Consolidated Case Nos. 20-15398, 20-15399, 20-16045 and 20-35044

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CITY AND COUNTY OF SAN FRANCISCO, et al.,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, et al.,

Defendants-Appellants.

On Appeal from the United States District Courts
for the Northern District of California and the Eastern District of Washington

BRIEF FOR APPELLANTS

Of Counsel:

ROBERT P. CHARROW
General Counsel

SEAN R. KEVENEY
Deputy General Counsel

U.S. Department of Health & Human Services

JOSEPH H. HUNT
Assistant Attorney General

DAVID L. ANDERSON
WILLIAM D. HYSLOP
United States Attorneys

MICHAEL S. RAAB
LOWELL V. STURGILL JR.
SARAH CARROLL
LEIF OVERVOLD
Attorneys, Appellate Staff
Civil Division, Room 7226
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-4631

TABLE OF CONTENTS

Page

ADDENDUM

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Regulations:

Rule:

Legislative Materials:

Other Authorities:

INTRODUCTION

Numerous federal statutes protect individuals and other entities who maintain 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 based on protected conscience objections.

In 2019, the Department of Health and Human Services (HHS) 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 the agency's 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, and addressing public confusion regarding, the conscience statutes, their protections, and HHS's enforcement of them.

Two district courts in this Circuit vacated the Rule in its entirety and universally, holding that it exceeds HHS's statutory authority, is inconsistent with other provisions of law, or violates the separation of powers and the Constitution's Spending Clause. But properly understood, the Rule merely gives effect to the unchallenged conscience statutes. For that reason and others, the Rule is within HHS's statutory authority; consistent with other laws, including the Administrative Procedure Act (APA); and constitutional. At the very least, the courts should have vacated only the parts of the Rule found unlawful and only as to plaintiffs.

STATEMENT OF JURISDICTION

The district courts had jurisdiction under 28 U.S.C. § 1331. The district court for the Eastern District of Washington entered judgment on November 21, 2019. Appellants filed a timely notice of appeal on January 17, 2020. ER72-74; *see* Fed. R. App. P. 4(a)(1)(B). The district court for the Northern District of California entered judgment in two cases on January 8, 2020, and a third on May 26, 2020. Appellants filed timely notices of appeal on March 6 and May 29. ER66-71. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether the district courts erred in holding that the Rule is contrary to statute, violates the APA, or is unconstitutional.

2. Whether the district courts erred in vacating the Rule in its entirety, in all of its applications and against all persons.

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

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

The Church Amendments protect those holding 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 or (2) in HHS-funded health service programs and research activities. *See* 42 U.S.C. § 300a-7.

Under these provisions, no entity receiving a grant, contract, loan, or loan guarantee under certain specified statutes 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 "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 contrary to his religious beliefs or moral convictions" or "because of his religious beliefs or moral convictions respecting sterilization procedures or abortions."

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

42 U.S.C. § 300a-7(c)(1). They impose similar obligations on entities receiving grants or contracts for biomedical or behavioral research under any HHS-administered program. *Id.* § 300a-7(c)(2).[2] Subsection 300a-7(d) also offer protections not limited to sterilization or abortion, providing 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." *Id.* § 300a-7(d).

Finally, the Church Amendments prohibit entities that receive certain funds or benefits 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. The Coats-Snowe Amendment

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

[2] Section 300a-7(b) makes clear that an individual or entity's receipt of funds under the statutes identified in subsection (c)(1) does not permit any court, public official, or "other public authority" to require the recipient to "perform or assist in the performance of any sterilization procedure or abortion," or 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).

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. *Id.* § 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). And it requires covered governments to deem such postgraduate physician training programs accredited in certain contexts where they would be accredited but for the reliance on 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." *Id.* § 238n(b)(1).

3. The Weldon Amendment

Since 2004, Congress has included a rider known as the Weldon Amendment (Weldon) in every appropriations act funding the Departments of Labor, HHS, and Education. *See* Protecting Statutory Conscience Rights in Health Care, 84 Fed. Reg. 23,170, 23,172 (May 21, 2019). Weldon 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 (2019).

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 the title requires "qualified health plans"—*i.e.*, health plans meeting 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." *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 [her] condition or disease," 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 prohibited practices. *Id.* at 78,078-81. To address these concerns, it 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. *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. It noted that, if an entity violated statutory conscience

provisions, HHS would attempt to facilitate voluntary compliance and, if necessary, "consider all legal options, 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, 83 Fed. Reg. 3880, 3881 (Jan. 26, 2018). HHS proposed definitions for various statutory terms, *id.* at 3892-95, and requirements that certain fund recipients maintain records, submit written assurances of compliance, and provide notifications regarding applicable conscience and anti-discrimination rights, *id.* at 3880. HHS also proposed clarifying OCR's responsibility for ensuring compliance with the conscience statutes and resolving complaints. *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 23,170. 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. *Id.* The Rule also states that funding

recipients and sub-recipients must maintain records and cooperate with OCR's investigations, reviews, and enforcement actions. *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. *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 prohibited grounds. 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.*

Entity: The Rule defines "entity" to mean "a 'person' as defined in 1 U.S.C. 1"; HHS; a State, its political subdivision or instrumentality, or various associated public entities; or, "as applicable, a foreign government, foreign nongovernmental organization, or intergovernmental organization." 45 C.F.R. § 88.2.

Health Care Entity: For purposes of Coats-Snowe, "health care entity" includes "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 the ACA, the term includes certain additional entities. *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. *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, the City and County of San Francisco filed a complaint in the Northern District of California challenging the Rule. *See* ER251. Similar actions were filed by the State of California, *see* ER224, and the County of Santa Clara along with certain private parties, *see* ER296. The district court designated these cases as related and assigned them to the same judge. *See* ER81. The same month, the State of Washington challenged the Rule in the Eastern District of Washington. *See* ER314.

After plaintiffs in each action moved for preliminary injunctions to block the Rule's implementation, both courts granted stipulated requests to postpone the Rule's effective date until November 22, 2019. *See* ER76-80. The parties then cross-moved for summary judgment. Before the Rule took effect, each district court granted summary judgment to plaintiffs and vacated the Rule in its entirety. *See* ER33, ER63-65.

a. The California court issued its decision first.

i. The court recognized that the Rule was, with "minor exceptions," "purely an interpretive rule, not a legislative rule." ER44. It concluded, however, that the Rule's definitions of certain terms used in the conscience statutes expanded the scope of the statutes' protections. ER44-59.

ii. Although the court recognized that HHS had certain express rulemaking authority under Coats-Snowe, the ACA, and the Medicare and Medicaid statutes, it concluded that HHS lacked authority to "change, add to, or subtract from" other conscience provisions like the Church and Weldon Amendments. ER60. The court also concluded that the "housekeeping statutes" HHS had invoked did not authorize the changes the Rule's definitional provisions effected in the court's view, that the Rule's enforcement provisions expanded HHS's existing authority to terminate funds, and that the conscience statutes did not impliedly delegate the relevant rulemaking authority. ER60-63.

iii. The court declined to attempt to sever specific provisions it found problematic, invalidating the Rule in its entirety. ER63. The court gave the vacatur nationwide scope, noting that its conclusions were not plaintiff-specific and that it believed the Rule was facially invalid. ER63-64.

b. The Washington court also invalidated the Rule, adopting several conclusions that a New York district court had reached in invalidating the Rule. ER30; *see New York v. HHS*, 414 F. Supp. 3d 475 (S.D.N.Y. 2019), *appeal pending*, Nos. 19-4254 et al. (2d Cir.). Those aspects of the *New York* decision are described below.

i. The *New York* court acknowledged that HHS had statutory authority to issue "some aspects" of the Rule. 414 F. Supp. 3d at 519. It concluded, however, that the Rule is "largely substantive," *id.* at 513; that the housekeeping statutes did not authorize issuance of substantive rules, *id.* at 519-23; that the conscience statutes did

not impliedly delegate substantive rulemaking authority, *id.* at 529-32; and that rulemaking provisions in the ACA and Medicare and Medicaid statutes did not authorize the Rule as a whole, *id.* at 532. The court also concluded that HHS lacked statutory authority to promulgate a Rule "authorizing the termination of all of a recipient's federal health care funds." *Id.* The Washington court added that, to the extent the Rule "can be read to authorize the withholding of federal funds from the Department of Labor and Department of Education," HHS exceeded its statutory authority. ER30.

b. The *New York* court additionally held the Rule "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* 414 F. Supp. 3d at 535. While Washington had challenged the Rule on this basis in its complaint, the Washington court did not expressly adopt this holding. *See* ER29-30, ER137.

c. The *New York* court further held the Rule to be arbitrary and capricious. *See* 414 F. Supp. 3d at 539-58. The court rejected HHS's observation that OCR had recently seen a "significant increase" in conscience-related complaints, *id.* at 541-44, and held that concern alone sufficient to invalidate the Rule, *id.* at 546. It faulted HHS for allegedly failing to identify evidence supporting the Rule's definitional provisions, *id.* at 545-46, and purportedly inadequately considering conclusions underlying the 2011 Rule, *id.* at 547-48. The court also criticized HHS for

inadequately considering funding recipients' reliance on HHS's historical interpretation of the conscience provisions. *Id.* at 552-53. The Washington court adopted these conclusions and also faulted HHS's consideration of access-to-care and medical-ethics issues and the Rule's effect on certain groups. ER29, ER31-32.

d. Based on its conclusion that the Rule expanded HHS's authority to withhold or terminate funding, the *New York* court held that the Rule violates the separation of powers and the Spending Clause (because the possibility of terminating all of a recipient's HHS funding renders the Rule "impermissibly coercive"). 414 F. Supp. 3d at 561-62, 569-71. The court also concluded that the Rule violates the Spending Clause because it creates "uncertain ground rules for compliance" and imposed new, retroactive obligations on States. *Id.* at 567-69.

e. The Washington court concluded that the Rule should be vacated in its entirety and nationwide, describing the violations it found as "numerous, fundamental, and far-reaching." ER32-33 (quoting *New York*, 414 F. Supp. 3d at 577). The court noted that it had not "rel[ied] on facts or considerations that are specific to the State of Washington" and concluded that it would be a "miscarriage of justice" if the Rule could be implemented in Idaho but not Washington. ER32-33.

SUMMARY OF ARGUMENT

While the district courts erred in several respects, their reasons for vacating the Rule ultimately flow from a single mistaken premise: that the Rule expands on 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 provisions, and there is no basis to set aside the entire Rule universally.

I. The district courts erred in concluding that the Rule exceeds 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 HHS funds subject to these conditions—a natural consequence. 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 it to ensure compliance in this fashion.

Third, the Rule's definitional provisions provide HHS's understanding of 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 statutory reading.

II.A. The Rule is also not contrary to law as plaintiffs contend and the *New York* court erroneously held in parallel litigation. Although the *New York* court emphasized that the Rule does not incorporate certain defenses that Title VII provides in religious discrimination cases, there is no basis for reading those defenses into the conscience statutes. That court also wrongly discerned a facial conflict with EMTALA based on a hypothetical situation HHS is not aware has ever occurred; regardless, EMTALA requires a hospital to provide care "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 promote compliance with preexisting duties and clarify HHS's enforcement procedures. HHS was not obligated to provide an extensive policy justification for such clarification but nonetheless amply explained why the Rule was warranted, carefully considered public comments, and adequately addressed issues commenters raised, including access-to-care and medical-ethics issues and the Rule's impact on vulnerable populations, on which the Washington court focused.

C. The Rule is also consistent with the Constitution. The Rule's enforcement provisions are not an unauthorized departure from HHS's statutory authority, and the Washington court identified no distinct basis to conclude that the Rule violates the separation of powers by intruding on the powers of another branch.

The Spending Clause challenge is not ripe because it 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 or retroactive conditions. It 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 courts erred by vacating the Rule as to all persons and in its entirety. Plaintiffs have not shown that vacatur 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 have been recognized as lawful.

STANDARD OF REVIEW

This Court reviews de novo the district courts' decisions granting summary judgment. *See Bear Valley Mut. Water Co. v. Jewell*, 790 F.3d 977, 986 (9th Cir. 2015).

ARGUMENT

I. The Rule Is Within HHS's Authority

The district courts erred in concluding that the Rule exceeds 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 undisputedly applicable funding conditions, and (C) gives HHS's interpretation of the best meaning of 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 HHS funding recipients 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 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 govern HHS's own conduct and ensure that the agency disburses funds in compliance with applicable conscience statutes.

The district courts did not take issue with HHS's general authority to enforce the conscience statutes. The Washington court, however, 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. ER29-30. That conclusion is erroneous.

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 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 matters 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.* Contrary to the Washington court's suggestion, ER30, the enforcement provision does not purport to regulate funds received by an

agency other than HHS. The preamble also 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 courts 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 *New York*—and apparently the Washington—court believed the Rule exceeded that existing authority because it

states that HHS may terminate "*all* federal funds that a recipient receives from HHS," 414 F. Supp. 3d at 516, 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 California court focused on the Rule's application to Medicaid and Medicare funds, to which the HHS UAR does not fully apply, *see* ER61; 45 C.F.R. §§ 75.101(e)(1)(iv)-(v), 75.502(h)-(i). But any failure to perfectly mirror the UAR in this regard is immaterial: as the preamble notes, 42 U.S.C. § 1302 specifically authorizes HHS to promulgate regulations relating to Medicaid and Medicare. *See* 84 Fed. Reg. at 23,184-85. The Rule specifies, moreover, that any action with respect to such funds must be taken "pursuant to statutes and regulations" governing, in relevant part, "CMS funding arrangements." 45 C.F.R. § 88.7(i)(3). As the preamble thus makes clear, "[t]o the extent that terms and conditions relating to [the conscience statutes] are incorporated into CMS's instruments or agreements, CMS would have the authority to enforce such terms pursuant to the relevant enforcement mechanism for each instrument or agreement." 84 Fed. Reg. at 23,185. This provision too consequently fits comfortably within HHS's existing authority.

Nor does HHS lack statutory authority "to terminate all of a recipient's funding streams from the agency for a breach of a Conscience Provision." *New York*, 414 F. Supp. 3d at 533. 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 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 funding recipients 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) (United States may sue to enforce contractual assurances of nondiscrimination "as a matter of federal common law, without the necessity of a statute"); *United States v. Mattson*, 600 F.2d 1295, 1299 n.6 (9th Cir. 1979) (similar). Where all of a recipient's HHS funding is subject to a particular conscience statute, a violation of that statute may lead to the termination of financial assistance from the Department "in whole." And where a recipient's violation might extend to each funding stream it receives, it is entirely reasonable—and certainly not facially invalid—to include a provision "reserv[ing] the right" (*New York*, 414 F. Supp. 3d at 534 n.36) to terminate all HHS funds as one potential enforcement mechanism for such a violation.

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 inclusion of a contract clause relating to conscience protections. *See* 48 C.F.R. §§ 352.270-9, 370.701.

The Washington court did not expressly refer to the *New York* court's criticism of this aspect of the Rule, which was premised entirely on a Second Circuit case, *Perales v. Sullivan*, 948 F.2d 1348 (2d Cir. 1991), that no party here cited. *See* 414 F. Supp. 3d at 526-27. For good reason, as *Perales* is inapposite. That case 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

[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.

accompanied by "assurance" at the time of filing that certain documentation existed. *Perales*, 948 F.2d at 1352. The 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, and it rejected HHS's arguments that an existing regulation or statute imposed the documentation requirement. *Id.* at 1354-57.

Regardless of whether the Second Circuit's cursory analysis was persuasive on the specific issue presented there—a new documentation requirement that no existing statute or regulation required, imposed without notice—this case presents a completely different issue. Here, plaintiffs are being given notice of the challenged requirements, and, more fundamentally, these certification requirements 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, 84 Fed. Reg. at 23,185 (citing *JEM Broad. Co. v. FCC*, 22 F.3d 320 (D.C. Cir. 1994)), and instead reflects duties that can be traced directly to existing statutory requirements. HHS needs no authority beyond the conscience statutes themselves (and HHS's authority to regulate its internal operations) 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 Washington court, following the *New York* decision, concluded that HHS needed substantive rulemaking authority to promulgate these definitional provisions and lacked that authority with respect to three conscience statutes. The California court, by contrast, acknowledged that the Rule was, with minor exceptions, "purely an interpretive rule, not a legislative rule," ER44, but concluded that certain definitions were inconsistent with the statutory provisions in which the terms were found. The California court correctly concluded that the definitional provisions are interpretive; therefore, no grant of substantive rulemaking authority is necessary. Contrary to that court's determination, however, the Rule's definitions reflect the best reading of the statutes and thus are valid.[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 rights, impose obligations, or effect a change in existing law pursuant to

[4] The Washington court apparently adopted the *New York* court's acknowledgement that HHS "undeniably had rulemaking authority to implement the ACA and the Medicare and Medicaid Conscience Provisions" (414 F. Supp. 3d at 528) but nonetheless invalidated the Rule as to those statutes. ER30, ER32-33. The California court similarly recognized that HHS had rulemaking authority under those statutes and Coats-Snowe, ER60, but nonetheless concluded that certain definitional provisions were invalid and that this perceived defect required invalidation of the entire Rule. Both courts erred, as discussed *infra* in section III.B.

authority delegated by Congress." *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082, 1087 (9th Cir. 2003). Interpretive rules, by contrast, "merely explain, but do not add to, the substantive law that already exists." *Id.*; *see also Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 97 (2015) (interpretive rules "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).

A rule is thus interpretive where it has no effects independent of a statute and the statute "provides an adequate legislative basis for enforcement" absent the rule. *Erringer v. Thompson*, 371 F.3d 625, 630-31 (9th Cir. 2004). "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 interpretive. *United Techs. Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987); *see also Erringer*, 371 F.3d at 632 n.12 ("[A]n interpretation that spells out the scope of an agency's pre-existing duty will be interpretive, even if it widens that duty[.]" (quotation marks and alterations omitted)).

The Rule's definitional provisions are interpretive under this framework. 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, and the

duties reflected in the Rule flow from the conscience statutes, not the Rule. *Cf. Miller v. California Speedway Corp.*, 536 F.3d 1020, 1033 (9th Cir. 2008) (rule is interpretive where it "added nothing to the existing rule except a definition of an ambiguous term").

It does not matter in this regard whether a rule "shapes the primary conduct of regulated entities." *New York*, 414 F. Supp. 3d at 48. Whether a rule is interpretive does not depend on whether it imposes "burdens" on the public; that "only goes to the substantial impact of the statute and regulations, not whether the regulations created law." *Alcaraz v. Block*, 746 F.2d 593, 613 (9th Cir. 1984); *see also White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 2003) ("[I]nterpretive rules may have substantive effects[.]").

The *New York* court further 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." 414 F. Supp. 3d at 523 (quotation marks and brackets omitted). "A rule does not become a legislative rule because it effects some unanticipated change; otherwise, only superfluous rules could qualify as interpretive rules." *Miller*, 536 F.3d at 1033. 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). Regardless of whether a rule embodies a changed or more detailed interpretation, where "the rule is an interpretation of a statute rather than an

extra-statutory imposition of rights, duties or obligations, it remains interpretive." *Lane v. Salazar*, 911 F.3d 942, 949 (9th Cir. 2018) (quoting *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 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 *New York* court 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." 414 F. Supp. 3d at 525. The California court similarly concluded that the phrase was intended to protect only individuals "in the operating room" (even though it is used in provisions that cover, for example, "research activity" with no obvious connection to operating rooms, 42 U.S.C. § 300a-7(d)). ER48. But nothing about the plain meaning of "assist" or "performance" restricts the statute's scope to a particular time or place.

Congress expressly extended the Church Amendments beyond individuals who "perform" procedures or other activities to those who "assist in"—and thus necessarily have a more ancillary relationship to—them. It is unsurprising that Congress sought to reach all forms of assistance, 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 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.

The California court focused on legislative history that it believed supported its extratextual operating-room restriction on the phrase's scope. The highlighted colloquies involving Senator Church indicate, however, only that the Church Amendments were not intended to protect a "frivolous objection from someone unconnected with the procedure" or someone with "no responsibility, directly or indirectly with regard to [its] performance," ER47 (emphasis omitted) (quoting 119 Cong. Rec. 9597 (1973)). That is entirely consistent with the Rule's requirement that an action have a "specific, reasonable, and articulable connection" to furthering a procedure and its recognition that assistance may be provided in a number of ways. In any case, "floor statements by individual legislators rank among the least illuminating forms of legislative history," *NLRB v. SW Gen., Inc.*, 137 S. Ct. 929, 943 (2017), and cannot be used to read into the statutory term a restriction absent from the text.

b. The Rule's definition of "discriminate or discrimination" likewise reflects the best reading of the relevant 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 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 prohibited grounds. 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 if 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 *New York* 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. 414 F. Supp. 3d at 523. As discussed *infra* in section II.A, the court erred in concluding that the conscience statutes import Title VII defenses that the conscience provisions nowhere mention. And while the *New York* court and the California court concluded that the Rule also improperly limited an employer's ability to inquire about conscience objections, *id.*; ER55-56, the relevant portion of the Rule generally describes conduct that will *not* be understood to constitute discrimination. Although questioning an employee or job applicant 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" 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. This provision offers additional flexibility

consistent with the varied forms discrimination under the conscience statutes may take.

c. The California court erred in invalidating the Rule's definition of "entity" on the ground that it includes individuals as well as organizations, which the court believed contravened the Church Amendments. ER54.

As a threshold matter, the court erred by introducing a challenge to this definition not raised by any of the parties before it. *Cf. United States v. Sineneng-Smith*, 140 S. Ct. 1575, 1579 (2020) ("In our adversarial system of adjudication, we follow the principle of party presentation."); *see also* ER75. Indeed, there is no indication that any of the plaintiffs have Article III standing to challenge this provision; none of the individual plaintiffs allege that they receive funds subject to the Church Amendments. *See* ER152-55. In any event, "entity" is a broad term referring to "[s]omething that has a real existence." *See Entity*, Oxford English Dictionary Online, https://www.oed.com/view/Entry/62904 (last visited June 15, 2020). Individuals fall naturally within that definition. *Cf. City of Abilene v. FCC*, 164 F.3d 49, 52 (D.C. Cir. 1999) (recognizing the term "entity" in the Telecommunications Act of 1996 "may include a natural person"). Indeed, as discussed *infra*, other conscience statutes define "health care entity" to include "individual physician[s]" or "other health care professional[s]." *See* 42 U.S.C. §§ 238n(c)(2), 18113(b); Further Consolidated Appropriations Act, 2020, § 507(d)(2), 133 Stat. at 2607. Congress's use of "entity" in the Church Amendments thus does not suggest an intent to exempt fund recipients

from the statutory requirements merely because they are individuals rather than organizations. The Rule's definition, moreover, defines "entity" for purposes of the Rule as a whole, so any concern specific to the Church Amendments cannot facially invalidate this provision, much less the entire Rule. *Cf. American Hosp. Ass'n v. NLRB*, 499 U.S. 606, 619 (1991) (rejecting facial challenge to rule despite possible impermissible applications).

d. 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 certain insurance-related entities as well. *Id.*

These definitions logically interpret the statutes, which 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). Weldon 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. The term "include" often, as the Supreme Court has recognized, "signal[s] that the list that follows is meant to be illustrative rather than exhaustive." *Samantar v. Yousuf*, 560 U.S. 305, 317 (2010); *see id.* at 317 n.10 ("The word 'includes' is usually a term of enlargement, and not of limitation." (brackets omitted)). And all three provisions 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 Weldon and the ACA. 42 U.S.C. §§ 238n(c)(2), 18113(b). The statutes thus plainly contemplate a broader group of health-care entities than those explicitly listed.

The *New York* court did not grapple with the presence of the catch-all provisions, suggesting any addition to the examples listed in the statutes was "substantive." 414 F. Supp. 3d at 526. The California court similarly reasoned that certain categories listed in the Rule, like pharmacists, were not expressly listed in the statutes and did not match what it perceived as the statutes' focus on individuals engaged in "the actual performance of," "assisting in," or "play[ing] a role specific to" the procedure in question. ER50, ER53.[5]

[5] The court recognized that pharmacists could properly be included with respect to the ACA's definition of this term. ER53.

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 Weldon and the ACA, because those statutes protect health "plans," *see* 84 Fed. Reg. at 23,195—play a crucial role in health-care delivery by paying for or administering health coverage or services and fall within the statutes' catch-all provisions as "any other kind of health care facility, organization, or plan." 42 U.S.C. § 18113(b). And, contrary to the California court's passing suggestion (ER50), nothing in the fact that certain terms are used in other conscience provisions but not specifically enumerated in Coats-Snowe (or Weldon or the ACA) indicates that they must be excluded from the broad ambit of the term "health care entity" as used in those statutes.

Representative Weldon's indication that the Weldon Amendment applies to "health insurance providers" among other specified categories also does not support the district courts' conclusion. *See New York*, 414 F. Supp. 3d at 525 (quoting 150 Cong. Rec. H10,090 (Nov. 20, 2004)); ER53. The identification of some protected entities does not impliedly limit the broad statutory text to foreclose protection of other entities involved in the provision of health care, like pharmacists or medical laboratories, or health payment or coverage, like plan sponsors or third-party

administrators. And in any case, as already noted, such floor statements "rank among the least illuminating forms of legislative history," especially when read to ignore the plain text of the statutory catch-all clauses. *SW Gen.*, 137 S. Ct. at 943.

e. Finally, the Rule's definition of "referral or refer for" is consistent with Weldon and Coats-Snowe (and the term's 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), 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). Weldon prohibits the funding of entities that discriminate against individuals or institutions because they do not "refer for abortions." Further Consolidated Appropriations Act, 2020, § 507(d)(1), 133 Stat. at 2607.

The Rule tracks the ordinary meaning of the statutory text, defining "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" providing 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. 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 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, and its use in referencing referrals for abortion-related *training*, suggests Congress did not intend to limit protection to conscience objections associated with providing a particular referral document, but protected conscience objections to sending or directing a person for abortions or training in a more general sense.

While the California court sought to rely on legislative history here, too, the statement from Representative Weldon is again inapposite even if such floor

statements could be thought instructive. The cited statement indicates that the Weldon Amendment will not affect "the provision of abortion-related information or services *by willing providers*." *See* ER58 (citing 150 Cong. Rec. 25,044-45 (2004)) (emphasis added; other emphasis omitted). But that simply reflects that the provision protects conscience objections, rather than restricting services or information offered willingly. Far from suggesting that the provision of information is categorically excluded from Weldon's protections, the statement underscores the opposite.

II. The Other Criticisms Of The Rule Lack Merit

A. The Rule Is Not Contrary To Law

Plaintiffs likewise err in challenging the Rule based on its purported inconsistency with Title VII or EMTALA. The *New York* court's acceptance of those claims in parallel litigation, *see* 414 F. Supp. 3d at 535-39, was erroneous.

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).

a. The *New York* court held that the Rule conflicts with Title VII because it does not include Title VII's reasonable-accommodation or undue-hardship defenses.

414 F. Supp. 3d at 536-37. But Congress neither included Title VII's defenses in the later-enacted conscience statutes nor incorporated Title VII's definition of "religion" in which those defenses are found. *See* 84 Fed. Reg. at 23,191. Indeed, the conscience statutes' protections are not limited to religious objections. *See, e.g.*, 42 U.S.C. § 300a-7.

The *New York* court nevertheless held that Title VII's defenses must be read into the conscience statutes because those statutes do not expressly abrogate them. 414 F. Supp. 3d at 536. But the conscience statutes are entirely distinct 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 *New York* court identified no authority for applying such a nonsensical clear-statement rule.

The *New York* court also faulted HHS for failing to identify evidence that Congress intended not to provide those defenses. 414 F. Supp. 3d at 536. 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 extratextual speculation about congressional intent is flawed on its own terms. It is entirely plausible that Congress 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 (and, therefore, warranting of greater exceptions) than the more targeted conscience statutes," which are "health care specific and often procedure specific." 84 Fed. Reg. at 23,191.

In addition, Congress enacted the conscience statutes *after* adding Title VII's undue-hardship and reasonable-accommodation defenses. Thus, Congress would have known how to provide those defenses had it so desired. *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 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").

b. While the Washington court did not expressly address Title VII, the California court considered whether the Title VII scheme should be "read into" the conscience statutes, despite recognizing that doing so would not "hew[] to the words actually used." ER57. The court found it unnecessary to reach that issue because it "expect[ed] that any undue hardships would supply persuasive justification" under the Rule for making pre-employment inquiries about possible conscience objections and rejecting applicants based on the information obtained. ER57. But while the Rule allows employers to ask applicants or employees about potential conscience objections when the employer has a "persuasive justification," *see* 84 Fed. Reg. at 23,263 (quoting 45 C.F.R. § 88.2), the Rule does not by its terms authorize rejecting

applicants (or firing employees) on that basis, nor equate the concept of "persuasive justification" with the Title VII concept of an "undue hardship." Because any conflict between Title VII and the Rule is illusory, as explained above, the California court's reading of the Rule is unnecessary and unwarranted.

2. The Rule Is Consistent With EMTALA

EMTALA provides that if any individual comes to a hospital that has elected 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 *New York* court 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. 414 F. Supp. 3d at 538-39. That concern does not demonstrate a "facial conflict" (*id.* at 539) 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. Eme Homer City Generation, L.P.*, 572 U.S. 489, 524 (2014). That principle has particular force here, since HHS emphasized in 2008 that it "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). If 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). 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 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. 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"); 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 *New York* court cited (414 F. Supp. 3d at 537) addressed the conscience statutes or any analogous 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 court also speculated that the Rule's provisions addressing employer inquiries about conscience objections might prevent hospitals from planning for conscience-related staff shortages. *New York*, 414 F. Supp. 3d at 539. 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 *New York* court also expressed concern that a hospital might lack funds to ensure a "conscience-cleared platoon" is available for every emergency. 414 F. Supp.

3d at 539. As noted, however, that court described a response to a hypothetical situation not known ever to have occurred, and EMTALA in any case requires provision of services "within the staff and facilities available at the hospital." 42 U.S.C. § 1395dd(b)(1)(A).

Finally, the *New York* court erred by relying on the statements of individual legislators to conclude that the conscience statutes do not apply in medical emergencies. 414 F. Supp. 3d at 538. 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 and EMTALA.

B. The Rule Is Not Arbitrary And Capricious

The Washington court likewise erred in holding the Rule arbitrary and capricious under the APA. 5 U.S.C. § 706(2)(A). That standard is "narrow and deferential"; the Court "must uphold a rule if the agency has examined the relevant considerations and articulated a satisfactory explanation for its action, including a rational connection between the facts found and the choice made." *California ex rel. Becerra v. Azar*, 950 F.3d 1067, 1096 (9th Cir. 2020) (en banc) (quotation marks omitted). The Court "defer[s] to the agency's expertise in interpreting the record" and, in particular, to "[a]gency predictions of how regulated parties will respond to its regulations" and determinations about "the appropriate course of action." *Id.*

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 Washington court's arbitrary-and-capricious analysis, including the incorporated *New York* 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, and announcing it through an interpretive rule also creates significant public-notice benefits. *Cf. Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 523 (2d Cir. 2017) ("[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, and HHS

found significant public "confusion over what is and is not required" under the conscience statutes. *Id.* at 23,175-78. 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 Washington and *New York* courts' criticisms of the Rule disregard its interpretive nature. The *New York* 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." 414 F. Supp. 3d at 541-44 (quoting 84 Fed. Reg. at 23,175). The court did not explain, however, why an agency must compile evidence of past statutory violations—much less 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, *id.* at 544, 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, *id.* at 545, to offer the best reading of statutory terms.

The Washington court's criticism that HHS inadequately considered potential costs of the Rule, including its effect on access to care, similarly fails to recognize that the definitional provisions reflect policy choices that Congress already made. *See* 84 Fed. Reg. at 23,182 (explaining that the Rule "enforces Federal conscience and anti-discrimination laws, which represent Congress's considered judgment that these rights are worth protecting even if they impact overall or individual access to a particular service").

2. The criticisms are also erroneous on their own terms. The *New York* court erred, for example, in concluding that HHS miscounted recent complaints to OCR alleging conscience violations. 414 F. Supp. 3d at 546. 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 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. *New York*, 414 F. Supp. 3d at 541-42; *see* 84 Fed. Reg. at 23,175.

That analysis was flawed multiple times over. First, 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 *New York* court thought "implicated the Conscience Provisions" (414 F. Supp. 3d at 542) 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 *New York* court relatedly criticized HHS for failing to compile complaints "indicating problems with its capacity to enforce the Conscience Provisions," expressing the belief that HHS had not investigated many complaints in the record. 414 F. Supp. 3d at 544. 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, among other things, HHS had "devoted no meaningful attention to those laws" and "ha[d] 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 *New York* court also believed HHS inadequately addressed the 2011 Rule's findings that the 2008 Rule created confusion and might "negatively affect the ability of patients to access care if interpreted broadly." 414 F. Supp. 3d at 548. 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 2011 Rule's "status quo" but concluded the Rule was necessary). Moreover, the *New York* 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 New York*, 414 F. Supp. 3d at 543 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. *See infra* section II.B.4.

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; *see Becerra*, 950 F.3d at 1096 ("[W]e [do

not] give heightened review to agency action that changes prior policy." (quotation marks omitted)). 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 New York*, 414 F. Supp. 3d at 552-54. 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 Washington and *New York* courts also held that, in promulgating the Rule, HHS failed to consider various issues. The *New York* court focused on "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." 414 F. Supp. 3d at 554-56. 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. 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. While the court faulted HHS's consideration of one hypothetical relating to the Rule's application to an ambulance driver (*New York*, 414 F. Supp. 3d at 555), HHS explained both 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.

The Washington court focused on the Rule's relationship to access-to-care issues and medical ethics. ER31-32. As the court recognized, however, HHS considered access-to-care issues in detail. *See, e.g.*, 84 Fed. Reg. at 23,181, 23,246-47, 23,250-54. "Agency predictions of how regulated parties will respond to its regulations" "are entitled to particularly deferential review." *Becerra*, 950 F.3d at 1096. While the court thought it "elementary that increasing the number of medical professionals who would deny care based on religious or moral objections would not increase access to care," ER31, HHS explained here, based on "[n]umerous studies and comments," that "the failure to protect conscience is a barrier to careers in the

health care field"; absent enforcement of conscience protections, providers might leave the field altogether (or decline to enter it in the first place). 84 Fed. Reg. at 23,246-47. HHS specifically considered whether, as the Washington court believed, increased conscience objections would diminish access to particular services. Studies in the record had found insufficient evidence to support that view, and HHS concluded in any event that the effect would likely be "outweighed by significant overall increases in access generated by th[e] Rule" in reducing the risk objecting professionals might leave the field altogether. 84 Fed. Reg. at 23,247, 23,251-52.

Contrary to the Washington court's view, HHS also considered the Rule's effect on "vulnerable populations." ER31-32. Neither the conscience statutes nor the Rule protect objections to serving particular populations; they instead primarily protect conscience objections to specified services such as abortion, sterilization, and assisted suicide. HHS further concluded that "predictions that the rule will reduce services in underserved communities may be based on incorrect assumptions," since the Rule "does not expand the substantive protections of Federal conscience and anti-discrimination laws" and might in fact increase the number of providers. 84 Fed. Reg. at 23,181; *see also id.* (noting lack of "data demonstrating the dire results predicted by some commenters"). Indeed, HHS noted, religious individuals and entities "are overrepresented in serving certain underserved populations" and will be more likely to continue doing so if their conscience rights are appropriately protected. *Id.* at 23,181-82; *see also id.* at 23-247-49. This is, again, a predictive judgment squarely within

HHS's expertise. *Becerra*, 950 F.3d at 1096. While the court criticized HHS for "disregarding 'anecdotal accounts of discrimination from LGBT' people," ER32, HHS considered those accounts and concluded they did not establish that laws protecting conscience rights had "played any causal role in the discrimination experienced." 84 Fed. Reg. at 23,252.

The Washington court also mistakenly concluded that HHS had failed to reasonably consider medical-ethics requirements. ER32. HHS considered this issue, explaining that the Rule "do[es] not prohibit any doctor or health care entity from providing information to their patients" or taking other steps if they feel they have a duty to do so. 84 Fed. Reg. at 23,200. The Rule simply "ensures that doctors can use their own professional, medical, and ethical judgment without being coerced by entities receiving Federal funds to violate their moral or religious convictions." *Id.* Here as in *Becerra*, "HHS examined the relevant considerations arising from commenters citing medical ethics and rationally articulated an explanation for its conclusion." 950 F.3d at 1103.

C. The Rule Is Constitutional

1. The Rule Is Consistent With The Separation Of Powers

The Washington court's adopted holding that the Rule violates the constitutional separation of powers is expressly derivative of the conclusion that the Rule exceeds HHS's statutory authority, *see New York*, 414 F. Supp. 3d at 562, and

thus fails twice over. *First*, the Rule's enforcement provisions are within HHS's authority. *See supra* section I.A. *Second*, in any event, 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." *Dalton v. Specter*, 511 U.S. 462, 472 (1994). Instead, the Court has carefully "distinguished between claims of constitutional violations and claims that an official has acted in excess of his statutory authority." *Id.* (collecting cases); *see also id.* at 473 & nn.5-6. Here, the district court did not and could not identify any constitutional violation separate and apart from the alleged lack of statutory authority.

2. Washington's Spending Clause Challenge Is Unripe And Meritless

The Washington court also erred in concluding that Washington's Spending Clause challenge is ripe and that the Rule violates that Clause.

a. Ripeness doctrine is designed "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Association of Am. Med. Colls. v. United States*, 217 F.3d 770, 779–80 (9th Cir. 2000) (quotation marks omitted). In determining whether a claim is ripe, a court must "first consider the fitness of the issues for judicial review, followed by the hardship to the parties of withholding court consideration." *Oklevueha Native*

Am. Church of Haw., Inc. v. Holder, 676 F.3d 829, 837 (9th Cir. 2012). Neither factor indicates that the claim here is ripe.

The Washington court adopted the *New York* court's conclusion that the Rule violates the Spending Clause because it authorizes HHS to "terminate all of a recipient's HHS funding" as one potential remedy for noncompliance. 414 F. Supp. 3d at 561-62 & n.67. The challenge is therefore premised not on an actual enforcement action, but on a hypothetical situation involving a chain of speculative contingencies, in which (1) Washington violates a conscience statute to which it is subject; (2) the incident comes to HHS's attention; (3) HHS determines it constitutes a violation implicating all funding streams Washington receives; and (4) notwithstanding the preamble's recognition that termination of funds for violations has been rare, HHS's expressed preference in the Rule for resolving matters informally, and the many other avenues for achieving compliance, HHS decides to enforce the statute by terminating all of Washington's conditioned funds. *See* 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); *see also Addington v. U.S. Airline Pilots Ass'n*, 606 F.3d 1174, 1179-80 (9th Cir. 2010) (similar). 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), involving the same purported consequences and risks asserted here.

To determine fitness for judicial review, a court must whether "further factual development would significantly advance [its] ability to deal with the legal issues presented." *Coons v. Lew*, 762 F.3d 891, 900-01 (9th Cir. 2014) (quotation marks omitted). This Court has particularly stressed that "a court cannot decide constitutional questions in a vacuum." *Alaska Right to Life Political Action Comm. v. Feldman*, 504 F.3d 840, 849 (9th Cir. 2007).

The further factual development that a concrete enforcement action would provide 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. *Cf. Connecticut v. Duncan*, 612 F.3d 107, 114 (2d Cir. 2010) (noting value of additional factual development in case involving Spending Clause challenge). The *New York* 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, as yet hypothetical administrative proceedings. *See, e.g.*, *San Diego Cty. Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1132 (9th Cir. 1996) (distinguishing *Abbot Laboratories* where issues in pre-enforcement challenge were not purely legal).

Nor can Washington demonstrate any undue hardship from delaying review unless and until its funds are actually terminated for a violation (or HHS has even given any indication it intends to pursue that remedy). 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 Weldon, if a concrete dispute does arise, administrative procedures give States a route to seek resolution with the agency and judicial resolution afterward if necessary. *See California*, 2008 WL 744840, at *6. A State may challenge the Rule on the same legal bases once any informal or administrative procedures have been completed. *See Colwell v. HHS*, 558 F.3d 1112, 1128-29 (9th Cir. 2009) (no hardship under such circumstances, particularly where regulations "do not contemplate any kind of financial sanction other than termination of federal funding"). Washington has 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 *New York* 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 purported expansion of HHS's enforcement authority 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.

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). Washington does not contend that the conscience statutes themselves violate this requirement. Instead, the *New York* court concluded that the Rule operates retroactively to impose unforeseen conditions on States after receipt of funds. 414 F. Supp. 3d at 567-69; *see id.* at 566 n.70 ("An agency which Congress has tasked with implementing a statute that imposes spending 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, Washington does not contest that it has long known that its receipt of HHS funds is conditioned on compliance with applicable conscience statutes. 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 *New York* 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 Washington's view merely represent different interpretations of conditions it has long known applied—are nowhere near the "transformation" described in *NFIB*'s controlling opinion. *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. *New York*, 414 F. Supp. 3d at 568. Conditions imposed on States "may be largely indeterminate, so long as the statute provides clear notice to the States that they, by accepting funds under the Act, would indeed be obligated to comply with the conditions." *Mayweathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002) (quotation marks and brackets omitted). The conscience statutes provide such notice (and Washington has not argued otherwise). And the Supreme Court has recognized that an agency's clarifying interpretations and violation determinations may be upheld where they are grounded in "statutory

provisions, regulations, and other guidelines provided by the Department" at the time of the grant. *Bennett v. Kentucky Dep't of Educ.*, 470 U.S. 656, 670-71 (1985). The statutes and the Rule (which simply provides such additional clarification) both easily satisfy applicable notice standards. *See, e.g.*, *Davis v. Monroe Cty. Bd. of Educ.*, 526 U.S. 629, 650 (1999) (no Spending Clause claim of insufficient notice where "statute made clear that there were some conditions placed on receipt of federal funds"; "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 *New York* 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 HHS 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* 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 Courts Erroneously Vacated The Rule Against All Persons And In Its Entirety

A. Any Relief Should be Limited to Plaintiffs

Under Article III of the Constitution, "[s]tanding is not dispensed in gross"; "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 of course 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) (quotation marks omitted). 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 1930-31; *Madsen*,

512 U.S. at 765. Accordingly, this Court has repeatedly rejected nationwide relief against rules promulgated by federal agencies. *See California v. Azar*, 911 F.3d 558, 584 (9th Cir. 2018); *Los Angeles Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 665 (9th Cir. 2011).

1. The district courts 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 courts made, or could make, any showing that such a sweeping remedy is necessary to provide plaintiffs with full relief.

The courts' refusal to limit their relief to plaintiffs also 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.

Nationwide relief would be particularly inappropriate here given that the Second Circuit is currently considering similar challenges to the Rule. *See New York v. HHS*, Nos. 19-4254 et al. (2d Cir.). If the government prevails in the Second 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,* 911 F.3d at 583 (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").

"[U]niversal 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 600-01 (Gorsuch, J., concurring). For all these reasons, the district courts erred by vacating the Rule as to all potential parties, rather than rendering it inapplicable to plaintiffs.

2. The California court conceded that this Court "has vacated nationwide preliminary injunctions when the record only demonstrated the impact the ruling would have on plaintiffs and not on the nation as a whole or when limited relief was sufficient to provide complete relief to the plaintiffs." ER63 (citing *City & Cty. of San Francisco v. Trump*, 897 F.3d 1225, 1244-45 (9th Cir. 2018), and *California v. Azar*, 911 F.3d at 582-84). The court distinguished those cases on the ground that the court

vacated the rule here rather than merely enjoining it, but the relevant principles remain fully applicable. Indeed, on the California court's theory, this Court would have been *required* to grant nationwide vacatur in *Haven Hospice*, rendering the injunction's scope largely immaterial. *See* 638 F.3d at 649 (holding challenged regulation "facially invalid"); *id.* at 664-65 (nevertheless rejecting nationwide injunction).

The California court reasoned that a rule held to be facially "not in accordance with law" under the APA "can only be vacated as to all applicable parties," ER64, but that is incorrect. Although the APA generally instructs that unlawful agency action "shall" be "set aside," 5 U.S.C. § 706(2), that language does not imply that the action shall be set aside *facially*, rather than *as applied* to plaintiffs. The latter interpretation is compelled 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'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 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.

None of those cases on which the California court relied for its contrary holding (ER63-64) adequately addressed the Article III and equity principles that generally require limiting relief to the plaintiff and the reasons (stated above) why that principle should apply in APA suits as well. Moreover, this Court has specifically held that the APA does *not* require a nationwide injunction where a rule is held facially invalid. *See Haven Hospice*, 638 F.3d at 664-65; *accord Virginia Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 393-94 (4th Cir. 2001). The court also reasoned that limiting relief to the plaintiffs would be "illogical" because "other courts have set aside the rule already," ER64, but as this Court noted in *Haven Hospice*, the fact that another court of appeals is reviewing the same issue counsels *against* relief that goes beyond plaintiffs. *See* 638 F.3d at 665.

3. The Washington court held that nationwide relief is appropriate because the court "did not rely on facts or considerations that are specific to the State of Washington." ER32. That reasoning confuses the scope of Washington's theory on

the merits with the scope of relief to which it is entitled: even if the Rule were invalid more broadly, Washington would be entitled to vacatur no broader than necessary to redress its own injuries. The court also erred in suggesting that limiting relief to plaintiffs would cause a "miscarriage of justice" because the rule "would affect any person living in the United States," including in Idaho, "20 miles down the road." ER32-33. Any such individual would be free to bring an action to redress his or her own asserted injury, or try to band together with others to bring a class action in which they would all win or lose together. Contrary to the court's view, it would be a miscarriage of justice if third parties could sit on the sidelines of this litigation, obtain relief under Washington's judgment if it prevails, but remain free to bring their own suits in other circuits if Washington loses.

B. Any Relief Should Be Limited To Specific Provisions

If the Court were to affirm the district courts' 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 Broads. 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 "severability presumption," *National Mining Ass'n v. Zinke*, 877 F.3d 845, 862 (9th Cir. 2017), 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 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 *New York* court conceded that "some aspects of the Rule are within HHS's authority." 414 F. Supp. 3d at 519.

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 courts ignored that fact, and otherwise failed to engage in the proper analysis, glossing over the question of severability by reasoning that the rulemaking exercise was "sufficiently shot through with glaring legal defects as to not justify a search for survivors," ER32 (quoting *New York*, 414 F. Supp. 3d at 577) or "saturated with error," ER63. 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.) (quotation marks omitted).

CONCLUSION

For the foregoing reasons, the judgments of the district courts should be reversed.

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

DAVID L. ANDERSON
WILLIAM D. HYSLOP
United States Attorneys

MICHAEL S. RAAB

s/ Leif Overvold
LOWELL V. STURGILL JR.
SARAH CARROLL
LEIF OVERVOLD
Attorneys, Appellate Staff
Civil Division, Room 7226
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-4631
leif.overvold2@usdoj.gov

Of Counsel:

ROBERT P. CHARROW
General Counsel

SEAN R. KEVENEY
Deputy General Counsel
U.S. Department of Health & Human Services

June 2020

STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, appellants state that they know of no related case pending in this Court beyond the four cases addressed in this brief. This Court has previously consolidated the appeals in *City & County of San Francisco v. Azar*, No. 20-15398; *County of Santa Clara v. U.S. Department of Health & Human Services*, No. 20-15399; and *State of Washington v. Azar*, No. 20-35044, and the government has moved to consolidate *State of California v. Azar*, No. 20-16045, with those three appeals as well.

s/ Leif Overvold
Leif Overvold

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form08instructions.pdf

9th Cir. Case Number(s) 20-15398, 20-15399, 20-16045 and 20-35044

I am the attorney or self-represented party.

This brief contains 17,371 **words**, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and typeface comply with Fed. R. App. P. 32(a)(5) and (6).

I certify that this brief *(select only one)*:

- ○ complies with the word limit of Cir. R. 32-1.
- ○ is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.
- ○ is an **amicus** brief and complies with the word limit of Fed. R. App. P. 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).
- ○ is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.
- ○ complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one):*
  - ○ it is a joint brief submitted by separately represented parties;
  - ○ a party or parties are filing a single brief in response to multiple briefs; or
  - ○ a party or parties are filing a single brief in response to a longer joint brief.
- ○ complies with the length limit designated by court order dated [ ].
- ◉ is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature s/ Leif Overvold **Date** Jun 15, 2020

(use "s/[typed name]" to sign electronically-filed documents)

Feedback or questions about this form? Email us at forms@ca9.uscourts.gov

CERTIFICATE OF SERVICE

I hereby certify that on June 15, 2020, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

s/ Leif Overvold
Leif Overvold

ADDENDUM

TABLE OF CONTENTS

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.

Pub. L. No. 116-94, Further Consolidated Appropriations Act, 2020

§ 507

* * *

(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. § 88.2

§ 88.2. Definitions

Assist in the performance means to take 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. This may include counseling, referral, training, or otherwise making arrangements for the procedure or a part of a health service program or research activity, depending on whether aid is provided by such actions.

* * *

Discriminate or *discrimination* includes, as applicable to, and to the extent permitted by, the applicable statute:

(1) To withhold, reduce, exclude from, terminate, restrict, or make unavailable or deny any grant, contract, subcontract, cooperative agreement, loan, license, certification, accreditation, employment, title, or other similar instrument, position, or status;

(2) To withhold, reduce, exclude from, terminate, restrict, or make unavailable or deny any benefit or privilege or impose any penalty; or

(3) To utilize any criterion, method of administration, or site selection, including the enactment, application, or enforcement of laws, regulations, policies, or procedures directly or through contractual or other arrangements, that subjects individuals or entities protected under this part to any adverse treatment with respect to individuals, entities, or conduct protected under this part on grounds prohibited under an applicable statute encompassed by this part.

(4) Notwithstanding paragraphs (1) through (3) of this definition, an entity subject to any prohibition in this part shall not be regarded as having engaged in discrimination against a protected entity where the entity offers and the protected entity voluntarily accepts an effective accommodation for the exercise of such protected entity's protected conduct, religious beliefs, or moral convictions. In determining whether any entity has engaged in discriminatory action with respect to any complaint or compliance review under this part, OCR will take into account the degree to which an entity had implemented policies to provide effective accommodations for the exercise of protected conduct, religious beliefs, or moral convictions under this part and whether or not the entity took any adverse action against a protected entity on the basis of protected conduct, beliefs, or convictions before the provision of any accommodation.

(5) Notwithstanding paragraphs (1) through (3) of this definition, an entity subject to any prohibition in this part may require a protected entity to inform it of objections to performing, referring for, participating in, or assisting in the performance of specific

procedures, programs, research, counseling, or treatments, but only to the extent that there is a reasonable likelihood that the protected entity may be asked in good faith to perform, refer for, participate in, or assist in the performance of, any act or conduct just described. Such inquiry may only occur 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.

(6) The taking of steps by an entity subject to prohibitions in this part to use alternate staff or methods to provide or further any objected-to conduct identified in paragraph (5) of this definition would not, by itself, constitute discrimination or a prohibited referral, if such entity does not require any additional action by, or does not take any adverse action against, the objecting protected entity (including individuals or health care entities), and if such methods do not exclude protected entities from fields of practice on the basis of their protected objections. Entities subject to prohibitions in this part may also inform the public of the availability of alternate staff or methods to provide or further the objected- to conduct, but such entity may not do so in a manner that constitutes adverse or retaliatory action against an objecting entity.

Entity means a "person" as defined in 1 U.S.C. 1; the Department; a State, political subdivision of any State, instrumentality of any State or political subdivision thereof; any public agency, public institution, public organization, or other public entity in any State or political subdivision of any State; or, as applicable, a foreign government, foreign nongovernmental organization, or intergovernmental organization (such as the United Nations or its affiliated agencies).

* * *

Health care entity includes:

(1) For purposes of the Coats-Snowe Amendment (42 U.S.C. 238n) and the subsections of this part implementing that law (§ 88.3(b)), an individual physician or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or behavioral research; a pharmacy; or any other health care provider or health care facility. As applicable, components of State or local governments may be health care entities under the Coats- Snowe Amendment; and

(2) For purposes of the Weldon Amendment (*e.g.*, Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, and Continuing Appropriations Act, 2019, Pub. L. 115–245, Div. B., sec. 507(d), 132 Stat. 2981, 3118 (Sept. 28, 2018)), Patient Protection and Affordable Care Act section 1553 (42 U.S.C. 18113), and to sections of this part implementing those laws (§ 88.3(c) and

(e)), an individual physician or other health care professional, including a pharmacist; health care personnel; a participant in a program of training in the health professions; an applicant for training or study in the health professions; a post-graduate physician training program; a hospital; a medical laboratory; an entity engaging in biomedical or behavioral research; a pharmacy; a provider-sponsored organization; a health maintenance organization; a health insurance issuer; a health insurance plan (including group or individual plans); a plan sponsor or third-party administrator; or any other kind of health care organization, facility, or plan. As applicable, components of State or local governments may be health care entities under the Weldon Amendment and Patient Protection and Affordable Care Act section 1553.

* * *

Referral or *refer for* includes 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. § 88.4

§ 88.4 Assurance and certification of compliance requirements.

(a) *In general*—(1) *Assurance.* Except for an application or recipient to which paragraph (c) of this section applies, every application for Federal financial assistance or Federal funds from the Department to which § 88.3 of this part applies shall, as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department pursuant to the application, provide, contain, or be accompanied by an assurance that the applicant or recipient will comply with applicable Federal conscience and anti-discrimination laws and this part.

(2) *Certification.* Except for an application or recipient to which paragraph (c) of this section applies, every application for Federal financial assistance or Federal funds from the Department to which § 88.3 of this part applies, shall, as a condition of the approval, renewal, or extension of any Federal financial assistance or Federal funds from the Department pursuant to the application, provide, contain, or be accompanied by, a certification that the applicant or recipient will comply with applicable Federal conscience and anti-discrimination laws and this part.

(b) *Specific requirements*—(1) *Timing.* Entities who are already recipients as of the effective date of this part or any applicants shall submit the assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section as a condition of any application or reapplication for funds to which this part applies, through any instrument or as a condition of an amendment or modification of the instrument that extends the term of such instrument or adds additional funds to it. Submission may be required more frequently if:

(i) The applicant or recipient fails to meet a requirement of this part, or

(ii) OCR or the relevant Department component has reason to suspect or cause to investigate the possibility of such failure.

(2) *Form and manner.* Applicants or recipients shall submit the assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section in the form and manner that OCR, in coordination with the relevant Department component, specifies, or shall submit them in a separate writing signed by the applicant's or recipient's officer or other person authorized to bind the applicant or recipient.

(3) *Duration of obligation.* The assurance required in paragraph (a)(1) of this section and the certification required in paragraph (a)(2) of this section will obligate the recipient for the period during which the Department extends Federal financial assistance or Federal funds from the Department to a recipient.

(4) *Compliance requirement.* Submission of an assurance or certification required under this section will not relieve a recipient of the obligation to take and complete any action necessary to come into compliance with Federal conscience and anti-discrimination laws and this part prior to, at the time of, or subsequent to, the submission of such assurance or certification.

(5) *Condition of continued receipt.* Provision of a compliant assurance and certification shall constitute a condition of continued receipt of Federal financial assistance or Federal funds from the Department and is binding upon the applicant or recipient, its successors, assigns, or transferees for the period during which such Federal financial assistance or Federal funds from the Department are provided.

(6) *Assurances and certifications in applications.* An applicant or recipient may incorporate the assurances and certifications by reference in subsequent applications to the Department or Department component if prior assurances or certifications are initially provided in the same fiscal or calendar year, as applicable.

(7) *Enforcement of assurances and certifications.* The Department, Department components, and OCR shall have the right to seek enforcement of the assurances and certifications required in this section.

(8) *Remedies for failure to make assurances and certifications.* If an applicant or recipient fails or refuses to furnish an assurance or certification required under this section, OCR, in coordination with the relevant Department component, may effect compliance by any of the mechanisms provided in § 88.7.

(c) *Exceptions.* The following persons or entities shall not be required to comply with paragraphs (a)(1) and (2) of this section, provided that such persons or entities are not recipients of Federal financial assistance or other Federal funds from the Department through another instrument, program, or mechanism, other than those set forth in paragraphs (c)(1) through (4) of this section:

(1) A physician, as defined in 42 U.S.C. 1395x(r), physician office, pharmacist, pharmacy, or other health care practitioner participating in Part B of the Medicare program;

(2) A recipient of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration for Children and Families, the purpose of which is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve—

(i) Medical or behavioral research;

(ii) Health care providers; or

(iii) Any significant likelihood of referral for the provision of health care;

(3) A recipient of Federal financial assistance or other Federal funds from the Department awarded under certain grant programs currently administered by the Administration on Community Living, the purpose of which is either solely financial assistance unrelated to health care or which is otherwise unrelated to health care provision, and which, in addition, does not involve—

(i) Medical or behavioral research;

(ii) Health care providers; or

(iii) Any significant likelihood of referral for the provision of health care.

(4) Indian Tribes and Tribal Organizations when contracting with the Indian Health Service under the Indian Self- Determination and Education Assistance Act.

45 C.F.R. § 88.7

§ 88.7 Enforcement authority.

(a) *In general.* OCR has been delegated the authority to facilitate and coordinate the Department's enforcement of the Federal conscience and anti-discrimination laws, which includes the authority to:

(1) Receive and handle complaints;

(2) Initiate compliance reviews;

(3) Conduct investigations;

(4) Coordinate compliance within the Department;

(5) Seek voluntary resolutions of complaints;

(6) In coordination with the relevant component or components of the Department and the Office of the General Counsel, make enforcement referrals to the Department of Justice;

(7) In coordination with the relevant Departmental funding component, utilize existing regulations for involuntary enforcement, such as those that apply to grants, contracts, or CMS programs; and

(8) In coordination with the relevant component or components of the Department, coordinate other appropriate remedial action as the Department deems necessary and as allowed by law and applicable regulation.

(b) *Complaints.* Any entity, whether individually, as a member of a class, on behalf of others, or on behalf of an entity, may file a complaint with OCR alleging any potential violation of Federal conscience and anti-discrimination laws or this part. OCR shall coordinate handling of complaints with the relevant Department component(s). The complaint filer is not required to be the entity whose rights under the Federal conscience and anti-discrimination laws or this part have been potentially violated.

(c) *Compliance reviews.* OCR may conduct compliance reviews or use other similar procedures as necessary to permit OCR to investigate and review the practices of the Department, Department components, recipients, and sub-recipients to determine whether they are complying with Federal conscience and anti-discrimination laws and this part. OCR may initiate a compliance review of an entity subject to this part based on information from a complaint or other source that causes OCR to suspect non-compliance by such entity with this part or the laws implemented by this part.

(d) *Investigations.* OCR shall make a prompt investigation, whenever a compliance review, report, complaint, or any other information found by OCR indicates a threatened, potential, or actual failure to comply with Federal conscience and anti-

discrimination laws or this part. The investigation should include, where appropriate, a review of the pertinent practices, policies, communications, documents, compliance history, circumstances under which the possible noncompliance occurred, and other factors relevant to determining whether the Department, Department component, recipient, or sub-recipient has failed to comply. OCR shall use fact-finding methods including site visits; interviews with the complainants, Department component, recipients, sub-recipients, or third-parties; and written data or discovery requests. OCR may seek the assistance of any State agency.

(e) *Failure to respond.* Absent good cause, the failure of an entity that is subject to this part to respond to a request for information or to a data or document request within 45 days of OCR's request shall constitute a violation of this part.

(f) *Related administrative or judicial proceeding.* Consistent with other applicable Federal laws, testimony and other evidence obtained in an investigation or compliance review conducted under this part may be used by the Department for, and offered into evidence in, any administrative or judicial proceeding related to this part.

(g) *Supervision and coordination.* If as a result of an investigation, compliance review, or other enforcement activity, OCR determines that a Department component appears to be in noncompliance with its responsibilities under Federal conscience and anti-discrimination laws or this part, OCR will undertake appropriate action with the component to assure compliance. In the event that OCR and the Department component are unable to agree on a resolution of any particular matter, the matter shall be submitted to the Secretary for resolution. OCR may from time to time request the assistance of officials of the Department in carrying out responsibilities in connection with the enforcement of Federal conscience and anti-discrimination laws and this part, including the achievement of effective coordination and maximum uniformity within the Department.

(h) *Referral to the Department of Justice.* If as a result of an investigation, compliance review, or other enforcement activity, OCR determines that a recipient or sub-recipient is not in compliance with the Federal conscience and anti-discrimination laws or this part, OCR may, in coordination with the relevant Department component and the Office of the General Counsel, make referrals to the Department of Justice, for further enforcement in Federal court or otherwise. OCR may also make referrals to the Department of Justice, in coordination with the Office of the General Counsel, concerning potential violations of 18 U.S.C. 1001 or 42 U.S.C. 300a–8 for enforcement or other appropriate action.

(i) *Resolution of matters.* (1) If an investigation or compliance review reveals that no action is warranted, OCR will so inform any party who has been notified of the existence of the investigation or compliance review, if any, in writing.

(2) If an investigation or compliance review indicates a failure to comply with Federal conscience and anti-discrimination laws or this part, OCR will so inform the relevant parties and the matter will be resolved by informal means whenever possible. Attempts to resolve matters informally shall not preclude OCR from simultaneously pursuing any action described in paragraphs (a)(5) through (7) of this section.

(3) If OCR determines that there is a failure to comply with Federal conscience and anti-discrimination laws or this part, compliance with these laws and this part may be effected by the following actions, taken in coordination with the relevant Department component, and pursuant to statutes and regulations which govern the administration of contracts (*e.g.*, Federal Acquisition Regulation), grants (*e.g.*, 45 CFR part 75) and CMS funding arrangements (*e.g.*, the Social Security Act):

(i) Temporarily withholding Federal financial assistance or other Federal funds, in whole or in part, pending correction of the deficiency;

(ii) Denying use of Federal financial assistance or other Federal funds from the Department, including any applicable matching credit, in whole or in part;

(iii) Wholly or partly suspending award activities;

(iv) Terminating Federal financial assistance or other Federal funds from the Department, in whole or in part;

(v) Denying or withholding, in whole or in part, new Federal financial assistance or other Federal funds from the Department administered by or through the Secretary for which an application or approval is required, including renewal or continuation of existing programs or activities or authorization of new activities;

(vi) In coordination with the Office of the General Counsel, referring the matter to the Attorney General for proceedings to enforce any rights of the United States, or obligations of the recipient or sub-recipient, under Federal law or this part; and (vii) Taking any other remedies that may be legally available.

(j) *Noncompliance with § 88.4.* If a recipient of Federal financial assistance or applicant therefor fails or refuses to furnish an assurance or certification required under § 88.4 or otherwise fails or refuses to comply with a requirement imposed by or pursuant to that section, OCR, in coordination with the relevant Department component, may effect compliance by any of the remedies provided in paragraph (i) of this section. The Department shall not be required to provide assistance in such a case during the pendency of the administrative proceedings brought under such paragraph.

45 C.F.R. § 88.10

§ 88.10 Severability.

Any provision of this part held to be invalid or unenforceable either by its terms or as applied to any entity or circumstance shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be severable from this part, which shall remain in full force and effect to the maximum extent permitted by law. A severed provision shall not affect the remainder of this part or the application of the provision to other persons or entities not similarly situated or to other, dissimilar circumstances.

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.