or religious grounds.” *Id.* § 1395w-22(j)(3)(B). Analogous provisions exist for Medicaid managed-care organizations. *See id.* § 1396u-2(b)(3).

B. Regulatory Background

1. 2008 and 2011 Regulations

In 2008, HHS issued regulations addressing the Church, Coats-Snowe, and Weldon Amendments. *See* Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law, 73 Fed. Reg. 78,072 (Dec. 19, 2008) (2008 Rule). The 2008 Rule found inconsistent awareness of these statutory protections among funding recipients and protected persons and entities and a need for stronger enforcement to ensure that HHS funds do not support practices that violate these statutes. *See id.* at 78,078-81. To address these concerns, the 2008 Rule defined several statutory terms, required certain funding recipients to provide written assurance of their compliance with the statutes, and designated HHS’s Office for Civil Rights (OCR) to receive complaints and coordinate enforcement. *See id.* at 78,097-101.

In 2009, HHS proposed rescinding the 2008 Rule. *See* Proposal, 74 Fed. Reg. 10,207, 10,209 (Mar. 10, 2009). In 2011, HHS rescinded most of the 2008 Rule and

issued a narrower rule. *See* Regulation for the Enforcement of Federal Health Care Provider Conscience Protection Laws, 76 Fed. Reg. 9968, 9969 (Feb. 23, 2011) (2011 Rule). The 2011 Rule retained the designation of OCR to receive complaints, emphasizing that “there must be a clear process for enforcement” of the conscience statutes. *Id.* at 9972. The preamble further noted that, if an entity violated statutory conscience provisions, HHS would attempt to facilitate voluntary compliance and, if necessary, “consider all legal obligations, including termination of funding [or] return of funds.” *Id.*

2. 2018 Notice of Proposed Rulemaking

In 2018, HHS published a Notice of Proposed Rulemaking (NPRM) concerning conscience protections in HHS-funded programs. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 Fed. Reg. 3880, 3881 (Jan. 26, 2018). HHS proposed definitions for various statutory terms, *see id.* at 3892-95, and proposed requirements that certain fund recipients maintain records, submit written assurances of compliance, and notify individuals and entities about applicable conscience and anti-discrimination rights, *see id.* at 3880. HHS also proposed making OCR responsible for assessing and ensuring compliance with the conscience statutes and resolving complaints. *See id.*

3. Final Rule

In May 2019, after carefully considering public comments and appropriately modifying the proposed rule, HHS published the Rule. *See* 84 Fed. Reg. at 23,180. As relevant here, the Rule has three principal provisions:

First, the Rule clarifies procedures for addressing violations of the conscience statutes. *See* 45 C.F.R. § 88.7. For example, the Rule authorizes OCR to conduct outreach, provide technical assistance, initiate compliance reviews, conduct investigations, and seek voluntary resolutions, and it provides that, where voluntary resolutions are not possible, OCR will coordinate compliance using existing procedures for enforcing funding conditions. *See id.* The Rule also states that funding recipients and sub-recipients must maintain records and cooperate with OCR's investigations, reviews, and enforcement actions. *See id.*

Second, the Rule requires that funding recipients provide written assurances and certifications of compliance with applicable conscience statutes. 45 C.F.R. § 88.4. Assurances and certifications must be submitted when applying and reapplying for federal assistance from HHS; entities receiving assistance on the Rule's effective date need not submit an assurance or certification until they reapply, alter the terms of existing assistance, or apply for new lines of assistance. *See id.*

Third, the Rule sets out HHS's definitions of terms in the conscience statutes, clarifying their scope and providing notice to entities against whom the statutes may be enforced. The following definitions are at issue in this case:

Assist in the Performance: The Rule defines “assist in the performance” as “tak[ing] an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity.” 45 C.F.R. § 88.2. It “may include counseling, referral, training, or otherwise making arrangements for the procedure” or activity at issue. *Id.*

Discriminate or Discrimination: The Rule defines “discriminate or discrimination” to “include[], as applicable to, and to the extent permitted by, the applicable statute,” “withhold[ing], reduc[ing], exclud[ing] from, terminat[ing], restrict[ing] or mak[ing] unavailable or deny[ing]” any grant, contract, or other benefit or privilege; “impos[ing] any penalty”; or “utiliz[ing] any criterion, method of administration, or site selection” that subjects protected individuals or entities to “any adverse treatment . . . on grounds prohibited under an applicable [conscience] statute.” 45 C.F.R. § 88.2.

The definition clarifies that, under HHS’s interpretation of these terms, an entity “may require a protected entity to inform it of objections to performing, referring for, participating in, or assisting in the performance” of specific procedures or activities, but “only to the extent that there is a reasonable likelihood that the protected entity may be asked in good faith” to engage in those activities. 45 C.F.R. § 88.2. An entity may make such inquiries only “after the hiring of, contracting with, or awarding of a grant or benefit to a protected entity, and once per calendar year

thereafter, unless supported by a persuasive justification.” *Id.* The definition further describes other situations in which HHS shall not regard an entity as having engaged in discrimination where the entity seeks to accommodate a protected entity or provide objected-to conduct through alternate means. *Id.*

Health Care Entity: For purposes of Coats-Snowe, “health care entity” is defined to include “an individual physician or other health care professional, including a pharmacist;” health-care personnel; certain health-professions training programs, participants, and applicants; hospitals; medical laboratories; pharmacies; biomedical or behavioral research entities; and “any other health care provider or health care facility.” 45 C.F.R. § 88.2. For purposes of the Weldon Amendment and the ACA, the term includes all people and entities included in the Coats-Snowe definition and certain others. *Id.*

Referral or Refer For: The Rule defines “referral or refer for” to “include[] the provision of information” where “the purpose or reasonably foreseeable outcome . . . 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.

The Rule contains myriad other provisions, including one identifying and collecting the requirements of the numerous conscience provisions that apply to HHS-funded health programs. *See* 45 C.F.R. § 88.3. And the Rule expressly provides that, if any part of the Rule is held invalid or unenforceable, it shall be severable, and

the remainder of the Rule shall remain in effect to the maximum extent permitted by law. *See id.* § 88.10.

The Rule’s preamble carefully considers, and responds at length to, the hundreds of thousands of public comments HHS received. After evaluating the comments and other available information, HHS determined that the Rule was warranted “to ensure knowledge of, compliance with, and enforcement of Federal conscience and anti-discrimination laws.” 84 Fed. Reg. at 23,175. HHS explained that the Rule “does not substantively alter or amend the obligations of the respective statutes,” *id.* at 23,185, instead providing notice of HHS’s reading of key statutory terms and clarifying how HHS will enforce them.

C. Procedural Background

In May 2019, twenty-three States and localities filed a complaint in the Southern District of New York challenging the Rule. *See* JA 131-210. Similar actions were later filed by the Planned Parenthood Federation of America, Inc. and Planned Parenthood of Northern New England, Inc., *see* JA 211-63, and the National Family Planning and Reproductive Health Association and Public Health Solutions, Inc., *see* JA 264-326. The district court consolidated the cases. *See* JA 1241-42.

Plaintiffs moved for a preliminary injunction to block implementation of the Rule. On July 1, 2019, the district court granted the parties’ stipulated request to postpone the Rule’s effective date until November 22, 2019. *See* JA 1291.

The parties then cross-moved for summary judgment. Before the Rule took effect, the district court granted summary judgment to plaintiffs and vacated the Rule in its entirety. *See* SA 146.

a. The court began by addressing HHS’s statutory authority to issue the Rule. The court acknowledged that authority existed for at least “some aspects” of the Rule. SA 42. It concluded, however, that the Rule is “largely substantive,” SA 31; that “housekeeping statutes” HHS had invoked did not authorize issuance of substantive rules, *see* SA 43-47; that the conscience statutes did not impliedly delegate substantive rulemaking authority, *see* SA 60-61; and that rulemaking provisions in the ACA and Medicare and Medicaid statutes did not authorize the Rule as a whole, *see* SA 64. The court also concluded that HHS lacked statutory 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.” SA 42.

b. The court additionally held that the Rule is “contrary to law” because it conflicts with Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e *et seq.*, and the Emergency Medical Treatment and Active Labor Act (EMTALA), *id.* § 1395dd. *See* SA 71. The court concluded that the Rule conflicts with Title VII because the Rule’s definition of “discrimination” fails to include two defenses—for “undue hardship” and “reasonable accommodation”—available under Title VII. SA 71. The court held that the Rule conflicts with EMTALA, which requires that federally funded

hospitals with emergency departments provide emergency care, because EMTALA does not make exceptions for religious or moral refusals to provide care. *See* SA 74.

c. The court further held the Rule to be arbitrary and capricious. *See* SA 79-109. The court rejected HHS's observation that OCR had recently seen a "significant increase" in conscience-related complaints, SA 79-81, and held that concern alone sufficient to invalidate the Rule, *see* SA 89. The court faulted HHS for allegedly failing to identify evidence supporting the Rule's definitional provisions, *see* SA 87-89, and purportedly inadequately considering the conclusions underlying the 2011 Rule, *see* SA 90-92. The court also criticized HHS for inadequately considering funding recipients' reliance on HHS's historical interpretation of the conscience provisions. *See* SA 99-101.

d. The court also held the Rule's definition of "discrimination" procedurally invalid under the APA, reasoning that the NPRM did not include the final rule's provisions addressing a funding recipient's ability to "accommodate or inquire about conscience objections." SA 110.

e. Based on its conclusion that the Rule expanded HHS's authority to withhold or terminate funding, the court held that the Rule violates the separation of powers (because Congress did not grant HHS such authority), *see* SA 116-17, and the Spending Clause (because the possibility of terminating all of a recipient's HHS funding renders the Rule "impermissibly coercive"), *see* SA 129-32. The court also concluded that the Rule violates the Spending Clause because it creates "uncertain

ground rules for compliance” and because the court believed it imposed new, retroactive obligations on States. *See* SA 125-28.

f. The court vacated the Rule in its entirety, describing the violations it found as “numerous, fundamental, and far-reaching,” even if “isolated parts” of the Rule were valid, and despite the Rule’s severability provision. SA 142-43. It gave the vacatur nationwide scope, noting that its conclusions about the Rule were not jurisdiction- or plaintiff-specific. *See* SA 144-45.

SUMMARY OF ARGUMENT

While the district court erred in several respects, its reasons for vacating the Rule ultimately flow from a single mistaken premise: that the Rule expands on the protections Congress enacted in the conscience statutes. To the contrary, the Rule simply clarifies and outlines procedures for enforcing unchallenged statutory provisions that have long governed recipients of HHS funds. At a minimum, that is indisputably true for many of the provisions, and the court had no basis to set aside the entire Rule.

I. The district court erred in concluding that the Rule exceeded HHS’s authority under the conscience statutes. In relevant part, the Rule does three things, all well within HHS’s statutory authority:

First, pursuant to HHS’s housekeeping authorities, the Rule sets forth procedures by which HHS will respond to conscience violations, including in certain instances by terminating funds subject to these conditions—a natural consequence for

such violations. These procedures permit HHS to take action only with respect to funds subject to a relevant provision and do not expand HHS's authority.

Second, the Rule's assurance and certification requirements merely require that funding recipients certify they will comply with duties the conscience statutes themselves impose. HHS's existing authorities permit the agency to ensure compliance in this fashion.

Third, the Rule's definitional provisions provide HHS's understanding of certain terms in the conscience statutes. No substantive rulemaking authority is needed to issue such an interpretive rule, and HHS's common-sense definitions reflect the best reading of the statutes.

II.A. The Rule is also not contrary to law. Although the district court emphasized that the Rule does not incorporate certain defenses that Title VII provides in religious discrimination cases, there is no textual or other basis for reading those defenses into the conscience statutes. The district court also wrongly discerned a facial conflict with EMTALA based on a hypothetical situation HHS is not aware has ever occurred; and regardless, EMTALA requires a hospital to provide care only "within the staff and facilities available," 42 U.S.C. § 1395dd(b)(1)(A), which is properly interpreted to accommodate staff unavailability caused by statutorily protected conscience-based objections.

B. The Rule is not arbitrary and capricious. The Rule's definitions, which reflect the best reading of the statutes, necessarily impose no costs beyond the statutes

themselves, while providing significant public clarity benefits. The certification and enforcement provisions likewise simply help ensure that funding recipients comply with preexisting duties and clarify HHS's own enforcement procedures. HHS was not obligated to provide an extensive policy justification to offer such clarification. In any event, HHS amply explained why the Rule was warranted, carefully considered public comments, and adequately addressed issues commenters raised. Although the district court erroneously thought HHS miscounted conscience-related complaints it had recently received, the record indisputably reflected many alleged violations of the conscience statutes, through both the complaints and other evidence before HHS.

C. The district court also erred in concluding that one aspect of the Rule's definition of "discrimination" was not a logical outgrowth of the NPRM. The APA's notice-and-comment requirements do not apply to the Rule's definitional provisions, which are merely interpretive. Plaintiffs had ample opportunity to comment in any event, and the challenged provision does nothing to harm plaintiffs by giving employers *more* flexibility in response to comments.

D. The Rule is also consistent with the Constitution. The Rule's enforcement provisions do not represent an unauthorized departure from HHS's statutory authority, and the district court further identified no basis to conclude that the Rule violates the separation of powers by intruding on the powers of another branch independent of the alleged lack of statutory authority.

The Spending Clause challenge is not ripe because that challenge is grounded in a hypothetical use of the Rule's enforcement provisions dependent on a chain of uncertain future events. The Rule also does not impose ambiguous and retroactive conditions. The Rule has no retroactive effect, confers no new enforcement authority on HHS, and simply provides additional guidance to States long aware they must comply with the conscience statutes if they accept conditioned funds. For similar reasons, the Rule is not unconstitutionally coercive.

III. Finally, the district court erred by vacating the Rule as to all persons and in its entirety. Plaintiffs have not shown that vacatur of the Rule as to all persons is needed to remedy their injuries, as Article III and equity require, and the APA neither requires nor authorizes such relief. Vacatur of the entire Rule, moreover, cannot be squared with the Rule's express severability clause and the independent value of numerous aspects of the Rule that are unchallenged or that the district court itself recognized were lawful.

STANDARD OF REVIEW

This Court reviews de novo the district court's decision granting summary judgment. *See Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 506 (2d Cir. 2017).

ARGUMENT

I. The Rule Is Within HHS's Authority

The district court erred in concluding that three aspects of the Rule exceed HHS's statutory authority. Properly understood, the Rule simply (A) sets forth the procedures HHS will use to enforce the conscience statutes and regulate its own compliance with them, (B) imposes assurance and certification requirements to ensure that recipients of HHS funds will comply with conditions that undisputedly apply to their funding, and (C) gives HHS's interpretation of the best meaning of relevant statutory terms.

A. The Rule's Enforcement Provisions Validly Set Out HHS's Existing Authority To Respond To Noncompliance With The Conscience Statutes

Numerous statutes specify that individuals and entities receiving HHS funding must comply with requirements protecting conscience rights. Where recipients violate those statutes, termination of the relevant funding is a natural consequence and indeed at times the express statutory directive.

HHS has the authority to regulate its enforcement of, and compliance with, these statutory mandates through 5 U.S.C. § 301, which authorizes the head of an Executive department to “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.” *Id.* This “housekeeping statute” has, with its predecessors, long empowered

department heads to regulate internal departmental affairs. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979). The Rule’s enforcement provision, which merely outlines steps HHS may take, reflects this authority to ensure that the agency disburses funds it administers in compliance with the conscience statutes.

The district court did not take issue with HHS’s general authority to enforce the conscience statutes, but concluded that one subparagraph of the Rule—indicating that HHS may effect compliance by “[t]erminating Federal financial assistance or other Federal funds from the Department, in whole or in part”—exceeded HHS’s authority. This provision is, however, neither the “extreme termination power” the district court described (SA 65), nor a departure from HHS’s existing authority.

The Rule’s enforcement provision is framed in permissive terms and sets out a variety of potential remedies through which HHS may enforce the conscience provisions. HHS thus may “[t]emporarily withhold[]” funding in whole or in part “pending correction of the deficiency”; “[d]eny[] use” of, or terminate, funding in whole or in part; “[w]holly or partly suspend[] award activities”; deny or withhold new funding requests; refer the matter to the Attorney General; or “[t]ak[e] any other remedies that may be legally available.” 45 C.F.R. § 88.7(i)(3). Any such action must be 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 preamble makes clear that “[t]he only funding

streams threatened by a violation of the Federal conscience and anti-discrimination laws are the funding streams that such statutes directly implicate.” 84 Fed. Reg. at 23,223.

As the preamble explains, “[t]ermination of funding as a possible remedy is a necessary corollary of Congressional requirements that certain funding not be provided to entities that engage in impermissible discrimination.” 84 Fed. Reg. at 23,223. Nevertheless, OCR’s investigations “are usually resolved by corrective action,” and “OCR only rarely imposes termination of funding as a penalty.” *Id.* “What specific remedy is appropriate in the case of a particular violation depends on the facts and circumstances.” *Id.*

These enforcement tools are consistent with preexisting regulations. Neither plaintiffs nor the district court have ever questioned the validity of those preexisting authorities, which authorize HHS to, among other things, “[w]holly or partly suspend . . . or terminate the Federal award,” “[i]nitiate suspension or debarment proceedings,” “[w]ithhold further Federal awards for the project or program,” or “[t]ake other remedies that may be legally available” when a funding recipient violates applicable requirements. Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, 79 Fed. Reg. 75,889, 75,918-19 (Dec. 19, 2014) (HHS UAR) (codified at 45 C.F.R. § 75.371). While the district court believed the Rule exceeded that existing authority because the Rule states that HHS may terminate “*all* federal funds that a recipient receives from HHS,” SA 37, if a compliance issue

extends to all of the awards a fund recipient has obtained, nothing in the HHS UAR precludes a recipient-wide termination of funds.

The district court was further incorrect to conclude that no statute empowers HHS “to terminate all of a recipient’s funding streams from the agency for a breach of a Conscience Provision.” SA 66. The Weldon Amendment states that “[n]one of the funds made available in this Act may be made available” to a federal agency or program or a State or local government that engages in prohibited discrimination. *See* Further Consolidated Appropriations Act, 2020, § 507(d)(1), 133 Stat. at 2607 (emphasis added). While the Church and Coats-Snowe Amendments simply impose requirements on recipients of certain federal assistance without specifying a consequence for noncompliance, termination of the relevant funding is a natural consequence for violations. *Cf. United States v. Marion Cty. Sch. Dist.*, 625 F.2d 607, 611 (5th Cir. 1980) (the United States may sue to enforce contractual assurances of nondiscrimination “as a matter of federal common law, without the necessity of a statute”). Where all of the funding a recipient receives from HHS is subject to a particular conscience statute, a violation of that statute consequently may naturally lead to the termination of Federal financial assistance from the Department “in whole.” And where a particular funding recipient’s violation (under the Weldon Amendment, for example) might also extend to each funding stream it receives, it is entirely reasonable, and certainly not facially invalid, to include a provision

“reserv[ing] the right” (SA 68 n.36) to terminate all HHS funds as one potential enforcement mechanism for a violation of that scope.

B. HHS Has Authority To Impose Assurance And Certification Requirements

HHS had authority to include in the Rule assurance and certification requirements designed to ensure compliance with the conscience statutes. Plaintiffs do not dispute that they must comply with these statutes if they accept HHS funds conditioned on compliance, and the certification requirements reflect that undisputed obligation.

Indeed, existing regulations *require* HHS to “manage and administer [a] Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements.” 45 C.F.R. § 75.300(a). The conscience statutes impose conditions on HHS funding, and HHS must ensure that funding recipients are in compliance to vindicate Congress’s requirements. For contracting, HHS is similarly authorized to “supplement the [Federal Acquisition Regulations]” to incorporate “agency policies, procedures, [and] contract clauses,” 48 C.F.R. § 1.301(a)(1).³ HHS has previously used that authority to require specific inclusion of a contract clause relating to

³ 40 U.S.C. § 121(c) authorizes “the head of each executive agency” to “issue orders and directives that the agency head considers necessary to carry out” regulations issued by the Administrator of General Services, such as 48 C.F.R. § 1.301.

conscience protections (which plaintiffs do not challenge here). *See* 48 C.F.R. §§ 352.270-9, 370.701.

The district court erroneously concluded that the assurance and certification requirements are substantive under this Court's decision in *Perales v. Sullivan*, 948 F.2d 1348 (2d Cir. 1991), and consequently unauthorized. *Perales* involved HHS's denial of New York's claim for Medicaid reimbursement based on a requirement (imposed without prior notice to the State) that the claim be accompanied by "assurance" at the time of filing that certain documentation existed. *See id.* at 1352. This Court explained that the requirement was substantive because it "precluded what would otherwise have been a valid claim for federal reimbursement," such that HHS had to give New York notice before enacting it. *Id.* at 1354. The Court rejected HHS's arguments that an existing regulation or statute imposed the documentation requirement. *Id.* at 1354-57.

Perales thus involved a new documentation requirement that no existing statute or regulation required, imposed without notice. Here, plaintiffs are plainly on notice of the challenged requirements. And more fundamentally, unlike in *Perales*, the certification and assurance requirements here simply recognize existing statutory and regulatory duties imposed on HHS and recipients of HHS funds subject to the conscience statutes. Unlike in *Perales*, the Rule "does not substantively alter or amend the obligations of the respective statutes" applicable to a fund recipient. *See* 84 Fed. Reg. at 23,185 (citing *JEM Broad. v. FCC*, 22 F.3d 320 (D.C. Cir. 1994)). This is not a

case like *Perales*, where the assurance requirement imposed a duty that could not be traced directly to an existing statutory requirement. HHS needs no authority beyond the conscience statutes themselves (and HHS's authority to regulate its internal operations to comply with them) to require that fund recipients certify they are, in fact, complying with statutory conditions attached to their receipt of federal funds.

C. The Rule's Definitional Provisions Are Interpretive And Reflect The Best Reading Of The Statutory Text

The Rule defines several terms that appear in the conscience statutes governing HHS-administered funds. *See* 45 C.F.R. § 88.2. The district court concluded that HHS needed substantive rulemaking authority to promulgate these definitional provisions and lacked that authority with respect to three conscience statutes. That conclusion was erroneous: the definitional provisions are interpretive, such that no grant of substantive rulemaking authority is necessary, and reflect the best reading of the statutes interpreted.⁴

1. The APA establishes a “central distinction” between substantive (or legislative) rules and interpretive rules. *Chrysler Corp.*, 441 U.S. at 301. Substantive rules “create new law, rights, or duties, in what amounts to a legislative act.” *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993); *see also Syncor Int'l Corp. v. Shalala*, 127 F.3d 90,

⁴ The court acknowledged that HHS “undeniably had rulemaking authority to implement the ACA and the Medicare and Medicaid Conscience Provisions” (SA 57) but nonetheless invalidated the Rule as to those statutes as well. It erred in doing so, as discussed *infra* in section III.B.

95 (D.C. Cir. 1997) (“[A] substantive rule *modifies* or *adds* to a legal norm based on the agency’s *own authority*.”). Interpretive rules, by contrast, “clarify existing law.” *United States v. Lott*, 750 F.3d 214, 217 (2d Cir. 2014); *see also Perez v. Mortgage Bankers Ass’n*, 575 U.S. 92, 97 (2015) (interpretative rules are issued “to advise the public of the agency’s construction of the statutes and rules which it administers” (quotation marks omitted)). An agency does not need substantive rulemaking authority to issue an interpretive rule. *See, e.g., Metropolitan Sch. Dist. of Wayne Twp. v. Davila*, 969 F.2d 485, 490 (7th Cir. 1992).

The district court erroneously stated that the test for determining whether a rule is substantive or interpretive is whether it “shapes the primary conduct of regulated entities.” SA 48. But whether a rule is interpretive does not depend on whether it has “significant effects on private interests,” for “interpretive rules may have substantive effects.” *White*, 7 F.3d at 303. Rather, the inquiry is whether a rule has “effect[s] *completely independent* of the statute.” *Mejia-Ruiz v. INS*, 51 F.3d 358, 364 (2d Cir. 1995) (brackets and emphasis in original). “If the rule is based on specific statutory provisions, and its validity stands or falls on the correctness of the agency’s interpretation of those provisions, it is an interpretative rule.” *United Techs. Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987).

The Rule’s definitional provisions are interpretive under this test. Indeed, the Rule specifies that it “does not substantively alter or amend the obligations of the respective statutes.” 84 Fed. Reg. at 23,185. The definitions simply advise the public

of HHS's understanding of various terms used in the conscience statutes, the "prototypical example" of an interpretive rule. *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 88 (1995). The definitional provisions have no independent effect that might render them substantive rather than interpretive, and the duties reflected in the Rule flow from the conscience statutes, not the Rule. *Cf. White*, 7 F.3d at 304 ("Because the rule clarifies an ambiguous term, it fits within the definition of an interpretive rather than a legislative rule.").

The district court confused the inquiry by concluding that the definitions were substantive because, in its view, they "go beyond merely expressing what [the] statute has always meant." SA 50 (quotation marks omitted). Interpretive rules need not, however, "so closely track the relevant statutory provisions as to make the rule virtually self-evident." *Mejia-Ruiz*, 51 F.3d at 364. For example, a rule "does not become a legislative rule merely because it supplies crisper and more detailed lines than the authority being interpreted." *Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 423 (D.C. Cir. 1994) (quotation marks omitted); *see also Central Texas Tel. Co-op., Inc. v. FCC*, 402 F.3d 205, 214 (D.C. Cir. 2005) (same). And if a rule "is an interpretation of a statute rather than an extra-statutory imposition of rights, duties or obligations, it remains interpretive even if the rule embodies the Secretary's changed interpretation of the statute." *White*, 7 F.3d at 304.

2. Each of the challenged definitions represents the best reading of the statutes.

a. HHS’s definition of “assist in the performance” is consistent with the Church Amendments, the only conscience statute containing the term. For example, 42 U.S.C. § 300a-7(d) states that “[n]o individual shall be required to perform or *assist in the performance* of any part of a health service program or research activity funded in whole or in part under a program administered by [HHS] if his performance or *assistance in the performance* of such part of such program or activity would be contrary to his religious beliefs or moral convictions.” *Id.* (emphases added). The Rule defines the term “assist in the performance” as “tak[ing] an action that has a specific, reasonable, and articulable connection to furthering a procedure or a part of a health service program or research activity undertaken by or with another person or entity.” 45 C.F.R. § 88.2. It “may include counseling, referral, training, or otherwise making arrangements for the procedure” or activity, “depending on whether aid is provided by such actions.” *Id.*

That definition reflects the ordinary understanding of the relevant statutory terms. “Assist” means “to give support or aid.” Webster’s Third New International Dictionary 132 (1968) (Webster’s). “Performance” means “the act or process of carrying out something” or “the execution of an action.” *Id.* at 1678. The Rule’s definition—“tak[ing] an action that has a specific, reasonable, and articulable connection to furthering” the procedure at issue—means the same thing as those dictionary definitions: supporting or aiding the process of carrying something out.

The district court (SA 52) faulted the definition for extending to “persons engaged in activities” that the court viewed as “ancillary to a covered procedure” and “activities carried out on days before and after these procedures.” But nothing about the plain meaning of “assist” or “performance” restricts the statute’s scope as the court envisioned.

Congress expressly extended the Church Amendments’ scope beyond individuals who “perform” procedures or other activities to those who “assist in”—and thus necessarily have a more ancillary relationship to—the procedure or activity. It is unsurprising that Congress sought to reach *all* forms of assistance in this context, for religious or moral objections to complicity in acts believed to be immoral often do not distinguish between ancillary and direct support. *Cf. Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 724 (2014) (noting the case implicated “a difficult and important question of religion and moral philosophy, namely, the circumstances under which it is wrong for a person to perform an act that is innocent in itself but that has the effect of enabling or facilitating the commission of an immoral act by another”); *Thomas v. Review Bd. of Ind. Emp’t Sec. Div.*, 450 U.S. 707, 715 (1981) (refusing to question “the line [a religious objector] drew”). Accordingly, activities such as “[s]cheduling an abortion or preparing a room and the instruments for an abortion are necessary parts of the process of providing an abortion” and properly within the statutory definition. 84 Fed. Reg. at 23,186.

b. The Rule’s definition of “discriminate or discrimination” likewise reflects the best reading of the relevant conscience statutes.

Virtually all of the conscience statutes covered by the Rule employ the term “discriminate” or “discrimination” without defining it. Coats-Snowe, for example, prohibits certain funding recipients from “subject[ing] any health care entity to discrimination” on certain bases, such as the “refus[al] to undergo training in the performance of induced abortions.” 42 U.S.C. § 238n(a)(1).

Consistent with the varying types of discrimination prohibited, the Rule provides a non-exhaustive list of actions that may constitute discrimination, including “withhold[ing], reduc[ing], exclud[ing] from, terminat[ing], restrict[ing] or mak[ing] unavailable or deny[ing]” any grant, contract, or other benefit or privilege; “impos[ing] any penalty”; or “utiliz[ing] any criterion, method of administration, or site selection” that subjects protected individuals or entities to “any adverse treatment . . . on grounds prohibited under an applicable [conscience] statute.” 45 C.F.R. § 88.2. The definition then clarifies its application to certain actions—such as repeatedly asking a person about his or her conscience objections—that might be considered “discrimination.” *Id.*

This definition flows directly from the statutory text. The common definition of “discriminate” is “to make a difference in treatment or favor on a class or categorical basis in disregard of individual merit.” Webster’s 648; *see also* Black’s Law Dictionary (11th ed. 2019) (defining “discrimination” as, among other things,

“[d]ifferential treatment; esp., a failure to treat all persons equally when no reasonable distinction can be found between those favored and those not favored”). All categories of conduct the Rule describes fall squarely within this common meaning; the Rule merely makes explicit the various manifestations of the capacious term. And to the extent there could be any doubt that the Rule’s definition is coextensive with the statutes, it expressly applies only “as applicable to, and to the extent permitted by the applicable statute.” 45 C.F.R. § 88.2.

The district court faulted the definition not for the examples it includes, but for its purported failure to include an “undue hardship” defense or “reasonable accommodation” framework like those applied under Title VII. SA 50. As discussed *infra* in section II.A, the district court erred in concluding that the conscience statutes import Title VII defenses that the conscience provisions nowhere mention. And while the court concluded that the Rule also improperly places “limits on an employer’s ability to inquire about conscience objections” (SA 50), the relevant portion of the Rule generally describes conduct that will *not* be understood to constitute discrimination. Although questioning an employee about conscience-based beliefs without justification might naturally be considered adverse differential treatment, the Rule clarifies that a regulated entity “may require a protected entity to inform it of” relevant conscience objections “to the extent that there is a reasonable likelihood that the protected entity may be asked” to participate in those activities and

may do so after hiring, contracting, or awarding a grant or benefit and annually thereafter, or at other times if there is a “persuasive justification.” 45 C.F.R. § 88.2.

c. The Rule’s definition of “health care entity” similarly represents the best reading of the relevant statutes. For purposes of Coats-Snowe, the term is defined to include “an individual physician or other health care professional, including a pharmacist”; health-care personnel; certain health-professions training programs, participants, and applicants; hospitals; medical laboratories; pharmacies; biomedical or behavioral research entities; and “any other health care provider or health care facility.” 45 C.F.R. § 88.2. For purposes of Weldon and section 1553 of the ACA, the term includes all persons and entities included in the Coats-Snowe definition, as well as various insurance-related entities. *Id.*

These definitions logically interpret the statutes, which all define “health care entity” through a nonexhaustive list of constituent entities. Coats-Snowe provides that the term “*includes* an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions.” 42 U.S.C. § 238n(c)(2) (emphasis added). The Weldon Amendment and the ACA provide that the term “*includes* 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); Further Consolidated Appropriations Act, 2020, § 507(d)(2), 133 Stat. at 2607. This Court has recognized

that the term “includes” indicates that what follows is nonexhaustive. *Lyons v. Legal Aid Soc’y*, 68 F.3d 1512, 1515-16 (2d Cir. 1995); *see also Samantar v. Yousuf*, 560 U.S. 305, 317 n.10 (2010) (“The word ‘includes’ is usually a term of enlargement, and not of limitation.” (brackets omitted)). And all three statutes contain catch-all phrases: “a participant in a program of training in the health professions” in Coats-Snowe, and “other health care professional” and “any other kind of health care facility, organization, or plan” in the Weldon Amendment and ACA. 42 U.S.C. § 238n(c)(2); *id.* § 18113(b). The statutes thus plainly contemplate a broader group of health-care entities than those explicitly listed.

The district court did not grapple with the presence of the catch-all provisions, suggesting any addition to the examples listed in the statutes was “substantive.” SA 54. But the items listed in the Rule fall within the plain meaning of “health care entity” and are consistent with the nonexclusive items enumerated. For example, a pharmacist subjected to discrimination on grounds specified in Coats-Snowe would fall naturally within the scope of its prohibition as to “any health care entity.” 42 U.S.C. § 238n(a). Similarly, plan sponsors and third-party administrators of plans—which the Rule includes only with respect to the Weldon Amendment and the ACA, because those statutes protect health “plans,” *see* 84 Fed. Reg. at 23,195—play a crucial role in the delivery of health care by paying for or administering health coverage or health-care services and fall within the statutes’ catch-all provisions as “any other kind of health care facility, organization, or plan.” 42 U.S.C. § 238n(c)(2).

Representative Weldon’s indication that the Weldon Amendment applies to “health insurance providers” does not support the district court’s conclusion either. *See* SA 54 (quoting 150 Cong. Rec. H10,090 (Nov. 20, 2004)). Representative Weldon’s identification of one category of protected entity as part of a list of such entities does not impliedly limit the broad statutory text to foreclose protection of other entities involved in the provision of health coverage, like plan sponsors or third-party administrators. And in any case, “floor statements by individual legislators rank among the least illuminating forms of legislative history,” all the more so when read to ignore the plain text of the statute’s catch-all clause. *NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 943 (2017).

d. Finally, the Rule’s definition of “referral or refer for” is consistent with the term’s meaning in the Weldon and Coats-Snowe Amendments (and its analogous use in other conscience provisions). Coats-Snowe uses this undefined term on several occasions. For example, it prohibits a recipient from discriminating against an entity because it refuses to “provide *referrals* for [certain] training or . . . abortions,” 42 U.S.C. § 238n(a)(1) (emphasis added), or because the entity attends or attended a training program that does not “*refer* for training in the performance of induced abortions,” *id.* § 238n(a)(3) (emphasis added). The Weldon Amendment prohibits the funding of entities that discriminate against individuals or institutions on the basis that they do not “*refer* for abortions.” Further Consolidated Appropriations Act, 2020, § 507(d)(1), 133 Stat. at 2607(emphasis added).

The Rule defines “referral or refer for” to “include[] the provision of information in oral, written, or electronic form (including names, addresses, phone numbers, email or web addresses, directions, instructions, descriptions, or other information resources), where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure.” 45 C.F.R. § 88.2. The Rule’s definition tracks the ordinary meaning of the statutory text. As HHS explained, this definition “comports with dictionary definitions of the word ‘refer,’ such as the Merriam-Webster’s definition of ‘to send or direct for treatment, aid, information, or decision.’” 84 Fed. Reg. at 23,200 (quoting *Refer*, Merriam-Webster.com, <https://www.merriam-webster.com/dictionary/refer>); *see also* Webster’s 1907. Recognizing the terms’ potential breadth, the Rule provides a non-exhaustive list that “guide[s] the scope of the definition,” recognizing that the terms “take many forms and occur in many contexts.” 84 Fed. Reg. at 23,201. But it makes clear that a referral requires both “the provision of information” and that the “purpose or reasonably foreseeable outcome of provision of the information is to assist a person” in obtaining or performing a particular service or activity. Together, these two requirements ensure that information provided is actually sending or directing a person for the particular activity.

The statutes’ structure also supports HHS’s definition. For example, Coats-Snowe protects not only a health-care entity that declines to refer a patient to an

abortion provider, but also an entity that declines to refer “for” abortions generally. *See, e.g.*, 42 U.S.C. § 238n(a)(1). That language, as well as its use in referencing referrals for abortion-related training, suggests that Congress did not intend to limit the statutory protection to conscience objections associated with providing a particular referral document, but rather protected conscience objections to sending or directing a person for abortions or training in a more general sense. The Rule’s definition thus follows from the statutory text and structure, and the statutes need not “make clear” such a result (SA 55) for that natural interpretation to be recognized.

II. The District Court’s Other Criticisms Of The Rule Lack Merit

A. The Rule Is Not Contrary To Law

The district court erroneously held (SA 69-78) that the Rule is contrary to Title VII and EMTALA. The contrived conflicts rest on atextual readings of the relationship between these statutes and the conscience statutes.

1. The Rule Is Consistent With Title VII

Title VII prohibits discrimination based on “religion.” *See, e.g.*, 42 U.S.C. § 2000e-2(a)(1)-(2). As amended in 1972, it defines “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” the religious observance or practice “without undue hardship on the conduct of the employer’s business.” *Id.* § 2000e(j).

The district court held that the Rule conflicts with Title VII because it does not include Title VII's reasonable-accommodation or undue-hardship defenses. SA 71-73. But Title VII does not require that its defenses be applied in this context, and the later-enacted conscience statutes neither include those defenses nor incorporate Title VII's definition of "religion" in which those defenses are found. *See* 84 Fed. Reg. at 23,191.

The district court nevertheless held that Title VII's defenses must be read into the conscience statutes because those statutes do not expressly abrogate them. *See* SA 72. But the conscience statutes are entirely distinct statutes from Title VII. If Congress intended to provide Title VII-like defenses, then it would have placed such defenses in the conscience statutes themselves. Congress certainly need not have expressly "abrogated" defenses that do not apply in the first place, and the district court identified no authority for applying such a nonsensical clear-statement rule.

The district court also faulted HHS for failing to identify evidence that Congress intended not to provide those defenses. *See* SA 72. There is no need, however, to identify legislative history confirming the meaning of a statute's plain text. *See, e.g., Bourjaily v. United States*, 483 U.S. 171, 178 (1987). Moreover, the district court's atextual speculation about congressional intent is flawed on its own terms. It is entirely plausible that Congress would have intended to protect conscience objections without providing the undue-hardship and reasonable-accommodation defenses Title VII applies to the general gamut of religious discrimination claims. As

HHS explained, Title VII’s “comprehensive regulation of American employers applies in far more contexts, and is more vast, variable, and potentially burdensome (thus warranting of greater exceptions) than the more targeted conscience statutes that are the subject of this rule, which are health care specific and often procedure specific.” 84 Fed. Reg. at 23,191.

In addition, the conscience statutes were enacted *after* Congress added Title VII’s undue-hardship and reasonable-accommodation defenses. Thus, Congress would have known how to provide those defenses had it wished to. *See* 84 Fed. Reg. 23,191. The timing confirms that Congress deliberately chose *not* to include the Title VII defenses in this context. *See DHS v. MacLean*, 135 S. Ct. 913, 920-21 (2015) (language in other statutes showed that Congress “knew how to distinguish between regulations that had the force and effect of law and those that did not, but chose not to do so”).

2. The Rule Is Consistent With EMTALA

EMTALA provides that if any individual comes to a hospital electing to operate an emergency room and the hospital determines that the individual has an emergency medical condition, the hospital must provide either (A) “within the staff and facilities available at the hospital, for such further medical examination and such treatment as may be required to stabilize the medical condition,” or (B) for “transfer of the individual to another medical facility” as permitted by EMTALA. 42 U.S.C. § 1395dd(b)(1).

The district court (SA 76-77) held that the Rule facially conflicts with EMTALA because an employer honoring a protected conscience objection might be unable to provide emergency services EMTALA requires. That concern does not demonstrate a “facial conflict” (SA 77) between the Rule and EMTALA, however, but a challenge to how the Rule would apply in particular circumstances.

“The possibility that [a] rule, in uncommon particular applications,” might be subject to as-applied challenge “does not warrant judicial condemnation of the rule in its entirety.” *EPA v. Emé Homer City Generation, L.P.*, 572 U.S. 489, 524 (2014). That principle has particular force here, since HHS emphasized in 2008 that “[i]t is not aware of any instance where a facility required to provide emergency care under EMTALA was unable to do so because its entire staff objected to the service on religious or moral grounds.” 73 Fed. Reg. at 78,087.

In any event, even if the hypothetical scenario were ever to arise, no conflict would exist. It is well established that courts must “interpret Congress’s statutes as a harmonious whole” where possible. *Epic Sys. Corp. v. Lewis*, 138 S. Ct. 1612, 1619 (2018). To the extent a situation arises in which these statutes must be harmonized, EMTALA is properly read not to permit or require a hospital to override conscience objections to provide medical treatment.

EMTALA requires emergency medical care only “within the staff and facilities *available* at the hospital.” 42 U.S.C. § 1395dd(b)(1) (emphasis added). Statutorily protected conscience objections by hospital employees can affect what staff are

“available at the hospital” under most of the conscience statutes. (The exception is the ACA, which specifies that its conscience protections should not “be construed to relieve any healthcare provider from providing emergency services as required by” EMTALA, 42 U.S.C. § 18023(d), but that just underscores that Congress did *not* include any such exemption in the other conscience provisions. *See MacLean*, 135 S. Ct. at 920-21.) If no staff are available because every staff member has a valid statutory conscience objection to a particular emergency treatment (an extreme hypothetical that, as noted above, HHS has indicated it was unaware had ever occurred), there is no violation of EMTALA, and no conflict between EMTALA and the Rule. *Cf., e.g., Arrington v. Wong*, 237 F.3d 1066, 1073 (9th Cir. 2001) (hospital may demonstrate compliance with EMTALA by showing, *inter alia*, that there was “insufficient emergency staff available”); *see also* 42 C.F.R. § 489.24(d) (requiring treatment “[w]ithin the capabilities of the staff and facilities at the hospital”).

Neither of the cases the district court cited (SA 74) addressed the conscience statutes or any similar situation involving a statutory right. *See In re Baby K*, 16 F.3d 590, 597 (4th Cir. 1994) (no EMTALA exception for treatment physicians deem medically or ethically inappropriate); *Burditt v. HHS*, 934 F.2d 1362, 1375 (5th Cir. 1991) (no EMTALA exception for services not rendered because of good-faith objections).

The district court (SA 75) also speculated that the Rule’s provisions addressing employer inquiries about conscience objections might prevent hospitals from

planning for conscience-related staff shortages. That concern is unfounded. While an employer generally may request an employee to disclose objections to assisting in the performance of health-care services only after hiring and annually thereafter, an employer also may make such requests when there is “a persuasive justification.” 45 C.F.R. § 88.2. That language, which the court failed to mention, gives employers additional flexibility to plan around staff conscience objections in potential emergencies.

The district court also expressed concern that a hospital might lack funds to ensure a “conscience-cleared platoon” is available for every emergency. SA 77. As noted, however, the district court describes a response to a hypothetical situation not known ever to have occurred, and EMTALA in any case requires only the provision of services “within the staff and facilities available at the hospital.” 42 U.S.C. § 1395dd(b)(1)(A).

Finally, the court erred by relying on the statements of individual legislators to conclude that the conscience statutes do not apply in medical emergencies. *See* SA 75. Again, such statements “rank among the least illuminating forms of legislative history,” *SW Gen.*, 137 S. Ct. at 943, and the statements here do not support overriding the congressional choices reflected in the text of the conscience statutes (which do not, other than the ACA, exempt emergency medical services) and EMTALA (which imposes requirements limited to the staff and facilities available).

B. The Rule Is Not Arbitrary And Capricious

The district court likewise erred in holding the Rule arbitrary and capricious under the APA. 5 U.S.C. § 706(2)(A). That standard is “deferential” and “narrow”; courts are to “determine only whether the Secretary examined the relevant data and articulated a satisfactory explanation for his decision, including a rational connection between the facts found and the choice made.” *Department of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019) (quotation marks omitted). A court “may not substitute [its] judgment for that of the Secretary.” *Id.* at 2569. Agency action satisfies the arbitrary-and-capricious standard so long as it is “within the bounds of reasoned decisionmaking.” *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 105 (1983).

1. The Rule easily satisfies this deferential standard. The Supreme Court has made clear that “an agency may justify its policy choice by explaining why that policy is more consistent with statutory language than alternative policies.” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) (quotation marks omitted). The district court’s arbitrary-and-capricious analysis focused on the Rule’s definitional provisions, which clarify and provide notice of HHS’s interpretations of various statutory provisions. As explained in Section I.C, *supra*, the definitions represent the best reading of the conscience statutes, which alone justifies their promulgation: an agency does not act arbitrarily or capriciously in adopting the best reading of a statute. Such a reading imposes no new obligations, by definition, moreover, and announcing it through an interpretive rule creates significant public-notice benefits. *Cf. Catskill*, 846

F.3d at 523 (“[A]gencies are not obligated to conduct detailed fact-finding or cost-benefit analyses when interpreting a statute.”).

Even if more could be required, HHS considered and responded to hundreds of thousands of public comments and conducted an extensive review of publicly available literature, surveys, and other information. Based on that analysis, HHS concluded that there was a need to increase “knowledge of, compliance with, and enforcement of, Federal conscience and anti-discrimination laws.” 84 Fed. Reg. at 23,175. Various forms of evidence, for example, indicated that many health-care providers had faced pressure or discrimination because of their beliefs, *id.* at 23,175-78, and HHS found significant public “confusion over what is and is not required” under the conscience statutes. *Id.* at 23,175. HHS thus determined that the Rule was warranted “to educate protected entities and covered entities as to their legal rights and obligations; to encourage individuals and organizations with religious beliefs or moral convictions to enter, or remain in, the health care industry; and to prevent others from being dissuaded from filing complaints.” *Id.* at 23,179.

The district court’s criticisms of the Rule disregard its interpretive nature. The court held the Rule arbitrary and capricious because, for example, the court believed HHS had miscounted recent complaints to OCR alleging violations of the conscience statutes when it noted a recent “significant increase.” 84 Fed. Reg. at 23,175; SA 80-85. The court did not explain, however, why an agency should have to compile evidence of past statutory violations—much less evidence of a particular *number* of

violations—before promulgating a rule clarifying the scope of statutes the agency implements and the procedures for enforcing them. Nor did the court explain why an agency must compile a record of complaints specifically “indicating problems with its capacity to enforce” a statute, SA 85-86, before clarifying its enforcement procedures. HHS likewise was not required to compile “evidence substantiating a need” for the Rule’s definitional provisions, such as complaints by particular individuals within the definitions’ scope, SA 87, to offer the best reading of statutory terms.

2. The district court’s conclusions are also erroneous on their own terms. The court erred, for example, in concluding that HHS miscounted recent complaints to OCR alleging conscience violations—an issue that the court thought was alone “enough to render the Rule arbitrary and capricious.” SA 89. The court appeared to focus on HHS’s statement, at the end of a long list of reasons for the Rule’s promulgation, that OCR had received “343 complaints alleging conscience violations” during the 2018 fiscal year, compared to 34 complaints between November 2016 and January 2018. 84 Fed. Reg. at 23,229; *see also id.* at 23,245. The court concluded that most of the complaints alleged conduct it thought was outside the scope of the relevant conscience statutes and declared that the complaints it viewed as relevant would not reflect the “significant increase” HHS had described. SA 81-82; *see* 84 Fed. Reg. at 23,175.

That analysis was flawed multiple times over. As an initial matter, HHS made clear that the complaints were but “one of the many metrics used to demonstrate the

importance of th[e] rule”: numerous comments in this rulemaking and earlier, for example, reported similar concerns. 84 Fed. Reg. at 23,175, 23,229. HHS also noted a recent increase in state and local laws and policies that allegedly violated federal conscience statutes. *See id.* at 23,176-78. HHS further identified evidence of confusion regarding the statutes’ scope, including confusion created by prior OCR guidance. *See id.* at 23,178-79. And HHS noted that the Rule would provide an opportunity to address conscience statutes not covered in previous Rules. *Id.* at 23,179. Finally, even the “20 or 21 complaints” that the district court thought “implicated the Conscience Provisions” (SA 82) would reflect a troubling number of alleged violations of important statutory protections over a short period, even putting aside the Rule’s many other justifications.

The district court relatedly criticized HHS for failing to compile a record of complaints “indicating problems with its capacity to enforce the Conscience Provisions,” expressing the belief that HHS had not investigated many complaints in the record. *See* SA 85-86. But if the court was unimpressed by HHS’s enforcement track record, that counsels in favor of clarifying the enforcement procedures, as HHS did. *Cf.* 84 Fed. Reg. at 23,178-79 (expressing concern about OCR’s prior approach to enforcement); *id.* at 23,183 (noting belief that some laws had “never been enforced” because HHS “has devoted no meaningful attention to those laws, has not conducted outreach to the public on them, and has not adopted regulations with enforcement procedures for them.”). Regulations related to other civil rights statutes

OCR enforces likewise “provide regulated entities notice of the enforcement tools available to HHS and the type of remedies HHS may seek.” *Id.* at 23,229.

3. The district court also believed HHS inadequately addressed the 2011 Rule’s findings that the 2008 Rule had created confusion and might “negatively affect the ability of patients to access care if interpreted broadly.” SA 91. But HHS explained that the 2011 Rule had itself “created confusion over what is and is not required under Federal conscience and anti-discrimination laws.” 84 Fed. Reg. at 23,175; *see also id.* at 23,254 (explaining that HHS considered maintaining the 2011 Rule’s “status quo” but concluded the Rule was necessary). Moreover, the district court did not find that the present Rule creates the “confusion” that the 2011 Rule identified about whether “federal provider conscience protections authorized refusal to treat certain kinds of patients rather than to perform certain medical procedures” and whether “the term ‘abortion’ included contraception,” 76 Fed. Reg. at 9973; *see* SA 84 n.49 (recognizing that the concern about contraception “has not been expressed in connection with the 2019 Rule”). HHS also addressed access-to-care issues in detail, acknowledging arguments that the Rule would diminish such access and explaining why it reached a contrary conclusion, including a prediction that the Rule could *increase* access by encouraging more health-care professionals to enter or remain in the field. *See, e.g.*, 84 Fed. Reg. at 23,181, 23,246-47.

HHS’s explanation easily satisfies APA requirements. Even where an agency is exercising policy discretion to change its statutory interpretation in a legislative rule,

the agency need only “display awareness that it is changing position,” “show that there are good reasons for the new policy,” and consider any “serious reliance interests.” *Encino Motorcars*, 136 S. Ct. at 2126. Although that standard should not apply to a mere interpretive rule, HHS displayed awareness that it was newly providing definitions of relevant terms and explained its good reasons for those definitions. As HHS explained, the Rule’s definitional provisions reflect the best reading of the statutory text, and Congress weighed the relevant policy considerations, including potential effects on access to care, when it enacted the statutes. *See* 84 Fed. Reg. at 23,182 (“[T]his final rule provides for the enforcement of protections established by the people’s representatives in Congress; the Department has no authority to override Congress’s balancing of the protections.”).

A regulated entity has no legitimate reliance interest, moreover, in an erroneous statutory interpretation. *See* SA 98-103. This is not a “policy” change of the sort considered in *Encino Motorcars*, 136 S. Ct. at 2126. But even if it were, “an agency may justify its policy choice by explaining why that policy is more consistent with statutory language than alternative policies.” *Id.* at 2127 (quotation marks omitted). That is precisely what HHS did, explaining at length why its interpretations reflect the best reading of the conscience statutes. *See* 84 Fed. Reg. at 23,186-204.

4. The district court also held that, in promulgating the Rule, HHS “entirely failed to consider an important aspect of the problem”—namely, “how the Rule would impact health care delivery in emergency situations” and the Rule’s “departure

from the Title VII reasonable accommodation/undue hardship framework.” SA 103-09 (quotation marks omitted). As explained in Section II.A *supra*, the Rule’s interpretation of the conscience statutes does not conflict with Title VII or EMTALA, and an agency need not give detailed consideration to an illusory conflict. And in any event, HHS addressed at length the Rule’s relationship to Title VII and its application in emergencies. *See* 84 Fed. Reg. at 23,183, 23,188, 23,191. Indeed, while the district court faulted HHS’s consideration of one hypothetical relating to the Rule’s application to an ambulance driver (SA 105), HHS explained both the particular reasons why that hypothetical may be unlikely to occur and why driving a person to a procedure could, depending on the facts and circumstances, be considered assistance in the performance of that procedure as a general matter given the scope of the term Congress chose. *See* 84 Fed. Reg. at 23,188.

C. The Rule Satisfies The APA’s Notice-And-Comment Requirement

An agency engaging in notice-and-comment rulemaking must provide a notice of proposed rulemaking with “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). Pursuant to that rule, a final rule must be “a logical outgrowth of the rule proposed.” *Id.*

The district court held (SA 110-15) that the Rule’s “discrimination” definition did not logically flow from the NPRM. But the Rule’s definitional provisions are

interpretive rather than substantive. *See supra* section I.B. The logical-outgrowth requirement is part of the APA's notice-and-comment requirement, which does not apply to an "interpretative rule[]." 5 U.S.C. § 553(b)(3)(A).

Regardless, this argument is meritless. The district court held (SA 111-12) that the NPRM gave no hint that HHS was considering making Title VII's reasonable-accommodation and undue-hardship defenses unavailable to employers. It would have been evident to all regulated parties, however, that the "discrimination" definition proposed by the NPRM did not include *any* employer defenses. Indeed, HHS in fact received and responded to comments objecting to the absence of employer defenses and the proposed rule's alleged inconsistency with Title VII. 84 Fed. Reg. at 23,189-92; *see, e.g.*, JA 1030-31, 1201-02; *Miami-Dade Cty. v. EPA*, 529 F.3d 1049, 1059 (11th Cir. 2008) (noting that "comments may be adduced as evidence of the adequacy of notice").

The district court also wrongly concluded that the NPRM failed to anticipate three additions the Rule made to the "discrimination" definition. *See* SA 110-11. To begin, plaintiffs lack standing to challenge the additions, which give employers *more* protections than the proposed rule did. For the same reason, plaintiffs' logical-outgrowth objection fails under the APA because plaintiffs cannot show the adoption of these protections after notice and comment caused them any prejudice. *See American Coke & Coal Chem. v. EPA*, 452 F.3d 930, 939 (D.C. Cir. 2006) (noting

plaintiff must demonstrate that agency's violation of notice-and-comment procedures "has resulted in 'prejudice'").

All three provisions were added to *accommodate* employers' interests, not impair them. Paragraph 4 provides that accommodating a conscientious objector is not itself prohibited discrimination where it is "effective" to eliminate a conscience objection voluntarily. 45 C.F.R. § 88.2. Paragraph 5 allows employers to inquire about conscience objections after hiring or the awarding of a contract or grant; annually thereafter; and otherwise when "supported by a persuasive justification." *Id.* Paragraph 6 clarifies that employing alternate staff or methods to provide objected-to services generally does not constitute prohibited discrimination. *Id.* HHS added these provisions in response to comments expressing concern that the proposed rule might preclude an employer from arranging for services an objecting employee or entity cannot conscientiously provide, *see* 84 Fed. Reg. at 23,191, and the limitations on the accommodation provided by paragraph 5 logically flow from the proposed "discrimination" definition, which included broad prohibitions on "intimidating or retaliatory action," "any adverse effect," and "[t]reat[ing] an individual differently from others in determining whether he satisfies any" admission requirement, 83 Fed. Reg. at 3892.

Plaintiffs had "ample opportunity to make all of [their] arguments" in commenting on the proposed rule, and requiring HHS to adopt exactly its proposed position, rather than a form of the protections employers requested in comments,

“would undermine the ‘purpose of notice and comment—to allow an agency to reconsider, and sometimes change, its proposal based on the comments of affected persons.’” *Miami-Dade Cty.*, 529 F.3d at 1062 (quotation marks omitted).

D. The Rule Is Constitutional

1. The Rule Is Consistent With The Separation Of Powers

The district court’s holding that the Rule violates the constitutional separation of powers is expressly derivative of its conclusion that the Rule exceeds HHS’s statutory authority, *see* SA 17, and thus fails twice over. *First*, the district court was mistaken to hold that the Rule’s enforcement provisions exceed HHS’s authority. *See supra* section I.A. *Second*, in any event, to violate the separation of powers, agency action must be “not only unauthorized but also intrusive on power constitutionally committed to a coordinate branch.” *New York v. Department of Justice*, 951 F.3d 84, 101 (2d Cir. 2020); *see also Dalton v. Specter*, 511 U.S. 462, 472 (1994) (noting that the Supreme Court’s cases “do not support the proposition that every action by the President, or by another executive official, in excess of his statutory authority is ipso facto in violation of the Constitution”); *id.* at 472 n.6 (noting observation that cases in which the only source of authority is concededly statutory raise no “constitutional questions whatever” but “only issues of statutory interpretation”). Here, the district court did not and could not identify any intrusion separate and apart from the alleged lack of statutory authority. In short, the Rule is not “unauthorized,” much less

“intrusive on power constitutionally committed to a coordinate branch.” *New York*, 951 F.3d at 101.

2. Plaintiffs’ Spending Clause Challenge Is Unripe And Meritless

The district court also erred in concluding that plaintiffs’ Spending Clause challenge is ripe and that the Rule violates that Clause.

a. In determining whether a claim is ripe, this Court considers “(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). These principles “bear heightened importance” when “the potentially unripe question presented for review is a constitutional question.” *Id.* at 113 n.13.

The district court held that the Rule violates the Spending Clause principally because it authorizes HHS to “terminate all of a recipient’s HHS funding” as one potential remedy for noncompliance. SA 115. The challenge is therefore premised not on an actual enforcement action against any plaintiff, but on a hypothetical situation involving a chain of speculative contingencies, in which (1) a State recipient of HHS funds subject to a conscience statute violates the statute; (2) the incident comes to HHS’s attention; (3) HHS determines it constitutes a violation implicating all funding streams the recipient receives; (4) and, notwithstanding the preamble’s recognition that termination of funds for violations has been rare, the Rule’s expressed preference for resolving matters informally, and the many other avenues for

achieving compliance, HHS decides to enforce the statute by terminating all of the State's conditioned funds. *See* SA 117; *see also* 45 C.F.R. § 88.7(i)(2)-(3); 84 Fed. Reg. at 23,223. This claim is not ripe because it rests upon “contingent future events that may not occur as anticipated, or indeed may not occur at all.” *Texas v. United States*, 523 U.S. 296, 300 (1998). Courts have dismissed previous challenges to the Weldon Amendment on ripeness or similar standing grounds, *see NFPRHA v. Gonzales*, 468 F.3d 826, 829-31 (D.C. Cir. 2006); *California v. United States*, No. 05-00328, 2008 WL 744840, at *3 (N.D. Cal. Mar. 18, 2008), and contrary to the district court's efforts to distinguish these cases (SA 122 n.69), they involved the same purported consequences and risks asserted here.

To determine fitness for judicial review, this Court also “must examine, among other factors, whether consideration of the underlying legal issues would necessarily be facilitated if they were raised in the context of a specific attempt to apply and/or enforce the regulations.” *Nutritional Health All. v. Shalala*, 144 F.3d 220, 225 (2d Cir. 1998) (brackets and quotation marks omitted); *see also Marchi v. Board of Coop. Educ. Servs. of Albany*, 173 F.3d 469, 478 (2d Cir. 1999) (claim unripe where court “would be forced to guess at how [a school] might apply [its] directive and to pronounce on the validity of numerous possible applications of the directive, all highly fact-specific and, as of yet, hypothetical”). A concrete enforcement action would facilitate this Court's consideration of the Spending Clause challenge, which depends, at the very least, on the nature of the violation prompting any hypothetical enforcement action and HHS's

chosen remedy. The district court's comparison to *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), is unavailing—unlike in that case, the Spending Clause challenge here is not purely legal, and the Rule itself makes clear it would arise concretely only after future administrative proceedings that have not been permitted to play out. *See Connecticut*, 612 F.3d at 114-15 (distinguishing *Abbott Laboratories* in these circumstances).

Nor can plaintiffs demonstrate any undue hardship from delaying review unless and until their funds are actually terminated for a violation (or HHS has indeed even given any indication it intends to pursue the remedy feared). If States accept funds conditioned by the conscience statutes and then do not comply with those conditions, the statutes themselves put the States' funding at risk. *See supra* section I.A. The Rule does not alter that, and setting it aside will not eliminate that risk. Moreover, as a court has recognized in a past challenge to the Weldon Amendment, in the event a concrete dispute does arise, administrative procedures give plaintiffs a route to seek resolution with the agency and judicial resolution afterward if necessary. *See California*, 2008 WL 744840, at *6; *cf. Connecticut*, 612 F.3d at 115 (citing availability of administrative remedies in considering hardship prong). Plaintiffs have thus not demonstrated that any “irremediable adverse consequences flow from requiring a later challenge.” *Toilet Goods Ass'n, Inc. v. Gardner*, 387 U.S. 158, 164 (1967).

b. On the merits, the district court held that the Rule violated two constraints on the federal government's power under the Spending Clause. First, it concluded

that the Rule imposed ambiguous and retroactive conditions on States due to the purportedly expanded enforcement authority reflected and unforeseen nature of the Rule's definitional provisions. Second, it concluded that the Rule's provision permitting termination of all of a recipient's HHS funds rendered it unconstitutionally coercive. Neither conclusion withstands scrutiny.

Congress has "broad" authority under the Spending Clause to "set the terms on which it disburses federal money to the States." *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006). The Rule does not run afoul of any constitutional limits on Congress's spending power.⁵

i. The Rule complies with the requirement that, if Congress conditions States' receipt of federal funds, it "must do so unambiguously" to "enabl[e] the States to exercise their choice knowingly, cognizant of the consequences of their participation." *South Dakota v. Dole*, 483 U.S. 203, 207 (1987) (quotation marks omitted). Plaintiffs do not contend that the conscience statutes themselves violate this requirement. Instead, the district court concluded that the Rule operates retroactively to impose unforeseen conditions on States after receipt of funds. SA 124-28; *see* SA 124 n.70 ("An agency which Congress has tasked with implementing a statute that imposes spending

⁵ The district court recognized that the Rule complied with two such limits, as the conditions imposed by the conscience statutes reflected in the Rule are not "unrelated to the federal interest in particular national projects or programs" and do not "induce the States to engage in activities that would themselves be unconstitutional." SA 132 (quotation marks omitted).

conditions is also subject to the Clause’s restrictions.”). But the Rule has no retroactive effect on funds received before the Rule’s effective date. The assurance and certification requirements, for example, are expressly tied to applications or reapplications for *new* funds. 45 C.F.R. § 88.4(b).

In addition, the State plaintiffs have long known their receipt of HHS funds is conditioned on compliance with applicable conscience statutes. *See* Mem. of Law in Supp. of Pls.’ Cross-Motion for Summ. J. at 39 (Sept. 25, 2019) (Dkt. No. 182) (disclaiming any challenge to the conscience statutes and indicating State plaintiffs “have complied with [those provisions] for years”). As already explained, the Rule imposes no new substantive obligations on funding recipients, simply setting forth HHS’s understanding of preexisting statutory requirements. And the Rule did not change HHS’s authority to terminate funding where a recipient refuses to comply with statutory funding conditions (much less retroactively). *See supra* section I.A. Both before and after the Rule’s promulgation, HHS may respond to a conscience violation by cutting off the funding stream implicated where appropriate, pursuant to authority arising from the statutes themselves. Finally, to the extent the district court relied on *NFIB v. Sebelius*, 567 U.S. 519 (2012), for the proposition that conditions may be retroactive as applied to new funds from an existing program, as discussed *infra*, the conditions here, which even on plaintiffs’ view represent different interpretations of conditions they have long known applied, are nowhere near the “transformation” described in the controlling opinion in *NFIB*. *Id.* at 584 (opinion of Roberts, C.J.).

The Rule also does not provide “uncertain ground rules for compliance” that might render it ambiguous for Spending Clause purposes. SA 126. “[I]n establishing federal grant programs, Congress cannot always prospectively resolve every possible ambiguity concerning particular applications of the [program’s statutory] requirements.” *New York*, 951 F.3d at 110 (quotation marks omitted; brackets in original). As a result, the Supreme Court “has upheld an administering agency’s clarifying interpretations, and even its violation determinations, as long they were grounded in ‘statutory provisions, regulations, and other guidelines provided by the Department’ at the time of the grant.” *Id.* (quoting *Bennett v. Kentucky Dep’t of Educ.*, 470 U.S. 656, 670-71 (1985)).

As explained, the Rule simply provides guidance about statutory requirements that plaintiffs have not argued are themselves ambiguous. Both the statutes and the Rule easily satisfy applicable standards. *See, e.g., Davis v. Monroe Cty. Bd. of Educ.*, 526 U.S. 629, 650 (1999) (concluding that there is no Spending Clause claim of insufficient notice “where the statute made clear that there were some conditions placed on receipt of federal funds” and that “Congress need not ‘specifically identify and proscribe’ each condition in the legislation) (quotation marks and brackets omitted).

ii. Nor does the Rule run afoul of the Supreme Court’s recognition that the financial inducement offered by Congress through conditioned funds could perhaps be “so coercive as to pass the point at which ‘pressure turns into compulsion.’” *Dole*, 483 U.S. at 211 (quotation marks omitted). As already discussed, the Rule did not

change HHS’s ability to terminate funding where a funding recipient violates applicable statutory conditions. The relevant enforcement provision simply states that HHS may terminate funding “pursuant to” preexisting “statutes and regulations” governing the administration of contracts, grants, and CMS arrangements. 45 C.F.R. § 88.7(i)(3). And the preamble makes clear that “[t]he only funding streams threatened by a violation of the Federal conscience and anti-discrimination laws are the funding streams that such statutes directly implicate” and HHS cannot terminate funding for such violations “unless Congress has applied that law to that funding.” 84 Fed. Reg. at 23,223. The Rule thus puts no more funding at risk than the unchallenged conscience statutes do.

Relying on *NFIB*, the district court held that the Rule was unconstitutionally coercive because a State violating a conscience statute might lose all of its funding. But the district court misread the Rule, under which the violation of a conscience statute gives rise, at most, to termination of the funding implicated by the violation, not all of a recipient’s HHS funding regardless of source. The Rule operates, moreover, in a fundamentally different way from the Medicaid expansion at issue in *NFIB*—the only controlling precedent that has *ever* found a federal spending condition unconstitutionally coercive. The Rule makes clear that termination of funding is not the default remedy; HHS has a variety of enforcement options and will always begin by trying to resolve informally a potential violation. *See* 45 C.F.R. § 88.7(i)(2)-(3). In *NFIB*, by contrast, the challenged provision of the Medicaid

expansion gave States a binary choice to accept a new program or sacrifice all funding under an existing program (save only for HHS’s “discretion” to limit termination to the categories or parts of the State plan affected). *See* 567 U.S. at 579-80; *see also* 42 U.S.C. § 1396c. There was no question that the magnitude of the loss of funds threatened was calculated to induce States to participate in the Medicaid expansion.

Moreover, because the threat of funding withdrawal is limited to funds associated with the particular condition a State violates, this is not a situation in which a State’s failure to create a new program threatens it with loss of funds associated with a distinct, existing program—which was critical to *NFIB*’s novel coercion holding. *See NFIB*, 567 U.S. at 583 (concluding that the Medicaid expansion “accomplishes a shift in kind, not merely degree,” transforming it into a distinct program from the existing Medicaid program). The Rule provides for enforcement of unchallenged conscience provisions that have been in place for years if not decades. *NFIB*’s reasoning relating to the efforts to induce States to participate in a “new health care program,” *id.* at 584, thus has no bearing here.

III. The District Court Erroneously Vacated The Rule In Its Entirety And Against All Persons

A. Any Relief Should be Limited to Plaintiffs

Under Article III of the Constitution, “[s]tanding is not dispensed in gross,” and “a plaintiff must demonstrate standing” for “each form of relief that is sought.” *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017) (quotation marks

omitted). It follows that any remedy ordered by a federal court “must be limited to the inadequacy that produced the injury in fact that the plaintiff has established.” *Gill v. Whitford*, 138 S. Ct. 1916, 1931 (2018). Equitable principles likewise require that any relief “be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs.” *Madsen v. Women’s Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (quotation marks omitted). Under these settled principles, a court may order a remedy that applies beyond the parties only where necessary to provide full relief to the plaintiff. *See Gill*, 138 S. Ct. at 1930; *Madsen*, 512 U.S. at 765.

1. The district court violated these precepts by vacating the Rule as to all potential parties instead of holding that it could not be enforced with respect to the particular plaintiffs here. Neither plaintiffs nor the court made, or could make, any showing that such a sweeping remedy is necessary to provide plaintiffs with full relief. The court instead stated that vacating the Rule only as to plaintiffs “would ultimately require a profusion of actions to assure that such a Rule was never applied,” SA 144, but that is how standing principles—which generally limit plaintiffs to seeking redress for *their own* injuries, *see Warth v. Seldin*, 422 U.S. 490, 499 (1975)—work. The court’s reasoning also would render the principles announced in *Gill* and *Madsen* inapplicable even to the facts of those cases, which also involved challenges to statutes, rules, and other government action. *See Gill*, 138 S. Ct. at 1923 (state legislative redistricting statute); *Madsen*, 512 U.S. at 759 (state court injunctive order); *see also Lewis v. Casey*, 518 U.S. 343, 346-47 (1996) (state prison policies and rules).

Even apart from Article III and equitable principles, the district court's reasoning contravenes historical and ordinary practice, under which legal challenges to government policies percolate among the lower courts before being resolved by the Supreme Court, *see Trump v. Hawaii*, 138 S. Ct. 2392, 2425 (2018) (Thomas, J., concurring); *DHS v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring); the government is not immediately bound by the first case it loses, *see United States v. Mendoza*, 464 U.S. 154, 160 (1984); and the way to obtain relief for every potential plaintiff without creating a profusion of lawsuits is to file a class action, in which plaintiffs are bound to a favorable or unfavorable judgment, *see Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (before certifying a nationwide class, courts should “ensure that nationwide relief is indeed appropriate” and “would not improperly interfere with the litigation of similar issues in other judicial districts”). Nationwide relief, by contrast, is an inequitable one-way class action, as Justice Gorsuch recognized in *DHS v. New York*, 140 S. Ct. at 601.

Indeed, nationwide relief would be particularly inappropriate here given that the Ninth Circuit is currently considering similar challenges to the Rule. *See* Nos. 20-15398, 20-15399, 20-35044 (9th Cir.). If the government prevails in the Ninth Circuit, nationwide relief here would render that victory meaningless as a practical matter, and also may preclude courts in other jurisdictions from adjudicating challenges brought by other plaintiffs. *See California v. Azar*, 911 F.3d 558, 583 (9th Cir. 2018) (noting that

the “detrimental consequences of a nationwide injunction” include adverse effects on “the equities of non-parties who are deprived the right to litigate in other forums”).

Finally, “universal injunctions” also “tend to force judges into making rushed, high-stakes, low-information decisions,” “sow chaos for litigants, the government, courts, and all those affected by these conflicting decisions,” and provide a “nearly boundless opportunity [for plaintiffs] to shop for a friendly forum to secure a win nationwide.” *DHS v. New York*, 140 S. Ct. at 600 (Gorsuch, J., concurring). For all these reasons, the district court erred by vacating the Rule as to all potential parties, rather than rendering it inapplicable to plaintiffs herein.

2. Despite all this, the district court (SA 145) emphasized that this is an APA claim, but the APA neither requires nor permits relief extending beyond what is necessary to redress plaintiffs’ own injuries. Although the APA generally instructs that unlawful agency action “shall” be “set aside,” 5 U.S.C. § 706(2), that language does not say that the action shall be set aside *facially*, rather than only *as applied* to plaintiffs. And the latter interpretation is further dictated by the principle that a court “do[es] not lightly assume that Congress has intended to depart from established principles” regarding equitable remedial practice. *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 313 (1982).

Indeed, in *Hecht Co. v. Bowles*, 321 U.S. 321, 328-30 (1944), the Supreme Court held that not even a provision directing that an injunction “shall be granted” with respect to a threatened or completed violation of a particular statute displaces

traditional equitable principles. Congress is presumed to have been aware of *Hecht Co.* when it enacted the APA two years later, and to have incorporated that understanding of the law into the APA. *See generally* A. Scalia & B. Garner, *Reading Law: The Interpretation of Legal Texts* 322-26 (2012) (addressing the “prior construction” canon).

In addition, the APA expressly states that APA’s statutory right of review does not affect “the power or duty of the court to . . . deny relief on any . . . appropriate legal or equitable ground,” 5 U.S.C. § 702(1), and that absent a special review statute, “[t]he form of proceeding for judicial review” under the APA is the traditional “form[s] of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction,” *id.* § 703. Those provisions confirm that “equitable defenses may be interposed” in an APA case. *Abbott Labs.*, 387 U.S. at 155.

The district court’s reliance on cases recognizing vacatur as the ordinary remedy for APA violations (SA 138-39) also is misplaced. None of those cases addressed the fact that Article III and equity principles generally require limiting relief to the plaintiff, and the reasons (stated above) why that rule should apply in APA suits as well as other federal actions. *See, e.g., Lewis*, 518 U.S. at 352 n.2 (noting that “the existence of unaddressed jurisdictional defects has no precedential effect”). And cases that have grappled with whether the APA requires nationwide vacatur have properly concluded that it does not. *See Los Angeles Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664-65 (9th Cir. 2011); *Virginia Soc’y for Human Life, Inc. v. FEC*, 263 F.3d 379, 393-94 (4th Cir. 2001). This Court should hold likewise.

B. Any Relief Should Be Limited To Specific Provisions

If the Court were to affirm the district court's conclusion that particular portions of the Rule are unlawful, the Court should still allow the remainder of the Rule to go into effect. In determining whether it is appropriate to sever invalid provisions, courts look to both the agency's intent and whether the regulation can function sensibly without the excised provision(s). *See MD/DC/DE Broad. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001). Here, the intent of the agency is clear: Section 88.10 of the Rule provides that, if a provision of the Rule is held to be invalid or unenforceable, "such provision shall be severable," and "[a] severed provision shall not affect the remainder of this part." 45 C.F.R. § 88.10; *see also* 84 Fed. Reg. at 23,226. Such a clause creates "a presumption in favor of severability," *FEC v. Survival Educ. Fund, Inc.*, 65 F.3d 285, 297 (2d Cir. 1995), and the remainder of the Rule could function even if the Court held particular provisions unlawful.

There is no dispute that numerous provisions of the Rule are valid, including (1) the definitions of terms plaintiffs do not challenge (including "federal financial assistance," "health service program," "instrument," "recipient," "sub-recipient," and "workforce"); (2) the definition of terms plaintiffs do challenge ("assist in the performance," "discrimination," "health care entity," and "referral"), to the extent those terms have applications plaintiffs do not contend are unlawful; and (3) the delegation to OCR of authority to facilitate and coordinate HHS's enforcement of the

conscience statutes. Indeed, the district court itself conceded that “some aspects of the Rule are within HHS’s authority.” SA 42; *see also, e.g.*, SA 57.

Those provisions—plus any challenged provisions this Court may uphold—have value even if other provisions are held unlawful, educating the public about how HHS will enforce the conscience statutes and clarifying HHS’s procedures for doing so. The district court ignored that fact, and otherwise failed to engage in the proper analysis, glossing over the question of severability by stating that the rulemaking exercise was “sufficiently shot through with glaring legal defects as to not justify a search for survivors.” SA 142. But a court cannot throw up its hands and refuse to conduct a proper severability analysis simply because it has determined that some provisions of a rule are invalid; the district court’s “duty” was instead “to maintain the [regulation] in so far as it is valid.” *Regan v. Time, Inc.*, 468 U.S. 641, 652 (1984) (plurality op.).

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

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CERTIFICATE OF COMPLIANCE

This brief complies with this Court's order of April 16, 2020 because it contains 15,989 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

s/ Leif Overvold

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CERTIFICATE OF SERVICE

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

s/ Leif Overvold

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ADDENDUM

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5 U.S.C. § 301

§ 301. Departmental regulations

The head of an Executive department or military 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. This section does not authorize withholding information from the public or limiting the availability of records to the public.

40 U.S.C. § 121

§ 121. Administrative

* * *

(c) Regulations by Administrator.—

(1) General authority.—The Administrator may prescribe regulations to carry out this subtitle.

(2) Required regulations and orders.—The Administrator shall prescribe regulations that the Administrator considers necessary to carry out the Administrator's functions under this subtitle and the head of each executive agency shall issue orders and directives that the agency head considers necessary to carry out the regulations.

* * *

42 U.S.C. § 238n

§ 238n. Abortion-related discrimination in governmental activities regarding training and licensing of physicians

(a) In general

The Federal Government, and any State or local government that receives Federal financial assistance, may not subject any health care entity to discrimination on the basis that—

- (1) the entity refuses to undergo training in the performance of induced abortions, to require or provide such training, to perform such abortions, or to provide referrals for such training or such abortions;
- (2) the entity refuses to make arrangements for any of the activities specified in paragraph (1); or
- (3) the entity attends (or attended) a post-graduate physician training program, or any other program of training in the health professions, that does not (or did not) perform induced abortions or require, provide or refer for training in the performance of induced abortions, or make arrangements for the provision of such training.

(b) Accreditation of postgraduate physician training programs

(1) In general

In determining whether to grant a legal status to a health care entity (including a license or certificate), or to provide such entity with financial assistance, services or other benefits, the Federal Government, or any State or local government that receives Federal financial assistance, shall deem accredited any postgraduate physician training program that would be accredited but for the accrediting agency's reliance upon an accreditation standards¹ that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training, regardless of whether such standard provides exceptions or exemptions. The government involved shall formulate such regulations or other mechanisms, or enter into such agreements with accrediting agencies, as are necessary to comply with this subsection.

(2) Rules of construction

(A) In general

With respect to subclauses (I) and (II) of section 292d(a)(2)(B)(i) of this title (relating to a program of insured loans for training in the health professions), the

requirements in such subclauses regarding accredited internship or residency programs are subject to paragraph (1) of this subsection.

(B) Exceptions

This section shall not—

- (i) prevent any health care entity from voluntarily electing to be trained, to train, or to arrange for training in the performance of, to perform, or to make referrals for induced abortions; or
- (ii) prevent an accrediting agency or a Federal, State or local government from establishing standards of medical competency applicable only to those individuals who have voluntarily elected to perform abortions.

(c) Definitions

For purposes of this section:

- (1) The term “financial assistance,” with respect to a government program, includes governmental payments provided as reimbursement for carrying out health-related activities.
- (2) The term “health care entity” includes an individual physician, a postgraduate physician training program, and a participant in a program of training in the health professions.
- (3) The term “postgraduate physician training program” includes a residency training program.

42 U.S.C. § 300a-7

§ 300a-7. Sterilization or abortion

(a) Omitted

(b) Prohibition of public officials and public authorities from imposition of certain requirements contrary to religious beliefs or moral convictions

The receipt of any grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act by any individual or entity does not authorize any court or any public official or other public authority to require—

(1) such individual to perform or assist in the performance of any sterilization procedure or abortion if his performance or assistance in the performance of such procedure or abortion would be contrary to his religious beliefs or moral convictions; or

(2) such entity to—

(A) make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or

(B) provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedures or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel.

(c) Discrimination prohibition

(1) No entity which receives a grant, contract, loan, or loan guarantee under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Services and Facilities Construction Act after June 18, 1973, may—

(A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or

(B) discriminate in the extension of staff or other privileges to any physician or other health care personnel,

because he performed or assisted in the performance of a lawful sterilization procedure or abortion, because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting sterilization procedures or abortions.

(2) No entity which receives after July 12, 1974, a grant or contract for biomedical or behavioral research under any program administered by the Secretary of Health and Human Services may—

(A) discriminate in the employment, promotion, or termination of employment of any physician or other health care personnel, or

(B) discriminate in the extension of staff or other privileges to any physician or other health care personnel,

because he performed or assisted in the performance of any lawful health service or research activity, because he refused to perform or assist in the performance of any such service or activity on the grounds that his performance or assistance in the performance of such service or activity would be contrary to his religious beliefs or moral convictions, or because of his religious beliefs or moral convictions respecting any such service or activity.

(d) Individual rights respecting certain requirements contrary to religious beliefs or moral convictions

No individual shall be required to perform or assist in the performance of any part of a health service program or research activity funded in whole or in part under a program administered by the Secretary of Health and Human Services if his performance or assistance in the performance of such part of such program or activity would be contrary to his religious beliefs or moral convictions.

(e) Prohibition on entities receiving Federal grant, etc., from discriminating against applicants for training or study because of refusal of applicant to participate on religious or moral grounds

No entity which receives, after September 29, 1979, any grant, contract, loan, loan guarantee, or interest subsidy under the Public Health Service Act, the Community Mental Health Centers Act, or the Developmental Disabilities Assistance and Bill of Rights Act of 2000 may deny admission or otherwise discriminate against any applicant (including applicants for internships and residencies) for training or study because of the applicant's reluctance, or willingness, to counsel, suggest, recommend, assist, or in any way participate in the performance of abortions or sterilizations contrary to or consistent with the applicant's religious beliefs or moral convictions.

42 U.S.C. § 1395w-22

§ 1395w-22. Benefits and beneficiary protections

* * *

(j) Rules regarding provider participation

* * *

(3) Prohibiting interference with provider advice to enrollees

(A) In general

Subject to subparagraphs (B) and (C), a Medicare+Choice organization (in relation to an individual enrolled under a Medicare+Choice plan offered by the organization under this part) shall not prohibit or otherwise restrict a covered health care professional (as defined in subparagraph (D)) from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the plan, if the professional is acting within the lawful scope of practice.

(B) Conscience protection

Subparagraph (A) shall not be construed as requiring a Medicare+Choice plan to provide, reimburse for, or provide coverage of a counseling or referral service if the Medicare+Choice organization offering the plan--

- (i)** objects to the provision of such service on moral or religious grounds; and
- (ii)** in the manner and through the written instrumentalities such Medicare+Choice organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service.

* * *

42 U.S.C. § 1396u-2

§ 1396u-2. Provisions relating to managed care

* * *

(b) Beneficiary protections

* * *

(3) Protection of enrollee-provider communications

(A) In general

Subject to subparagraphs (B) and (C), under a contract under section 1396b(m) of this title a medicaid managed care organization (in relation to an individual enrolled under the contract) shall not prohibit or otherwise restrict a covered health care professional (as defined in subparagraph (D)) from advising such an individual who is a patient of the professional about the health status of the individual or medical care or treatment for the individual's condition or disease, regardless of whether benefits for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

(B) Construction

Subparagraph (A) shall not be construed as requiring a medicaid managed care organization to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization—

- (i)** objects to the provision of such service on moral or religious grounds; and
- (ii)** in the manner and through the written instrumentalities such organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization adopts a change in policy regarding such a counseling or referral service.

Nothing in this subparagraph shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

* * *

42 U.S.C. § 18023

§ 18023. Special rules

* * *

(b) Special rules relating to coverage of abortion services

(1) Voluntary choice of coverage of abortion services

(A) In general

Notwithstanding any other provision of this title (or any amendment made by this title)—

(i) nothing in this title (or any amendment made by this title), shall be construed to require a qualified health plan to provide coverage of services described in subparagraph (B)(i) or (B)(ii) as part of its essential health benefits for any plan year; and

(ii) subject to subsection (a), the issuer of a qualified health plan shall determine whether or not the plan provides coverage of services described in subparagraph (B)(i) or (B)(ii) as part of such benefits for the plan year.

* * *

(4) No discrimination on basis of provision of abortion

No qualified health plan offered through an Exchange may discriminate against any individual health care provider or health care facility because of its unwillingness to provide, pay for, provide coverage of, or refer for abortions[.]

(c) Application of State and Federal laws regarding abortion

* * *

(2) No effect on Federal laws regarding abortion

(A) In general

Nothing in this Act shall be construed to have any effect on Federal laws regarding—

(i) conscience protection;

(ii) willingness or refusal to provide abortion; and

(iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

* * *

(d) Application of emergency services laws

Nothing in this Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1395dd of this title (popularly known as “EMTALA”).

42 U.S.C. § 18113

§ 18113. Prohibition against discrimination on assisted suicide

(a) In general

The Federal Government, and any State or local government or health care provider that receives Federal financial assistance under this Act (or under an amendment made by this Act) or any health plan created under this Act (or under an amendment made by this Act), may not subject an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

(b) Definition

In this section, the term “health care entity” includes 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.

(c) Construction and treatment of certain services

Nothing in subsection (a) shall be construed to apply to, or to affect, any limitation relating to—

- (1) the withholding or withdrawing of medical treatment or medical care;
- (2) the withholding or withdrawing of nutrition or hydration;
- (3) abortion; or
- (4) the use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.

(d) Administration

The Office for Civil Rights of the Department of Health and Human Services is designated to receive complaints of discrimination based on this section.

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* * *

(d)(1) None of the funds made available in this Act may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

(2) In this subsection, the term “health care entity” includes 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.

45 C.F.R. § 75.300

§ 75.300. Statutory and national policy requirements

(a) The Federal awarding agency must manage and administer the Federal award in a manner so as to ensure that Federal funding is expended and associated programs are implemented in full accordance with U.S. statutory and public policy requirements: Including, but not limited to, those protecting public welfare, the environment, and prohibiting discrimination. The Federal awarding agency must communicate to the non-Federal entity all relevant public policy requirements, including those in general appropriations provisions, and incorporate them either directly or by reference in the terms and conditions of the Federal award.

* * *

45 C.F.R. § 75.371

§ 75.371. Remedies for noncompliance

If a non-Federal entity fails to comply with Federal statutes, regulations, or the terms and conditions of a Federal award, the HHS awarding agency or pass-through entity may impose additional conditions, as described in §75.207. If the HHS awarding agency or pass-through entity determines that noncompliance cannot be remedied by imposing additional conditions, the HHS awarding agency or pass-through entity may take one or more of the following actions, as appropriate in the circumstances:

- (a) Temporarily withhold cash payments pending correction of the deficiency by the non-Federal entity or more severe enforcement action by the HHS awarding agency or pass-through entity.
- (b) Disallow (that is, deny both use of funds and any applicable matching credit for) all or part of the cost of the activity or action not in compliance.
- (c) Wholly or partly suspend (suspension of award activities) or terminate the Federal award.
- (d) Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding agency regulations at 2 CFR part 376 (or in the case of a pass-through entity, recommend such a proceeding be initiated by a HHS awarding agency).
- (e) Withhold further Federal awards for the project or program.
- (f) Take other remedies that may be legally available.

48 C.F.R. § 1.301

§ 1.301. Policy

(a)(1) Subject to the authorities in paragraph (c) below and other statutory authority, an agency head may issue or authorize the issuance of agency acquisition regulations that implement or supplement the FAR and incorporate, together with the FAR, agency policies, procedures, contract clauses, solicitation provisions, and forms that govern the contracting process or otherwise control the relationship between the agency, including any of its suborganizations, and contractors or prospective contractors.

(2) Subject to the authorities in (c) below and other statutory authority, an agency head may issue or authorize the issuance of internal agency guidance at any organizational level (e.g., designations and delegations of authority, assignments of responsibilities, work-flow procedures, and internal reporting requirements).

* * *

48 C.F.R. § 352.270-9

§ 352.270-9. Non-Discrimination for Conscience.

As prescribed in HHSAR 370.701, the Contracting Officer shall insert the following provision:

NON-DISCRIMINATION FOR CONSCIENCE (DEC 2015)

(a) Section 301(d) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, as amended, provides that an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961, under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, or under any amendment to the foregoing Acts for HIV/AIDS prevention, treatment, or care—

- (1) Shall not be required, as a condition of receiving such assistance, to—
 - (i) Endorse or utilize a multisectoral or comprehensive approach to combating HIV/ AIDS; or
 - (ii) Endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.
- (2) Shall not be discriminated against under the provisions of law in subparagraph (a) for refusing to meet any requirement described in paragraph (a)(1) in this solicitation.

(b) Accordingly, an offeror who believes this solicitation contains work requirements requiring it endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS, or endorse, utilize, make referral to, become integrated with, or otherwise participate in a program or activity to which it has a religious or moral objection, shall identify those work requirements it excluded in its technical proposal.

(c) The Government acknowledges that an offeror has specific rights, as cited in paragraph (b), to exclude certain work requirements in this solicitation from its proposal. However, the Government reserves the right to not make an award to an offeror whose proposal does not comply with the salient work requirements of the solicitation. Any exercise of that Government right will be made by the Head of the Contracting Activity.

48 C.F.R. § 370.701

§ 370.701. Solicitation provision.

The contracting officer shall insert the provision at 352.270–9, Non-Discrimination for Conscience, in solicitations valued at more than the micro-purchase threshold:

(a) In connection with the implementation of HIV/AIDS programs under the President’s Emergency Plan for AIDS Relief established by the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended;
or

(b) Where the contractor will receive funding under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, as amended. In resolving any issues or complaints that offerors may raise regarding meeting the requirements specified in the provision, the contracting officer shall consult with the Office of Global Health Affairs, Office of the General Counsel, the Program Manager, and other HHS officials, as appropriate.