

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, *Plaintiff-Appellee*,

v.

ALEX M. AZAR II, et al., *Defendants-Appellants*.

COUNTY OF SANTA CLARA, et al., *Plaintiffs-Appellees*,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., *Defendants-Appellants*.

STATE OF CALIFORNIA, *Plaintiff-Appellee*,

v.

ALEX M. AZAR, et al., *Defendants-Appellants*.

STATE OF WASHINGTON, *Plaintiff-Appellee*,

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

**ANSWERING BRIEF OF PLAINTIFFS-APPELLEES
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INTRODUCTION

The U.S. Department of Health and Human Services' (HHS) regulation, "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority," 84 Fed. Reg. 23,170 (May 21, 2019) (to be codified at 45 C.F.R. pt. 88) (Rule), is an extreme reinterpretation of federal law that vastly—and unlawfully—expands the agency's authority and upends Congress's carefully drawn provisions preserving patient health and religious beliefs. The Rule allows anyone involved in the delivery of healthcare—from doctors to ambulance drivers to front office staff—to deny patients care. It permits them to omit information and deny treatment options to patients, even a referral to another provider for care. The Rule does not require any pre-notification to the patient nor the arrangement of alternative care. It provides no guidance to employers that must navigate how to accommodate such refusals. It contains no exception for emergencies. Its vague requirements leave both patients and employers at the mercy of the objector.

Federal law does not permit such a radical regulation. Thus, it is no surprise that every court to consider the Rule to date has found it unlawful. As those courts have recognized, HHS violated the Administrative Procedure Act (APA) by expanding statutory definitions in direct

contravention of the statutory text, and by granting itself broad enforcement powers unmoored from any statutory scheme. Further, the Rule is contrary to numerous other federal statutes, including the Emergency Medical Treatment & Labor Act (EMTALA) and Title VII of the Civil Rights Act of 1964. Finally, the regulatory process preceding the Rule's publication was arbitrary and capricious. HHS ignored the significant reliance interests of plaintiffs-appellees and offered justifications that were not only insufficient, but demonstrably false.

The Rule poses such a dramatic threat to state and local governments that it also violates the Spending Clause of the U.S. Constitution. The federal government cannot use its spending power to coerce States into adopting its policy choices. But the Rule threatens the termination of billions of dollars in federal funds unless the States capitulate to the Rule's unlawful and vague provisions. Indeed, California is an express target; HHS cites California law dozens of times as justification for the Rule. That assault on California's sovereignty poses a real risk to the health and welfare of all Californians.

JURISDICTIONAL STATEMENT

California agrees with defendants-appellants' statement of jurisdiction.

AOB 2.

ISSUES PRESENTED FOR REVIEW

1. Whether the Rule violates the APA.
2. Whether the Rule is unconstitutional.
3. Whether the district courts properly vacated the Rule in its entirety.

STATEMENT OF THE CASE

A. Statutory Framework

The Rule interprets more than 30 federal laws that “provid[e] protections in health care for individuals and entities on the basis of religious beliefs or moral convictions.” 84 Fed. Reg. at 23,170, 23,264-69 (collecting statutes). The Rule primarily focuses on four: (1) the Church Amendments, 42 U.S.C. § 300a-7; (2) the Coats-Snowe Amendment, *id.* § 238n; (3) the Weldon Amendment, Pub. L. No. 116-94, Div. B., § 507(d)(1) (2019); and (4) provisions of the Affordable Care Act (ACA). These statutory provisions allow healthcare providers, in limited circumstances, to refuse to provide abortions, sterilizations, or physician-assisted suicide on religious or moral grounds. Congress tailored each law to its specific purpose, considering providers’ moral and religious views and patients’ right to access healthcare. *See* ER 63 (CA op.). Congress did not intend to deny patients emergency medical treatment. *See, e.g.*, SER 1660 (Senator Church: “[I]n an emergency

situation—life or death type—no hospital, religious or not, would deny such [abortion or sterilization] services” under the Church Amendments).

Church Amendments. Enacted in 1973, the Church Amendments bar government entities from requiring an individual or entity that receives specific federal funds to “*perform or assist in the performance* of any sterilization procedure or abortion” if it is contrary to the individual’s “religious beliefs or moral convictions.” 42 U.S.C. §§ 300a-7(b)(1), 300a-7(b)(2) (emphases added). The Church Amendments also prohibit “[*d*]iscrimination” in employment or personnel privileges because an individual either chooses to “*perform[] or assist[] in the performance* of a lawful sterilization procedure or abortion,” or refuses to do so due to “religious beliefs or moral convictions.” *Id.* § 300a-7(c)(1) (emphases added). The Church Amendments do not define “assist in the performance” or “discriminate.”

Coats-Snowe Amendment. The Coats-Snowe Amendment, enacted in 1996, bars “*discrimination*” against a “*health care entity*” for refusing to train or make arrangements for training for abortions. 42 U.S.C. § 238n(a) (emphases added). The Coats-Snowe Amendment defines “health care entity,” but does not define “discrimination.” *Id.* § 238n(c)(2).

Weldon Amendment. The Weldon Amendment is an appropriations policy rider that has been included in every appropriations bill for the Departments of Labor, Education, and HHS since 2005. It states that no funds may be given to a government that “*discriminat[es]*” against an “institutional or individual *health care entity*” because it does not provide, pay for, cover, or “*refer for*” abortions. *See* Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 507(d)(1), 133 Stat. 2534, 2607 (2019) (Appropriations Act) (emphases added). The rider was only intended to “affect[] instances when a government requires that a health care entity provide abortion services [and] not [to] affect access to abortion, the provision of abortion-related information or services by willing providers or the ability of States to fulfill Federal Medicaid legislation.” ER 58 (CA op.) (quoting Rep. Weldon). The Weldon Amendment defines the term “health care entity,” but does not define “*discriminat[es]*” or “*refer for.*” Appropriations Act at § 507(d)(2).

Affordable Care Act. In 2010, Congress passed the ACA to eliminate barriers to healthcare and healthcare coverage through a series of reforms. *Nat’l Fed’n of Indep. Bus. v. Sebelius (NFIB)*, 567 U.S. 519, 538-39 (2012); *King v. Burwell*, 576 U.S. 473, 478-79 (2015); 42 U.S.C § 18091(2)(C), (F) & (G). The ACA contains two conscience provisions that are relevant here.

42 U.S.C. §§ 18113(a), 18023(b)(4). The ACA definition of “health care entity” matches the Weldon Amendment. *Id.* § 18113(b).

Existing alongside these conscience provisions are a number of federal laws that ensure patients’ access to care. For example, EMTALA requires hospitals participating in the federal Medicare and Medicaid programs to screen patients to determine “whether or not an emergency medical condition . . . exists” and, if so, to stabilize the patient or transfer the patient to another facility. 42 U.S.C. §§ 1395dd(a), (b)(1), (c)(1). Title VII likewise strengthens access to care by adopting a “reasonabl[e] accommodat[ion]” framework for religious objections whereby healthcare employers may decline accommodations that cause “undue hardship.” *See* 42 U.S.C. §§ 2000e(j), 2000e-2(a)(1). As such, Title VII requires an ongoing dialogue between the employer and employee to balance employees’ religious beliefs with employers’ obligations to patients, their business, and other employees.¹

¹ In addition to EMTALA and Title VII, the ACA contains two provisions that ensure patients’ access to healthcare. Section 1557 prohibits discrimination on the basis of race, color, national origin, sex, disability, and age in healthcare programs and activities receiving federal funding. 42 U.S.C. § 18116. Section 1554 prohibits the HHS Secretary from, among other things, promulgating any regulation that creates any unreasonable barriers or impedes timely access to healthcare. *Id.* § 18114.

B. Regulatory Background

In December 2008, HHS promulgated a rule “to ensure that Department funds do not support morally coercive or discriminatory practices or policies in violation of federal law.” 73 Fed. Reg. 78,072 (Dec. 19, 2008). The rule had three primary components. First, it “define[d] certain key terms” used in the federal conscience provisions, including “assist in the performance” and “health care entity.” *Id.* at 78,072, 78,097. Second, it required recipients of HHS funds to provide written certification of their compliance with the rule. *Id.* at 78,072, 78,098. Third, the rule designated HHS’s Office for Civil Rights (OCR) to receive and coordinate the handling of complaints based on the conscience statutes. *Id.* at 78,072, 78,101. When presented with an alleged violation, HHS would first “work with such government or entity to . . . comply or come into compliance.” *Id.* at 78,074. Only after that effort failed would HHS “consider all legal options, including termination of funding.” *Id.*

The 2008 rule did not go into effect until 2009, and it was short lived. 74 Fed. Reg. 10,207 (Mar. 10, 2009). Just months later, HHS proposed to rescind the 2008 rule. *Id.* In 2011, HHS issued a new final rule, which eliminated the 2008 definitions of statutory terms and the certification requirements. 76 Fed. Reg. 9968, 9971 (Feb. 23, 2011). HHS found the 2008

rule could “negatively affect the ability of patients to access care if interpreted broadly.” *Id.* at 9974. Recognizing that the federal conscience provisions do not require “promulgation of regulations for their interpretation or implementation,” HHS found most of the 2008 rule unnecessary. *Id.* at 9975.

The 2011 rule did retain OCR’s authority to coordinate complaints of violations of the conscience statutes. *Id.* at 9976-77. Over a period of ten years—from 2008 to January 2018—OCR received only 44 complaints related to moral and religious objections. 83 Fed. Reg. 3880, 3886 (Jan. 26, 2018). Nonetheless, on January 26, 2018, HHS issued a Notice of Proposed Rulemaking “to enhance the awareness and enforcement” of the federal conscience provisions. *Id.* at 3881.

The proposed rule sought to “generally reinstate the structure of the 2008 Rule” (*id.* at 3891) and create new rights for conscience objectors. *See New York*, 414 F. Supp. 3d at 522 n.19 (noting “President Trump’s statement about the Rule: ‘Just today we finalized new protections of conscience rights for physicians, pharmacists, nurses, teachers, students and faith-based charities. They’ve been wanting to do that a long time.’”).

HHS received over 242,000 comments on the proposed rule. 84 Fed. Reg. at 23,180 n.41. Comments in opposition came from a broad array of

individuals, medical associations, public health experts, state and local governments, providers, and patient groups. ER 41 (CA op.). Despite the volume of comments raising a number of significant concerns about patient access and care, HHS issued a largely identical final rule in May 2019.

C. The 2019 Rule

According to the Rule’s preamble, HHS’s principal reason for its policy change is to address “confusion” from the rescission of the 2008 rule via the 2011 rule. 84 Fed. Reg. at 23,175. HHS cites to a “significant increase” in complaints to OCR relating to the federal conscience provisions, and seeks to give itself “the proper enforcement tools” to better enforce those laws. *Id.* The Rule does so not only by reinstating many of the rescinded provisions of the 2008 rule, but also by “significantly expand[ing] the scope of protected conscientious objections” beyond that of the prior rule. ER 45 (CA op.).

Specifically, the Rule expands on the following key statutory terms:

- “Health care entity” under the Weldon Amendment is expanded to include 11 additional categories of “individuals and organizations,” including a plan sponsor or third party administrator. 84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. pt. 88.2).
- “Assist in the performance” in the Church Amendments is expanded to include anything with a “specific, reasonable and articulable connection” to a procedure or service, including “counseling, referral, training, or otherwise making arrangements.” *Id.*

- “Discriminate” is defined to include actions based on an individual’s refusal to do certain activities based on “religious, moral, ethical, *or other* reasons,” and limits when an employer can inquire about an employee’s potential objections. *Id.* (emphasis added).
- “Referral” and “refer for” are defined to include “the provision of information” that might assist the individual in obtaining or performing a particular procedure or service. *Id.*

The Rule grants OCR broad enforcement tools, including permitting it to temporarily or permanently withhold current or future funding—“in whole or in part”—from any covered entity deemed to have discriminated in violation of the federal conscience provisions. 84 Fed. Reg. at 23,272.

D. The Rule’s Focus on California and Its Laws

The Rule expressly points to California and its laws as justification for the rulemaking. In fact, the Rule mentions California no fewer than 44 times. *See* 84 Fed. Reg. at 23,176-79. For example, it cites California as a State with “health care laws and policies that have resulted in lawsuits by conscientious objectors.” *Id.* at 23,176.

HHS focuses in particular on its 2016 decision regarding three complaints filed by religious employers against California alleging a violation of the Weldon Amendment. 84 Fed. Reg. at 23,178-79; *see also* 83

Fed. Reg. at 3890-91.² In 2016, HHS concluded that California did not violate the Weldon Amendment because the complainants were not “health care entities.” HHS further noted that enforcing the Weldon Amendment against California could “‘potentially’ require revocation of” California’s federal funding, thus violating the Spending Clause. 84 Fed. Reg. at 23,179 n.38 (Letter from OCR (June 21, 2016), *available at* <https://perma.cc/G4WP-V69V> (citing *NFIB*)); *see also* 83 Fed. Reg. at 3890.

But, in the preamble to the Rule, HHS now states that its prior interpretation of the Weldon Amendment “no longer reflects” its current position, notwithstanding the prior constitutional concerns. 84 Fed. Reg. at 23,179. HHS specifically acknowledges that its new, broadened interpretation of the term “health care entity” provides justification for renewed targeting of California. *Id.* Indeed, HHS has since reopened its

² The complaints concerned 2014 letters to seven health plans by California’s health plan regulator. *See* 84 Fed. Reg. at 23,177 n.35. The agency explained that state law requires the provision of basic healthcare coverage and the California Constitution prohibits health plans from discriminating against women who choose to terminate a pregnancy. *Id.*; *see also* *Missionary Guadalupanas of the Holy Spirit, Inc., v. Rouillard*, 38 Cal. App. 5th 421 (2019).

previously closed investigations.³ And a Weldon Amendment violation under the Rule could result in California losing billions in federal funding for “a single instance of noncompliance.” ER 61 (CA op.); *see also* SER 1272-77 (Ghaly Decl. ¶¶ 8-21), 938-41(Cantwell Decl. ¶¶ 2, 5, 8-9).

E. Procedural Background

Numerous parties challenged the Rule before it went into effect, with cases filed in the Northern District of California, the Eastern District of Washington, and the Southern District of New York. California’s Complaint alleged that the Rule violated the APA and the Spending and Establishment Clauses of the United States Constitution. SER 43-53 (Complaint). California’s case was subsequently related to the cases filed by the City and County of San Francisco and the County of Santa Clara. ER 81.

Considering the cases together, the California district court granted summary judgment to the plaintiffs and vacated the Rule in its entirety.

³ SER 1461-67 (Palma Decl. Ex. B) (August 2018 OCR Letter). HHS then issued a Notice of Violation to California on January 24, 2020. *See* Press Release, U.S. Dep’t. of Health and Human Services, HHS Issues Notice of Violation to California for its Abortion Coverage Mandate (Jan. 24, 2020), <https://www.hhs.gov/about/news/2020/01/24/hhs-issues-notice-of-violation-to-california-for-its-abortion-coverage-mandate.html>. And in January 2019, OCR sent a letter concluding that California had violated the Weldon and Coats-Snowe Amendments via its FACT Act. 84 Fed. Reg. at 23,177 n.30.

ER 34-65. The court held that HHS violated the APA because the regulation’s “new definitions conflict with the underlying statutes” and “impos[ed] draconian . . . penalties.” ER 60, 63. Based on its conclusion that HHS had exceeded its authority and acted contrary to law, the court vacated the Rule. ER 63-64. The court did not reach the parties’ arbitrary and capricious APA claim or the constitutional claims.⁴

In the Eastern District of Washington, the district court granted summary judgment to plaintiff-appellee the State of Washington and likewise vacated the Rule in its entirety. ER 32-33. The court adopted an earlier decision from the Southern District of New York, which had found that the Rule exceeded HHS’s authority, was contrary to law, was arbitrary and capricious, and violated separation of powers and the Spending Clause. *New York*, 414 F. Supp. 3d at 475; *see* ER 30-33.

Defendants have appealed each of these district court rulings. The California and Washington appeals have been consolidated in this Court.

⁴ Because the court granted judgment in its favor, California dismissed its arbitrary and capricious, Spending Clause, and Establishment Clause claims as moot. ER 2. San Francisco dismissed its remaining claims as moot (ER 4) and the court entered judgment in the Santa Clara case, concluding that reaching the other claims was unnecessary (ER 6).

SUMMARY OF ARGUMENT

1. HHS violated the APA in promulgating the Rule in at least three respects:

- HHS exceeded its statutory authority when it expanded statutory definitions in several federal laws far beyond the text of those statutes and granted itself broad enforcement powers unmoored from any statutory scheme. And HHS’s inflation of its enforcement authority permits it to withdraw *all* federal funding—without regard to the underlying statutes’ ties to specific funding streams—for a violation of any part of the Rule.
- The Rule is “not in accordance with law,” 5 U.S.C. § 706(2)(A), because it conflicts with EMTALA and Title VII. “By its terms, EMTALA does not include any exception for religious or moral refusal to provide emergency care.” *New York*, 414 F. Supp. 3d at 537-38; *see* ER 30 (fully adopting “the reasoning set forth in [the *New York* order]”). Yet the Rule brooks no concession to emergencies. The Rule is similarly incompatible with the undue hardship/reasonable accommodation framework of Title VII.
- The Rule is arbitrary and capricious. In promulgating the Rule, HHS offered justifications that were unsupported by the evidence before it and, in one instance, provably false. HHS ignored the significant reliance interests plaintiffs-appellees had in HHS’s prior rulemaking. And the agency provided insufficient justifications for its policy change, relying instead on speculative conclusions about its benefits.

2. The Rule is an unconstitutional abuse of the Spending Clause for at least four reasons:

- First, the Rule is impermissibly coercive because it leaves States and local governments no practical alternative but to surrender and comply with the Rule or risk losing billions of dollars of

critical funding. *NFIB*, 567 U.S. at 581.

- Second, the Rule’s conditions are so vague that States and local governments cannot reasonably anticipate what actions by them or their sub-recipients might violate the Rule. *Id.* at 583.
- Third, the Rule imposes new compliance obligations on funding recipients and their sub-recipients that they could not have anticipated when they accepted federal funds, marking a “shift in kind, not merely degree.” *Id.*
- Fourth, the Rule places a large number of federal funds at risk that are untethered to the laws the Rule purports to enforce.

3. The APA requires the Rule to be “set aside” and vacated in its entirety. 5 U.S.C. § 706(2). HHS’s request that the Court grant geographically-limited relief finds no support in the APA or case law.

STANDARDS OF REVIEW

This Court reviews a grant of summary judgment de novo. *U.S. ex rel. Ali v. Daniel, Mann, Johnson & Mendenhall*, 355 F.3d 1140, 1144 (9th Cir. 2004). It can “affirm a grant of summary judgment on any ground supported by the record, even if not relied upon by the district court.” *Id.*; *Barnes-Wallace v. City of San Diego*, 704 F.3d 1067, 1084 (9th Cir. 2012).

ARGUMENT

I. THE RULE WAS ADOPTED IN VIOLATION OF THE APA

The APA instructs courts to “hold unlawful and set aside agency action” that is “arbitrary [and] capricious,” “not in accordance with law,” or

“in excess of statutory jurisdiction.” 5 U.S.C. § 706(2)(A), (C). The courts below properly held that this Rule violates the APA on all three counts.

A. HHS Exceeded Its Authority in Promulgating the Rule

As every court to have considered the Rule has concluded, the Rule violates the APA because it exceeds HHS’s statutory jurisdiction. 5 U.S.C. § 706(2)(C).⁵ The question the Court must answer in evaluating this claim is “simply, *whether the agency has stayed within the bounds of its statutory authority.*” *City of Arlington, Tex. v. FCC*, 569 U.S. 290, 297 (2013) (emphasis in original). HHS has not. The Rule substantively alters statutory definitions and establishes “draconian” enforcement mechanisms that are far outside the bounds of the federal conscience laws. ER 30-31, 59-61.

1. HHS’s expansive definition of “health care entity” conflicts with the statutory definitions

The Rule adopts a number of definitions that significantly expand statutory terms or create new definitions from whole cloth. The courts below correctly concluded that HHS lacks authority to do so.⁶

⁵ California adopts San Francisco’s additional arguments that HHS exceeded statutory authority in promulgating the Rule at pages 16-40. *See* Fed. R. App. P. 28(i).

⁶ California discusses here only the Rule’s definition of “health care entity.” It adopts San Francisco’s additional challenges to the Rule’s definitions at pages 18-36.

An agency must have substantive rulemaking authority in order to promulgate legislative rules imposing new duties on affected parties. *See, e.g., La. Pub. Serv. Comm'n v. F.C.C.*, 476 U.S. 355, 374 (1986). Because the Rule's definitional provisions nonetheless "grant rights" and "impose obligations" on regulated parties and have "significant effects on private interests," they are impermissible legislative rules. *Zaharakis v. Heckler*, 744 F.2d 711, 713 (9th Cir. 1984) (quoting *Batterton v. Marshall*, 648 F.2d 694, 701-02 (D.C. Cir. 1980)).

HHS has abandoned its previous argument that it had substantive rulemaking authority to promulgate legislative rules in this area. *Compare* AOB 27-28 ("The Rule's definitional provisions are interpretive . . .") *with* SER 1928-30 (Motion), 1967-69 (Reply). HHS's pivot is not tenable. No matter how HHS characterizes it, the Rule effects a dramatic change in existing law. As this Court has long recognized, "[a] regulation may not serve to amend a statute, nor add to the statute 'something which is not there.'" *Cal. Cosmetology Coalition v. Riley*, 110 F.3d 1454, 1460 (9th Cir. 1997). That applies whether a rule is "interpretive" or not. As the California district court recognized, an interpretive rule "can never add to or subtract from a statute itself." ER 59-60.

By including nearly a dozen new entities, the Rule has given the term “health care entity” “a meaning so broad that it is inconsistent with its accompanying words, thus giving ‘unintended breadth to the Acts of Congress.’” *Gustafson v. Alloyd Co., Inc.*, 513 U.S. 561, 575 (1995). For California, transforming the definition of “health care entity” under Weldon would impose new and significant obligations on the State. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019) (holding that an interpretive rule does “not impose any ‘legally binding requirements’ on private parties”). HHS previously found that California *did not* violate Weldon because the provision did not apply to “institutions or individuals who purchase or are insured by those plans.” *See* 84 Fed. Reg. at 23,179. The Rule’s expansion of “health care entity” now allows HHS to find California in violation of discriminating against plan sponsors and move to strip the State of billions in federal funding. That transformative effect demonstrates that the Rule’s definition is not the mere interpretive rule HHS claims it to be.

HHS does not have authority to make legislative rules concerning the definition of “health care entity.” The Coats-Snowe Amendment delegates only limited rulemaking authority. *See* 42 U.S.C. § 238n(b)(1) (conferring rulemaking authority only as to accreditation of postgraduate physician training programs); ER 37 (CA op.). The Weldon Amendment delegates

none at all. Without such authority, the Rule’s substantive changes are invalid. *See Pharm. Research & Manufacturers of Am. v. HHS*, 43 F. Supp. 3d 28, 45-47 (D.D.C. 2014) (vacating rule because HHS lacked statutory authority to issue it); *see also, e.g., Air Alliance Houston v. E.P.A.*, 906 F.3d 1049, 1060-66 (D.C. Cir. 2018) (vacating EPA rule for lack of statutory authority).

But even if the Court concludes the definitional provisions are interpretive rules, as HHS now urges (AOB 28), the agency’s definitions would still be invalid. As HHS concedes, in evaluating an interpretive rule, the question is whether the challenged definition reflects the “best reading” of the statute. AOB 30; *see also Citizens to Save Spencer County v. EPA*, 600 F.2d 844, 876 n.153 (D.C. Cir. 1979) (an interpretive rule merely “reminds’ affected parties of existing duties”). HHS’s proposed definition is contrary to the plain terms of the statutes that define it.

Each of the three federal conscience provisions that expressly defines “health care entity” does so by enumerating a list of individuals or organizations that qualify. The Coats-Snowe Amendment, for instance, defines the term to “include[] 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). The Weldon Amendment and

the ACA state that “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.” 42 U.S.C. § 18113; Appropriations Act § 507(d)(2) (same). Where a statute expressly defines a term, the “[s]tatutory definitions control the meaning of statutory words.” *Lawson v. Suwanee Fruit & Steamship Co.*, 336 U.S. 198, 201 (1949).

Yet HHS argues the use of the word “includes” in the Weldon and Coats-Snowe amendments suggests that “the examples enumerated in the text are intended to be illustrative, not exhaustive.” *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012); *see* AOB 36-37. However, any additional entities must be similar to those enumerated and “within the purview of the statute.” *U.S. v. Hockings*, 129 F.3d 1069, 1071 (9th Cir. 1997); *see also, e.g., Davis v. Michigan Dept. of Treasury*, 489 U.S. 803, 809 (1989) (“[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme.”).

The Rule’s definition of “health care entity” is well outside the reach of the statutory provisions. The Rule’s expanded definition for the Coats-Snowe Amendment, for instance, sweeps a number of new entities into the

statute, including “pharmac[ies],” and “medical laborator[ies].” 84 Fed. Reg. 23,264 (45 C.F.R. § 88.2). These are entities that have “never [previously] appeared in any conscience statute.” ER 50 (CA op.). And with good reason. The Coats-Snowe Amendment was enacted to address concerns that the medical accreditation organization was requiring hospitals and medical training programs to train residents to induce abortions. *Id.* at 49 (citing 142 Cong. Rec. 2264-65 (1996)). The entities that Congress included in its definition speak directly to that purpose.

By contrast, the entities that the Rule would bring within the scope of the statute are far removed. Pharmacies or medical laboratories do not offer training on abortion, nor are they involved in the performance of the procedure itself. The entities the Rule has added to the statutory definition simply are not of the same kind as the entities Congress itself included. *See, e.g., Gutierrez v. Ada*, 528 U.S. 250, 255 (2000) (“words and people are known by their companions”). As the California district court put it, “[t]he Coats-Snowe Amendment was aimed at protecting doctors, residents, and medical students in the context of training. Pharmacists . . . don’t fit.” ER 50-51.

The same is true regarding the Weldon Amendment and the ACA. The entities listed in the statutory definition all have a direct connection to

healthcare. 42 U.S.C. § 18113; Appropriations Act § 507(d)(2). The Rule, however, adds nearly a dozen new entities, including “plan sponsors” (i.e. employers) and “third-party administrators,” among others. 84 Fed. Reg. 23,264 (to be codified at 45 C.F.R. § 88.2); ER 51-54 (CA op.).

Those broad categories do not fall within the meaning of these statutes. The statutory definition Congress provided—including the catch-all clause “any other kind of health care facility, organization, or plan” on which HHS relies, 42 U.S.C. § 18113; Appropriations Act § 507(d)(2); *see* AOB 37—must be “understood against the background of what Congress was attempting to accomplish in enacting” the statute. *Gustafson*, 513 U.S. at 575. And it must be “construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words.” *Yates v. United States*, 574 U.S. 528, 545 (2015). The Weldon Amendment offers no support for including those entities within its scope. They are distinct from those listed in the Weldon Amendment’s definition, and from the purpose of the Weldon Amendment itself.

A “plan sponsor,” for instance, could cover *any* employer—not just those in the healthcare industry—who provides employee health benefits. *New York*, 414 F. Supp. 3d at 525. And a “third-party administrator” could refer to anyone who processes benefit claims or performs other

administrative tasks. *Id.* Neither term is limited to the actual *provider* of healthcare, which is what the Weldon Amendment aims to regulate. *See, e.g.*, ER 53 (the Weldon Amendment was intended “to protect the decisions of physicians, nurses, clinics, hospitals, medical centers, and even health insurance”).⁷ An employer’s decision to provide group health insurance to its employees is an administrative function of being an employer. It does not transform the employer into a direct participant in the healthcare industry, or render it a “health care facility, organization, or plan.”

2. The Rule expands HHS’s enforcement authority to terminate or withhold all federal funding, without statutory authorization

The Rule also exceeds HHS’s statutory enforcement authority. The Rule provides that “[i]f OCR determines that there is a failure to comply” with *any* of the federal provisions listed in the Rule or the Rule itself, OCR may immediately terminate or withhold *all* HHS-administered federal

⁷ As the California district court observed, “when interpreting Congress’s intent or administrative regulations, the word ‘include’ is nonetheless bounded by the intent expressed in the legislative history.” ER 51 (citing cases). HHS’s assertion that this legislative history is entitled to little or no weight is incorrect. *See Fed. Energy Admin. v. Algonquin SNG, Inc.*, 426 U.S. 548, 564 (1976) (statement of one of legislation’s sponsors deserved to be accorded “substantial weight” in interpreting statute); *see also INS v. Cardoza-Fonseca*, 480 U.S. 421, 432 & n.12 (1987) (courts may review legislative history for legislative intent).

financial assistance received by the entity, “in whole or in part.” 84 Fed. Reg. at 23,272 (to be codified at 45 C.F.R. pt. 88.7(i)(3)). Although the Rule states that noncompliance “will be resolved by informal means whenever possible,” it nonetheless authorizes OCR to “simultaneously” proceed to terminate or withhold all of an entity’s HHS-administered federal funding even during the pendency of efforts for informal resolution and good-faith compliance. *Id.* pt. 88.7(i)(2)-(3).

These enforcement provisions well exceed the bounds of the agency’s authority. *See, e.g., City of Arlington*, 569 U.S. at 297-98 (“[T]he question . . . is always whether the agency has gone beyond what Congress has permitted it to do”). For one, the enforcement mechanisms set out by the underlying statutes are decidedly narrower than the Rule’s, implicating only specific streams of funding. No statute generally authorizes HHS to terminate *all* sources of a state’s federal financial assistance based on a single violation of any of the more than thirty federal statutes referenced in the Rule. For instance, the Church Amendments apply only to recipients of Public Health Service Act funds. 42 U.S.C. § 300a(c)(1). Similarly, the exemptions for providing or paying for “a counseling or referral service” on conscience-related grounds apply only to certain Medicaid managed care organizations and Medicare Advantage. *See* 42 U.S.C. §§ 1395w-

22(j)(3)(B), 1396u-2 (b)(3)(B). But the Rule does not distinguish between the different statutes in its imposition of penalties. Instead, the Rule provides that a single violation of a discrete provision of the Church Amendments, as interpreted by the Rule, would permit HHS to terminate or withhold *all* of a State’s federal healthcare funding—including funding not mentioned in the Church Amendments. ER 61 (CA op.).

HHS attempts to downplay the more draconian aspects of the Rule’s enforcement provision. For instance, HHS argues that a funding recipient’s violation of the federal conscience provisions will lead only to “termination of the relevant funding,” citing the preamble’s provision 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.” AOB 20-22 (citing 84 Fed. Reg. at 23,223). But the actual text of the Rule does not contain any limiting language. On its face, Section 88.7 permits “[w]holly” rescinding funding if “there is a failure to comply with Federal conscience and anti-discrimination laws or this part.” 84 Fed. Reg. at 23,272 (to be codified at 45 C.F.R. pt. 88.7(i)(3)). It is the text of the Rule that controls this Court’s inquiry, not the agency’s litigating position. *See, e.g., Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988) (“Congress has delegated to the administrative official and not to appellate

counsel the responsibility for elaborating and enforcing statutory commands.”) (citation omitted). That is especially true where, as here, the litigating position is “wholly unsupported” by the text of the regulation. *Id.*; accord, e.g., *Johnson v. Bd. of Trustees of Boundary Cty. Sch. Dist. No. 101*, 666 F.3d 561, 566 n.7 (9th Cir. 2011) (declining to give deference to agency litigating position that is “at odds with the plain text of the regulation”).

HHS also locates its authority in the text of the Weldon Amendment AOB 23. But the Rule does not limit funding terminations to Weldon Amendment violations alone. Instead, it applies to *all* of the statutes HHS purports to interpret—even those that are tied to specific and discrete funding streams. HHS emphasizes that “termination of *the relevant funding* is a natural consequence for violations,” yet in the same breath argues that it is well within its authority “to terminate all HHS funds as one potential enforcement mechanism.” AOB 24 (emphasis added). Thus, even the agency’s litigating position leaves unclear whether the agency would limit enforcement to specific—rather than entire—funding streams. *See Bowen*, 488 U.S. at 212.

Such extreme enforcement power is not mere “housekeeping.” AOB 20 (citing 5 U.S.C. § 301).⁸ “The idea that Congress gave” HHS such “broad” authority through a statutory authorization intended to cover such mundane matters as the preservation of agency records, papers, and property “is not sustainable.” *Gonzales v. Oregon*, 546 U.S. 243, 267 (2006). Congress does not “hide elephants in mouseholes.” *Id.* Nor is HHS’s reliance on the Uniform Administrative Requirements availing (AOB 22-23) when its remedy is limited to the specific source of funding at issue. *Cf.* 45 C.F.R. § 75.372(a)(1) (“*The Federal award may be terminated . . . if the non-federal entity fails to comply with the terms and conditions of the award.*”) (emphasis added). HHS cannot use the Requirements’ restrained and limited process to justify the Rule’s expansive enforcement powers.

B. The Rule Conflicts with Other Healthcare Laws

The APA also instructs a court to “hold unlawful and set aside agency action” that is “not in accordance with law.” 5 U.S.C. § 706(2)(A). This “means, of course, *any* law, and not merely those laws that the agency itself

⁸ HHS relies on *Chrysler Corp. v. Brown* for the proposition that department heads have been “long empowered” by 5 U.S.C. § 301 “to regulate internal departmental affairs.” AOB 20 (citing 441 U.S. 281, 309 (1979)). But *Chrysler* acknowledges that authority’s limited scope. 441 U.S. at 309 n.39.

is charged with administering.” *FCC v. NextWave Pers. Commc’ns, Inc.*, 537 U.S. 293, 300 (2003) (emphasis in original). This Rule directly conflicts with a number of federal statutes relating to healthcare.⁹ Most crucial is the unavoidable and potentially catastrophic conflict between the Rule and EMTALA, which guarantees all patients emergency medical treatment at facilities that participate in Medicare and Medicaid. As the Washington district court properly recognized, the Rule violates the APA on this ground as well. ER 30 (adopting *New York* order); *New York*, 414 F. Supp. 3d at 538 (vacating the Rule in part because it conflicts with EMTALA).

EMTALA was enacted by Congress in 1986 in response to growing concern about the provision of adequate medical services to individuals, particularly the indigent and the uninsured, who seek care at hospital emergency rooms. 42 U.S.C. § 1395dd(a); *Jackson v. East Bay Hosp.*, 246 F.3d 1248, 1254 (9th Cir. 2001). Under EMTALA, if “any individual”

⁹ Plaintiffs-appellees below identified three separate laws with which this Rule conflicts—EMTALA, Title VII, and the ACA. The district courts did not reach all these arguments, vacating the Rule on other grounds. California addresses here the Rule’s conflict with EMTALA, and adopts Washington and San Francisco’s argument that the Rule conflicts with Title VII. The California court did not reach the State’s claims that the Rule is contrary to ACA Sections 1554 and 1557. If the Court does not affirm the judgment on any of the grounds addressed in appellees’ briefs, it should remand for the district court to consider California’s ACA claims in the first instance.

comes to a hospital's emergency room, "the hospital must provide for an appropriate medical screening examination . . . to determine whether or not an emergency medical condition . . . exists." 42 U.S.C. § 1395dd(a). The hospital must then provide either "treatment as may be required to stabilize the medical condition" or "transfer of the individual to another medical facility." *Id.* § 1395dd(b). A hospital's violation of the statute subjects it to a private civil action for damages. *Id.* § 1395dd(d).

"Through EMTALA, Congress sought to provide an adequate first response to a medical crisis for all patients." *Matter of Baby K*, 16 F.3d 590, 593 (4th Cir. 1994); accord *Brooker v. Desert Hosp. Corp.*, 947 F.2d 412, 415 (9th Cir. 1991) (similar). As a result, "courts have declined to read exceptions into EMTALA's mandate." *New York*, 414 F. Supp. 3d at 537 (citing cases). Consistent with that inclusive purpose, EMTALA "does not include any exception for religious or moral refusals to provide emergency care." *Id.*; see also, e.g., *Baby K*, 16 F.3d at 597 ("EMTALA does not provide an exception for stabilizing treatment physicians may deem medically or ethically inappropriate."); *Cleland v. Bronson Health Care Grp., Inc.*, 917 F.2d 266, 272 (6th Cir. 1990) (observing that EMTALA's plain text prohibits a hospital from refusing treatment based on "political or cultural opposition"). The Rule, however, "creates, via regulation, a

conscience exception to EMTALA’s statutory mandate.” *New York*, 414 F. Supp. 3d at 538. In so doing, it conflicts with EMTALA’s plain terms and purpose.

The Rule’s conflict with EMTALA is not just theoretical; it is “consequential.” *Id.* at 539. It subjects hospitals to competing obligations, making it impossible for hospitals to guarantee the emergency care EMTALA requires. For instance, as the California district court observed, “an entity could lose all of its HHS funding if it fired a hospital front-desk employee for refusing to tell a woman seeking an emergency abortion for an ectopic pregnancy which floor she needed to go to for her procedure.” *Compare ER 58 with 41 U.S.C. § 1395dd(a)* (requiring hospital provide “appropriate medical screening examination” for “any individual [who] comes to the emergency department”).

Indeed, HHS conceded that the Rule would permit a paramedic to refuse to transport a patient with a life-threatening complication that may require an emergency abortion and “could potentially impose liability” on an employer for insisting the paramedic provide transport. *See New York*, 414 F. Supp. 3d at 539. Yet that refusal would deny the patient the emergency stabilizing treatment EMTALA guarantees. “[T]he absence of any exception in the Rule’s mandates [for emergencies] creates a clear conflict between the

Rule and EMTALA.” *Id.* at 538.

HHS offers several reasons why this Court should disregard this obvious conflict. None withstand scrutiny. First, HHS claims that the incompatible obligations under the Rule “do[] not demonstrate a ‘facial conflict,’ . . . but a challenge to how the Rule would apply in particular circumstances.” AOB 44. But the conflict between EMTALA and the Rule is clear on its face, as HHS later concedes. AOB 45 (“If a situation arises in which these statutes must be harmonized, EMTALA is properly read not to permit . . . a hospital to override conscience objections to provide medical treatment.”).

Second, HHS’s relies on its statement from over a decade ago that it was “unaware of any instance” where a facility was unable to provide emergency care because its entire staff objected based on conscience (AOB 44-45). Ample evidence before the agency belies this claim. *See* SER 89 (ACLU Letter), 245 n.86 (CRR Letter), 300 n.18 (FMF Letter), 626 n.8 (Oregon Foundation for Reproductive Health Letter); 970-72 (Chavkin Decl. ¶¶ 14-21); 83 Fed. Reg. at 3888-89 & n.36 (citing *Means* case in which hospital denied emergency medical care to a woman who experienced pregnancy complications likely to result in her injury or death and fetal

death).¹⁰ The American College of Emergency Physicians warned HHS that patients experiencing crises “may not have time to wait to be referred to another physician . . . if the present provider has a moral or religious objection.” SER 112 (ACEP Letter). Thus, on its face, the Rule interferes with the split-second decisions providers must make when faced with emergencies—with patients’ lives hanging in the balance.

Moreover, the Rule prevents a hospital from addressing those conflicting obligations by restricting the hospital’s ability to inquire about conscience objections during the hiring process or to reassign an employee if the hospital becomes aware of an objection. *See* 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. pt. 88.2 (definition of “discriminate”)). That is especially problematic since, as the above examples illustrate, a single employee can obstruct a patient’s ability to obtain emergency care and yet simultaneously cannot be required to provide a referral or any assistance in ensuring a patient receives care from a non-objecting colleague. By

¹⁰ HHS relies on *EPA v. EME Homer City Generation, L.P.* to justify its “facial” versus “as applied” dichotomy. AOB 44 (quoting 572 U.S. 489, 524 (2014)). But in *EPA*, the agency had been delegated the authority to determine the challenged allocation method. Moreover, the concrete examples in the record contradicts HHS’s characterization of conflicts with EMTALA as “uncommon particular applications.” *See id.*

preventing hospitals from taking precautions against such a situation, the Rule makes it impossible for them to ensure that they can adhere to EMTALA while respecting conscience objections.¹¹ That is not a problem of application; it is a problem inherent in the Rule's broad scope.

HHS's proposal to "harmonize" EMTALA with the Rule (AOB 45) defies the "commonplace of statutory construction that the specific governs the general." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012). EMTALA speaks directly to medical emergencies. The provisions the Rule purports to implement do not. In fact, the legislative history of those provisions suggests that Congress did not intend them to apply "in an emergency situation" at all. SER 1660 (statement of Sen. Church); *see also* SER 1683 (the law "ensures that in situations where a mother's life is in danger a health care provider must act to protect a mother's life") (Rep. Weldon), 1693 ("[A] resident needs not to have

¹¹ HHS contends that this risk is mitigated by the Rule's exception allowing employers to request advance notice of conscience objections where there is "a persuasive justification." AOB 46. Given the wide variety of situations in which a single employee can thwart adherence to EMTALA under this Rule, that exception hardly cures the conflict. Moreover, given HHS's position that EMTALA must yield to HHS's interpretation of the conscience statutes, AOB 45, it is unlikely that a hospital's need to provide emergency care would be accepted as a "persuasive justification."

performed an abortion . . . to have mastered the procedure to protect the health of the mother if necessary”) (Sen. Coats). Thus, even if the Rule’s interpretation of these provisions were correct (which it is not), it would be the conscience objection that must yield in an emergency, not EMTALA.¹² *See RadLAX*, 566 U.S. at 645 (“To eliminate the contradiction, the specific provision is construed as an exception to the general one.”).

Finally, HHS points to the text of EMTALA, which “requires emergency medical care only ‘within the staff and facilities available at the hospital.’” AOB 45. According to HHS, a staff member who objects to providing emergency treatment is simply not “available,” so “there is no violation of EMTALA” when the staff member refuses emergency care. *Id.* This twisting of the statute’s terms reaches too far. In *Baby K*, the Fourth Circuit rejected a hospital’s similar argument that it had “no physicians available” to treat Baby K because its physicians refused to provide

¹² Also unavailing is HHS’s parenthetical assertion that the ACA’s explicit prohibition on conscience objections in the emergency context “underscores that Congress did not include any such exemption in other conscience provisions.” AOB 45. The ACA simply directs compliance with EMTALA. That other conscience provisions do not explicitly mention EMTALA does not render it inapplicable. *MacLean* does not hold otherwise. *DHS v. MacLean*, 574 U.S. 383, 394 (2015) (examining whether “law” in a statute encompassed regulations when “law, rule, or regulation” was used in the same sentence).

respiratory support treatment they found medically or ethically inappropriate. *Baby K*, 16 F.3d at 597. Moreover, this Court has held that under HHS’s own rules, a hospital may only refuse a patient if it “is in ‘diversionary status,’ that is, it does not have the staff or facilities to accept any additional emergency patients,” or there is a “valid treatment-related reason for doing so.” *Arrington v. Wong*, 237 F.3d 1066, 1072–73 (9th Cir. 2001); *see also* 42 C.F.R. §489.24(d)(1) (defining a hospital’s “capabilities” as “the level of care that the personnel of the hospital can provide within the training and scope of their professional licenses” and the “physical space, equipment, supplies, and specialized services that the hospital provides”). HHS’s proposed reading of EMTALA conflicts with this case law and with HHS’s own rules that assess a hospital’s capability accounting for all personnel whether or not they object to a particular treatment.

C. The Rule Is Arbitrary and Capricious

The APA also requires courts to “hold unlawful and set aside agency action” that is “arbitrary [and] capricious,” 5 U.S.C. § 706(2)(A), and the touchstone of review is reasoned decision making. *E. Bay Sanctuary Covenant v. Barr (Barr)*, 964 F.3d 832, 849 (9th Cir. 2020). Agency action is invalid if the agency “entirely failed to consider an important aspect of the problem” or “offered an explanation for its decision that runs counter to the

evidence before the agency.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). In addition, where an agency departs from a prior policy, it must show that “there are good reasons” for the reversal, and “must also be cognizant that longstanding policies may have ‘engendered serious reliance interests that must be taken into account.’” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (quoting *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)).

As the Washington district court recognized, the Rule cannot survive arbitrary and capricious review for numerous reasons. ER 30. California addresses three of those reasons here.¹³ First, the justifications that HHS provided for its policy reversal are contrary to the evidence in the record. Second, HHS fails to account for the substantial reliance interests created by the agency’s prior policy. Third, the claimed benefits of the new policy are entirely speculative.

1. HHS’s justifications for the Rule are contrary to the evidence in the record

An agency’s change in policy is arbitrary and capricious if the

¹³ California adopts Washington (pp. 43-62), San Francisco (pp. 47-52), and Santa Clara’s (pp. 48-62) additional arbitrary and capricious arguments.

agency's explanation "runs counter to the evidence before the agency." *State Farm*, 463 U.S. at 43.

In justifying the Rule, HHS stated that it sought to address "two categories of problems": (1) lack of awareness and purported "confusion" from the 2011 Rule concerning the obligations of covered entities under the Federal conscience provisions, and (2) inadequate enforcement tools to address complaints of discrimination and coercion faced by protected persons and entities. 84 Fed. Reg. at 23,228 (discussing "Need for the Rule"); *see also id.* at 23,175 ("Overview of Reasons for the Final Rule"). To illustrate both problems, HHS relied primarily on "a significant increase" in complaints alleging conscience violations. *Id.* at 23,175. Specifically, HHS claimed that it received 343 such complaints in fiscal year 2018 alone. *Id.* at 23,229, 23,245. The increase, HHS asserted, underscored the need for HHS to have "proper enforcement tools available to appropriately" enforce federal conscience provisions. *Id.* at 23,175. The evidence in the record simply does not support the agency's attempt to upend the status quo.

HHS's claim of an increase in complaints in fiscal year 2018 as the justification for the Rule is "demonstrably false." *New York*, 414 F. Supp. 3d at 541 (citing 84 Fed. Reg. at 23,175); ER 30. Indeed, HHS has now conceded that it received only 20 complaints in fiscal year 2018 that actually

implicated the federal conscience provisions—not 343. *New York*, 414 F. Supp. 3d at 542 (“THE COURT: Yes or no: Are we down to about 20 that actually implicate these statutes as opposed to other problems? MR. BATES: Yes. In that ballpark.”).¹⁴ HHS also concedes that in the year prior to 2018, before it issued the proposed rule on January 26, 2018, it received only 34 *complaints* alleging violations of conscience. 84 Fed. Reg. at 23,229. In short, HHS’s claim that a “significant increase” in 2018 necessitated the present rulemaking is “flatly untrue.” *New York*, 414 F. Supp. 3d at 541. “HHS’s reliance even ‘*in part* on the basis of’ these patently inapposite complaints is enough to render the Rule arbitrary and capricious.” *Id.* (quoting *Animal Legal Def. Fund, Inc. v. Perdue*, 872 F.3d 602, 619 (D.C. Cir. 2017) (emphasis added)); see also *Barr*, 964 F.3d at 850–52 (finding federal government acted arbitrarily and capriciously by “misrepresent[ing] . . . the record”).

¹⁴ Twenty-two of the 343 complaints were duplicates. *New York*, 414 F. Supp. 3d at 541-42; SER 961 (Chance Decl. ¶¶ 7-8). Of the 321 remaining unique complaints, 260 of those complaints (81%) relate to state vaccination mandates, which HHS concedes the Rule does not preempt. SER 963 (Chance Decl. ¶ 11); 84 Fed. Reg. at 23,212; see also *New York*, 414 F. Supp. 3d at 542 (finding that 79% of the non-duplicative complaints were related to vaccinations). Thus only 18 of the 343 complaints concern abortion. SER 965 (Chance Decl. ¶ 15).

HHS now attempts to downplay its reliance on the illusory 343 complaints, arguing that an agency need not compile a particular number of violations in order to promulgate a rule. AOB 48-49. But that is beside the point. An “agency must defend its actions based on the reasons it gave when it acted.” *Dep’t of Homeland Sec. v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1909 (2020). And the Court’s review is “limited to evaluating the agency’s contemporaneous explanation in light of the existing administrative record.” *Dep’t of Commerce v. New York*, 139 S. Ct. 2551, 2573 (2019). HHS cannot now, mid-litigation, backtrack from its reliance on the “significant increase” in complaints because its justification has proven false. *See, e.g., Bowen*, 488 U.S. at 212; *Johnson*, 666 F.3d at 566 n.7.

HHS also contends that the increase in complaints was merely “one of the many metrics used to demonstrate the importance of the rule.” AOB 50 (quotation and alteration marks omitted). This misrepresents the record. HHS repeatedly relied on a “significant increase” in complaints in 2018 to justify its rulemaking. 84 Fed. Reg. at 23,175, 23,183. That it has been revealed to be untrue makes it “an unsupported assumption on which [HHS’s] decision necessarily relied.” *Nat. Res. Def. Council, Inc. v. Rauch*, 244 F. Supp. 3d 66, 95–96 (D.C. Cir. 2017) (invalidating rule where record “show[s] its critical . . . assumption to be false”); *Dep’t of Commerce*, 139 S.

Ct. at 2575-76 (invalidating agency action where “the evidence tells a story that does not match the explanation the Secretary gave for his decision”). On this basis alone, the Court should affirm the judgments below.

HHS also cites to lawsuits that have resulted from state and local healthcare laws and policies concerning conscience protections to demonstrate “confusion” about the scope of the conscience laws. AOB 51 (citing 84 Fed. Reg. at 23,176-178). Some of those lawsuits were brought by employers challenging California’s law requiring insurers to include abortion coverage in their plans. *See* 84 Fed. Reg. 23,177 (citing *Foothill Church* and *Skyline Wesleyan Church* cases); *see also* AOB 51 (citing 84 Fed. Reg. at 23,178-79). But OCR definitively held in 2016 that California’s law did not violate the Weldon Amendment because the Amendment’s protections “extend only to health care entities and not to individuals who are patients of, or institutions or individuals that are insured by, such entities.” SER 858 (HHS Letter). Any “confusion” regarding the scope of Weldon stems from HHS’s reversal of its 2016 decision, not the 2011 rule.

2. HHS failed to adequately explain its change in position or acknowledge reliance interests

Where an agency exercises policy discretion to change its statutory interpretation by regulation, the agency must “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. HHS failed to meet this standard. HHS claimed that it promulgated the Rule to correct “confusion” caused by the 2011 rule. 84 Fed. Reg. at 23,175. Yet HHS wholly ignored its finding in the 2011 rule that it was the 2008 rule that had caused “greater confusion” in its attempt to define and clarify the conscience provisions, just as this Rule attempts to do here. 76 Fed. Reg. at 9969. HHS’s failure to account for its change in position or offer justifications for its policy change is fatal.

HHS was also obliged to consider the “serious reliance interests” engendered by its prior interpretations of the conscience provisions, consider the regulation’s impact on these interests, and give “a more detailed justification” for the disruption. *Fox Television Stations*, 556 U.S. at 515. The record shows that many entities have for decades shaped their policies in reliance on federal conscience provisions. In particular, California has relied on OCR’s prior “sub-regulatory guidance,” *see* 84 Fed. Reg. at 23,178, which ensured that California would not face the loss of billions of federal dollars for its residents because of its nondiscrimination laws requiring insurers to include abortion coverage. SER 855-74 (HHS Letter, DMHC Letters). Many other states and localities—including plaintiffs-

appellees—have enacted similar nondiscrimination laws in reliance on that guidance, all of which now place their funding in jeopardy. SER 173-79 (California Letter), 180-87 (CDI Letter), 272-80 (Santa Clara Letter), 682-85 (SFDPH Letter), 722-25 (Washington Letter); 256-60 (NYC); 253-55 (Miami Beach), 267-71 (Pennsylvania Letter). HHS *never* acknowledged these reliance interests. Nor did HHS provide any “detailed justification” for the change or “adequately analyze” the potential “consequences” of enforcing this new regime against state and local governments. *Fox Television Stations*, 556 U.S. at 515; *Am. Wild Horse Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017). HHS merely stated summarily that the prior rule “no longer reflects the Department’s position on . . . Weldon.” 84 Fed. Reg. at 23,179. And despite the interests at stake, the Rule is unclear as to what the protocols and rights of states and localities would be if HHS alleges a violation of the Rule. That is insufficient.

HHS now argues that “[a] regulated entity has no legitimate,” or at least substantially relevant, “reliance interest” in the “erroneous statutory interpretation” it asserts the 2011 rule occasioned. AOB 53. Support for HHS’s argument is not found in the requirements of *Fox Television Stations* or *Encino Motorcars*. In any event, the 2011 rule did not redefine the meaning of certain terms of the conscience provisions as the Rule now does.

If anything, California’s reliance was on the underlying conscience provisions themselves, in addition to the agency’s own determination regarding the bounds of the term “health care entity.” Under clearly applicable law, HHS was required to consider the reliance interests at stake and give a more detailed justification. It did not.

3. The supposed benefits of the Rule are speculative and unsupported

In determining whether an agency decision was arbitrary and capricious, a court need not defer to an agency’s “conclusory or unsupported suppositions.” *McDonnell Douglas Corp. v. U.S. Dep’t of the Air Force*, 375 F.3d 1182, 1186–87 (D.C. Cir. 2004). The agency must “examine the relevant data and articulate a satisfactory explanation for its action including a “rational connection between the facts found and the choice made.” *State Farm*, 463 U.S. at 43. Agency action that fails to provide this explanation is arbitrary and capricious. *Id.*

The benefits HHS used to justify the Rule are so speculative and unsupported by the evidence in the record that there is no rational connection between the facts before the agency and HHS’s ultimate decision to promulgate the Rule. *See* 84 Fed. Reg. at 23,246 (“Estimated Benefits”). In relying on the supposed influx of health professionals that HHS

anticipates entering the profession as a result of the Rule, HHS completely ignored its prior findings that held the exact opposite. HHS previously acknowledged that an “overwhelming number” of the 97,000 comments HHS received in 2011 (after it proposed rescinding the 2008 rule) expressed concern that the 2008 rule unacceptably restricted access to care. 76 Fed. Reg. at 9971; *see also New York*, 414 F. Supp. 3d at 549. Indeed, in promulgating the 2011 rule, HHS rejected comments that the partial rescission of the 2008 rule would result in some providers either leaving or avoiding entering the profession. 76 Fed. Reg. at 9974. HHS also “agree[d] with comments that the 2008 rule may negatively affect the ability of patients to access care if interpreted broadly”; in particular, it noted the concern that the rule might limit access to reproductive services and contraception for women, especially in areas with few providers. *Id.* In adopting the Rule, however, HHS failed to address these 2011 findings, including its finding that access to care would diminish if the rescinded terms of the 2008 rule were in place. *New York*, 414 F. Supp. 3d at 550. HHS must “provide a more detailed justification than what would suffice for a new policy created on a blank slate,” and it “cannot simply disregard contrary or inconvenient factual determinations that it made in the past.” *Id.*

(quoting *Fox Television Stations*, 556 U.S. at 515; *id.* at 537). Its failure to address its prior findings was arbitrary and capricious.

HHS claims it relied on “[n]umerous studies and comments” to show that “the failure to protect conscience is a barrier to careers in the health care field,” and that absent enforcement of conscience protections, providers might leave the field altogether (or decline to enter it in the first place). AOB 54-55 (citing 84 Fed. Reg. at 23,246-47). Yet HHS repeatedly cites to decade-old polling concerning “conscience rights” in healthcare conducted by Kellyanne Conway on behalf of the Christian Medical and Dental Associations. *See, e.g.*, 84 Fed. Reg. at 23,246 n.309; *id.* at 23,247 nn.316–18. This non-representative polling is the *only* data that HHS cited in support of its assertion that the Rule will increase the number of healthcare providers.¹⁵ *See id.* at 23,246 n.309, 23,247 nn.316-18, 23,253 nn.347 & 349.

¹⁵ HHS also purports to rely on “anecdotal” evidence it received concerning violations of conscience laws. 84 Fed. Reg. 23,247. But, as the Washington district court observed, HHS’s willingness to “rely on anecdotes of bias and animus in the health care sector against individuals with religious beliefs and moral convictions, but disregard[] [for] anecdotal accounts of discrimination from LGBT people, citing the lack of suitable data for estimating the impact of the rule,” is “internally inconsistent” and arbitrary and capricious. ER 32 (citations omitted).

Even if this polling could justify a policy change, the data cannot bear the weight that HHS places upon it. First, the polling is dated—it was almost a decade old at the time of rulemaking and the information is stale.¹⁶ Second, the polling was already a part of the record, and its findings considered and rejected when HHS issued the 2011 rule. *See New York*, 414 F. Supp. 3d at 551 n.58. Third, the participants in the online survey were “self-selecting.” SER 881-85 (polling). The polling cautions that it was “not intended to be representative of the entire medical profession [or even] of the entire membership rosters of these organizations.” *Id.* at 885. Finally, as the Washington district court observed, it is “elementary that increasing the number of medical professionals who would deny care based on religious or moral objections would not increase access to care” and would instead “deteriorate” access, “especially for those individuals in vulnerable populations who will be the target of the religious or moral objections.”

ER 31. In short, the principal benefit that HHS relies on is unsubstantiated

¹⁶ The 2009 poll was conducted before the Catholic Church became one of the nation’s largest healthcare providers. *See Eleanor Barczak, Ethical Implications of the Conscience Clause on Access to Postpartum Tubal Ligations*, 70 *Hastings L.J.* 1613, 1621 (2019) (today the Church “operat[es] 649 hospitals” and “provid[es] care for one in six patients receiving medical attention every day”). Accordingly, the Rule would now affect significantly more patients.

by competent evidence, “do[es] not suffice to explain its decision,” and is not entitled to the court’s deference. *Encino Motorcars*, 136 S. Ct. at 2127.

II. THE RULE VIOLATES THE SPENDING CLAUSE

The California district court did not resolve the various constitutional challenges. However, the Washington district court held that the Rule violated the Separation of Powers and the Spending Clause. ER 29-30. The Court should affirm the Washington district court as to the Spending Clause claim.¹⁷

A. The Spending Clause Challenge Is Ripe

HHS challenges the ripeness of a Spending Clause claim. AOB 57-60. But whether this final agency action violates the Spending Clause is a purely legal question that is ripe for adjudication. *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). “[W]here a dispute over agency action ‘presents legal questions and there is a concrete dispute between the parties, the issues are fit for judicial decision,’ even where the ‘factual record is not yet fully developed.’” *New York*, 414 F. Supp. 3d at 564. Moreover, a legal issue is ripe when, as here, (1) delayed review would cause hardship to the plaintiff; (2) judicial intervention does not inappropriately interfere with

¹⁷ California did not allege a Separation of Powers claim.

administrative action; and (3) further factual development is unnecessary.

Ohio Forestry Ass'n v. Sierra Club, 523 U.S. 726, 733 (1998).

First, delayed review would result in a substantial hardship to plaintiffs-appellees because, if allowed to take effect, the Rule requires them to immediately comply or risk ruinous penalties. *Abbott*, 387 U.S. at 152. The Rule requires that funding recipients and sub-recipients furnish an assurance and certification for the duration of funding as a condition for continued funding, and for the renewal and extension of such funds. *See* 84 Fed. Reg. at 23,269-70 (to be codified at 45 C.F.R. pts. 88.4(a)(1),(2), 88.4(b)(3), 88.4(b)(5)); *see also id.* at pt. 88.4(b)(8) (penalties for failure to furnish an assurance or certification); pt. 88.7(j) (allowing for full slate of penalties for noncompliance). Indeed, HHS rejected a comment to the 2018 proposed rule asking for a one-year safe harbor so that regulated entities could gradually come into compliance. *Id.* at 23,216.

As a result, absent judicial intervention, plaintiffs-appellees would be forced to decide immediately whether to forgo federal funding with devastating consequences, or to rewrite existing laws, change their operations, and incur additional costs and administrative burdens. *See New York*, 414 F. Supp. 3d at 564 (recognizing that the Rule “will require major and immediate changes in the policies and actions of the state plaintiffs-

appellees and their sub-recipients, including with respect to hiring, staffing, transfer, and other employment decisions”). For example, California’s Medicaid program would need to spend \$4.5 to 6.5 million to develop an oversight structure to ensure compliance by all 58 counties; its community colleges would need to spend over \$7 million to ensure compliance at 90 health centers; and its Department of State Hospitals and the California Correctional Health Care Services would need to develop policies to ensure patients, including transgender patients, receive constitutionally-mandated medically necessary treatment. SER 939-40 (Cantwell Decl. ¶¶ 6-7), 1354-55 (Harris-Caldwell Decl. ¶ 10), 1536-38 (Price Decl. ¶¶ 9-17), 1604-05 (Toche Decl. ¶¶ 7-8).

In addition, all providers would need to immediately alter their policies and employee contacts, especially those committed to providing reproductive and LGBTQ healthcare. SER 912-13 (Barnes Decl. ¶ 20-23), 932-34 (Burkhart Decl. ¶¶ 19-21), 1191 (Chen ¶¶ 10-13), 1282 (Halladay Decl. ¶ 5), 1373-74 (Lorenz Decl. ¶¶ 19-20), 1423 (Miller Decl. ¶ 7), 1590-93 (Sproul Decl. ¶¶ 4-14). Thus, the “impact” of the Rule would be “felt immediately” because plaintiffs-appellees would need to alter “their day to day affairs” immediately to comply. *See Ohio Forestry*, 523 U.S. at 734 (explaining that “agency regulations can sometimes force immediate

compliance through fear of future sanctions”); *Nat’l Park Hosp. Ass’n v. Dep’t of Interior*, 538 U.S. 803, 808 (2003) (concluding that while regulations, standing alone, are “ordinarily” not ripe, the “major exception” is a rule requiring plaintiffs to immediately adjust conduct).

HHS disagrees, relying on *National Family Planning & Reproductive Health Ass’n v. Gonzales*, 468 F.3d 826 (D.C. Cir. 2006). AOB 58. But, in that case, the plaintiffs did not face any immediate burdens. Instead, the court held that the plaintiffs failed to show that the Weldon Amendment required a “material change” to avoid loss of federal funding because the Church Amendments already forbid discrimination based on an individual’s refusal to refer or provide abortions. *Gonzales*, 468 F.3d at 830. In contrast, the Rule’s expanded definitions and compliance requirements create new obligations with immediate consequences.

Second, judicial review will not inappropriately interfere with administrative action because plaintiffs-appellees’ litigation is not based on an “actual enforcement action.” AOB 58. Third, factual development is unnecessary. HHS has made clear that it is promulgating the Rule to foster more “robust” enforcement, 84 Fed. Reg. at 23,179, and, further, HHS considers California’s laws to currently be in direct conflict with the Rule, *id.* at 23,177-79. This is no abstract disagreement over administrative

policies. It is a ripe dispute impacting millions of people and affecting billions of dollars. *See Ohio Forestry*, 523 U.S. at 736.

B. The Rule Violates All Four Limits on Spending Power

Under the Spending Clause, U.S. Const., art. I, § 8, cl. 1, Congress may not impose conditions on federal funds that are (1) so coercive as to compel (rather than merely encourage) States to comply, (2) ambiguous, (3) retroactive, or (4) unrelated to the federal interest in a particular program. *NFIB*, 567 U.S. at 575–82; *South Dakota v. Dole*, 483 U.S. 203, 206–08 (1987). The Rule violates all four of these prohibitions. The Rule puts States and local governments at risk of catastrophic sanctions by allowing HHS to wield its newly expanded authority to terminate, deny or withhold billions in federal funds. 84 Fed. Reg. at 23,271-72 (to be codified at 45 C.F.R. § 88.7(i)(3)(iv)-(v)).

1. The Rule is unconstitutionally coercive

The Rule is a “gun to the head” of States and local governments that depend on federal funds. *NFIB*, 567 U.S. at 581. It strips them of any “legitimate choice whether to accept the [Rule’s] conditions in exchange for federal funds.” *Id.* at 578.

In *NFIB*, the Supreme Court considered whether the ACA’s Medicaid expansion, which “threatened to withhold . . . States’ existing Medicaid

funds” if they did not accept new conditions, had crossed the line from permissible “encouragement” to impermissible “coercion.” 567 U.S. at 579-80. The Court found that the legislation did, observing that States choosing to opt out of the Medicaid expansion “st[ood] to lose not merely ‘a relatively small percentage’ of its existing Medicaid funding, but *all* of it.” *Id.* at 581. The Court also found it significant that States “ha[d] developed intricate statutory and administrative regimes over the course of many decades” in reliance on that funding. *Id.*

The Supreme Court’s ruling in *NFIB* squarely applies. In some respects, this Rule is more coercive than the threatened loss of Medicaid funding in *NFIB* because the Rule threatens not merely Medicaid funding but funding from an array of health, education, and employment programs. ER 30-31 (WA op.); *see also NFIB*, 567 U.S. at 581-82 (“[t]he threatened loss of over 10 percent of a State’s overall budget” amounted to “economic dragooning that leaves the States with no real option but to acquiesce”). For California alone, the Rule puts in jeopardy \$77.6 billion in federal funding to its Health & Human Services Agency (CHHS)—almost half of CHHS’s annual budget—including \$63 billion to provide healthcare services for *one-third of Californians* (SER 1272-73, 1274-75 (Ghaly Decl. ¶¶ 5, 8, 13-14); 938-41 (Cantwell Decl. ¶¶ 2, 5, 8); approximately half of the annual budget

for the California Department of Public Health, including \$1.5 billion for emergency preparedness, chronic and infectious disease prevention, and healthcare facility licensing programs (SER 1425-30 (Nunes Decl. ¶¶ 5, 9-12, 16), 1275-77 (Ghaly Decl. ¶¶ 17-20)); and approximately one-quarter of the budget for the California Department of Social Services, including \$10.8 billion for child welfare and in-home care for seniors and people with disabilities (SER 1275 (Ghaly Decl. ¶ 15), 954-57 (Cervinka Decl. ¶¶ 7-16)). The effect on other plaintiffs-appellees is similar: Federal HHS funds make up approximately 10% of San Francisco’s annual budget, including one-third of its public health budget. SER 1549 (Rosenfield Decl. ¶¶ 8-10). And federal funds account for two-thirds of Santa Clara’s health and human services budget. SER 1374-75 (Lorenz Decl. ¶¶ 22-24).

The Rule even places at risk numerous sources of funding that have no connection to healthcare. In bootstrapping the Weldon Amendment’s funding provisions,¹⁸ the Rule threatens California’s U.S. Department of Labor funding supporting unemployment insurance, apprenticeships, and

¹⁸ Appropriations Act at § 507(d) (“None of the funds made available in *this Act* . . .”) (emphasis added); 84 Fed. Reg. at 23,172 (referencing funds in “Labor, HHS, and Education appropriations act”); *see also* ER 30 (observing that the Rule can be read to implicate Labor and Education funds via the Weldon Amendment).

occupational safety (SER 1598-1601 (Sturges Decl. ¶¶ 5-9)); roughly \$8.3 billion in educational funding for state and local programs, including to support instruction for special education, vocational education, and childcare and preschool programs, SER 1434-60 (Palma Decl. Ex. A); and hundreds of millions of dollars for public colleges and universities (SER 1503-04 (Parmelee Decl. ¶¶ 4-9), 927 (Buchman Decl. ¶ 11)).

HHS previously recognized the constitutional problem that would arise if the federal government asserted sweeping new authority to strip States of such funding in the name of enforcing federal conscience laws. SER 858-59 (HHS Letter). But HHS has now abandoned that position. Especially in light of the unbounded, discretionary enforcement authority HHS has granted itself, the Rule permits the exact type of “economic dragooning” the Supreme Court found unlawful in *NFIB*. 567 U.S. at 581–82.

NFIB’s concern for States’ reliance interests is also implicated here. The Rule’s onerous requirements coerce States and localities into abandoning the “intricate statutory and administrative regimes” they have developed in reliance on the long-established statutory and regulatory scheme, becoming instead a “national bureaucratic army” advancing the federal government’s policies. *Id.* at 584-85. The Rule makes clear that “recipients are responsible for . . . their sub-recipients[’] compl[iance] with

these laws.” 84 Fed. Reg. at 23,180. Thus, the Rule’s “unprecedented” scope means that California will be required to develop a costly system for tracking compliance by sub-recipients of Medi-Cal, including independent subdivisions such as the counties. SER 1273-74 (Ghaly Decl. ¶ 10), 939-40 (Cantwell Decl. ¶ 7). This type of threat is unconstitutional under *NFIB*. See also *New York*, 414 F. Supp. 3d at 571; ER 30-31 (WA op.).

HHS argues that the district courts misread the Rule, reiterating that it “puts no more funding at risk than the unchallenged conscience statutes do.” AOB 64. In so arguing, HHS forfeits any colorable defense to plaintiffs-appellees’ Spending Clause claims should the Court find that HHS exceeded its authority in promulgating the Rule’s enforcement provisions. As already discussed, HHS has done so by granting itself authority to terminate all funding streams for a violation of any part of the Rule. See *supra* Section I(A)(II).

2. The Rule is unconstitutionally ambiguous

If Congress desires to condition States’ receipt of federal funds, it “must do so unambiguously.” *Pennhurst v. State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). Because “[t]here can, of course, be no knowing acceptance [of federal funds] if a State is unaware of the conditions or is unable to ascertain what is expected of it,” *id.*, courts evaluate statutes

“from the perspective of a state official who is engaged in the process of deciding whether the State should accept [the] funds and the obligations that go with those funds,” *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006).

The Rule fails the ambiguity test. HHS concedes that the Spending Clause demands that States be on “clear notice” as to their federal obligations. AOB 62. But HHS incorrectly claims that the Rule is clear because it merely “mirror[s]” existing federal law, 84 Fed. Reg. at 23,222, and imposes “no new substantive obligations on funding recipients.” AOB 61-62. On the contrary, the Rule “changes the ‘who,’ ‘what,’ ‘when,’ ‘where,’ ‘why,’ and ‘how’ with respect to how regulated entities must respond to conscience-based objections” in an indefinitely expansive fashion. *New York*, 414 F. Supp. 3d at 571.

“[B]road interpretations of ambiguous language” in a funding condition are fundamentally unfair and violate the Spending Clause. *Clovis Unified Sch. Dist. v. Cal. Office of Admin. Hr’g*, 903 F.2d 635, 646 (9th Cir. 1990). As demonstrated above, the Rule expands the scope of the limited conscience provisions by broadly defining “health care entity” far beyond the limits of the statutory text. *See supra* at Section I(A)(1). In addition, the Rule allows any “health care personnel” to deny medical care based on

“ethical[] or other reasons.” 84 Fed. Reg. at 23,263. The phrase “or other reasons” gives the Rule infinite scope, rendering it impossibly vague for state officials to implement. Given this sweeping and indefinite language, States and local governments cannot know if they are violating the Rule if they take action against medical providers or programs that deny care, as virtually any reason seems to suffice under the Rule.

Citing *Mayweathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002), HHS contends conditions imposed on States may be “largely indeterminate,” so long as the statute provides clear notice that by accepting the funds, the States will be obligated to comply with the conditions. AOB 62. But, in this case, the Rule amounts to an “unforeseeable departure” from the status quo. *New York*, 414 F. Supp. 3d 569. As such, the “existence of the condition” is not “explicitly obvious.” *Mayweathers*, 314 F.3d at 1067. And HHS’s reliance on *Davis v. Monroe County Board of Education* is similarly inapposite. There, the Supreme Court held that Title IX forbids sexual harassment with “sufficient clarity” to satisfy notice requirements to funding entities. 526 U.S. 629, 649-50 (1999). The Rule offers no such clarity.

The Rule’s ambiguity is exacerbated by HHS’s vague assurances that it will “harmonize” the Rule with federal laws such as EMTALA, without providing concrete guidance as to how covered entities should plan for or

address the interplay. *New York*, 414 F. Supp. 3d at 568; *supra* Section I(B). HHS provides no clear notice of what is required of regulated entities during emergencies in order to avoid penalties. But entities like Zuckerberg San Francisco General Hospital do not have time to parse whether the Rule or EMTALA will prevail when faced with decisions concerning life or death. SER 1214 (Colwell Decl. ¶¶ 8, 11-12).

The Rule is also unconstitutionally vague as to the funding streams at issue. *See supra* Section I(A)(2). “If the funds at stake are not clear, the [c]ounties cannot voluntarily and knowingly choose to accept the conditions on those funds.” *Cty. of Santa Clara v. Trump*, 250 F. Supp. 3d 497, 532 (N.D. Cal. 2017); *City of Chicago v. Barr*, 961 F.3d 882, 907 (7th Cir. 2020).

The Rule is also so broadly and vaguely written that it is impossible to ascertain how plaintiffs-appellees should communicate with and monitor their sub-recipients’ compliance, including local governments, SER 939-40 (Cantwell Decl. ¶ 7), in a manner that effectively protects funding. 84 Fed. Reg. at 23,180 (clarifying recipients are responsible for ensuring their sub-recipients comply with the Rule). This requirement jeopardizes plaintiffs-appellees’ federal funding even if they had no notice or approval of a sub-recipient’s violation. The Spending Clause does not allow such an outcome.

3. Conditions on funding already accepted

“[O]nce a State has accepted funds pursuant to a federal program, the Federal Government cannot alter the conditions attached to those funds so significantly as to ‘accomplish[] a shift in kind, not merely degree.’” *New York*, 414 F. Supp. 3d at 567 (quoting *NFIB*, 567 U.S. at 583). This action would “surpris[e] participating States with post-acceptance or ‘retroactive’ conditions” in violation of the Spending Clause. *NFIB*, 567 U.S. at 584.

First, the Weldon, Church, and Coats-Snowe Amendments impose “specific standards” that “condition funding” on “specific prohibitions.” *New York*, 414 F. Supp. 3d at 567-68 (observing that the Church Amendments’ restrictions apply only to “grant[s] or contract[s] for biomedical or behavioral research”). Public entities such as California accepted federal funding with the expectation that they would receive the funds under existing agreements and conditions. SER 1273-74 (Ghaly Decl. ¶¶ 9-10), 1598-00 (Sturges Decl. ¶¶ 6-7); 1538 (Price Decl. ¶ 16), 1504 (Parmelee Decl. ¶ 7), 1227 (Nunes Decl. ¶ 11), 1374-75. But the Rule upends this planning by requiring entities to immediately comply with new provisions (for example, new definitions and assurance and certification requirements) that apply to the thirty-plus conscience provisions encompassed by the Rule or risk the entirety of their HHS funding. This

transformation “in kind, not merely degree,” melds so many disparate obligations and new conditions that it “exposes a State to a heightened risk, in the middle of a funding period,” forcing it to recast budgets and funding expectations that have long been decided. *New York*, 414 F. Supp. 3d at 568; *see also NFIB*, 567 U.S. at 583.

Notably, California’s Department of Health Care Services expected to receive more than \$63 billion in federal funding in Fiscal Year 2018-2019, including for operation of the Medi-Cal program to provide healthcare for the State’s most vulnerable residents. But much of the Medi-Cal budget is spent up-front by the State in expectation of reimbursement from the federal government. SER 1274 (Ghaly Decl. ¶¶ 11, 13). The reconditioning of existing funding, which would deprive California the Medi-Cal reimbursements it is entitled to, violates the Spending Clause.

Second, through the assurance and certification requirements, the Rule imposes new compliance obligations on funding recipients and their sub-recipients. In order to safeguard existing funds and awards from termination, state personnel will be obligated to implement the Rule’s new federal standards of conduct and investigate infractions. SER 939-40 (Cantwell Decl. ¶ 7). States could not have anticipated this “unforesee[n] departure

from the status quo” when they agreed to accept their present funding. *New York*, 414 F. Supp. 3d at 569.

HHS contends that the Rule has no retroactive effect on funds received before the Rule’s effective date. AOB 61. This is yet another newly devised litigation position that directly contradicts the Rule. *See* 84 Fed. Reg. at 23,271–72 (to be codified at 45 C.F.R § 88.7(i)(3)(i)-(vii) (allowing the claw back of funding)). If the Rule were to go into effect, for example, California could be found in violation of the Weldon Amendment based on complaints filed in 2014, and it is unclear under the Rule whether HHS would be able to claw back funds from 2014 or from 2014 forward, notwithstanding HHS’s finding of no violation in June 2016.

4. The conditions on funding are unrelated to conscience objections

As the Washington district court held, the Rule places at risk federal funds “entirely unrelated to health care.” ER 30. The Spending Clause requires that funding conditions “bear some relationship to the purpose of the federal spending,” *New York v. United States*, 505 U.S. 144, 167 (1992), and be “reasonably calculated” to address the “particular . . . purpose for which the funds are expended.” *Dole*, 483 U.S. at 208-09. “Conditions on federal grants might be illegitimate if they are unrelated to the federal

interest in particular national projects or programs.” *Id.* at 207 (quotations omitted). The Rule fails *Dole*’s relatedness test.

The Rule places various federal funds at risk—such as those for Medicaid, emergency preparedness, chronic and infectious disease prevention, in-home assistance for elderly and disabled individuals—even though the purposes of those statutes are wholly unrelated to the protection of conscience objections. *See supra* Section II(B)(1). The Rule further jeopardizes funding for numerous labor and educational programs, which lack any nexus or relationship whatsoever to the Rule’s healthcare restrictions. ER 30-31 (WA op.); Appropriations Act at § 507(d) (“None of the funds made available in *this Act* . . .”) (emphasis added); 84 Fed. Reg. at 23,172 (referencing funds in “Labor, HHS, and Education appropriations act”); SER 858-59 (HHS Letter), 1598-00 (Sturges Decl. ¶¶ 5-8), 1503-04 (Parmelee Decl. ¶¶ 5-9).

HHS concedes that it cannot terminate funding for violations “unless Congress has applied that law to that funding.” AOB 63-64 (citing 84 Fed. Reg. 23,223). But the Rule contains no such limitation. *See* 45 C.F.R. § 88.7(i)(3)(iv). Whereas the 2011 rule said HHS’s OCR would coordinate the handling of complaints with specific “departmental funding component(s),” 76 Fed. Reg. 9976-77 (45 C.F.R § 88.2), the Rule now gives

OCR the authority to terminate, deny or withhold “Federal Funding Assistance,” which is defined broadly to include *all* federal funds to a recipient. 84 Fed. 23,264 (45 C.F.R § 88.2). Accordingly, the Court should also find the Rule unconstitutional for this reason.

III. THE DISTRICT COURTS PROPERLY VACATED THE RULE

Under the APA, a reviewing court shall “set aside agency action” found to be arbitrary, capricious, not in accordance with law, or in excess of statutory jurisdiction. 5 U.S.C. § 706(2)(A) & (C). This Court should affirm and apply the “ordinary” remedy for unlawful rules under the APA. *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989).¹⁹

HHS suggests that the district courts erred in vacating the Rule in its entirety, rather than limiting any relief to plaintiffs or to severing specific provisions. AOB 65-71. As the California district court observed, that suggestion is “illogical.” ER 63. Under this Court’s ordinary practice, rules promulgated in violation of the APA are vacated as a whole, not just with respect to certain parties or provisions. *Regents of Univ. of Cal. v. U.S. Dep’t of Homeland Sec.*, 908 F.3d 476, 511 (9th Cir. 2018). That is especially so

¹⁹ California adopts Santa Clara (pp. 65-70) and San Francisco’s (pp. 58-61) additional arguments that the district courts correctly vacated the Rule in its entirety.

where the Rule “is so saturated with error.” and the errors are so widespread that “there is no point in trying to sever the problematic provisions. The whole rule must go.” ER 63. And HHS fails to cite any instance where a rule has been vacated in its entirety, but limited only to the parties. *Id.* There is no support in the APA, this Court’s case law, or the facts of this case for imposing a more limited remedy here. The district courts properly vacated the Rule in its entirety.

CONCLUSION

The Court should affirm the district courts’ judgments.

Dated: October 13, 2020

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STATEMENT OF RELATED CASES

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

Pursuant to Ninth Circuit Rule 28-2.6, appellee states that it knows of no related cases pending in this Court beyond those consolidated with this case.

s/ Neli N. Palma

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**UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT**

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